Draft proposed responses to public submission on draft default guideline values

Toxicant: PFOS in freshwater

Summary of public comments	Response	Action to be taken
Submission A		
1. Concerns over use of the Burr Type III model for the species sensitivity distribution (SSD).	The use of the Burr Type III model was in accordance with the use of the Burrlioz 2.0 software as specified in the DGVs derivation method (Warne et al. (2018). Nevertheless, and in response to this comment and similar comments made in other submissions, a comparison was undertaken between the use of the Burrlioz 2.0 and shinyssdtools (v 0.2.0) SSD software packages for the PFOS DGVs. Notably, the Australian and New Zealand governments have already approved the transition from the use of Burrlioz to shinyssdtools for deriving DGVs, although this transition process is not yet complete and the latter is yet to be formally adopted. The software comparison showed that shinyssdtools (using model averaging) produced more defensible DGVs and also that the Burr Type III model was among the poorest fitting SSD models of the seven models used in shinyssdtools. Consequently, and given the impending transition to shinyssdtools, the jurisdictional review/approval committees approved the use of shinyssdtools (using model averaging) for deriving the PFOS freshwater DGVs.	The DGVs will be revised using the shinyssdtools software (v 0.2.0) and its associated model averaging approach.
2. Concerns over the inclusion of the *Danio rerio* (zebrafish) multigenerational study by Keiter et al. (2012).	Independent review of the Keiter et al. (2012) study concluded that the study was unreliable and should not be used in the final dataset for deriving the PFOS freshwater DGVs. Another toxicity value for the zebrafish will need to be selected. Refer to the accompanying PFOS independent review committee report for details (Dawson et al. 2024).	The Keiter et al. (2012) study will be removed from the final dataset and another value will be selected for the zebrafish from a range of other reliable studies.
Submission B		
1. Concerns over the use of the Burrlioz 2.0 SSD software for deriving the DGVs.	See response to comment 1 from submission A.	The DGVs will be revised using the shinyssdtools software and its associated model averaging approach.
2. Concerns that the guidance in the technical brief on how to account for bioaccumulation of PFOS was not consistent with national policy/guidance and other DGV technical briefs. Key points raised included:	It should be noted that the information in ANZG (2018) and ANZECC/ARMCANZ (2000) represents guidance, and is not policy as such. Published data for PFOS show that meeting the draft 99% species protection DGV of 0.0091 µg/L does not necessarily mean that tissue concentrations in aquatic biota will be below relevant wildlife protection values (i.e. Baddiley et	No action required.

Summary of public comments	Response	Action to be taken
• Consistency with national policy • animal ethics considerations • when biota sampling may be appropriate.	al. 2020). Given this evidence is now available, it is considered that it is reasonable and valid to include statements that may differ from other DGVs where such evidence is lacking. Moreover, both ANZG (2018) and ANZECC/ARMCANZ (2000) clearly state that the guidance to use the 99% species protection DGV for bioaccumulative compounds is arbitrary and not based on any evidence of biological protection. Neither ANZG (2018) nor ANZECC/ARMCANZ (2000) state that using the 99% species protection DGV will always provide adequate protection from bioaccumulative compounds and that no other assessment is required. Note that both sets of guidelines clearly promote a multiple lines of evidence approach to water quality assessment, whereby basing conclusions and decisions on comparisons with guideline values alone can be insufficient. The PFOS independent review committee (Dawson et al. 2024) recommended that the bioaccumulation guidance in the draft technical brief be retained as is. Refer to the accompanying PFOS independent review committee report for details (Dawson et al. 2024).	
3. Concerns over the inclusion of the *Danio rerio* (zebrafish) multigenerational study by Keiter et al. (2012).	See response to comment 2 from submission A.	The Keiter et al. (2012) study will be removed from the final dataset and another value will be selected for the zebrafish from a range of other reliable studies.
4. Concerns over limitations of the data quality scoring process used for the Warne et al. (2018) DGVs derivation method.	These concerns have been noted. It is acknowledged that the data quality scoring process, while useful overall, has a limited ability to identify unreliable studies. Notably, Warne et al. (2018) clearly states that the data quality scoring process should not be solely relied upon when making decisions on the inclusion of data. Nevertheless, it is acknowledged that the DGVs derivation method would benefit from an update of the data quality scoring process, such that it is less weighted towards the reporting of specific test conditions and more weighted towards factors that more closely align with test reliability, including (but not limited to) the use of measured contaminant concentrations, the presence of an adequate concentration-response relationship, the use of an appropriate statistical method, and the use and reporting of reference toxicity test results. Consequently, the data quality scoring process will be updated as part of the update of the Warne et al. (2018) derivation method that is currently underway.	The data quality scoring process will be updated to improve its ability to identify data reliability. However, this is unlikely to be done within the timeframe of the revisions to the PFOS freshwater DGVs. The thorough review process that has been undertaken for the PFOS freshwater DGVs is sufficient to have confidence in the data selections.
Submission C		

Summary of public comments	Response	Action to be taken
1. Concerns that the toxicity data screening and associated selections were unclear and inconsistent with official rules for DGV derivation. The issues raised included: • Where test concentrations differed by 10-fold or more • Studies that used only one exposure concentration (in addition to a control) • Where data selection decisions were inconsistent with the Warne et al. (2018) hierarchy of acceptable toxicity estimates • Where rules for calculation of geometric means for toxicity data were not followed.	Warne et al. (2018) makes it clear that there may be a significant amount of professional judgement required when making data selection decisions, and that all such decisions should be clearly justified in the technical brief. This means that it is possible that different experts could arrive at different decisions. In addressing this comment, all data selection decisions that fell into the categories listed by the submitter were independently reviewed. The outcomes of this review can be seen in the accompanying PFOS independent review committee report (Dawson et al. 2024). The recommendations of this report will be used to inform the revision of the PFOS freshwater DGVs dataset.	The PFOS freshwater DGVs dataset will be updated in accordance with the recommendations in Dawson et al. (2024).
2. Concerns over the inclusion of the *Danio rerio* (zebrafish) multigenerational study by Keiter et al. (2012).	See response to comment 2 from submission A.	The Keiter et al. (2012) study will be removed from the final dataset and another value will be selected for the zebrafish from a range of other reliable studies.
3. The PFOS freshwater dataset is bimodal and, therefore, the DGVs should be derived using the approved approach for bimodal distributions.	The draft technical brief for the PFOS freshwater DGVs provided the details of a comprehensive assessment of the modality of the PFOS freshwater DGVs dataset (Appendix B of the draft technical brief). This assessment found that: • There was an indication of taxa-specific sensitivity, with simple planktonic algae being less sensitive than other taxa groups, but that the samples sizes for these algal groups were too small to enable definitive conclusions on this. • Despite the possible taxa-specific sensitivity for algae/plants, this does not result in a bimodal SSD for PFOS (noting that taxa-specific sensitivity is not unusual and it does not automatically translate to an SSD being bimodal). Therefore, it was, and is still, considered to be appropriate to model the dataset using a unimodal distribution. Nevertheless, once the dataset is revised to address the responses to public comments, a new full modality assessment will be performed.	No action proposed, although the updated dataset (once public submissions are addressed) will be subjected to a new modality assessment, as per standard procedure for the DGV derivation method.
Submission D		

Summary of public comments	Response	Action to be taken
1. Minor discrepancy in 99% species protection DGV reported in the draft technical brief (0.0091 µg/L) compared with submitter-derived value using the same dataset and software (0.0093 µg/L).	Noted. However, this issue is redundant given that the dataset and DGVs will be revised to address public comments.	No action required.
1. Concerns over use of the Burr Type III model for the species sensitivity distribution (SSD).	See response to comment 1 from submission A.	The DGVs will be revised using the shinyssdtools software and its associated model averaging approach.
2. Concerns over the inclusion of the *Danio rerio* (zebrafish) multigenerational study by Keiter et al. (2012).	See response to comment 2 from submission A.	The Keiter et al. (2012) study will be removed from the final dataset and another value will be selected for the zebrafish from a range of other reliable studies.
Submission E		
1. Concerns over the inclusion of the *Danio rerio* (zebrafish) multigenerational study by Keiter et al. (2012).	See response to comment 2 from submission A.	The Keiter et al. (2012) study will be removed from the final dataset and another value will be selected for the zebrafish from a range of other reliable studies.
2. Concerns about the guidance in the technical brief on how to account for bioaccumulation of PFOS. Key points raised included: • consistency in guidance • need for clarity on biota sampling requirements (for assessing bioaccumulation) • dealing with other catchment sources of PFOS.	See response to comment 2 from submission B.	No action required.
Submission F		
1. Supported the comments from submission C	See responses to comments 1 – 3 from submission C.	See proposed actions for comments 1 – 3 from submission C.

References

ANZECC/ARMCANZ 2000. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. National Water Quality Management Strategy, Paper No. 4, Australian and New Zealand Environment and Conservation Council and Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia

ANZG 2018. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia. https://www.waterquality.gov.au/anz-guidelines/guideline-values/default/water-quality-toxicants/local-conditions#bioaccumulation.

Baddiley BL, Munns T, Braun C & Vardy S 2020. Queensland Ambient PFAS Monitoring Program 2019-2020. Queensland Department of Environment and Science, Brisbane.

Dawson P, Le-Steere C, Mann RM, Stauber J & Vardy 2 2024. Independent Review of Key Issues Arising from Public Comments on the PFOS Freshwater Draft Guideline Values. Report for the Australian Government Department of Climate Change, Energy, the Environment and Water, Canberra.

Keiter S, Baumann L, Färber H, Holbech H, Skutlarek D, Engwall M & Braunbeck T 2012. Long-term effects of a binary mixture of perfluorooctane sulfonate (PFOS) and bisphenol A (BPA) in zebrafish (*Danio rerio*). *Aquatic Toxicology*, 118–119, 116–129.

Warne MStJ, Batley GE, van Dam RA, Chapman JC, Fox DR, Hickey CW & Stauber JL 2018. Revised Method for Deriving Australian and New Zealand Water Quality Guideline Values for Toxicants – update of 2015 version. Prepared for the revision of the Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Australian and New Zealand Governments and Australian state and territory governments, Canberra, 48 pp.