Australian Government
Department of Climate Change, Energy, the Environment and Water

Australian & New Zealand
GUIDELINES FOR FRESH & MARINE WATER QUALITY

Response to public submissions on draft default guideline values for Bisphenol A in freshwater

July 2023

Draft default guideline values (DGVs) for Bisphenol A in freshwater were published on the Water Quality Guidelines website for a 3-month public consultation period. During this period, comments for the draft DGVs for Bisphenol A in freshwater were received via public submission.

Responses to comments and any associated edits to the draft DGV technical brief are outlined in this report, de-identified for public record. The responses and revisions have been approved by the original peer reviewers and the jurisdictional technical and policy oversight groups, and noted by the National Water Reform Committee.

The default guideline values for Bisphenol A in freshwater are now published as final. For additional information on the publication process, please refer to the pathway for toxicant default guideline value publication.

The Water Quality Guidelines Improvement Program thanks all submissions for their valuable contribution to the development of default guideline values for the protection of aquatic ecosystems.

Response to public submissions on draft default guideline values

Toxicant: Bisphenol A in freshwater

Comment	Response	Action taken
Consider additional/missing toxicity data. Long-term, freshwater toxicity data used in Canada's Federal Environmental Quality Guideline (FEQG) for BPA (ECCC 2018) that were not considered in the Australia and New Zealand freshwater DGV for BPA have been listed below. Authors may wish to consult these studies to see if the species, endpoints, and effects would be acceptable for inclusion in the DGV for BPA. De Kermoysan et al 2013: Three-spine stickleback (*Gasterosteus aculeatus*) – a 165 day MATC* for growth (gonad size) of 3.16 µg/L was included in the FEQG for BPA and was the lowest endpoint in the dataset. This study and species were not included or considered in the DGV for fresh water or marine. Haubruge et al 2000: Guppy (*Poecilia reticulata)*- a 21-day LOEC for effects on reproduction (sperm count) of 274 µg/L was included in the FEQG for BPA. This study and species were not included or considered in the DGV. Heimeier et al 2009: African clawed frog (*Xenopus laevis*)- the FEQG included a 21-day LOEC for delayed metamorphosis of 23 µg/L. This endpoint is lower than the endpoint included in the DGV for this species. Sieratowicz et al 2011: New Zealand mud snail (*Potamopyrgus antipodarum*)- the FEQG included a 28-day MATC for reproductive success of 20 µg/L. This study and species were not included or considered in the DGV. Sun et al 2014- Japanese medaka (*Oryzias latipes*)- a 44-day MATC for hatching success of 110 µg/L was included in the	Thank you for bringing the additional studies to our attention. We have addressed them individually, below: **De Kermoysan et al 2013: Three-spine stickleback (*Gasterosteus aculeatus*) – a 165 day MATC for growth (gonad size) of 3.16 µg/L** This study looked at effects of BPA on three trophic levels (macrophytes, macroinvertebrates and fish) in a lotic mesocosm study. The 10-fold range in exposure concentrations is not ideal, but does not necessarily exclude the study. The effect on fish gonad size at 10 µg/L has not been demonstrated to be ecologically relevant. Although there were some differences in the fish population structure at 100 µg/L, there was no effect on the total number of fish. Therefore, ecologically relevant effects on the fish at 10 µg/L have not been demonstrated. Thus, the gonad size endpoint is inadmissible according to Warne et al. (2018). Even the ecological relevance of the fish demographic effects at 100 µg/L are unclear. Effects on macrophytes and macroinvertebrates were observed at 100 µg/L. In considering this study, it was considered more appropriate for use as a validation study for the final DGVs. That is, at the 95% species protection DGV of 1.3 µg/L, no ecologically relevant effects were observed in the mesocosm study, which provides some support for the DGVs. **Haubruge et al 2000: Guppy (*Poecilia reticulata)*- a 21-day LOEC for effects on reproduction (sperm count) of 274 µg/L** This study looked at the effects of 274 and 549 µg/L BPA on sperm endpoints (testis size, sperm count, sperm length). Only assessing two concentrations is not ideal, but does not automatically exclude the study. A significant reduction in sperm count was observed at both concentrations. However, the endpoints assessed are not considered to have demonstrated ecologically relevance and, therefore, they are inadmissible for use in DGVs according to Warne et al. (2018). Regardless, the concentrations at which effects were observed in this study are well above ecologically relevant negligible effect concentrations for other fish species that were included in the derivation.	Study not used in the derivation but was used as a validation study for the DGVs. Study not used in the derivation.

Comment	Response	Action taken
FEQG. This endpoint is lower than endpoint included in the DGV for this species. * MATC: maximum acceptable toxicant concentration.	**Heimeier et al 2009: African clawed frog (*Xenopus laevis*) 21-day LOEC for delayed metamorphosis of 23 µg/L** This study looked at the effects of 23 and 2300 µg/L BPA on metamorphosis. This very wide range of only two concentrations is not ideal, but does not automatically exclude the study. There was no difference in metamorphosis between control and BPA treatments. However, when the tadpoles were also exposed to the thyroid hormone, triiodothyronine (T3), which is known to stimulate metamorphosis, BPA at both concentrations was shown to inhibit the T3-induced metamorphosis. However, this effect in the presence of additionally applied T3 is not relevant to how tadpoles would be exposed in the environment. The exposure comparison of relevance is the negative control with BPA only, and this showed no significant effect. Thus, this study should not be included in the derivation given that additional data for *X. laevis* were available from another study that demonstrated significant effects of BPA (Pickford et al. 2003; 90-d exposure to tadpoles, six BPA concentrations from 1 to 500 µg/L).	Study not used in the derivation.
	Sieratowicz et al 2011: New Zealand mud snail (*Potamopyrgus antipodarum*) 28-day MATC for reproductive success of 20 µg/L This study looked at the effects of 5,10, 20, and 40 µg/L BPA on embryo number at three temperatures (7, 16 and 25°C). Embryo number is an ecological relevant endpoint. An increase in embryo number with increasing BPA exposure was generally observed. This was consistent with the estrogenic effect caused by 17a-ethinylestradiol (EE2). The BPA NOECs at 7, 16 and 25°C were 5, 20 and 5 µg/L, respectively. A positive effect of BPA on embryo numbers does not preclude this study from being included in the BPA dataset, as this still represents an ecologically relevant effect. This study passed the quality assessment and the above endpoint can be used in the derivation. The toxicity value obtained at 16°C is likely to be the most appropriate given that the authors noted it as being the preferred temperature for this species, which was supported by the higher control performance at this temperature compared to 8 and 25°C. Also, the BPA concentrations in the 25°C treatments were markedly more variable than the other treatments.	This study was included in the derivation. Associated revisions have been made to the technical brief.
	Sun et al 2014- Japanese medaka (*Oryzias latipes*)- a 44-day MATC for hatching success of 110 µg/L This study looked at the effect of 6, 20, 60, 200 and 600 µg/L BPA on a range of ecologically relevant endpoints (e.g. hatching success, survival, growth.	This study was included in the derivation. Associated revisions have been made to the technical brief.

Comment	Response	Action taken
	Hatchability (decrease) and female body weight (increase) were significantly different at 200 µg/L, with the NOEC being 60 µg/L. This study passed the quality assessment and the above endpoint can be used in the derivation. The reviewer suggested the use of the 44-d MATC (reproduction) of 110 µg/L. However, as the Warne et al. (2018) derivation method recommends the use of NOECs before LOECs or MATCs, the NOECs represent the relevant values for consideration in the derivation.	
Authors may wish to consider additional effect endpoints (e.g. gonad size/weight, sperm count) beyond standard effects (i.e. survival, typical measures of growth and reproduction) given that BPA can produce estrogenic, hormonal, developmental and/or various reproductive effects. The DGV technical brief does specifically note that endocrine disruption was the most sensitive endpoint, and notes the various effects caused by BPA beyond standard toxicity tests for survival, growth and reproduction, but does not include them in guideline derivation.	The current DGV derivation method (Warne et al. 2018) is clear that non-standard endpoints can only be used "…provided that their ecological relevance for the species, or closely related species, has been demonstrated.". Moreover, Warne et al. (2018) also states that "Non-traditional endpoints that have not had their ecological relevance unambiguously demonstrated should only be used as an additional line of evidence in weight of evidence (WoE) based risk assessments.". Thus, the derivation of the DGVs followed the approved derivation method. It is noteworthy that the draft ANZG 95% species protection level DGV of 7 µg/L, which is based on only standard endpoints, is of the same order of magnitude as the corresponding ECCC (2018) FEQG for BPA in freshwater, which included non-standard endpoints, of 3.5 µg/L.	No changes made to technical brief.
Regarding model fit- the fit of the model looks good, especially in the lower tail, where if anything, the model over-predicts toxicity. Were any goodness-of-fit criteria calculated?	The approved methodology for deriving default guideline values in Australia and New Zealand (Warne et al. 2018) does not include formal goodness of fit testing for SSDs. This is because, given the small datasets often used to derive DGVs, it has generally been found that any reasonable candidate distribution will not be rejected by a statistical test of goodness-of-fit due to low statistical power (Batley et al. 2018)	No changes made to technical brief.
Was the use of the software SSDTools considered for the species sensitivity distribution, rather than Burrlioz software?	Although Australia and New Zealand have recently decided to adopt ssdtools for deriving DGVs, implementation is some time away and, until then, Burrlioz 2.0 remains the relevant software for deriving DGVs in Australia and New Zealand.	No changes made to technical brief.
RE the statement "*The theoretical protection offered by the DGVs for 99%, 95%, 90% and 80% species protection is considered to be adequate*"- the statement implies that some species are not protected; however, it is a "no-effect" curve.	The statement is indicating that, when all of the toxicity data are considered (including data that may not have been used in the derivation), there is confidence that the DGVs will provide at least the % species protection that they are based on. It does not imply that the remaining % of species will be affected. This step in the derivation method is described in Section 3.11 of Warne et al. (2018).	No changes made to technical brief.

References

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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