PFAS/2023/02 Annex 4

In this guide

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Quantitative data

In the narrative and/or table, do members want quantitative data presented (e.g. XX increase in Y endpoint, vs significant increase in Y endpoint)?

If members wish to see the quantitative values, do members have a preference for data being presented as absolute values compared to controls or as a percentage change compared to controls?

Examples of each option are given below. 9To note these are made of illustrative data rather than data taken from studies).

Example of quantitative data presented as absolute values

‘All studies, with the exception of Loveless *et al* (2009) noted a decrease in TT4 and FT4. NTP (2022a) reported a decrease in male rats following exposure to 62.6 mg/kg bw/day PFHxA (TT4 – 3.4 ± 0.23 ng/ml vs 4.26 ± 0.15 ng/ml in treated and controls, respectively; FT4 – 2.16 ± 0.17 pg/ml vs 2.88 ± 0.09 pg/ml), 0.625 mg/kg bw/day PFOA (TT4 – 3.2 ± 0.45 ng/ml vs 4.26 ± 0.15 ng/ml; FT4 – 1.25 ± 0.17 ng/ml vs 2.88 ± 0.09 ng/ml) and PFNA (TT4 – 3.2 ± 0.68 ng/ml vs 4.26 ± 0.15 ng/ml; FT4 – 1.55 ± 0.18 ng/ml vs 2.88 ± 0.09) and 0.312 mg/kg bw/day PFDA (TT4 – 3.25 ± 0.165 ng/ml vs 4.26 ± 0.15 ng/ml; FT4 – 2.39 ± 0.21 ng/ml vs 2.88 ± 0.09 ng/ml) for 28 days’.

Example of quantitative data presented as a percentage

If quantitative data as a percentagae change are included, the text would look like the following:

‘All studies, with the exception of Loveless *et al* (2009) noted a decrease in TT4 and FT4. NTP (2022a) reported a decrease in male rats following exposure to 62.6 mg/kg bw/day PFHxA (TT4 – 20% decrease compared with controls; FT4 – 25% decrease), 0.625 mg/kg bw/day PFOA (TT4 – 25% decrease; FT4 –22% decrease) and PFNA (TT4 – 46% decease; FT4 – 24% decrease) and 0.312 mg/kg bw/day PFDA (TT4 – 24% decrease; FT4 – 17% decrease) for 28 days’.

Presenting data in this format could help in future papers that will investigate if such toxicological effects in terms of adversity. For example, the biological significance, clinical relevance and relationship with adversity of a 20% decrease in TT4 will be investigated during selection of the critical, most sensitive endpoint.

Example of qualitative data

If quantitative data are not included, the text would look like the following:

‘All studies, with the exception of Loveless *et al* (2009) noted a decrease in TT4 and FT4. NTP (2022a) reported a decrease in male rats following exposure to 62.6 mg/kg bw/day PFHxA, 0.625 mg/kg bw/day PFOA and PFNA, and 0.312 mg/kg bw/day for 28 days’.

It is anticipated that once a critical endpoint is selected, on the basis of dose, then quantitative data would then be assessed in terms of biological relevance and adversity as described above.

Alternatively, quantitative data could be presented in tables (Table 2).

Again, absolute data or data as a percentage of controls could be presented.

Table 2 Example of the table three different presentations of the observed effects.

Substance	Species / sex / number / study type	Dose / route of administration / duration (mg/kg bw/day)	Serum / plasma concentration (µg/mL)	Observed effects at LOAEL (treated vs control)	Published NOAEL / LOAEL (mg/kg bw/day)	Referenc
PFOA	SD rats / male and female / 10/group / repeated dose study.	0, 0.625, 1.25, 2.5, 5 or 10 (males), 0, 6.25, 12.5, 25, 50, or 100 (females) / gavage / 28 days.	At 0.625 mg/kg bw/day Plasma: 50.690 ± 2.207 in males.	**Without quantitative data** ↓ TT4, FT4 and TT3 in males.	NA / 0.625.	NTP (2022a).

				With absolute quantitative data		
PFOA	SD rats / male and female / 10/group / repeated dose study.	0, 0.625, 1.25, 2.5, 5 or 10 (males), 0, 6.25, 12.5, 25, 50, or 100 (females) / gavage / 28 days.	At 0.625 mg/kg bw/day Plasma: 50.690 ± 2.207 in males.	↓ TT4 in males (3.4 ± 0.23 ng/ml vs 4.26 ± 0.15 ng/ml for treated and controls, respectively). ↓ FT4 in males (2.16 ± 0.17 pg/ml vs 2.88 ± 0.09 pg/ml). ↓ TT3 in males (3.2 ± 0.68 ng/ml vs 4.26 ± 0.15 ng/ml).	NA / 0.625.	NTP (2022a).
Substance	**Species / sex / number / study type**	**Dose / route of administration / duration (mg/kg bw/day)**	**Serum / plasma concentration (µg/mL)**	**Observed effects at LOAEL (treated vs control)**	**Published NOAEL / LOAEL (mg/kg bw/day)**	**Referenc**

				With relative quantitative data		
PFOA	SD rats / male and female / 10/group / repeated dose study.	0, 0.625, 1.25, 2.5, 5 or 10 (males), 0, 6.25, 12.5, 25, 50, or 100 (females) / gavage / 28 days.	At 0.625 mg/kg bw/day Plasma: 50.690 ± 2.207 in Males.	↓ TT4 in males (20% reduction compared to controls). ↓ FT4 in males (25% reduction). ↓ TT3 in males (25% reduction).	NA / 0.625.	NTP (2022a).