

The analysis of Harmful and Potentially Harmful Constituents (HPHC's) in waterpipe tobacco products.

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Background

The "Deeming Rule", published on the 10th May 2016 by the USA Food and Drug Administration (FDA) subjects waterpipe tobacco products to the existing Food, Drug and Cosmetics Act (FD&CA) requirements, including the provision of data regarding the relative quantities of "Harmful and Potentially Harmful Constituents" (HPHCs) under sections 904(a)(3), 905(j), and 910.

FDA have not released a waterpipe tobacco specific HPHC list, or provided guidance on whether HPHC's should be determined in waterpipe tobacco or aerosol. In the absence of validated and standardised methods for aerosol collection, the provision of such data would be of limited value, since waterpipe tobacco aerosol yields have been shown to be inconsistent¹ and therefore unsuitable² for product comparison purposes under 905(j) and 910.

The present study therefore focused on the determination of a selection of tobacco constituents present in waterpipe tobacco. Initially, methods used in the analysis of cigarette, roll-your-own and smokeless tobacco were applied to determine their suitability for the analysis of waterpipe tobacco products.

Materials & Methods

Global Laboratory Services Inc. (GLS) were commissioned to determine the relative quantities of selected tobacco constituents (Table 1) in waterpipe tobacco, using a product representative of those available in the USA between 2006 and 2017 ($n=12$; 5 replicate measurements per sample).

Table 1: Constituents selected for evaluation in waterpipe tobacco.

Classification	Constituent ^a	LOQ ^b
Alkaloid	Nicotine	0.5mg/g
Heavy Metal	Arsenic	0.0125µg/g
	Chromium	0.0125µg/g
	Lead	0.05µg/g
	Mercury	0.05µg/g
Poyclic Aromatic Hydrocarbon	Benzo[a]pyrene	2ng/g
Tobacco-Specific Nitrosamine (TSNA)	NNN	0.004µg/g
	NNK	0.004µg/g

^a The inclusion of an analyte, should not be interpreted as an endorsement by Al Fakher Tobacco F.Z.E of the utility of that analyte as being relevant for the protection of public health as described in Family Smoking Prevention and Tobacco Control Act.

^b Limit of Quantification (LOQ) determined by Global Laboratory Services Inc.

The results of this analysis are summarised in box-plots (Charts 1 to 4). Boxes are bound on the top by the third quartile, and on the bottom by the first quartile. The median divides the box, and error bars extend upward from the third quartile to the maximum, and downward from the first quartile to the minimum. The red line denotes the approximate position of the analytical method LOQ (Table 1).

Results

Chart 1: Nicotine content of waterpipe tobacco samples (2006 – 2017) $n=12$.

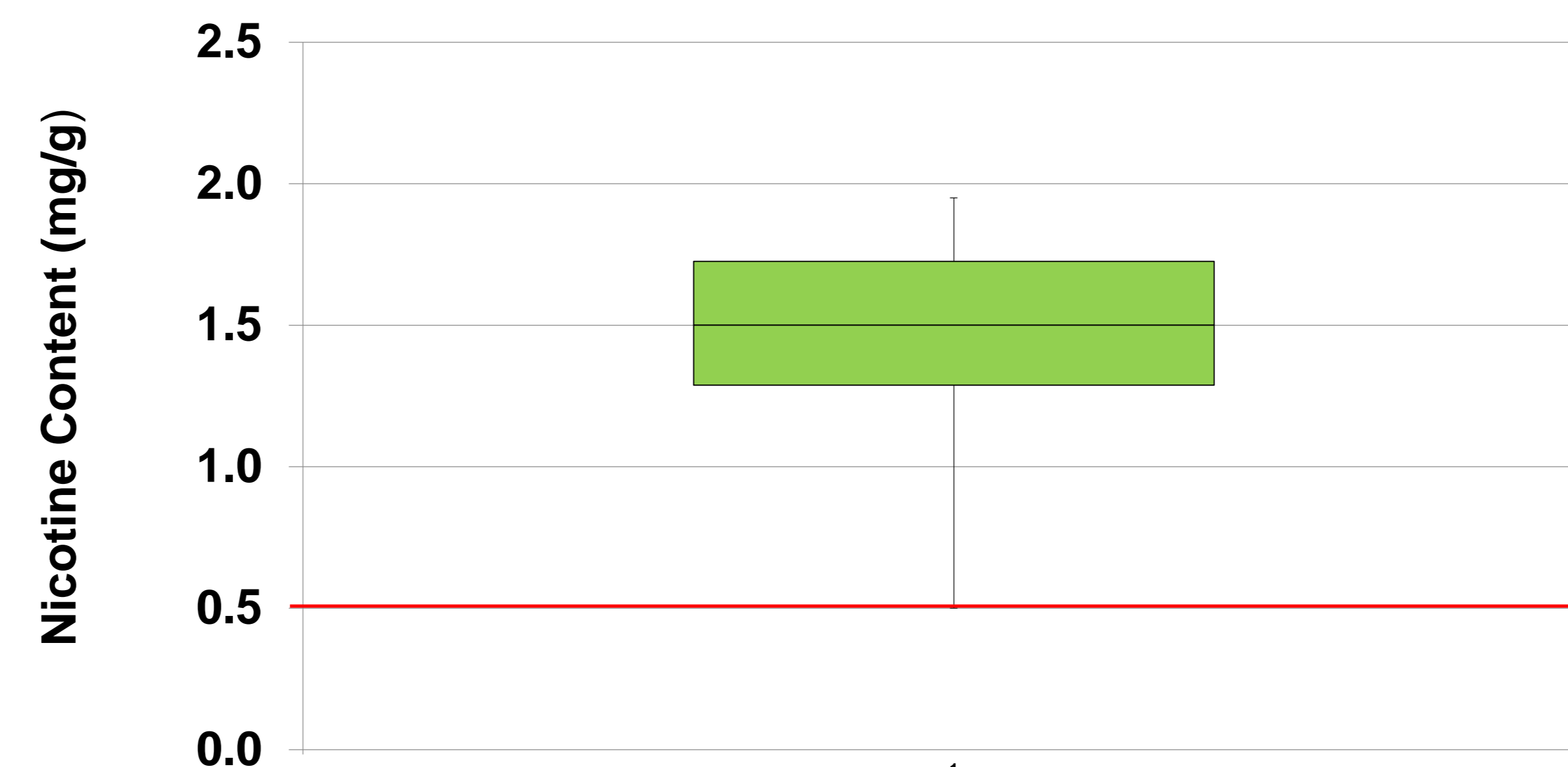
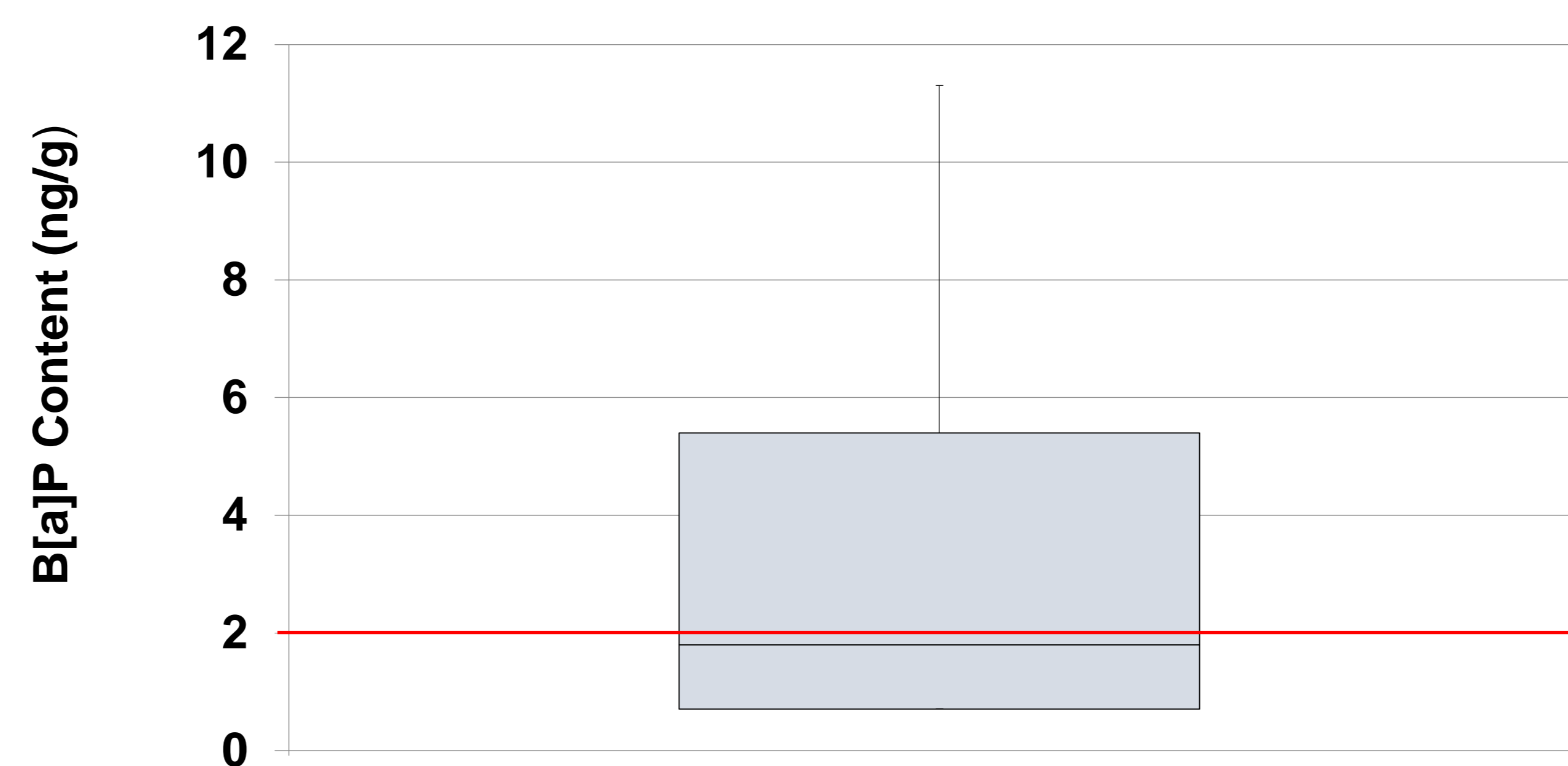
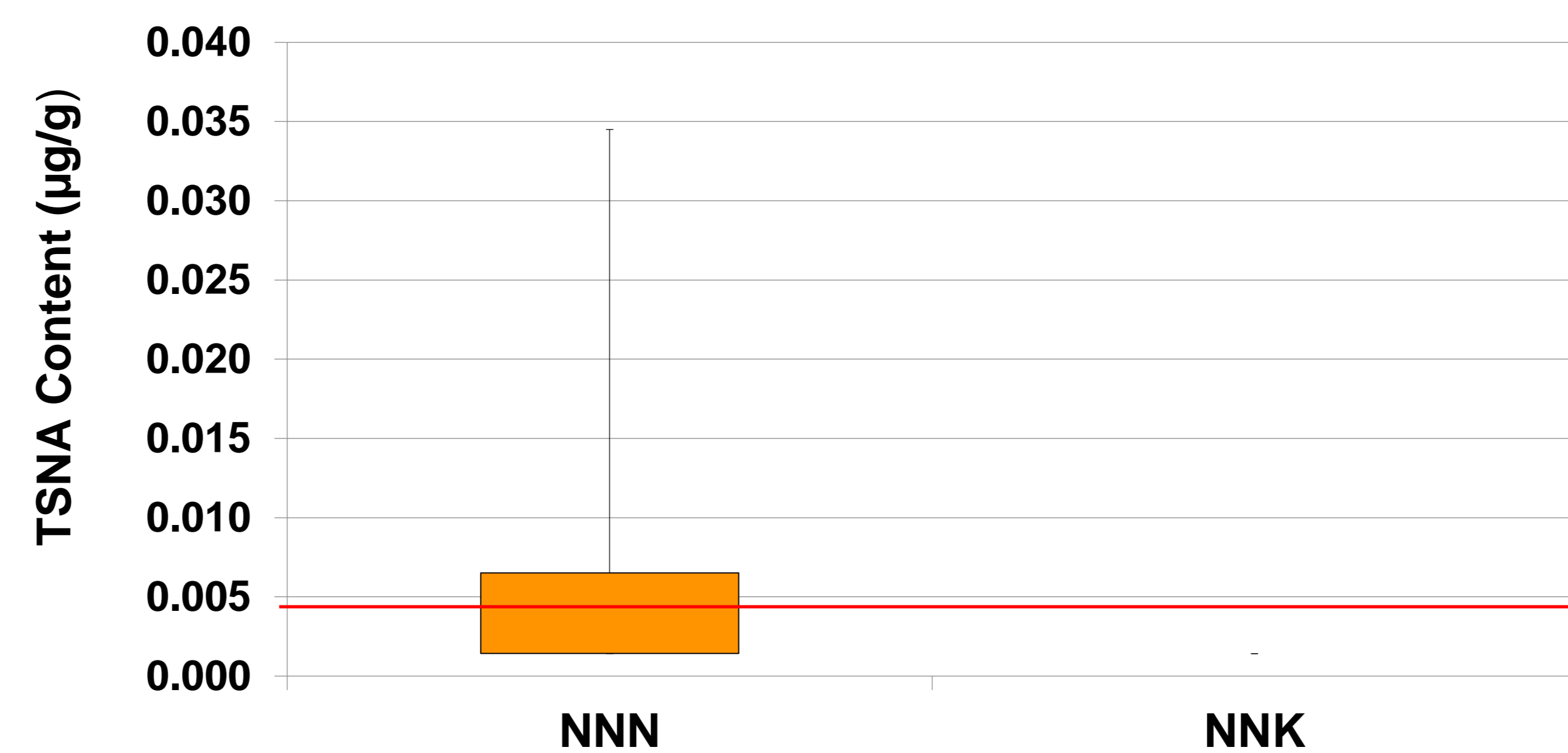


Chart 2: B[a]P content of waterpipe tobacco samples (2006 – 2017) $n=12$.



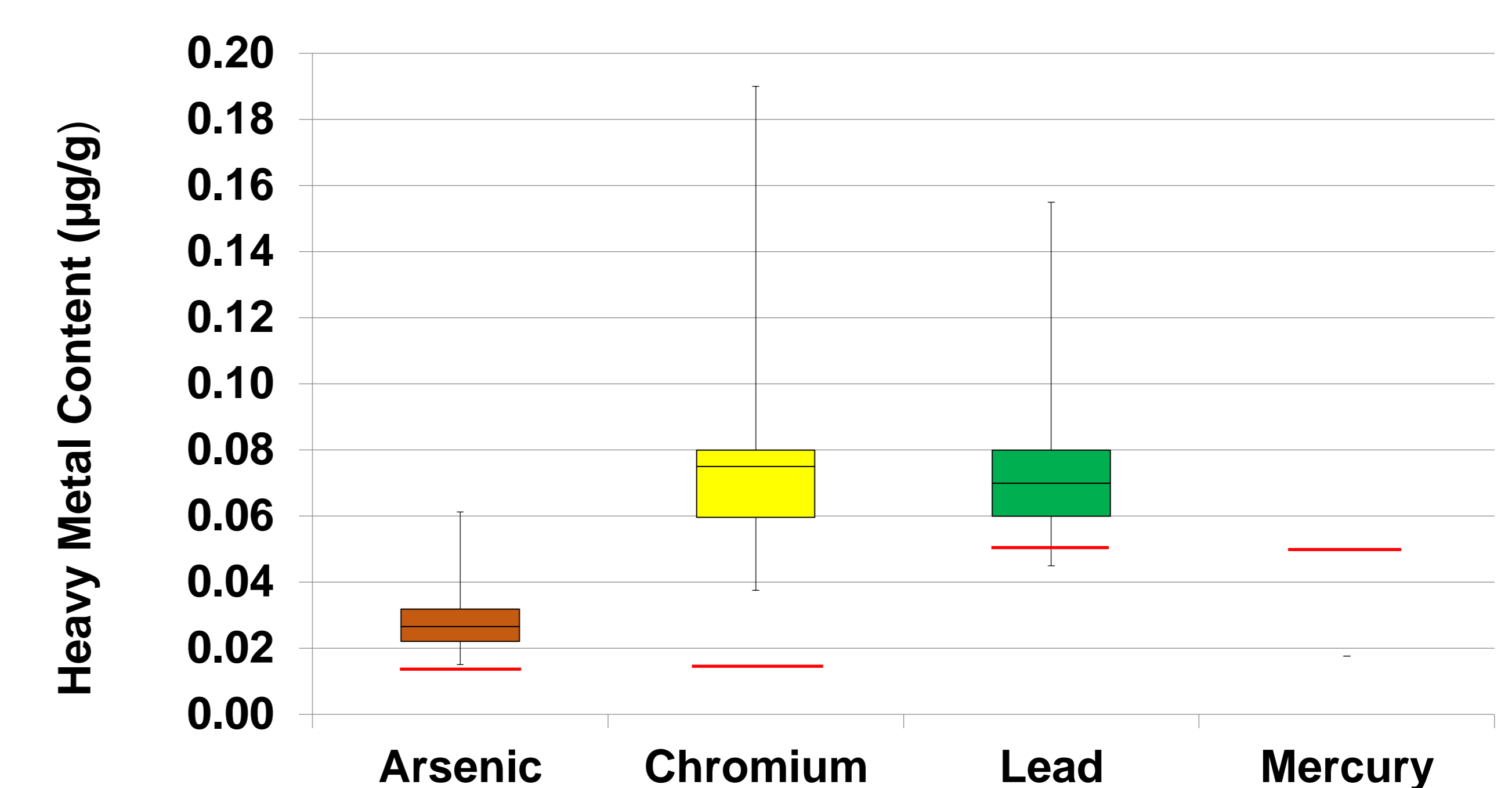
A total of 19 datapoints were below the method LOQ.

Chart 3: TSNA content of waterpipe tobacco samples (2006 – 2017) $n=12$.



For NNN, a total of 25 datapoints were below the method LOQ. NNK was not quantifiable across all 60 datapoints.

Chart 4: Metal content of waterpipe tobacco samples (2006 – 2017) $n=12$.



Levels of mercury were not quantifiable across all 60 datapoints.

Where a measurement resulted in a value below the Limit of Quantification (LOQ), this result was substituted by a constant derived from the product of LOQ / Sqrt2.

Discussion & Conclusion

Analysis of the waterpipe tobacco product ($n = 12$), representative of those commercialised in the USA provides evidence of tobacco blend stability in terms of the constituents evaluated over the preceding decade.

For several waterpipe tobacco constituents, the reported yields for some or all replicates were below the Limit of Quantification (<LOQ) of the analytical method. Consequently, these data highlight significant technical challenges in the ability to accurately and reliably measure such constituents in waterpipe tobacco aerosol for product comparison purposes.

Whilst the determination of certain tobacco constituent levels in waterpipe tobacco (i.e. B[a]P, TSNA's, and heavy metals) remains a challenge when levels are consistently below or near the LOQ, tobacco rather than aerosol analysis may represent a more robust approach in meeting the requirements of FD&CA where product comparisons are mandated.

References

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- Purkis S.W., Meger, M., Wuttke, R., 2012. A review of current smoke constituent measurement activities and aspects of yield variability. *Reg. Toxicol. Pharmacol.* 62, 202-213.