Letter to the Editor

Analysis of the data variability in the Australian Benchmark Study 2000–2001

EDITORS – I read with interest a recent paper on mainstream smoke emissions of Australian and Canadian cigarettes in (1) that included analysis and comment of by-manufacturer smoke yield variation. The authors observed that such variation had some predictive power for several of the studied emissions and disputed the claim that any differences in emissions among flue-cured brands would be "minimal if not undetectable" as being rather wide of the mark (2). At the time of the Australian Benchmark Study in 2000–2001, I was one of the co-ordinators of the study on behalf of Imperial Tobacco Australia (ITA) and I would like to discuss these conclusions (1) in the context of smoke emission measurement and variability, some aspects of which were discussed in the last issue of this journal (3).

For this benchmark study, some of the most popular selling ITA and PM cigarette brands, based loosely on their market share, were sent to Labstat in Canada, the preferred contract laboratory selected by the Australian Federal Department of Health (FDH). Their subsequent analysis was carried out in the period September to December 2000 when the so called "Hoffmann Analytes" (4) were tested under both ISO (5) and the "Canadian Intense" (6) smoking conditions on 3 ITA brands and 6 PM brands according to protocols mandated by Health Canada (7).

The mean Nicotine Free Dry Particulate Matter data (NFDPM) measured by Labstat for one of the ITA brands were quite high (8.48 mg), compared to the most recent ITA quality control data (8.00mg). Such biases between testing laboratories are by no means unexpected and are the main reason for the sophisticated understanding of variation undertaken during the development of ISO approved methods.

Even so, we requested that Labstat fully repeat the testing for this brand with associated payment as data were at the limits of the tar band. ITA submitted mean data from the two datasets to the FDH. The repeat analysis was done at the same time as the Labstat analysis of brands from British American Tobacco (BAT) who also joined in the study. It followed that Labstat analysed 6 BAT brands and one ITA brand in the period January to March 2001.

For many of the smoke analytes there was a good correlation with NFDPM across brands from all three companies. However, looking at the ITA data produced in the two time periods, we observed that for some emissions the yields of ITA brands fell better in line with PM yields for products measured in late 2000 and better in line with BAT yields for the product measured in early 2001.

The data from each of the two ITA datasets has been separated out in Figures 1 and 2 and comparisons can be made with BAT and PM yields. All NFDPM yields below 15 mg were obtained under the ISO smoking regime and those above 15 mg were obtained by the Canadian Intense smoking regime.

The most pronounced difference in data was found for 1-aminonaphthalene as shown in Figure 1. We asked Labstat to look at their Canadian CM7 monitor data for this compound obtained in the two time periods. The average CM7 yield over 100 measurements over a period of time was found to be 16.8 ng but the yield at the time of the early study was 24.2 ng and at the time of the later study was 15.5 ng although all yields were within their accepted range for 95% statistical confidences i.e. mean ± 2 standard deviations (8). Since the aromatic amines are found at nanogram quantities in cigarette smoke, this level of variation might not be unexpected and I should point out that this is not a reflection of Labstat performing badly.

The data, shown in Figure 2, suggested that *N*-nitrosonornicotine (NNN) yields might also have shown temporal effects, especially for data produced under the Canadian intense regime although we did not scrutinise relevant CM7 monitor data at that time.

The inherent variability when repeating the same measurement on a standard (unchanging) cigarette (CM7) in the same laboratory over a period of time demonstrates the constraints on the reliability of such measurements. This variability should be taken into account when interpreting the significance of numbers such as those from the Australian benchmark study. Laboratories doing routine testing usually monitor such variability on reference cigarettes and indeed Labstat carried out analysis on Canadian CM7 cigarettes in both time periods as part of their quality control procedure. Such temporal monitor data also needs to be taken into account before making conclusions.

Subsequently, the level of variability within one laboratory of various smoke analytes has been the subject of a presentation and publication by Labstat (9) and describes the variability typically expected within their laboratory. Similar variability would also be expected within other proficient laboratories and the range can be quite wide for certain compounds with problematic methodologies or for those compounds present at relatively low measured levels

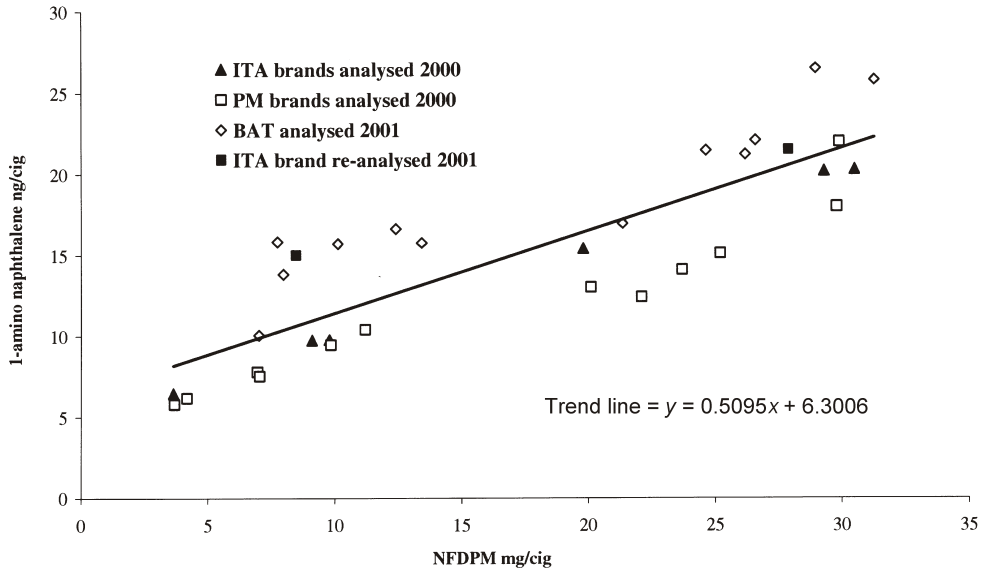

Figure 1. Relationship between 1-aminonaphthalene and NFDPM smoke yields under ISO and Canadian intense smoking regimes

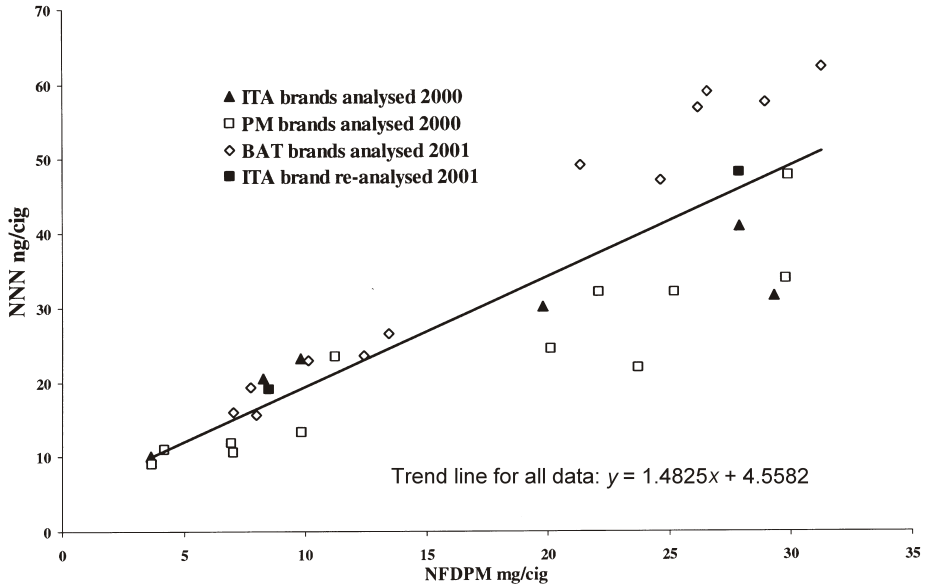

Figure 2. Relationship between NNN and NFDPM smoke yields under ISO and Canadian intense smoking regimes

i.e. in microgram or nanogram quantities per cigarette. The levels of both within and among laboratory variability across a wide range of proficient laboratories using their in-house methodologies has been summarised in the work organised and published by CORESTA (3) and previously described by other groups (10, 11). The analysis (1) is one such example that highlights the need for standardised methods for smoke emission measurement and also the need for the setting of tolerances around measurements, based on real-life within- and among-variability before data are over-interpreted.

In summary, the Australian benchmark study shows some temporal effect on long-term measurement variability within a laboratory and it is clear that to those not involved initially in this study, this analytical variability issue would not be obvious. Since the analysis (1) had not taken into account this systematic and within-laboratory variation, caution should be taken in the treatment of these measurements and any over-interpretation when making conclusions. Variability of data between different laboratories is likely to introduce even greater uncertainties and is the reason for the tolerance values given in the relevant standard (12) and already applied to NFDPM, nicotine and CO measurements during the verification process used by Government laboratories.

For the 100% flue-cured style products on sale in Australia in 2000, I would re-iterate the claim made by ITA and questioned by KING *et. al.* (1) that it is not unlikely that individual brand differences between products of the same tobacco style would have a minimal, if not undetectable, impact on emission data when taking into account measurement variability both within-laboratory over time and when emissions are measured at different laboratories. This observation applies to countries such as Australia where only flue-cured tobaccos are popularly smoked. However it is clear that different conclusions would be

made when analysing blended cigarettes, on sale in other countries where various proportions of differently cured tobacco types are used such as those studied in the Massachusetts benchmark (13).

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