

Variability of NNN in Tobacco and NNN Levels in Smokeless Tobacco Products

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Overview

- Historical NNN levels in different tobacco types grown in the US
- NNN levels measured in 7 smokeless tobacco product bases during processing
- NNN levels reported to Health Canada for U.S. Smokeless Tobacco Company (USSTC) products distributed in Canada
- Look at FDA's estimate that 30% of moist smokeless tobacco (MST) products have dry weight NNN \leq 1 ppm.*

* Given in Table 3 of Tobacco Product Standard for N-nitrosornicotine Level in Finished Smokeless Tobacco Products, Preliminary Regulatory Impact Analysis, Docket No. FDA-20 16-N-2527

Tobacco Leaf Sampling

- NNN levels of dark fire cured, dark air cured, and burley tobaccos were examined
- Sample number varied from year to year and from tobacco type to tobacco type
- Dark tobacco samples were collected from 2005 to 2013 and in 2016 – Hopkinsville area
- Burley tobacco samples were collected from 2010 to 2016 and represent 4 burley production regions

Tobacco Leaf Sampling

Dual-Core Sampler

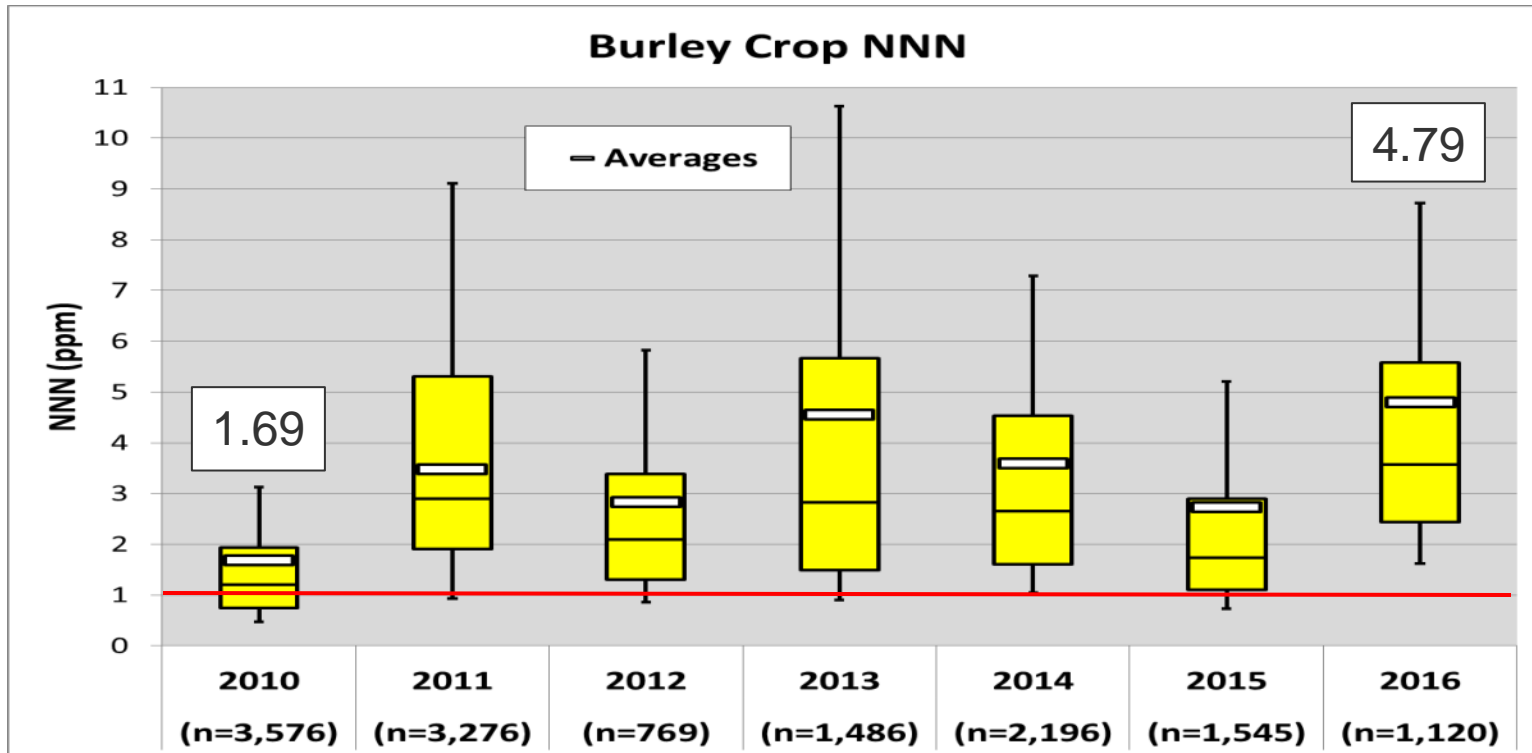


Sample Processing

- Immediately frozen using liquid nitrogen
- Ground using a 20-mesh screen
- Stored at -20°C

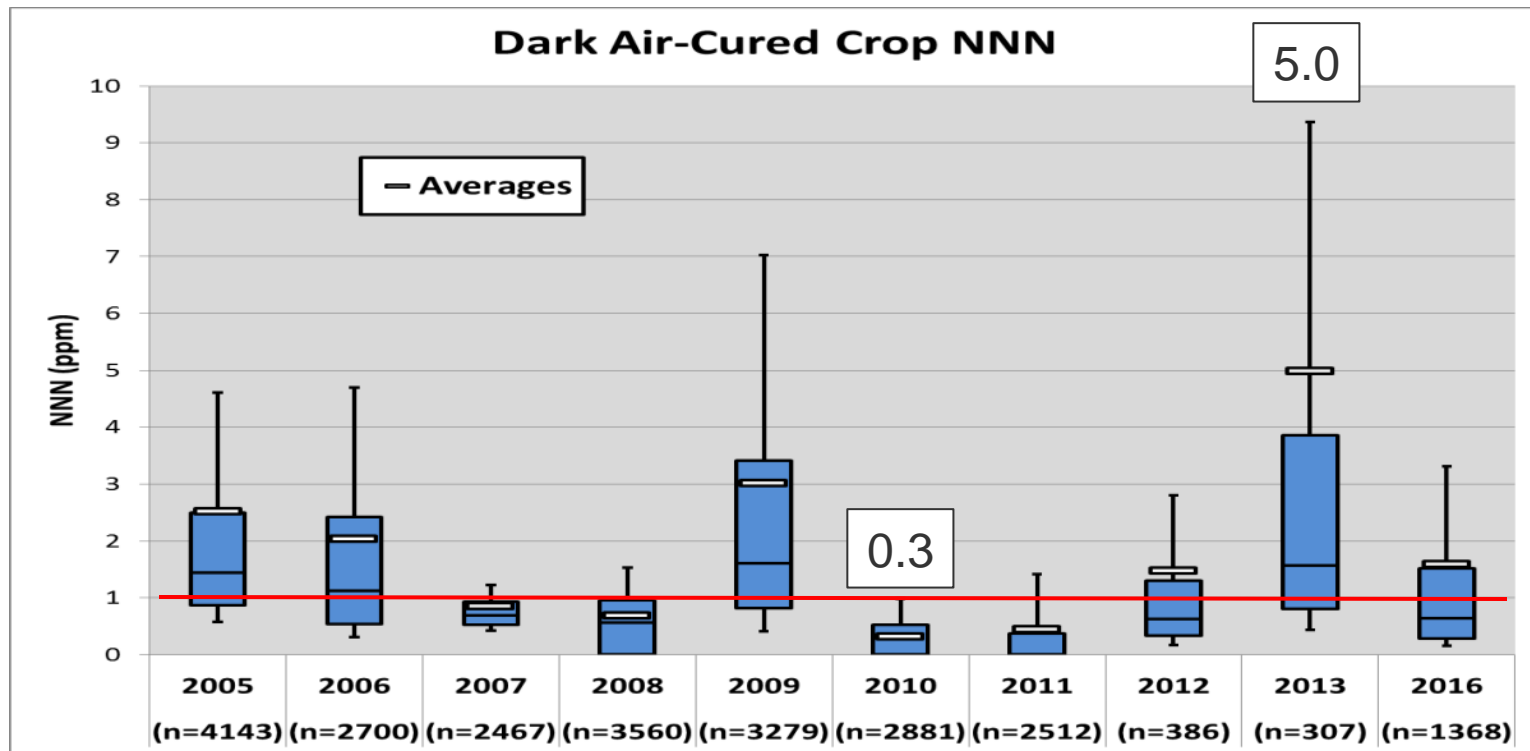
Basket

Burley Tobacco NNN Levels



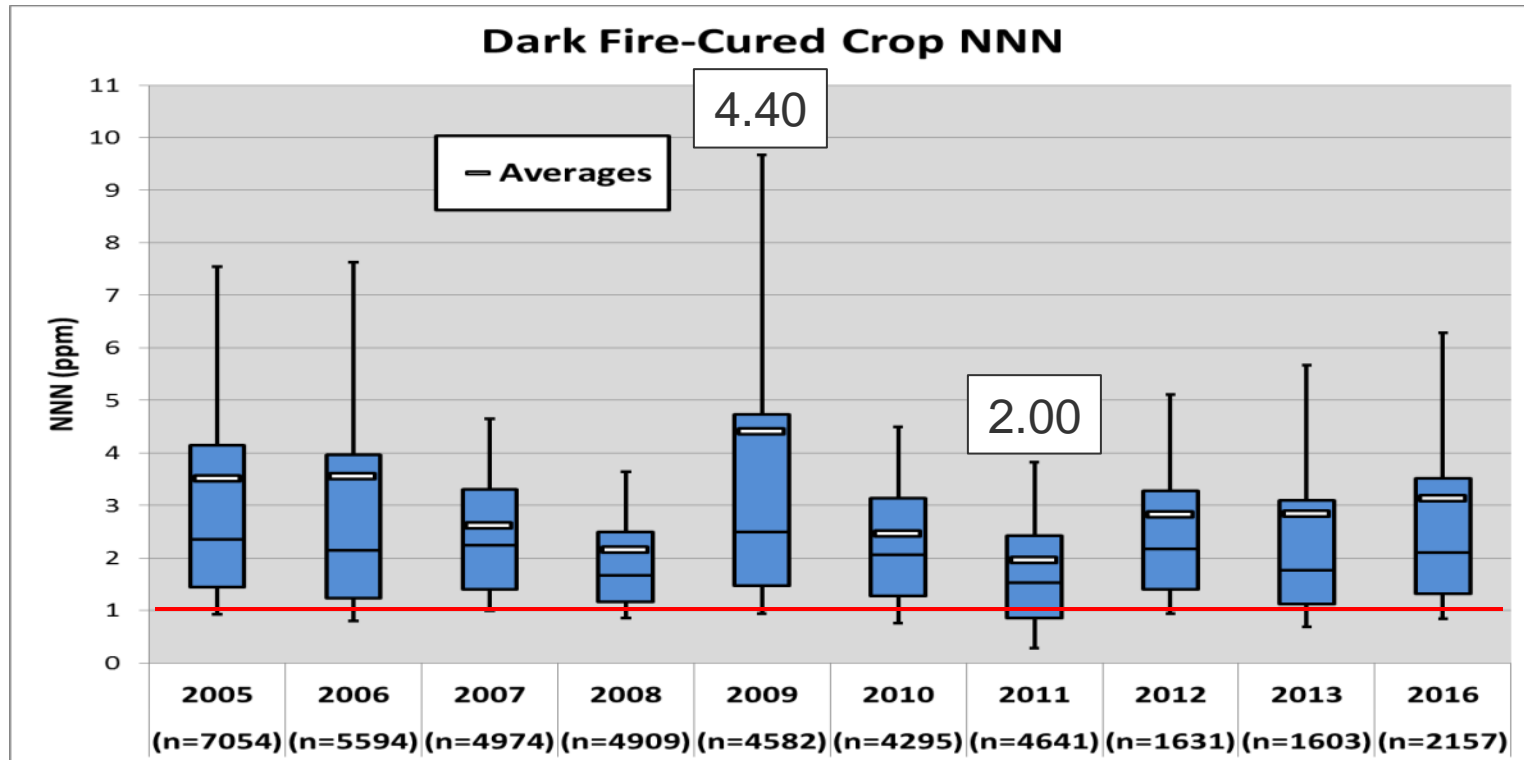
The outer whiskers of the box plot represent the 10th and 90th percentiles, the box represents the 25th to 75th percentiles, the median is represented by the black line across the middle of the box, and the annual mean is displayed by the white bars.

Dark Air-Cured Tobacco NNN Levels



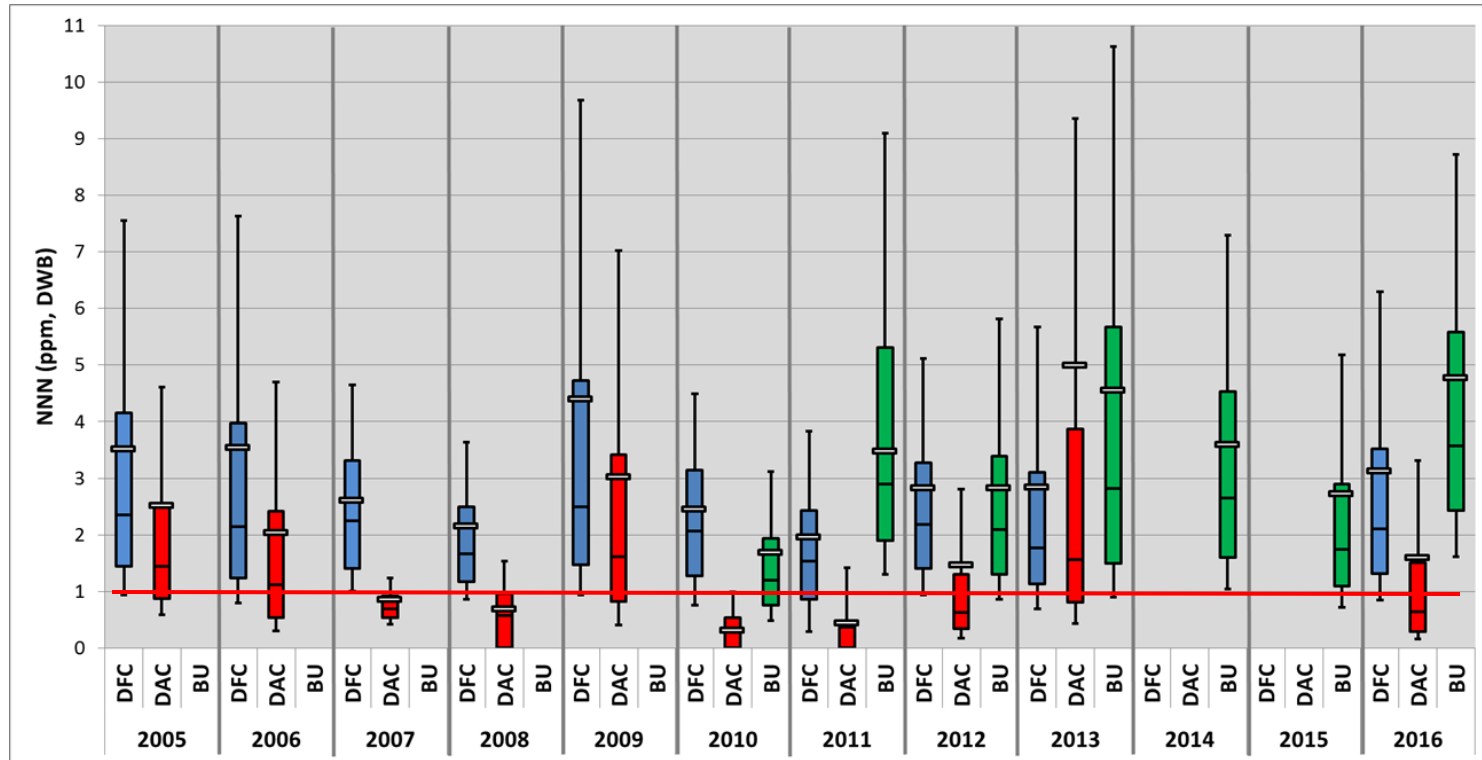
The outer whiskers of the box plot represent the 10th and 90th percentiles, the box represents the 25th to 75th percentiles, the median is represented by the black line across the middle of the box, and the annual mean is displayed by the white bars.

Dark Fire-Cured Tobacco NNN Levels



The outer whiskers of the box plot represent the 10th and 90th percentiles, the box represents the 25th to 75th percentiles, the median is represented by the black line across the middle of the box, and the annual mean is displayed by the white bars.

Tobacco NNN Levels

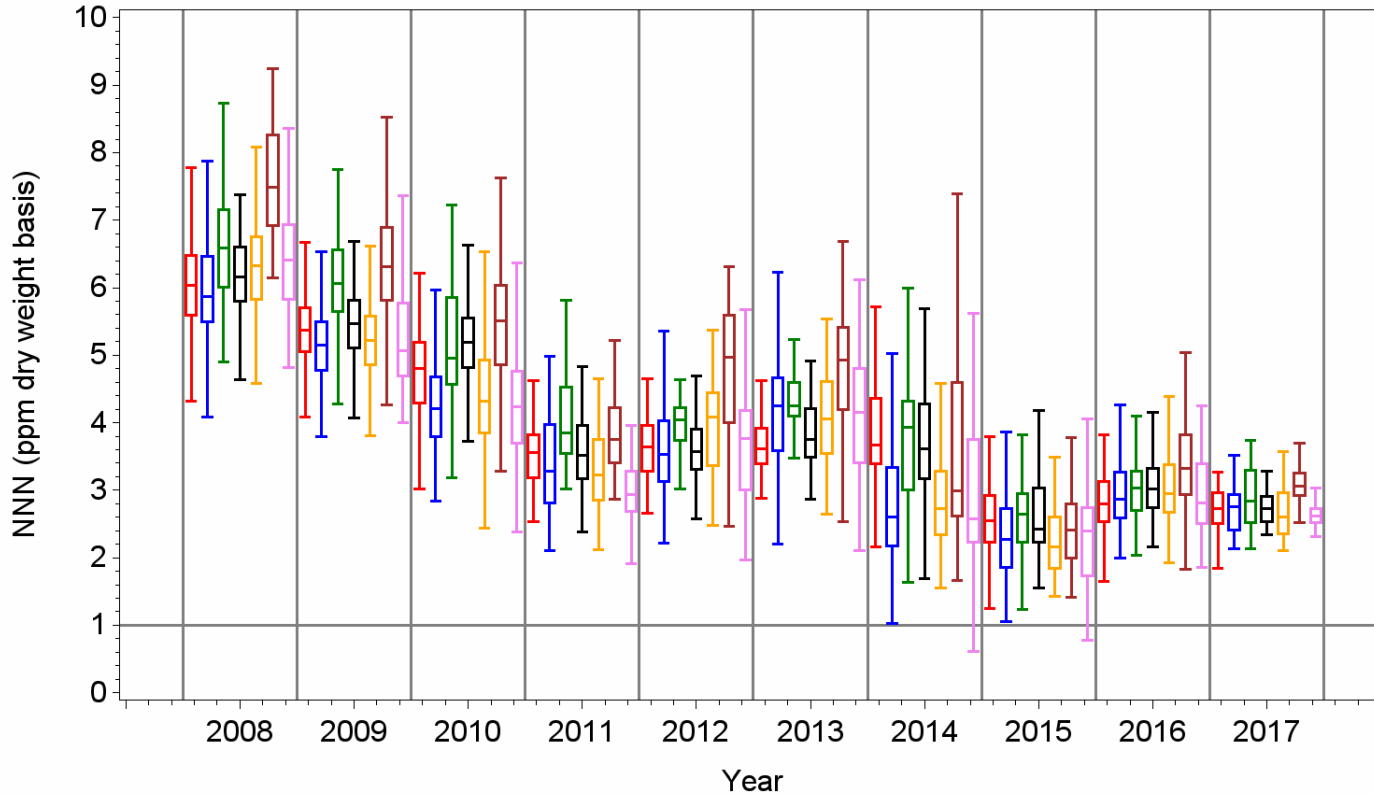


The outer whiskers of the box plot represent the 10th and 90th percentiles, the box represents the 25th to 75th percentiles, the median is represented by the black line across the middle of the box, and the annual mean is displayed by the white bars.

NNN Levels in Tobacco Bases

NNN levels measured in 7 smokeless tobacco product bases during processing

NNN Levels in Smokeless Tobacco Base During Processing



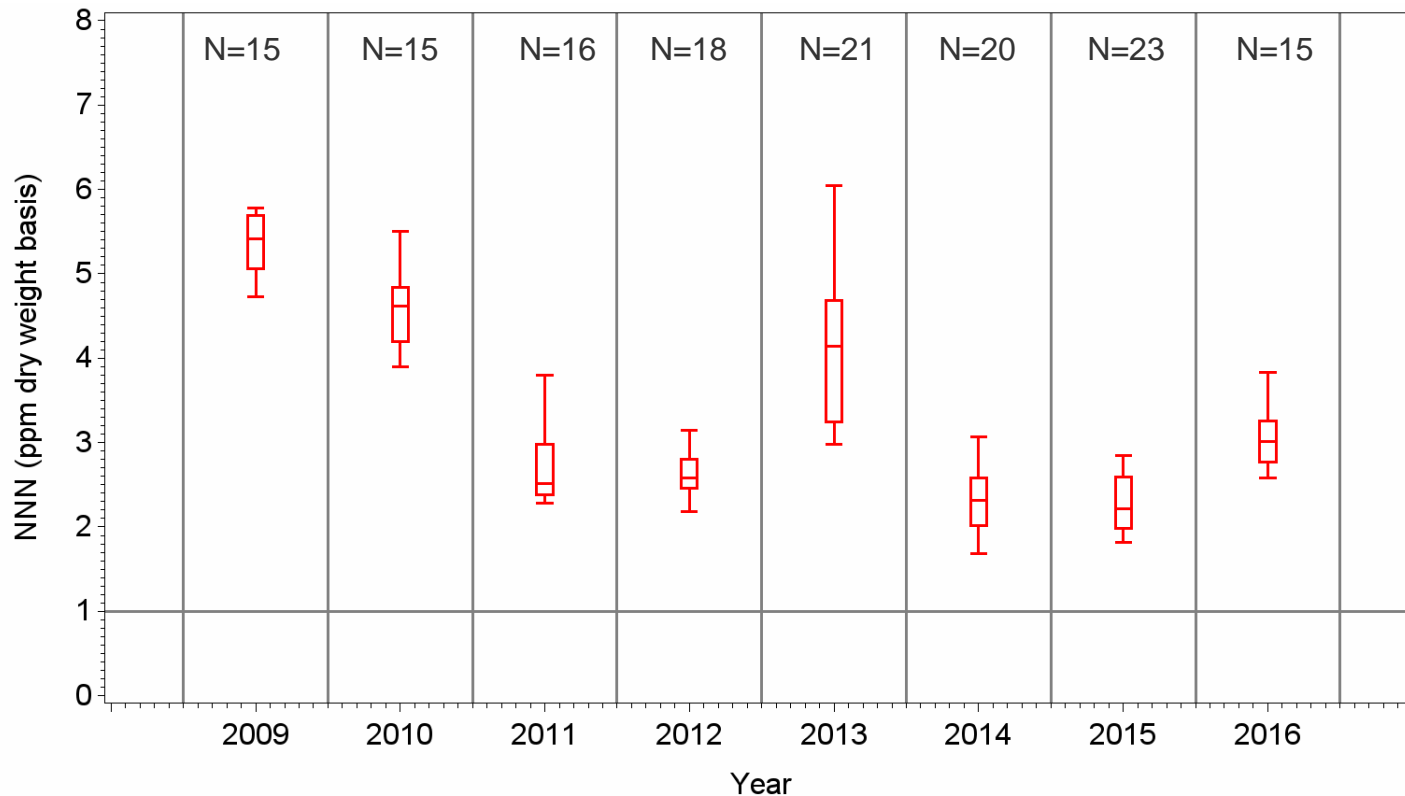
Boxes within each year show the seven different base tobacco blends cure. The whiskers show the minimum and maximum points, the boxes extend from the 25th to 75th percentiles and the line within the box shows the median.

NNN Values Reported to Health Canada

Under Canada *Tobacco Reporting Regulations* annual constituent reporting (including NNN) is required for products distributed in Canada

Data from 15 to 23 products were reported from 2009 to 2016

NNN Levels in MST Products Distributed in Canada

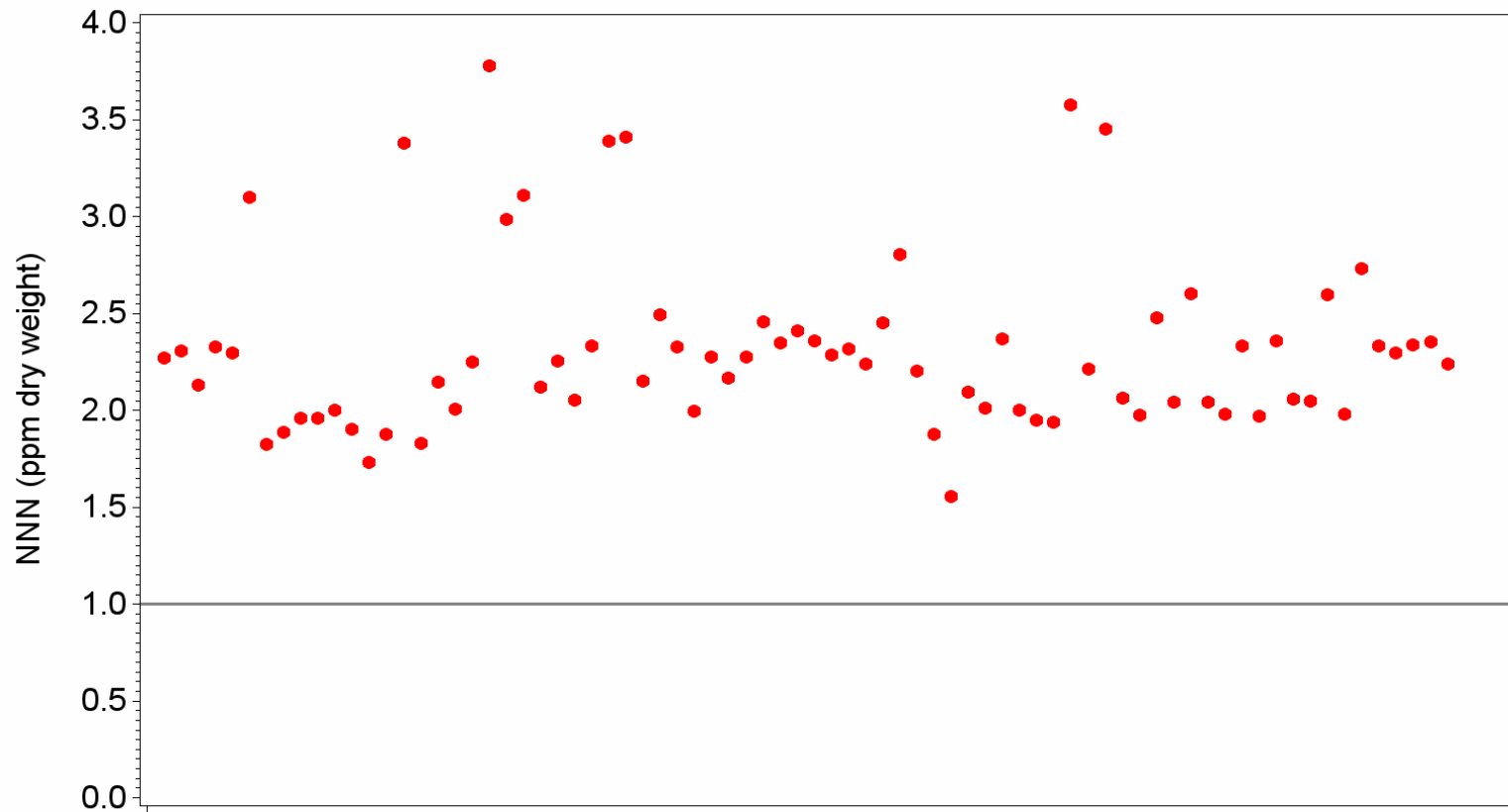


Boxes within each year show the USSTC products distributed in Canada and reported to Health Canada. The whiskers show the minimum and maximum points, the boxes extend from the 25th to 75th percentiles and the line within the box shows the median.

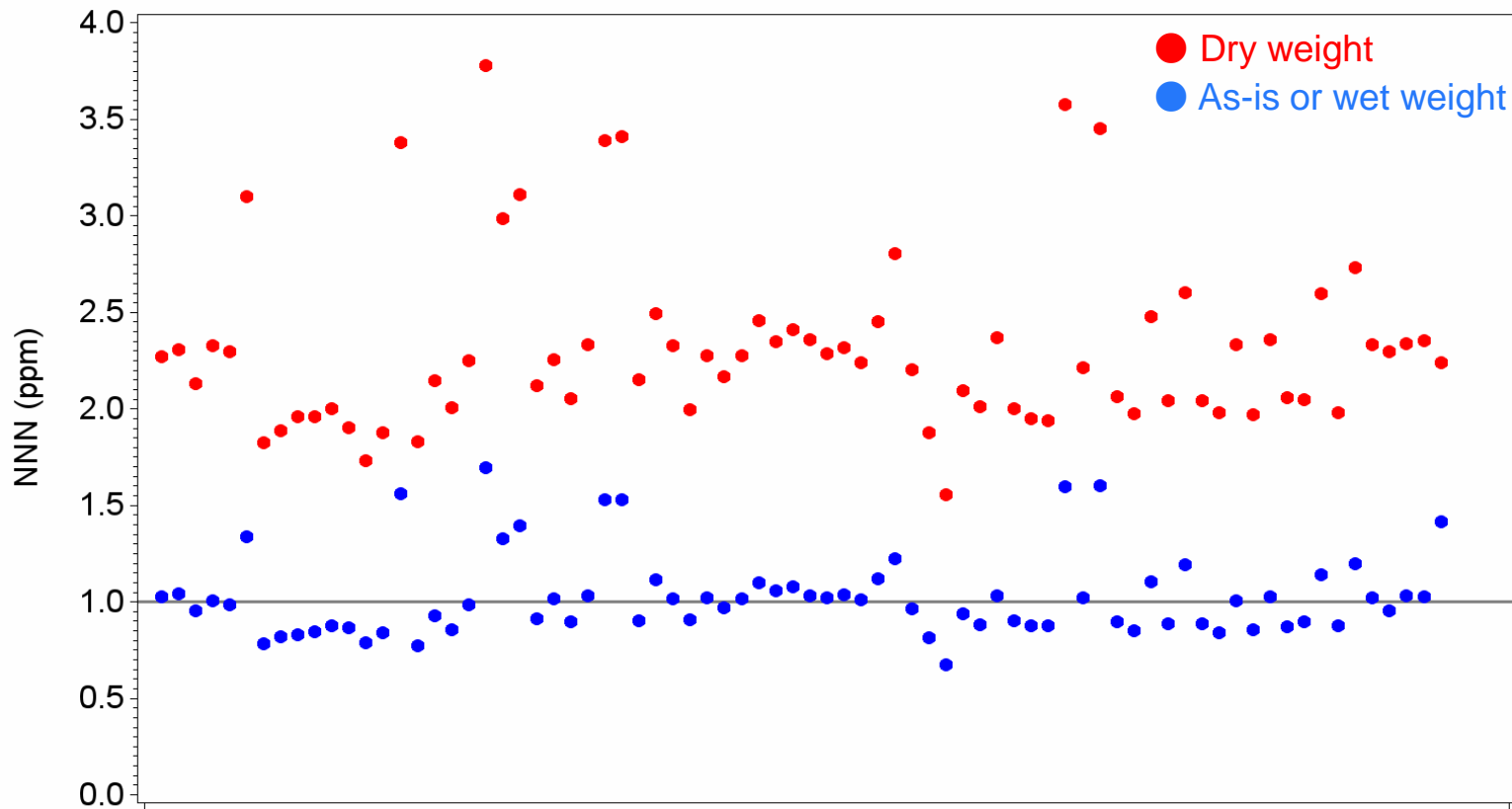
FDA Proposed Product Standard

- Early this year, the FDA proposed a product standard for smokeless tobacco products. (*Federal Register/ Vol 82, No. 13 / January 23, 2017 / pp. 8004-8053*)
- Proposed standard: the mean level of NNN in any batch of smokeless tobacco product should not exceed 1.0 $\mu\text{g/g}$ [or ppm] (**dry weight basis**) throughout its shelf life
- As part of the FDA analysis, the current percent of MST products estimated to meet the standard was **30%**

USSTC 2012 MST NNN Testing Results Reported to FDA



USSTC 2012 MST NNN Testing Results Reported to FDA



Conclusions and Observations

- NNN levels in tobaccos used in moist smokeless tobacco products are highly variable and generally have dry weight NNN values above 1.0 ppm.
- Corresponding product bases and finished products are also extremely variable in NNN content and the measured dry weight NNN values of MST products are almost universally above 1.0 ppm.
- The FDA estimate of 30% for MST products meeting the proposed 1 ppm dry weight standard does not agree with USSTC product data

Questions