Mycotoxins 2018: Fit For Purpose σ Review

Do we inform or do we instruct?
The Role of ffp $\sigma$ in Z Scores for the Mycotoxin PT Scheme

$Z$ is a Normalized measure of where you stand relative to the other participants in the scheme. ffp $\sigma$ is the normalizing factor.

\[
Z = \frac{x_{LAB} - X_{AV}}{\sigma_{ffp}}
\]

- Measured as the difference between your analysis ($x_{LAB}$) and our best estimate of the true analyte concentration ($X_{AV}$) described as the Assigned Value.

- And here’s the issue: This difference is divided by the Modified Horwitz SD ($\sigma_{ffp}$ is $\sigma_{Modified \ Horwitz}$).
How ffp $\sigma$ Affects Z Scores in the Mycotoxin PT Scheme

We are currently using the Thompson (January, 2000) Modified Horwitz %RSD to estimate the fit-for-purpose SD in the Mycotoxin scheme.

$$Z = \frac{X_{LAB} - X_{AV}}{\sigma_{\text{Modified Horwitz}}}$$

$\sigma_{\text{Modified Horwitz}}$ controls your Z score.
If it is too low, you will get a higher (failing) Z.
If it is too high, a lower Z and an artificial PASS.
\[
\begin{align*}
\sigma_R &= 0.22 \times C \\
\sigma_R &= 0.02 \times C^{0.8495} \\
\sigma_R &= 0.01 \times C^{0.5} \\
\%RSD &= 22 & \text{if } C < 1.2 \times 10^{-7} \\
\%RSD &= 2 \times C^{-0.1505} & \text{if } 1.2 \times 10^{-7} \leq C \leq 0.138 \\
\%RSD &= C^{-0.5} & \text{if } C > 0.138
\end{align*}
\]

Mycotoxin analysis usually in ppb range.
Are we representing the real data adequately??
Modified Horwitz, our PT Program Approach
BIPEA, Another PT Program Approach
BIPEA, Another PT Program Approach
Animal Feed & Pet Food Data 2013 to 2018 Data
Modified Horwitz Curve

6,821 Data Points
Over 5 years
From ~65 samples

Only 6% of Data is > 20% RSD
Fitting only Mycotoxin data to a Thompson like modification.
Back to the Original Horwitz Approach  
J. AOAC, 1980

Relationship between $\sigma$ (Reproducibility SD) and concentration $C$ (mass fraction).

$$\sigma = AC^B$$  
Where $A$ and $B$ are constants

$$\log(\sigma) = \log(A) + B \times \log(C)$$

Straight line plot of Log (reproducibility SD) vs Log (concentration)  
With Slope $B$ and Intercept $\log(A)$.

**Original Horwitz Equation:**  
$$\sigma = 0.02 \times C^{0.8495}$$  
$$\%RSD = 2 \times C^{-0.1505}$$
137 Data Points From 2015 to 2018

\[ y = 0.9729 \times C - 0.6793 \]

\[ R^2 = 0.9817 \]

\[ \sigma = 0.21 \times C^{0.9729} \]

\[ \%RSD = 21 \times C^{-0.0271} \]

\[ y = 0.8495x - 1.699 \]

\[ R^2 = 1 \]

\[ \sigma = 0.02 \times C^{0.8495} \]
New Horwitz Trumpet for AAFCO Mycotoxins

\[
\% \text{RSD} = 21 \times C^{-0.0271}
\]
Proposed new ffp criteria for AAFCO Mycotoxins

- Horwitz
- Modified Horwitz
- BIPEA 1, Afla. & Ochra.
- BIPEA 2, DON, Zearal., T2, HT2 & Fumes.
- Horwitz for AAFCO Mycotoxins
Effect of New Horwitz Proposal on Z Scores

Based on 2,400 Z Scores over 3 Years

<table>
<thead>
<tr>
<th>Z Option</th>
<th>Modified Horwitz</th>
<th>New Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action</td>
<td>302 (14.4%)</td>
<td>127 (6.0%)</td>
</tr>
<tr>
<td>Warning</td>
<td>277 (13.1%)</td>
<td>95 (4.5%)</td>
</tr>
<tr>
<td>Compliant</td>
<td>1,529 (72.5%)</td>
<td>1,886 (89.5%)</td>
</tr>
</tbody>
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14.4% Actionable!

More like Feed and Petfood Schemes
In Summary:

- Horwitz not necessarily “one-size-fits-all” approach.
- Our 137 Mycotoxin data points indicate a strong linear log-log relationship different to Horwitz.
- I suggest we implement the “New Proposal” as a “Fitness-For-Purpose” function for AAFCO Mycotoxins.
  
  \[ \%RSD = 21 \times C^{-0.0271} \]

- I recommend “tune ups” every couple of years to refine the relationship, until we reach a point of diminishing returns.
Should we proceed?

The question is, “do we inform or do we instruct?”