University of Sussex

Prof Erik Millstone
SPRU- Science and Technology Policy Research
Freeman Centre, Jubilee Building
University of Sussex, Brighton BN1 9SL, England

5 January 2014

EFSA on Aspartame, January and December 2013

This document provides an outline critique of the recent publication by the European Food Safety Authority of its *Scientific Opinion on the Re-Evaluation of Aspartame (E 951) as a Food Additive*, on 10th December 2013 and an earlier draft assessment issued on 8th January 2013.

The central argument of my critique of the assessments of aspartame provided by EFSA'S Panel on Food Additives and Nutrient Sources added to Food (ANS), published firstly in January and then in December of 2013, is that the criteria by which the individual studies were interpreted were 'consistently inconsistent' and biased against consumer protection. The EFSA Panel opportunistically accepted at face value almost all of the studies suggesting that aspartame is harmless, while entirely discounting every single study indicating that aspartame may be harmful, even though the quality, power and sensitivity of many of the studies that were discounted were markedly superior to those of the contrary studies deemed reliable.

In Tables 1 and 2 below, I provide an analysis of the ways in which the ANS Panel's reports of January and December 2013 interpreted two main categories of toxicological studies: namely those that did and those that did not appear to indicate that aspartame could be harmful to consumers. They provide estimates of the numbers of studies deemed reliable and unreliable, and the percentage of them that were variously commercially or non-commercially funded.

Table 1 specifies the number of toxicological studies, for which the panel provided an interpretation, which reported no indication that aspartame is harmful. It differentiates those studies under two headings, namely those the ANS Panel deemed reliable and those it deemed unreliable, for both the January and December 2013 documents. It also estimates the percentage of those that were commercially funded. Table 2 provides similar figures but for all those studies that did indicate that aspartame might be harmful, and also reports the percentage that were funded non-commercially.

contact us Professor of Science Policy SPRU Freeman Centre University of Sussex, Brighton BN1 9SL
T +44(0) 1273 877380
F +44(0) 1273 685865
e.p.millstone@sussex.ac.uk
www.sussex.ac.uk

Table 1: EFSA's interpretation of the reliability of studies *not* indicating harm, by number of studies

	Number of studies reviewed	Percentage funded commercially	Number treated as reliable	Number treated as unreliable
Jan 2013	83	96%	80	3
Dec 2013	66	97%	53	13

Table 2: EFSA's interpretation of the reliability of studies indicating possible harm, by number of studies

	Number of studies reviewed	Percentage funded non-commercially	Number treated as reliable	Number treated as unreliable
Jan 2013	27	100%	0	27
Dec 2013	66	100%	0	55

Those tables show that the EFSA panel twice reached the conclusion that aspartame is safe, not by consistently applying uniformly critical standards to the evidence from all studies, but by routinely forgiving almost all the shortcomings of favourable studies, while being unremitting critical of all the studies suggesting any possible risks. Numerous putative false negatives were treated as if they provided true negatives, although they were almost all from commercially-funded studies, while every single putative 'positive' toxicological finding was discounted as a false positive, even though they were all from studies supported by non-commercial funding. The panel's overall conclusions were driven more by its biased interpretative assumptions than by the evidence

adduced. However you might wish to construe that pattern, it cannot be remotely characterised as 'putting the consumer first'.

If the panel had taken a genuine position of ethical, social and policy neutrality, it might have been equally sensitive to possible false negatives in Table 1 and possible false positives in Table 2. If it had put consumers first, it would have given greater attention to potential false negatives than to false positives. In practice the ANS Panel twice took a pro-industry view, being massively more critical of studies suggesting possible harm than of their opposites.

The shortcomings of the studies that suggested aspartame may be harmless (which were deemed reliable) were often far greater than those of studies suggesting that aspartame may cause harm (which were deemed entirely unreliable). The benchmarks of credibility were therefore distinctly asymmetric, in a way that failed to put consumers first.

For example: the EFSA Panel discounted as entirely unreliable the results of the only non-commercially funded long-term aspartame rodent feeding studies, which were conducted by the Ramazzini Foundation and published this century. In contrast, studies conducted in the 1970s by, or under contract to, aspartame's commercial sponsor (G D Searle) were conducted incompetently and reported misleadingly, but EFSA treated almost all of them as if reliable.

The failure to acknowledge the very serious shortcomings in at least 15 of the early studies is especially troubling given that I provided EFSA, in response to a specific request from EFSA in 2011, with detailed evidence – in the form of photocopies of original documentation – which showed for example that "Observation records indicated that animal A23LM was alive at week 88, dead from week 92 through week 104, alive at week 108, and dead at week 112."[1] How a study characterised by such a feature could be treated as reliable entirely escapes me.

In the rebuttal I provided to EFSA on 22nd February 2013 to its draft review, I yet again drew the Panel's attention to the reasons why the apparent findings of many of Searle's studies were seriously unreliable, but a collective set of blind eyes have been turned to the evidence showing that at least 15 of the initial portfolio of studies cannot be relied upon. Nonetheless, studies E11, E33-34, E40, E41, E43 and E70 were treated as if reliably indicating that aspartame is safe.

If the EFSA panel's criteria of appraisal had been symmetrical between possible false positives and false negatives, and reasons for discounting studies had been consistently applied, then the numbers of studies deemed unreliably reassuring would have risen by at least 15.

EFSA's credibility has been seriously damaged, while the ANS Panel has lost whatever little credibility it might previously have had. As EFSA is failing to meet its responsibility to protect consumers from food-borne risks, the responsibility for sorting this mess out falls to the Parliaments and Governments in the EU Member States.

Yours faithfully,

Erik Millstone

[1] Bressler J et al, *Establishment Investigation Endorsements, of Searle Laboratories Division of G.D. Searle, Chicago, for the Bureau of Foods*, 18th July 1977 and 7th August 1977 7 Aug 1977 p. 2