

Scottish Government Public Petition Committee By e-mail <u>chris.hynd@scottish.parliament.uk</u>

18th January 2014

Dear Committee members.

Ref: PE1376

You will no doubt be aware that EFSA have yet again declared aspartame safe and it is OK to consume methanol every day in your food; they have just condemned Scotland to another 10years of methanol poisoning.

We totally disagree with EFSA's decision and regard this opinion fatally flawed, it does not contain all the evidence presented to the ANS panel, and does not demonstrate the total safety of aspartame. In fact it is a disgrace.

On the 10th of December 2013 when the EFSA opinion was published, I was at the House of Lords with a representative of EFSA commenting on the opinion, at a meeting of the Parliamentary Food and Health Forum (FHF) Our presentation was well received; the full minutes can be read here :- <u>http://www.fhf.org.uk/meetings.php?meeting_id=27</u> and a press follow-up here:-

http://www.foodnavigator.com/Science-Nutrition/Aspartame-sparks-methanol-row-at-food-forum

Today I distributed to the entire membership of the EFSA Advisory Forum, my critique of the Final Opinion to ensure that they have knowledge of our concerns and can make a better judgement on the matter. I invite the Scottish PPC to do the same. Here is a link to my critique and e-mail.



My original request to the PPC was to inform Scotland, invite discussion and alert the medical profession, to the danger of the methanol in aspartame. I had hoped that health being a devolved matter, Scotland could take a lead in deciding for itself whether consuming methanol was a good idea or not. Regrettably Scotland's Government and FSA appears to have reneged on its responsibilities and will do nothing until they hear from London or Europe on this matter; Europe has now spoken.

My question now is. Considering all the evidence we have put forward (please read all he links in this letter) in opposition to EFSA's opinions and the hidden damage to the health of the Scottish people due to methanol poisoning from aspartame. Is the Scottish Government and the SFA to burry its head in the sand again or take a lead and independently investigate this matter further.

Yours Sincerely

James McDonald (UKAAC)



James McDonald

Critique of:

Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive1

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)2, 3 European Food Safety Authority (EFSA), Parma, Italy

<u>http://www.efsa.europa.eu/en/efsajournal/doc/3301.pdf</u> final opinion. <u>http://www.efsa.europa.eu/en/search/doc/523e.pdf</u> Technical report

EFSA first produced a Draft Opinion (Jan. 2013) this was followed by two public consultations; one on-line $(8^{th} Jan. - 15^{th} Feb. 2013)$ followed by a scientific meeting in Brussels (9th April 2013) The final opinion due out in May 2013 was extended by 6 Months (to Nov. 2013) "to consider the new information and comments made in the consultations" The final opinion supported by a technical report was finally published on 10th December 2013.

As always; this Opinion concludes that the artificial sweetener aspartame is safe to consume every day of our lives at an ADI of (40mg/kg) It also states that the 10% methanol in aspartame (4.0mg/kg) will do us no harm. We profoundly disagree and consider this scientific Opinion to be fatally flawed and it does not unequivocally demonstrate the safety of aspartame

- From 2009 to date we have provided COT FSA and EFSA with evidence which suggests that the ADI of aspartame is 35 times too high and its NOAEL contains enough methanol to kill a human (Appendix 1) This evidence has never been challenged refuted nor disproved by EFSA so is still valid.
- 2) Not all the information presented to EFSA in the consultations has been addressed, leading to major inaccuracies and suspect conclusions. Our prime concern is how EFSA have <u>not</u> dealt with the methanol component of aspartame.
- 3) Almost without exception, all the studies reviewed by EFSA supporting the "safety" of aspartame in this Final Opinion and in every Opinion since 1982, have been conducted on animals using the whole aspartame molecule. Using the evidence in Appendix 1 we will see this operational model is unsafe and masks the dangerous toxic effect of methanol in humans.
- 4) To justify the presence of methanol in aspartame EFSA relies on uncorroborated wishful thinking; they tell us "The methanol in aspartame and fruits and vegetables is the same; there is more methanol in fruits and vegetables than is released by aspartame so aspartame can do us no harm; and the body treats both methanols in the same way" These are sound bites without a shred of scientific verification supporting them.

- 5) This opinion provides no acknowledgement of the submissions by Professor Woodrow Monte; this is a serious omission and demonstrates a huge gap in knowledge of the ANS panel. Monte has studied "Aspartame: Methanol and human health" for over 30 years and is a leading expert; his website <u>www.whilesciencesleeps.com</u> contains over 700 valuable scientific references which have not been consulted.
- 6) Study results in this paper are constantly compared with the aspartame ADI of (40mg/kg) this is only relevant if the ADI is correct.

Methanol is aspartame's most dangerous component the other two are amino acids. Logically, one would expect the NOAEL of aspartame to be based on the most potentially harmful component, this would automatically cancel out any threat from the other two; instead the NOAEL of aspartame is determined using acute doses of aspartame fed to rats. The logic explaining this is - *"if there is anything wrong with the components, it will show up in the testing"* The problem here is, without knowledge of the individual toxicology of each component how does one know which component could be causing any problems found and how does one know that the dosing regime is correct; also, testing on animals using an individual component without an ADI is surely working without any reference.

The methanol in the NOAEL of aspartame in rats is (400mg/kg) this is more than the lethal dose of methanol in humans, a rat consuming this amount of methanol would certainly not show any ill effects. The practise of carrying out studies on animals using aspartame effectively masks any methanol effect in humans - this is exactly how EFSA decides the "safety" of aspartame today.

An NOAEL of aspartame in rats - is NOT an NOAEL of methanol in humans

In Appendix1 we established two vital undisputed benchmarks for the toxicity of methanol **in humans**, using data collected **from humans**; The blinding dose (114mg/kg) and The fatal dose (343mg/kg) Using this data we can make some realistic comparisons with the conclusions / assumptions drawn in this final opinion, purporting to prove the safety of aspartame - Please read Appendix 1 now.

Note: There is no suitable animal that can be used for testing the effect of methanol in humans.

Note: It is assumed by EFSA that test results in animals are directly transportable to humans?

FO – methanol -5.2.1 acute oral toxicity – p111 - This lists the LD50's for methanol in some popular test animals; we are comparing them here with the lethal dose in humans.

Ld50* mg/kg	Mice *	Monkeys *	Rats *	/	Humans (Lethal dose mg/kg)
	7300	7000	5628	/	343
Times higher than humans	x 21	x20	x16		

In this simple table we can see that these animals are significantly more resistant to methanol poisoning than humans therefore any study results which do not take this into consideration must be suspect. The vast difference in lethal amounts of methanol between animals and humans is accounted for by the fact that all animals have 4 separate routes available for the metabolism and clearance of methanol; humans only have one and that is damaged. Animals use methanol as a food source so only very high doses are poisonous to them – EG methanol is fatal in rats at (5628mg/kg)

In humans the metabolism of methanol to formaldehyde is relatively easy but is dependent on the amount of Ethanol in our blood being zero. For formaldehyde to metabolise to the 2nd metabolite formic acid it requires the attention of two enzymes one of which is damaged. The damaged enzyme (Catalase) prevents the formaldehyde from "finding" the second enzyme (Aldehyde Dehydrogenase ADH III) so metabolism to the safe formic acid is blocked leaving formaldehyde molecules free to cause us harm where ever they appear – Methanol is fatal in humans at (343mg/kg)

Every molecule of unnatural methanol in humans can potentially become a molecule of formaldehyde. The only safe ADI for unnatural methanol in humans is (0.0mg/kg)

Testing using aspartame in rats hides the methanol threat in humans: The highest dose of aspartame used in an EFSA rat study in the Opinion paper (FO - 3.2.5.2.1) is (9600mg/kg) - containing (960mg/kg) of methanol. No effects of any methanol poisoning were recorded in the study, indicating at that level (and anything less) the rats were using the methanol as a food and therefore would be unlikely to show any adverse reactions. Testing aspartame on animals and applying the results to humans masks the methanol danger for humans.

"Methanol from aspartame and that from fruits and vegetables are the same": - No they are not.

- 1) Aspartame's methanol 10% of the molecule by weight is unnatural; it is released in the gut at 86 degrees f from its original methyl ester, which is manufactured using industrial methyl alcohol (methanol) at high strength. This methanol when released in the GI tract rapidly enters the bloodstream waiting for the Ethanol count to drop to zero, before metabolising to formaldehyde; our bodies have absolutely no control over this process. This methanol is the same as that which causes methanol poisoning and death in cases of adulterated potable drinks. Daily chronic amounts of this methanol adds significantly to the burden of naturally occurring methanol.
- 2) Methanol from fruits and vegetables –is totally natural and exists as part of flesh, juices and skin of the plant. It is released during preparation, cooking, mastication and digestion; the strength of this methanol has to be weak to enable the body to handle it. Natural methanol is used by our bodies for its own use and is closely controlled, release of this methanol is a slow process which matches our body's ability to clear it from our blood via breath, urine and sweat. It is no secret that whatever the quantities involved, natural methanol does us no harm and should never be compared to the unnatural methanol from aspartame.

"There is more methanol in fruits and vegetables than is released by aspartame so aspartame can do us no harm":

This is nothing but speculation and a cynical attempt without a shred of scientific corroboration, to divert scientific interest away from aspartame's methanol – Unfortunately it has been a spectacular success.

"The body treats both methanols in the same way"

Again speculation without corroboration; see 1) & 2) above - nothing can be further from the truth, yet a spectacularly successful sound bite.

Formaldehyde is the real problem - (W.C. Monte "While Science sleeps" 2012):

Specific to humans, the powerhouse behind the unnatural little methanol molecule in aspartame is the destructive power of its formaldehyde which has only one objective; to kill our cells and alter our DNA indiscriminately wherever it appears. Formaldehyde is a slow, silent, lethal destroyer of cells and protein over time (0-20yrs) it is also the cause of the rapid methanol poisoning seen almost annually in cases of adulterated alcoholic drinks.

Note: Methanol is the only poison that has a high and low acute dose, both of which will kill humans.

Acting as a Trojan horse for formaldehyde, the little methanol molecule can by-pass all our biological barriers and in the bloodstream can be carried to literally anywhere in the body down to our DNA and in all our most sensitive organs – Brain, breast, lungs etc.

When the ethanol present in our blood falls to zero freeing up the enzyme alcohol dehydrogenase (ADH I) Any methanol molecules at a site containing (ADH I) can metabolise to molecules of formaldehyde: a highly reactive molecule which wants to attach itself to any cellular protein, DNA or even the unprotected nucleus of generator cells nearby, doing damage to them in the process.

When the formaldehyde molecule attaches itself to its target it has left the General circulation and becomes undetectable in our blood "it has disappeared" this happens within a minute or two of first appearing.

Formaldehyde's attack on its target protein etc; is detected by our body's auto immune system triggering it to fight the intruder (formaldehyde)

Only a small percentage of our cells contain the enzyme (ADH I) which turns methanol into formaldehyde but they are in the most sensitive of our organs, Monte identifies 11 of them: Brain, Eye, Blood vessels, Skin, Breast, Kidney, Bone, Pancreas, Lung, Fetus, and Liver.

Countless numbers of animal studies have been offered in support of this ANS decision; many of which have been heavily criticised by others as being - too old (circa 1974), manufacturer funded (80%) of questionable quality and given preferable consideration by EFSA over better independent studies.

We have provided another prospective, whereby every facet of EFSA's case for the safety of aspartame is questioned and found wanting we have found:-

- 1) EFSA have suppressed our challenges to its ADI and NOAEL (appendix 1) of aspartame since 2009; they have never disproved them or demonstrated them false.
- 2) EFSA have not demonstrated a clear understanding of the danger of aspartame's methanol in humans so have missed the potential for harm.

- 3) The dependency of uncorroborated comments for comparing methanol types to "prove" methanol safe to consume have been found to be false.
- 4) The reliance on studies where aspartame is fed to animals has been shown to be unsafe and masks the potential for methanol poisoning in humans.
- 5) There is a distinct lack of understanding of the metabolism of methanol to formaldehyde and formaldehydes role in methanol poisoning. This gap in knowledge would not be there if EFSA had included the submissions of Woodrow C. Monte, supported by his book "while Science Sleeps"

For all these reasons this Scientific Opinion is unworthy of the organisation that produced it and who are charged with protecting the health of over 500 million people; we deserve better.

The true scale of the harm caused by 32 years of slow poisoning by aspartame's methanol has yet to be determined but what is certain; we must STOP consuming methanol in our diet NOW.

Appendix 1 represents data produced by scientists which has been publically available for over 50 years. It is the key to the unsafe status of aspartame but is not recognised nor refuted by EFSA.

We call for our data in appendix 1 to be verified or refuted publically by independent non food scientists and for the submissions by Woodrow C. Monte together with his publication "while Science Sleeps" be considered at the same time.

Woodrow Monte says:-

"Something is wrong in our world today; good people are becoming sick and dying from a range of diseases collectively called "Diseases of Civilization" (DOC) the names of which are on 75% of today's death certificates; they include – MS, Alzheimer's disease, breast cancer, Lupus, erythematosus, rheumatoid arthritis, cardiovascular diseases, melanoma and autism. All these with obesity and diabetes are currently at epidemic proportions and our scientists have no idea what the cause is" – I offer for your consideration Professor Monte's hypotheses:-

"Methanol is the etiological cause of all the Diseases of Civilisation"

We must stop adding methanol to our food NOW

Abbreviations:

СОТ	Committee on Toxicology (UK)
FSA	Food Standards Agency (UK)
EFSA	European food Safety Authority
ADI	Acceptable daily intake
NOAEL	No Observable Adverse Effect Level
LD 50	Lethal dose where 50% of test animals die
ANS	SCIENTIFIC PANEL ON FOOD ADDITIVES AND
	NUTRIENT SOURCES ADDED TO FOOD
DNA	Double stranded Nucleic acid.

Yours Sincerely,

James McDonald

(UKAAC) 16th January 2014

ADI of methanol

Based on the data compiled over the years by doctors who treated patients poisoned by methanol as a result of consuming adulterated alcoholic drinks, we were able to set an ADI and NOAEL of methanol.

From the literature the generally accepted acute doses of methanol which harm humans are-

- i) The blinding dose 1 tablespoon 10ml (114mg/kg)
- ii) The fatal dose 3 tablespoons 30ml (343mg/kg)

There is no data in humans from which to confirm an NOAEL but it must be somewhere between 0 and 114 mg/kg we chose 10% of the blinding dose – 11.4 mg/kg as the NOAEL of methanol.

The methanol ADI is calculated by taking the NOAEL (11.4mg/kg) and dividing it by 100 = (0.114mg/kg)

The current ADI of aspartame (40mg/kg) contains 10% methanol (4.0mg/kg)

The methanol in aspartame today is 35 times too high for safety.

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Methanol: in the NOAEL of aspartame.

If the ADI of aspartame is wrong so must be its NOAEL. The current NOAEL of aspartame is (**4000mg/kg**) comprising of: - (mg/kg)*

Phenylalanine 50%	Aspartic Acid 40%	Methanol 10%	/	(Lethal dose of Methanol in humans)
2000*	1600*	400*	/	343*

It is clear the amount of methanol in the NOAEL of aspartame in rats exceeds the lethal dose of methanol in humans. - The current NOAEL of aspartame is totally wrong.

An NOAEL of aspartame in rats - is NOT an NOAEL of methanol in humans:

Using methanol as the most toxic component of aspartame its current ADI should be (1.14mg/kg)