

PE1376/E

Dear Madam Convenor,

REF: Petition PE1376

14th January 2011

The answers given by the Scottish Government and Scottish FSA to the PPC questions of 8th Dec. 2010, do not in any way address my concerns - I request that the Petition stays open – and offer the attached papers in support.

UKAAC response to letters from Scottish Government and Scottish Food Standards Agency:

Scottish Government questions:

The letter from Mr Fergus Millan Chief medical officer and Health Directorate, does not comment on our request to alert medical professionals of the methanol in our diet. Could the Committee please ask him why he did not comment?

- **“No. Current evidence does not support a ban”**

The curtness of this reply indicates that perhaps Mr Millan is not in possession of all the facts; is he aware for instance that the FSA and SFSA are out of step with most of Europe regarding the safety of aspartame?

At the 36th meeting of the EFSA Advisory Forum in May 2010, the majority of delegates from the 27 EU Nation States indicated they were not convinced aspartame is safe, by not endorsing their own scientific expert's recommendation to that effect. The UK delegate at the Forum was Dr. Andrew Wadge, FSAs' Chief Scientist. I have a letter from Mr Tim Smith Chief Executive of FSA confirming that the FSA opinion at the forum for the UK was – “no change to the current opinion” IE aspartame is still safe for our food!

Would it be in order for the PPC to request from Dr Wadge, the reason why the consensus of the AF delegates at the meeting rejected their own National Experts recommendations?

The evidence that people who consume aspartame over time and are harmed by it, is confirmed by the vast amount of anecdotal evidence available (mainly from the US) and as contained in our own GPs' patient's records.

- I have no comments to make on the second question posed.

Scottish FSA questions :

Prof. Milne in his letter went to great lengths to clarify the roles of the SFSA and SFAC; I believe the first paragraph of his second page is the relevant statement and I will assume therefore, when he refers to “The Agency” he means the Scottish Food Standards Agency.

It is worth noting at this stage that the SFSA deals only with issues that purport to “prove” that the consumption of aspartame over the last 28years has been “safe”, Our campaign concentrates on the initial approval process of aspartame by COT in 1982 and some serious errors which has led to free methanol being present in our diet for the last 28yrs without the knowledge of our population or our doctors.

“The Agency does not support the Petition”:

Para. 3 –*“The Agency agrees with the petitioner that when aspartame is metabolised one of the breakdown products is methanol. However, we do not agree on the toxicological significance of this”*

COMMENT 1:-

This statement says it all, and is inaccurate in one very important area – The methanol released by aspartame is FREE methanol and the toxicological significance is that free methanol is a slow stealthy killer of humans. This is not the case for methanol found naturally in the diet, our alcoholic drinks or that manufactured by the body for its own use, this methanol is always bound to inhibitors which slows down the methanol metabolism allowing time for it to be eliminated from the body safely - It is significant that Prof. Milne did not mention free methanol anywhere in his letter.

Para 3 - *“Dietary methanol was not thought to be a problem”*

COMMENT 2:-

This statement is very revealing, used in paragraph 7 of annex 1 when discussing COT’s initial approval of aspartame in 1982 it clearly indicates that COT then and FSA /SFSA today have not been aware of or will not admit to, the severe metabolic toxicity of free methanol in humans (see background paper)

The word “dietary” is inappropriate when describing or alluding to the free methanol released by aspartame and is totally misleading. Free methanol is not a food and adds nothing to the diet. Also dietary amounts of natural methanol are well in excess of that released from aspartame, the term “dietary amounts” cannot be justified here either - No one should be consuming free methanol in ANY quantity, it is far too dangerous (see background paper)

Para. 3 – *“The COT agreed that it would be worthwhile to review the available data on the chronic toxicity of methanol”*

COMMENT 3:-

28 years too late!! – Without this vital knowledge in 1982 and right up to OCT. 2009, the FSA and EFSA have been rubberstamping the safety of a product for use in our food without crucial toxicological knowledge of 10% of that product which if known, would surely have condemned it as unsafe and prevented it ever reaching the food chain; The knowledge COT required has been in the public domain since well before 1982 – **the MSDS of methanol** (see background papers)

Written Questions:

“What action needs to be taken by Government on the use of free methanol?”

Para 1 - *“There is no evidence of health concerns with the currently permitted levels of aspartame”*

COMMENT 4:-

Wrong: The EFSA Advisory Forum members demonstrated in May 2010 **they are not now convinced** of the safety of aspartame - The FSA and SFSA **are just discovering** the severe toxicity of free methanol - The 1058 cases of anecdotal evidence reports analysed in the last review and the challenges put forward by the UKAAC (the UK Aspartame Awareness Campaign) in OCT 2010 all point to the fact that something must be wrong. Also, The UKAAC has challenged FSA that their permitted level of aspartame in food is **35 times too high,** - they have never refuted nor challenged this?

The FSA and SFSA should surely be erring on the side of caution here and rigorously testing our claims - this is not happening. In Oct.2009 we presented to the FSA and SFSA on behalf of the British people, evidence that showed the possibility that our nation, has been inadvertently consuming free methanol from aspartame for the best part of 28 years with potential serious medical consequences, so far we have been ignored by the UK Chief Medical officer, Government ministers and health departments refer us back to the

FSA had the FSA constantly ignoring or sidestepping the crucial questions the nation needs answers to - we have had a similar response from the SFSA – the British people deserve better.

Para 1 - *“ongoing need to review any new relevant properly accredited scientific information”*

COMMENT 5:-

Here we have it - forget what has happened in the last 28yrs and how physically and mentally sick our society may have become, let's just carry on as before and if we find any purely scientific information from our trusted sources, peer reviewed and relevant to what we want to say, we will have a look at it - this is just not good enough, the Scottish people deserve better.

Any potential health alert / threat MUST be properly investigated; aspartame victims are already sick and sick people should be looked after by their doctor. The current FSA SFSA inactivity is denying our physicians the knowledge to do this.

Prof. Milne in his letter - states that *“Annex 1 provides details on the natural occurrence of methanol in the diet and the ability of the body to safely metabolise this”*

COMMENT 6:

Please read COMMENT 1 – We are in full agreement that the body can cope safely with the natural occurrence of methanol in the diet also any methanol produced by the body, is very tightly controlled and works well within the body's capability to cope. If the body handled natural methanol in the same way as for free methanol, our vegetarians would be very ill indeed and we probably would not have any vegans. The human body has absolutely no defences against the presence of free methanol which has no inhibitors to prevent it following its destructive metabolic pathway: - METHANOL > FORMALDEHYDE > ASPARTIC ACID > Co2 > H2o (see background paper)

Annex 1:

Please read comment 6 – This paper is superfluous and contains irrelevant and misleading information. Instead of providing information we have already agreed it would have been more constructive to explain specifically why they consider consuming free methanol every day is harmless.

Analysis :-

Paragraphs 2, 3, & 4 are irrelevant - Paragraph 5 is clearly trying to include the free methanol from aspartame in its explanation for natural methanol - **Paragraph 6** is astonishing, the only similarity of the methanol's' referred to is the chemical name MEoH. *“The key issue is the amount consumed”* this cannot be true - there is no limit on the amount of natural methanol we can eat in our diets – the only methanol where the amount is critical is for pure /free methanol (see background paper) – **Paragraph 7** please see COMMENT 2 - When *“COT initially approved aspartame they know methanol was released but did not consider it was of concern due to the quantity involved”* Here again we are mixing free methanol with natural and citing the quantity involved as the reason it is safe.

Paragraph 8 – Anecdotal evidence. There are tens of thousands of anecdotal case reports in the US and UK and the reports are basically the same; People suffer a range of medical problems (some very severe) which had developed slowly over time (0-20 yrs) their physician could not pin the cause down to any particular diagnoses (he is totally unaware of the methanol in our diets) They “discovered” aspartame , ceased using it and their symptoms rapidly improved or disappeared altogether.

The FSA /SFSA are on record here stating they don't trust anecdotal evidence, they dismiss it as a credible source of data or any evidence that something might be wrong; it just happens that the results of the FSA Pilot study currently being conducted in Hull based on anecdotal evidence reports, is to be the defining factor in the EFSA's decision on the safety of aspartame in July 2011.

The EFSA is taking our challenges seriously and their momentous decision to ignore their own experts advice is a world first in the sordid history of aspartame, we are in constant communication with EFSA – attached is a recent letter from the Executive Director.

SUMMARY:

Considering all the information the UKAAC has provided to SFSA and FSA since Sept 2009, the content of these two letters is very disappointing, I Expected a credible, professional, science based reply from the SFSA which kicked our case into touch and provided the British people with the confidence that aspartame was indeed safe also that the free methanol from aspartame was not a health risk – this did not happen.

The FSA believes that the body treats free methanol from aspartame in the same way as for natural dietary methanol and since the body handles the larger amounts of dietary methanol without harm the small amounts of free methanol from aspartame should be no problem. This being the case they need to show solid scientific proof of this – I do not see the proof.

We can show that COT did not take the severe metabolic toxicity of the free methanol released from aspartame into account when it was first approved in 1982; COT have confirmed in their reports that they nor the EFSA have ever established an ADI (Approved Daily Intake) for pure / free methanol; We can show that because the ADI of the free methanol was not taken into consideration when the ADI of aspartame was set at 40mg/kg it is 35 times higher than it should be!

Sick people today are testament to the damage being caused through this daily drip feeding of free methanol in our diet. The SFSA letter does not address any of our challenges and I request the PPC seek answers to the following relevant questions:-

- 1) **To Mr Fergus Millan:** *“What comment does the Government have on the petitioner’s proposal to advise Medical professionals of the daily consumption of methanol in the diet from aspartame”*
- 2) **To Dr Andrew Wadge:** *“Why did the Advisory Forum delegates at the 36th AF meeting reject their own scientific experts recommendation that aspartame was safe”*
- 3) **To Prof. Milne – the following:-**
 - i) *“ What scientific evidence do you have which confirms SFSA’s contention that free methanol is safe to consume in regular daily doses irrespective of quantity”*
 - ii) *“It is suggested by the petitioner that the current ADI for aspartame is 35 times higher than it should be because the toxicity of free methanol is not included – your comments please”*
 - iii) *“The petitioner quotes the current Hull Pilot study as being “a defining factor in the EFSA’s decision on the safety of aspartame”” could you explain please and what is the current progress of the study”*

Yours Sincerely,

James McDonald
UKAAC

14th January 2011

Methanol in nature

Methanol which is found naturally in our diets from the ingestion of fruits vegetables etc. is rendered harmless to us by the presence of inhibitors such as Ethanol or Pectin. Methanol produced by the body for its own use is limited, very tightly controlled and causes us no harm. No one has ever become ill through the consumption of fruits and vegetables.

It is wrong to include the methanol contained in our alcoholic drinks here; they are manufactured products and the methanol is bound to the Ethanol which is present in much greater amounts - It is well known that overindulgence can cause health problems.

Methanol in aspartame

Aspartame is a chemical compound of three constituents, Methanol 10% - Phenylalanine 50% and Aspartic Acid 40%. Aspartame contains no inhibitors to the metabolism of its methanol. The constituents separate in the gut and go their own separate way – the methanol is now FREE to follow its dangerous metabolic pathway - Methanol > Formaldehyde > Formic acid – it is the last two which cause methanol poisoning.

Pure /Free Methanol

These are exactly the same chemical and poison us in the same way. PURE methanol is manufactured for use in industry; FREE methanol is released into the bloodstream from aspartame. The release of free methanol can be likened to drinking of a small amount of PURE methanol, the dangers of which are very well known through the deaths of many people who deliberately or inadvertently consume pure methanol.

To keep a perspective here, the scientifically recognised harmful effects of pure methanol on humans are; one tablespoonful (10ml) will make you blind, three tablespoonfuls (30ml) could kill you. These are very modest amounts, if taken in one dose the body's ability to cope is completely overwhelmed and the result is methanol poisoning.

How does the small amount of free methanol delivered form aspartame harm us?

Methanol is the smallest of the Alcohol molecules, it rapidly enters the bloodstream and can easily by-pass all of our protective biological barriers. The first stage of metabolisation is to FORMALDEHYDE by which time (2-4hrs) the methanol can be anywhere in the body. Being a much larger molecule methanol takes the formaldehyde to where it normally cannot go.

PURE/FREE methanol is a slow stealthy killer in humans it operates at the molecular level and over time 0-20 yrs. eventually causes severe organ, tissue and neurological damage to our bodies (methanol Poisoning) Free Methanol is a cumulative poison and its metabolism follows zero order of kinetics, this literally means that irrespective of the dose consumed it takes the body the same amount of time to clear the poison out of our system by which time it has completed its destructive metabolic journey -whether you consume 1mg or 1000mg the free methanol could be in your system for anything up to 30 hrs. The worst possible scenario is where the body receives chronic regular daily amounts of free methanol (irrespective how small they are) IE as from aspartame consumption.

Public information on pure methanol toxicity:

Here we must look to the manufacturer's MSDS (Material Safety Data sheet) for pure methanol, which was available well before 1982. The following links are to two current MSDS form for pure methanol – Note: Methanex is the world's largest producer:-

http://www.methanex.com/products/documents/MSDS_USenglish.pdf Methanex

<http://www.methanol.org/pdf/MethanolMSDS.pdf> Terra

The important features of pure /free methanol which have to be taken into account when considering the effect on the human body are:

Pure/free methanol :-

- i) Is toxic if inhaled, ingested or absorbed through the skin.
- ii) Cannot be rendered non-toxic in humans.
- iii) Is only very slowly eliminated from the body.
- iv) Is a cumulative poison.
- v) Metabolism follows Zero order of kinetics.

What is the ADI of a product?

It is the "Approved Daily Intake" of a product expressed in mg/kg of body weight and represents the amount of a product scientists believe we can consume everyday of our lives without harm.

To calculate an ADI, the toxicity of each product constituent must be established using animal studies to establish a NOAEL ; this is the "No Observable Adverse Effect Level" of the constituent. The NOAEL is then divided by 100 to allow for the difference in species (EG rats to man) and man to man. If a constituent is felt to be non-toxic a NOAEL would not be required.

For aspartame COT did not calculate a NOAEL for any of the main three components but did establish one for DKP (Diketopeperazine) which is a small breakdown product of the Phenylalanine, The ADI for aspartame was set at **40mg/kg** when the ADI of free methanol is taken into account the ADI for aspartame is **1.14mg/kg – 35 times lower!!** – Calculations showing this is on the petition website under written submissions for the Petition - Realistically the only safe ADI for free methanol is **0.0mg/kg**.

Aspartame approval – wrong – aspartame is unsafe:

Why the severe toxicity of the free methanol from aspartame was unknown to the COT scientists in 1982, is for them to explain, had it been considered aspartame would certainly never been approved as a food product. Because it was, practically everyone in the UK has been consuming aspartame/methanol in increasing amounts in their diet for the last 28yrs, at a level that is demonstrably 35 times higher than it should be for safety.

The free methanol which constitutes 10% of aspartame is one of the most dangerous toxins in man even the very small amounts delivered from aspartame build up in the body over time eventually reaches a saturation point where physical damage appears (anecdotal evidence) many of the symptoms reported are exactly the same as for methanol poisoning. There is a very wide variation in an individual's resistance to pure/free methanol ingestion, so the time for poisoning symptoms to appear in individuals varies greatly.

In the US, the ADI for aspartame is **50mg/kg** this means the Americans are consuming 25% more aspartame with each bite than in the UK. Proof that the quantity of free methanol consumed is significant lies in the fact that almost immediately after aspartame was approved for general use in the US (1983) complaints were being reported of harm, citing aspartame as the cause. In the period 1983 until 1995 when the FDA ceased recording aspartame complaints, analysis shows 85% of the total food complaints were about aspartame and there were 10,00 complaints covering 92 symptoms. The US has a huge survivor net work in place, the UK does not –yet.

The aspartame/ free methanol effect in the UK has been less dramatic; we eat less of it and took it up less quickly than the US there are however signs we are catching up fast.

Someone needs to ask the question –WHAT IF WE ARE RIGHT?

James McDonald
UKAAC

EXECUTIVE DIRECTOR

Parma, 20 December, 2010
Ref. CGL/JM/cm (2010) - out- **5433097**

James McDonald
UK Aspartame Awareness Campaign

@: **bigmac2@freenetname.co.uk**

Re: Aspartame

Dear Mr McDonald,

Thank you for your letter of 8 November, 2010.

EFSA acknowledges your comments regarding the work currently being undertaken by the FSA and as you have noted the Advisory Forum agreed to defer further consideration on the issue of aspartame until the results of the FSA pilot study become available.

As explained to you previously, the Scientific Committee on Food (SCF) have established the basis for the current ADI for aspartame and the details of the relevant SCF reports were provided to you in May 2010. I would be pleased to receive the 'copious amounts of scientific evidence' you refer to indicating that methanol from aspartame is handled in a different way to that from fruit and vegetables. All known scientific references have previously been considered by the SCF and in the case of the Soffritti studies, by EFSA, and no new evidence has been presented on this issue.

EFSA is also aware of the most recent study of the Ramazzini Foundation and the conclusions where the authors mention the hypothesis of Trocho et al (1998) that formaldehyde converted from methanol may form adducts and linked this hypothesis to a possible explanation of their findings.

EFSA is looking forward to the successful completion of the FSA pilot study and I thank you again for your continued interest in EFSA's activities in this area.

Yours sincerely,



Catherine Geslain-Lanéelle

Cc: Mr Tim Smith, Chief Executive, Food Standards Agency
(Tim.Smith@foodstandards.gsi.gov.uk)

- Andrew Wadge (AW)