

Report of the meetings on aspartame with National Experts

Summary of Responses from Stakeholders

Introduction

The Report of the meetings on aspartame with National Experts was published on the EFSA web site on March 30, 2010. As a means of consulting on the report, with the publication of the report an open invitation was issued for interested parties to participate in a Workshop which was to be held in Frankfurt on April 23, 2010. Unfortunately due to the eruption of the Icelandic Volcano Eyjafjallajökull and the subsequent restrictions on flights within Europe, the proposed workshop was cancelled.

Interested parties were given the opportunity to make written submissions on the report. While this was originally offered to those who would not be able to attend the meeting, it was reiterated to all interested parties when the workshop was cancelled. The responses have been collated and presented in the table below.

There were seven written submissions received. One from a National Agency, one from Industry representatives and the remainder from stakeholders against the use of aspartame.

Many of the comments and issues raised are outside the scope of the work of the National Experts. The full copies of all submissions are included in Annex 1.

Table of Comments and Questions from Interested Stakeholders:

Person/Organisation	Comment	Response
Diane Benford – Food Standards Agency, UK	Regarding the tables summarising the papers for each section of the review. The comments column lacks consistency in approach both within and between endpoints – sometimes it is information uncritically transposed	This opinion is noted

	<p>from the paper and in others it is a critique. This makes it difficult to get a feel for the overall data.</p> <p>There is too much reliance on the industry-written/funded reviews (e.g. Magnuson et al, 2007; Butchko et al, 2002). These should not be quoted as authoritative sources, at the very least there should be an acknowledgement that they have a conflict of interest, because of the potential to be selective and put specific slants on the data</p>	<p>The National Experts are aware of the potential bias in Industry written/funded reviews and acknowledge the concern. Where the National Experts reviewed the original papers referenced in Magnuson and Butchko, the conclusions of the authors of the paper were supported.</p>
	<p>Exposure data Last sentence of page 14 notes that tabletop sweeteners may not be included in the estimates. This could be a significant source. This should be addressed or concluded as a data gap.</p> <p>Check text of table 1 for Arcella study features - should read "Intake based on 12-d (3x4) dietary record and manufacturers levels ".</p>	<p>The comment is noted and the National Experts consider that any future intake estimates should take account of this.</p> <p>Typographical error</p>
	<p>Brain function For the in vitro studies showing effects of aspartame metabolites it would be important to take a view on the validity of the authors' claims that concentrations were relevant to human exposure before dismissing them as less relevant just because they were in vitro studies.</p> <p>In table 2.1, Christian et al (2004) seems to be dismissed because it was not to OECD guidelines. This is not appropriate and again gives firm footing to</p>	<p>The discussion in this section outlines the reason for concluding on the relevance.</p> <p>The discussion on page 20 details the limitations of the Christian et</p>

	<p>those who say EFSA ignores non-industry studies. All studies should be considered on their merits. It is not clear why the Magnuson review is included in this table.</p> <p>In a number of places, studies are criticised as having been conducted at doses e.g. 50 times above the ADI. This is not a valid criticism. Effects at 50 times the ADI in animals implies the ADI is too high because you have less than 100-fold uncertainty factor (which should be on NOAEL not LOAEL). The emphasis should be on the irrelevance of the i.p. route of administration. In the discussion under Lau the 5 bullets are all part of the 3rd bullet.</p> <p>Is the conclusion robust enough given the limitations of each individual study and the lack of consistency in the database?</p> <p>The wording in this section is ambiguous, offering opportunity for critics to deliberately misinterpret, i.e. study being not to OECD guidelines or only 50 times the ADI. The relevant sentences need to be reworded to make clear that the problem is lack of dose response info, or irrelevance of the i.p. route when assessing the safety of aspartame (as this gives systemic exposure to unchanged aspartame orders of magnitude greater than the ADI) .</p>	<p>al (2004) study.</p> <p>The discussion and comments in the table provides some clarity to the reasoning</p> <p>The National Experts are satisfied with the conclusions in the context of the work undertaken</p> <p>The discussion details the reasoning behind the comments made. The concern on misinterpretation is noted.</p>
	<p>Satiation and appetite</p> <p>How the 13 papers in the table selected from the 49 available needs to be clearly stated. Renwick and Nordmann should not be included since it is an overview of an industry meeting.</p> <p>Much of this criticises studies for not being specifically on aspartame.</p>	<p>Paragraph 4 on Page 21 states “Some papers did not report findings of studies on aspartame but referred to it in discussion. These were not considered further”</p>

	<p>This could be considered as disingenuous since the theory is about intense sweeteners in general, not specifically aspartame. That this is postulated as an effect of intense sweeteners in general and not aspartame in particular needs to be more obvious.</p>	<p>It was outside the remit of the National Experts to consider sweeteners in general.</p>
	<p>Allergenicity Why is the focus almost entirely on allergenicity and ignoring intolerance? Two of the 4 papers cited in table 4.1 are industry reviews and rely on similar data to earlier reviews e.g. by SCF, the other two are case reports which would be better considered alongside the anecdotal evidence.</p> <p>The discussion cites a challenge study conducted at 2000 mg as being reassuring – but this is less than the ADI so is not informative.</p> <p>Immunotoxicity The reasons for dismissing the relevance of the in vitro concentrations appear speculative as no evidence is given.</p> <p>Parthasarathy studies are criticised for a number of reasons, and then the opinion states it is possible to conclude. This does not seem valid. It would be better to say what cannot be concluded.</p> <p>Conclusions of section 4 do not address intolerance.</p>	<p>The introduction to this section provides some detail on intolerance. All original papers written on the topic deal with food allergy and also discuss clinical symptoms that only appear in the case of allergy. As some clinical features are the same in the case of intolerance this can not be ruled out. However as specified in paragraph 5 on page 25 above Table 4.1 it is stated that ‘No reports have been published referring to food intolerance reactions attributable to aspartame intake.’</p> <p>The industry reviews cited in 4.1 are used to ‘set the stage’ in this section. The original papers have been read by the National Experts and the conclusions of the original authors supported. The case reports are added as they are published in scientific journals.</p>

		<p>The comment on the 2000 mg is not understood. It is only indicated that up to levels of 2000 mg no clear reproducible adverse reactions to aspartame are observed with regard to clinical symptoms related to allergy.</p>
	<p>Carcinogenicity Could the conclusion on the Epidemiology be strengthened a little from the no evidence line to “the evidence does not support an association”?</p> <p>Experimental section seems to give more weight to the VKM on the Ramazzini studies, than to EFSA. This seems a bit strange, COC could similarly be cited, but it would be better to focus on EFSA. The EFSA opinions need more emphasis and the conclusion needs to acknowledge these and that they are more recent than the SCF opinion. The EFSA opinions should at least be mentioned in the conclusion otherwise someone who reads only the conclusions and not the text will think the Ramazzini studies have been ignored. It appears that Ramazzini have recently acknowledged the presence of mycoplasma infections within their animal colony.</p> <p>Genotox Conclusion (no evidence to indicate) is weaker than that of SCF. Unless this is suggesting that the evidence of lack of genotoxicity is now weaker, why not specify “evidence does not show genotoxic potential”? This needs</p>	<p>The conclusion for this section states that “there is no evidence to suggest that aspartame is carcinogenic”. The proposed statement goes beyond what the review was able to establish.</p> <p>The second EFSA Opinion was published after the scientific review had been completed. The importance of the EFSA Opinions is agreed.</p> <p>The proposed statement is not consistent with the work of the National Experts. The conclusion</p>

	<p>to acknowledge the substantial body of genotoxicity data in the previous evaluations and emphasise the overall weight of evidence in the conclusion.</p>	<p>on Page 49 stating “no new evidence that requires a revision of the existing opinions indicating a lack of genotoxic/mutagenic potential.” is considered sufficiently clear.</p>
	<p>Anecdotal data Whilst it is accepted that further statistical analysis is not appropriate on this quality of data, in addition to the descriptive report produced by EFSA there are several minor aspects that may provide a more complete descriptive report. These include:</p> <ul style="list-style-type: none"> -An investigation into the variable 'exposure'. -A table for symptom combinations (for combinations of 2 and 3 symptoms) for all cases with 2 or more symptoms. -The most commonly reported symptoms are headache, dizziness and giddiness, mild cognitive disorder and recurrent depressive disorder, an investigation of the combinations of symptoms most commonly reported with headache has been produced. It may be useful to extend this to show a similar investigation into dizziness and giddiness, mild cognitive disorder and recurrent depressive disorder. -Assessment of the most commonly reported symptoms related to aspartame dose groups. <p>How can there be a total percentage of cases that equals almost 180% in table 1 and 200% in table 2 - the figures need scaling correctly either use symptoms (not cases) as denominator or only score in one category.</p>	<p>EFSA has made the compiled data available to the Food Standards Agency, UK and although the suggested work was not undertaken by the National Experts, it is possible for the UK or other MS to carry out further analysis as suggested</p> <p>Each percentage is of the number of cases – as many cases reported more than one symptom, the total is more than 100%. Using symptoms as the denominator was considered to be less clear to understand and open to</p>

	<p>One of the tasks of the Organising Team was to “conduct a thorough analysis of studies and other information available on aspartame”. The review of the scientific literature has been undertaken in a systematic and robust manner. The same cannot be said of the review of the other, often referred to as ‘anecdotal’, information. Further exploration of this area with more analysis of the data set chosen for analysis could have been undertaken, for example there has been no analysis of correlation between the reported symptoms. There has been no discussion of the usefulness of this data by the National Experts. This is a major limitation of the report.</p>	<p>misinterpretation on the number of cases considered.</p> <p>The discussion and conclusions presented in the report (page 46) do not exclude the possibility of further work being conducted on the anecdotal information.</p>
	<p>Conclusions The current conclusion of “no evidence” is easily misinterpreted, this conclusion could be strengthened by stating that "the evidence does not support an association".</p>	<p>The conclusion states that the “...National Experts have not identified any new evidence to recommend to EFSA that the previous Opinions...need to be reconsidered.” The statement only refers to the evidence that has been available to the national experts and should not be interpreted in any other wider way.</p>
<p>Mr James McDonald – UK Aspartame Awareness Campaign (UKAAC)</p>	<p>The Trocho Study 1998 - Why did the National Experts omit this very important European study?</p>	<p>This study was considered by the SCF in the 2002 Opinion and was therefore not considered further.</p>
	<p>Anecdotal evidence - Apart from the fact that the anecdotal evidence was not collected through a scientific model study but by individual human experience, how can the experts ignore their own facts that 1059</p>	<p>The anecdotal information was not sufficiently robust to be able to make such conclusions as</p>

	people clearly and individually stated, when they consumed aspartame over time they suffered in excess of 20 separate symptoms from 9 separate food items containing aspartame and rapidly regained their health when they stopped consuming aspartame.	proposed, as detailed in the discussion on page 36 of the report.
	Anecdotal evidence - What is the experts opinion of the fact that the consumption figures reported in the anecdotal cases (15mg/kg) is far in excess of that reported in their own analysis of national studies. < 5mg/kg.	As explained in Appendix 2, there are many assumptions made on the case information. A great deal of caution must be exercised in making any interpretation on this data.
	Anecdotal evidence - How can the experts ignore the fact (in the report) that the population group most likely to exceed the ADI of 40mg/kg is CHILDREN. and diabetics are the group most likely to be the highest users	General consumption by adults and children was found to be below the ADI. One study taking the worst possible case for diabetics shows potential for the subgroup of diabetic children to exceed the ADI, but the authors state that this was for a small number and not by a high percentage (114% of ADI) and conclude that based on toxicological and pharmacokinetic data there is a safety margin even for high consuming diabetics.
	Are the Experts concerned that new evidence was omitted from their review	The 'new evidence' referred to relates to non-scientific opinion. This information was submitted by the correspondent to the Food

		Standards Agency UK and was known to the UK experts
	How can aspartame be considered safe, when the toxicity of free methanol was never included in its initial approval nor in any review of aspartame safety since	The issue of methanol is discussed in the report.
Ms Felicity Mawson – Mission Possible, UK	<p>I decided against circulating my contacts to comment to yourselves on the Aspartame Report, as EFSA already has plenty of anecdotal evidence as set out in the Report. On reading the average accounts of people's suffering, they state clearly the connection between aspartame and their symptoms; their eliminating aspartame from their diet and the reduction/cessation of symptoms. At this stage, more of what EFSA has been informed of already, is not needed. It is a fact that with the sufferers' reports presented to yourselves over a sustained period of time, EFSA scientists now have a pattern of evidence to enable/guide Advisory Forum members to promote knowledge/information to the 27 Member States' medical professions about aspartame sensitivity <u>as a priority</u>.</p> <p>This can be done together with setting up national pilot systems in several EU Member States run by medical professionals: to monitor the results of patients' elimination of aspartame products and noting their health status/changes after one month, two months and three months. I expect the EFSA Advisory Forum members to acknowledge the suffering of people internationally and specifically in the EU over decades and to call for such monitoring please. The detailed efforts by EFSA to analyse the anecdotal evidence needs to be represented into a simple format to be promoted to Advisory Forum members, which in turn can be taken back</p>	The comments are noted.

	to their respective Member States to start to deal with aspartame sensitivity.	
	Front Page: there is an emboldened paragraph stating that <i>"This report deals with the review of scientific literature and the conclusions drawn by the National Experts. Detailed discussion and conclusion on anecdotal data is to be added to complete the report."</i> - when are these items to be added and to what data does this Front Page paragraph refer - or does the Front Page actually belong to an earlier draft version?	Format/Typographical error. The paragraph related to an earlier version of the report which did not include Section 7. The report is complete.
	I note that the term "metabolomics" is used in several places in the Report with regard to the acknowledged position of people presenting with "aspartame sensitivity". Since in effect, the Report promotes this particular analytical method: do EFSA National Experts have specific information that say, methanol and formaldehyde toxicity can be deduced from such methods?	Metabolomics would allow identification of the metabolites methanol and formaldehyde in urine samples collected from human volunteers. The method is semi-quantitative, so with the appropriate samples a significant difference in the metabolic profile after consumption of aspartame compared with consuming no aspartame, could be detected.
	In the National Experts' Minutes (9th November 2009) it is stated that they were seeking clarity. (a) Where in the Report does it confirm that clarity has been gained and all their questions answered? It would appear that, without the information on clarity, there seems to be a gap regarding their knowledge of the metabolism of (free) methanol. See http://www.efsa.europa.eu/en/events/event/af091110-m.pdf Also, it is	This reference relates to the discussions on the drafting of Section 5 of the report. The discussion and conclusion (pp 32-34) covers this.

	<p>specifically minuted by Djien Lien that <i>"It was not possible to prepare the conclusion and recommendations for the Advisory Forum until all of the issues raised in the discussions could be considered."</i></p> <p>(b) What were those issues and at what meetings (ie after November 2009) were they explored/discussed/agreed by the National Experts prior to completing the Report?</p> <p>This situation was also reported in the Minutes of the 39th Plenary Meeting of the EFSA Scientific Committee (17th November 2009) http://www.efsa.europa.eu/it/events/event/sc091117-m.pdf - mentioning <i>"continued public concern"</i> and that <i>"more work is needed before the report can be finalised"</i> (p.5)</p>	
	<p>Page 30 etc, the term "methanol induced stress" is used. Can this be expanded upon please - is this term an acknowledgment by the National Experts referring to the poisonous effects of (free/unbound) methanol - direct and/or otherwise?</p>	<p>The immune system is extremely sensitive to stress and extreme high dose levels of a test compound can lead to indirect stress-induced immunotoxicity. This means that the observed effects are not directly caused by the test compound but result from the stress induced changes by the test compound.</p>
<p>Valerie Szilardy</p>	<p>Page4 - Background : chemical structure of aspartame: Safety issues raised in the passed includes</p> <p>“The possibility of toxicity from methanol and/or its systemic metabolite formaldehyde”</p>	<p>There is adequate discussion in the report on the metabolism of aspartame and the metabolite methanol in the report, particularly pages 28-29 and 33.</p>

	<p>Since 1983 until now the manufacturers of aspartame, FDA, FSA and EFSA are all of the opinion, that the free methanol released by aspartame is the same as is found in nature and the amount is so small it can cause humans no harm; The National Experts and EFSA have only recently confessed, to having insufficient knowledge of the metabolism of aspartame nor it's metabolite Methanol that it could not make a recommendation to the AF in January without it. This fact alone makes this Expert's report null and void.</p> <p>Q1 - Methanol (MEoH) has not changed in 150 years and has always been highly toxic, particularly in humans. What scientific evidence do EFSA and the experts have to support their belief that free methanol from aspartame and that found in nature are the same?</p>	
	<p>Page7 – Objectives: states - “As part of the review the team considered and identified, data gaps in the available knowledge” Yet in Page2 Summary: They report “In conclusion, The National Experts have not identified any new evidence---“ clearly this is contradictory and confusing If the gaps in knowledge relate to their insufficient knowledge of the metabolism of aspartame and methanol. This surely is very important and should have been made very clear in the report – the report is again suspect therefore unsafe.</p>	<p>Comparison between the objectives and conclusions does not make sense. The conclusion specifies that no major gaps were identified and the conclusion is valid.</p>
	<p>Q2 – Were the National Experts aware that the ADI of aspartame at 40mg/kg was being challenged as being 35 times too high for safety, based on the severe toxicity of the free methanol released by aspartame?.</p>	<p>As specified on page 5 of the report, the ADI of 40mg/kg has been reaffirmed in the opinions of the SCF in 1985, 1989, 1997 and 2002.</p>

	<p>It is of great concern that the experts relied so often in the report on industry scientists to verify the results of others studies: Magnuson, Stegink, Butchko etc. these are well known aspartame sympathisers who always favour the aspartame result. This is not healthy if we are genuinely looking at whether this product is safe or not.</p> <p>Pages 27-30 – 4.2 Immunotoxicity . This area I believe deals partly with the “metabolic clarification “required, regarding the gap in knowledge of the metabolism of aspartame and methanol as recorded in the experts Nov 2009 minutes. This makes disturbing reading, the lack of knowledge is clear throughout and a new methanol symptom has apparently been invented to cover this. E.G. when methanol/ formaldehyde is attributed to some adverse effect and the experts have no scientific answer, it is referred to as “Methanol induced stress” – this term occurs 5 times in this section.</p>	<p>This opinion is noted.</p> <p>The issue of methanol has been commented on above.</p>
	<p>Pages 31-34 – “Effects of aspartame on metabolism of----“ This appears to be another part of the “metabolic clarification” process but the “discovery” of metabolomics, which has been around since the 1940’s should not be such a revelation. As to its suitability for use in determining the toxicity levels of aspartame and its metabolites methanol, please note the following quote from:-</p> <p>Woodrow C. Monte PhD Professor Emeritus of Food Science and Nutrition, Arizona State University.</p> <p>“Low levels of methanol are not metabolized in the liver, due to the Interference of endogenous methanol being produced in the colon. This leaves only the extra hepatic sites of ADH 1 available to metabolize</p>	<p>The issue of methanol has been commented on above.</p>

	<p>Methanol into Formaldehyde. Modern metabolomics can not be used to model such a shunting of the liver and can not at any rate model the Human predicament, Metabolomics does not function as a model under circumstances of abject species incompatibility.”</p>	
	<p>Page 12 - Areas reviewed - (Anecdotal evidence)</p> <p>1) Exposure Data: Concludes - "The data on aspartame exposure since 2001 confirms the SCF conclusions of 2002 and the National Experts conclude that there are no indications that a population group could exceed the ADI for aspartame". This statement is wrong for the following reasons:-</p> <p>Page14 - last Paragraph: tells us that most of the intake estimates used, were based on the use of soft drinks alone and in particular excludes table top sweeteners, what it is also saying therefore is the inadvertent consumption of sweeteners in the other 6000 food products which contain aspartame / methanol / formaldehyde were omitted! The actual intake of real people recorded by 31% of the anecdotal evidence sufferers show an adult average of 15mg/kg the report says <5mg/kg - someone must be wrong!</p> <p>Page 15 High intake scenarios: "The experts conclude that only a small percentage of the population (CHILDREN) would exceed the ADI (Ilback et al.2003) So That's all right then, it seems it is OK for our children to consume 40mg/kg+ of aspartame per day and the rest of us <5mg/kg. I don't find that acceptable, and neither should the experts. – The above conclusion is seriously flawed.</p>	<p>The paragraph on page 14 states that the levels were 1/10th of the permitted level except in <u>vitamin supplements</u> which contained contain a mean of 6.4mg/g of product. The intake level refers to intake per kg body weight per day and the two can not be compared.</p> <p>This has been commented on above.</p>

	<p>Brain Function: No comment, except to say that it is noticeable that any time methanol or formaldehyde is associated with an adverse effect the comment is invariably that "The dose of methanol administered to the rats is unrealistic when compared with the ADI of 40mg/kg for aspartame, making the significance of the obtained results very questionable". The experts seem unaware, that rats are 15 times more resistant to methanol than humans. Without a thorough knowledge of methanol and its particular danger to man, any literary study reviews will be suspect and therefore unsafe.</p>	<p>The issue of methanol has been commented on above.</p>
	<p>Anecdotal Evidence: The experts have dismissed all the evidence presented and have not taken any of it into consideration in their conclusion and recommendation to the AF. This is very irresponsible since much of the data from the analysis is very pertinent and proves aspartame to be far from safe. I find this of great concern, and as a long term sufferer of aspartame poisoning this is also a great affront to me, and to others like me.</p>	<p>The limitations of the data are explained in the report The information has not been 'dismissed' as the conclusion is that it can be useful in guiding the design and format of any investigative study that may be undertaken to determine individual sensitivity to aspartame.</p>
	<p>The Barcelona Study (Trocho) 1998 - I am very surprised that there is no mention of this very important European study, after 2 years work; It deals specifically with the effect of methanol metabolism and proves that formaldehyde remains in the body attached to tissue with catastrophic effects. There are at least 3 other pre 2001 studies referred to in the report so the date of the study cannot be the reason.</p> <p>Q3 - Why was this study omitted?</p>	<p>As mentioned above, the Trocho study was considered by the SCF in 2002.</p>

Due to the EFSA and Experts confession to having insufficient knowledge of the metabolism of aspartame and free methanol, their report, Question Number:EFSA-Q-2009-00488, is fatally flawed and must be withdrawn. Without the vital metabolic knowledge of 10% (the free methanol) of the product under review, this report cannot possibly be considered as reliable evidence in any decision on the safety of aspartame. It is inconceivable that the organising team obviously ignored this serious gap in the scientist's knowledge and pretended it was not there when they stated in the summary "Overall the Organising team did not identify any major in information on aspartame".

Since scientists are only just "discovering" that free methanol in aspartame is a serious health risk we must consider the effect this lack of knowledge must have had on pervious reviews IE The ADI and approval of aspartame in 1983, SCF reviews in 1985,1989, 1997, COT in 1992 and SCF in 2002, every literary review since 1983 must be regarded as unsafe.

What is being "discovered" today by scientists does not excuse the serious actions of the past which have caused this heinous product to remain in our diet for 27years. The information on methanol toxicity and metabolism has been available to scientists since before aspartame came on the scene; I am a long term victim of Methanol poisoning almost losing my eyesight, my sanity, my health, and consequently my independence and quality of life - I was on the verge of becoming a burden to my family and to society due to my inability to function. I made a rapid and remarkable recovery (90%) after stopping the use of aspartame sweeteners and having made no other

The opinions are noted.

	<p>changes whatsoever to my diet or lifestyle.</p> <p>I want this product declared unsafe NOW as it should have been 27years ago.</p>	
<p>Mrs Patience Purdy, National Council of Women of Great Britain.</p>	<p>Once again one is disappointed at the report on EFSA work on the safety of aspartame in food and drink. Once again the committee has chosen to disbelieve the consumers who react to it and say it is safe because those they cant understand why it isn't. There are many peer-reviewed scientific papers which claim aspartame is unsafe [over 90 I believe] but for some reason the people reviewing them believe they know better than the scientists who did the work. Foolishly perhaps, NCW thought the duty of such organizations as EFSA and the FSA in the UK was to protect the public which would mean that the producers would have to show the chemical is safe by collecting all the doctors, scientists and those who experience adverse effects - people who believe aspartame to be unsafe - and proving them wrong. Interestingly most of us who report the adverse effects are able to avoid aspartame to a large extent. Our pressure to have it banned is purely for the protection of others. We can - to a large extent but not completely - can avoid it. Perhaps we are doing what we believe EFSA, the FSA and the FDA in the United States should be doing. It is also worth mentioning that aspartame has been suggested as the possible culprit in the concerning rise in the incidence of Sudden Cardiac Death [SCD] in the UK and the USA. where the number of people dying from SCD is quoted as 460,000. If it is not Aspartame what is it? Prevention is better than cure. Scientists do get it wrong - they could be wrong about aspartame being safe.</p>	<p>The comments are noted by the National Experts.</p>
<p>International Sweeteners</p>	<p>[The SCF Opinion, 2002]... includes a section on 'Absorption, distribution,</p>	<p>The National Experts are familiar</p>

<p>Association</p>	<p>metabolism and excretion of aspartame' which could be helpful to the Experts in answering some of the points raised in the Report.</p> <p>For example, the statement that "The National Experts considered that research into whether aspartame and its metabolites affect gene expression, protein synthesis and enzyme activities of different cytochrome P450 enzymes in the brain could be useful to extend knowledge in this area," makes little sense if it is understood that:</p> <p>a) aspartame is broken down completely to its component parts, in the digestive system, i.e aspartame does not enter the bloodstream. and b) these components are found in foods consumed as part of a normal diet, often in much greater quantities. The body does not distinguish between the methanol in fruit juice and that produced when aspartame is digested, or the aspartic acid and phenylalanine found in milk and the same metabolites from aspartame.</p> <p>Useful though the technique is, metabolomics is unlikely to distinguish between the same metabolites from different dietary sources, especially as aspartame is only a minor contributor to total daily intake, even in high users.</p> <p>Similarly, an understanding that aspartame brings nothing new to the diet means that it would be difficult to hypothesise any plausible mechanism for "individual sensitivity to aspartame".</p> <p>The Report, in cataloguing 'anecdotal' data, primarily from one source, seems to ignore the post-marketing surveillance on aspartame, which is unique for a food ingredient, undertaken by The NutraSweet Company</p>	<p>with the SCF Opinion, 2002. The comments were made in the context of the papers reviewed.</p> <p>The comment is noted.</p> <p>This viewpoint is noted.</p> <p>The National Experts included the Butchko paper in the literature review.</p>
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between 1981 and 1993 and reported on in the literature by Butchko (2002)¹ and subsequently by Magnusson et al (2007)². These papers reference the well-designed clinical studies, undertaken by leading scientists in the field of each complaint, for the six most frequently reported symptoms (which cover more than 80% of all of the case reports).

Finally, two of the statements made in the Background section of the Report require validation:

"However there continues to be public concern with respect to the health risks of aspartame in food".

Well-conducted consumer research shows little evidence of genuine public concern about aspartame. It would be helpful to know the basis on which this statement is made.

and

"Numerous anecdotal reports of adverse reactions following dietary exposure to aspartame have also been well documented".

Given the very low level of individual case reports submitted to the Experts, and the reliance on a decade-old book of reports collected by an individual to construct a database, the likelihood of there being a significant number of people with identifiable "adverse reactions" seems remote.

People who attribute adverse reactions to consumption of food/beverages sweetened with aspartame should be encouraged to seek proper medical diagnosis, lest they attribute to aspartame symptoms which have another more serious cause.

The public concern continues to be raised at national level with the competent authorities.

In addition to the anecdotal information mentioned in the report, the National Experts were made aware of many other unpublished reports gathered by interested parties in several countries.

The limitations in the anecdotal information are acknowledged in the report. The published volume of Dr Roberts was used as source for the anecdotal information considered as the cases had been broadly categorised and collated and were of a similar nature to other reports brought to the attention of the National Experts.

		The National Experts agree that consumers who believe they have adverse reactions to any food should seek medical advice.
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