Annex A

Request

You requested the following:

> *Documented proof that Aspartame is safe and that the tests were carried out on humans - some of whom had dental amalgam, undergone vaccinations for example, which would burden their immune systems and de-toxification organs (liver and kidneys) before ingesting the chemical sweetener.*

You also subsequently requested why a few countries in the world, Sweden being one if your information is correct, have banned the substance.

Response

As a background to your question, the safety of all currently authorised food additives has been assessed by the Scientific Committee on Food (SCF) and/or the European Food Safety Authority (EFSA). Before being authorised, additives are evaluated based on a dossier containing the chemical identification of the additive, its manufacturing process, reaction and fate in food, the case of need, the proposed uses and toxicological data. The toxicological data must contain information on metabolism, sub-chronic and chronic toxicity, carcinogenicity; genotoxicity, reproduction and developmental toxicity and, if required, other studies. The current requirements for such dossiers can be found on the EFSA website.

The Committee on Toxicology (COT), an independent expert committee, evaluated aspartame in 1982, when it was first approved for consumption in the UK. A number of human trials were considered during the COT evaluation. The Food Standards Agency (FSA) does not hold data of the studies dissimilar to information already in the public domain. The studies considered by COT in 1982 are included with the original studies now listed on the EFSA website:
http://www.efsa.europa.eu/en/dataclosed/call/110601.htm

Aspartame has been extensively tested and reviewed for safety by independent experts at national, EU and international level. Despite this, some consumers believe they have suffered ill-health effects following consumption of aspartame containing products. In 2009 the FSA commissioned the University of Hull to undertake a study looking at self-diagnosed individuals who consider they experience adverse effects after consuming aspartame in order to identify any effects. The research has been completed and the results have been submitted for publication in a peer reviewed journal. Given the interest in this work, in the interim, the FSA requested the COT to consider the results of the study and publish their headline conclusion on the research. The COT position paper states that the results presented did not indicate any need for action to protect the health of the public:
http://cot.food.gov.uk/sites/default/files/cot/cotposponaspar.pdf.

Once the results have been published in a scientific journal the FSA will then publish the final report. As this information is intended for future publication the FSA is withholding the report from disclosure in accordance with Section 22(1) of the Act. Please see Annex B for details of our use of this exemption.

Although outside of the request I can provide some additional information. During EFSA's re-evaluation in 2013, mentioned in my previous letter to you dated 15 December 2014, 600 datasets were considered and these studies are listed with the original studies mentioned above. Some of the studies listed involved clinical human trials.

In response to your additional question about aspartame being banned in other countries I would like to inform you that the food additives legislation, *Regulation (EC) 1333/2008 of the European Parliament and of the Council on food additives*, is agreed and negotiated at European Union level and applies in all 28 European Union (EU) Member States. Aspartame is therefore permitted in Sweden. The FSA cannot provide information regarding the legislation in countries outside the EU.