substantiated and not misleading; (ii) must be based on scientific methodology that is sufficiently thorough and comprehensive to support the claim and that produces accurate and reproducible results; (iii) information concerning the procedure, methodology and any criteria used to support environmental claims must be available and provided upon request to all interested parties; and (iv) the formulation of environmental claims must take into consideration all relevant aspects of the life cycle of the goods or service, although not necessarily considering a full life cycle analysis'.

At the international level, there is only limited coordination regarding methodologies for measuring the environmental performance of products and organisations. Examples for coordination initiatives include guidance for the development of product category rules, coordination in the framework of the International Standards Organisation (ISO), and efforts to approximate carbon footprint methodologies through the Climate Disclosure Standards Board (CDSB).[11]

The three-year testing period announced in the Communication is expected to be launched soon after its adoption. Open calls will be published by the European Commission on the Internet websites for the Product Environmental Footprint (PEF)[12] and the Organisation Environmental Footprint (OEF)[13], inviting companies, industrial and stakeholder organisations in the EU and from third countries to participate in the development of product-group specific and sector-specific rules. A second phase will build on an in-depth evaluation of the results of the three-year testing and on additional actions carried out under the Communication and the Recommendation. The European Commission has announced that based on this evaluation, it will decide on further policy applications of the PEF and OEF methods.

IV. Conclusion

The EU should exercise care in relation to the way it *'disciplines'* the area of environmental claims and their assessment. Even though it is perhaps not done by means of mandatory regulation, but through non-binding guidelines, these might (*de facto*, if not *de jure*) give a layer of *'governmental'* authority to the standards measuring and benchmarking environmental performance, triggering the application of the WTO Agreement on Technical Barriers to Trade. Assessing eco-labelling, packaging and recycling requirements recalls the debate on private voluntary standards, in particular in the areas of food safety and animal health, which, although providing in many cases a stimulus to improved production practices and performance in exporting countries, and potentially giving a competitive advantage to complying producers, may also act as significant barriers to market access for some industries in a number of countries, especially least developed ones.[14] Manufacturers, importers, distributors, retailers or anyone else making environmental or *'green'* claims or thinking about making them on the one side and, on the other side, Governments and private initiatives operating such *'green'* schemes are encouraged to monitor this process launched in the European Commission's Communication or even actively participate.

11 Available on the Internet at: <http://www.cdsb.net> (last accessed on 5 August 2013).

12 Available on the Internet at: <http://ec.europa.eu/environment/eussd/smgp/product_footprint.htm> (last accessed on 5 August 2013).

13 Available on the Internet at: <http://ec.europa.eu/environment/eussd/smgp/organisation_footprint.htm> (last accessed on 5 August 2013).

14 Tim Josling, *Private Standards and Trade*, in Joseph A. McMahon and Melaku Desta (eds.), Research Handbook on the WTO Agriculture Agreement (Cheltenham, UK: Edward Elgar, 2012), pp. 202 et sqq.; Paolo Vergano and Ignacio Carreño, *Private Voluntary Standards within the WTO Multilateral Framework*, Legal analysis in the study commissioned by the United Kingdom Department for International Development under the Programme of Advisory and Support Services (WTO document G/SPS/GEN/802 of 9 October 2007); Spencer Henson, *The Role of Public and Private Standards in Regulating International Food Markets*, Journal of International Agricultural Trade and Development, Volume 4 Issue 1, 2008, p. 63.

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Food

This section aims at updating readers on the latest developments of risk-related aspects of food law at the EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.

Manufacturing Uncertainty out of Manufactured Sweeteners: The Curious Case of Aspartame

*Adam Burgess**

Away from the high profile campaign around bees and pesticides back in April 2013, was a much more behind-the-scenes and low key regulatory dispute around people and food additives; specifically the

low-calorie sweetener, aspartame. The European Food Safety Authority (EFSA) held what they called a 'follow-up meeting on the web-based Public Consultation on Aspartame' as part of a continuous re-evaluation of additives.[1] Yet this was more than a routine exercise, as the EFSA explained that the deadline for the re-evaluation of aspartame had been moved forward, whilst reviews of other sweeteners were to be completed by the end of 2020. More surprising was the explanation that the change had come about in the 'light of new scientific information'.

The on-going tale of aspartame is an interesting story of how even a man-made substance acknowledged to be as unlikely to cause harm as its possible to imagine can still become the subject of at least minor controversy and regulatory manoeuvres. Whilst relatively inconsequential in direct terms, the uncertainty created as a result can still be problematic in the context of the importance of promoting sugar-free alternatives, in a world where challenging obesity is a high priority. The first 'key message' in the UK government's current 'Change for Life' campaign, for example, are 'sugar swaps', that is: 'swapping food and drink with added sugar for options that are lower in sugar or sugar-free.' Data already indicate a welcome consumer shift in this direction, as sales of 'diet' drinks continue to eclipse those such as traditional 'red' coke.

There appear to have been no significant 'new scientific information' about aspartame discussed at the EFSA meeting and it is unclear what that might have been given aspartame's simple character and long history of regulatory examination and approval. It was discovered accidentally back in 1965 by a chemist working for Searle in the USA. Known also by trade names such as NutraSweet, aspartame is some 200 times sweeter than sugar, and widely used as the low-calorie sweetener that tastes most like it. Used in over 100 countries, it was approved by several European Union countries in the 1980s with EU-wide approval in 1994. It has a history of over 25 years incident-free use, in a range of soft drinks, sugar-free and reduced confectionery and foods.

Aspartame is an unlikely candidate for concern from a risk perception perspective; it brings nothing new to the table, let alone anything 'scary'. It's made from two amino acids (the building blocks of protein) naturally found in the foods of a normal diet, such as meat, fish and cheese, so consumption does not involve ingesting anything which is not already found in the diet greater quantities. It is digested in the same way as other foods, after which aspartame is no longer present in the body.

Thus the EU's Scientific Committee on Food concluded in 2002 that "Aspartame is unique among the intense sweeteners in that the intake of its component parts can be compared with intakes of the same substances from natural foods."[2] One by product of consumption is methanol, but this is the same as the methanol that we produce during normal metabolism and studies show that levels are not increased by aspartame.[3] Thus the same EU committee in 2002 concluded that aspartame was only a minor source of methanol, as did, more recently the Committee on Toxicity.[4] Aspartame is not classified as a carcinogen, a conclusion backed by the major European, American and international regulatory bodies. The only qualification is the advice that it be avoided by people with the rare genetic condition, Phenylketonuria (PKU). Returning to risk perception, it has no scary 'genetic' or 'radiation'-like words in its name. And there are other factors mitigating against concern, not least the focus of critics on its more problematic alternative, sugar. It's unsurprising then that there has been no sustained campaign anything like that against pesticides.

But this isn't to say that there are no voices of alarm about aspartame. An international e-mailing campaign is led by a woman called Betty Martini, based in Georgia, USA. It is a characteristically aggressive, conspiratorial-infused campaign suggesting cover-up and collusion of government agencies, manufacturers and scientists. She believes, among many other things, that both Michael Jackson and the actress Farrah Fawcett were killed by the sweetener, and has a network of international collaborators. There are

1 See <http://www.efsa.europa.eu/en/events/event/130409.htm#documents> (last accessed on 6 August 2013).

2 EC Health & Consumer Protection Directorate-General, Scientific Committee on Food, Directorate C - Scientific Opinions, C2 - Management of scientific committees II; scientific co-operation and networks, SCF/CS/ADD/EDUL/222 Final, 10 December 2002. Available at: <http://ec.europa.eu/food/fs/sc/scf/out155_en.pdf> (last accessed on 6 August 2013).

3 Foods sweetened with aspartame contain smaller quantities of these components than many other foods. For example, a 115 g banana contains as much methanol as a 330ml can of carbonated soft drink sweetened entirely with aspartame.

4 Committee on Toxicity in Chemicals in Food, Consumer Products and the Environment, COT Statement on the Effects of Chronic Dietary Exposure to Methanol, March 2011, Available at: <http://cot.food.gov.uk/pdfs/cotstatementmethanol201102revjuly.pdf> (last accessed on 6 August 2013).

also a few more mainstream critics set against aspartame on a more precautionary basis, such as Erik Millstone from the University of Sussex in the UK. Like with any other modern risk story there are also maverick scientific and political voices. The principal example of the former is an Italian researcher – and colleague of Martini – called , Morando Soffritti, from an unusual scientific institute called the Ramazzini Foundation in Bologna. A study in 2005 suggesting a higher incidence of cancer in rats by Soffritti was dismissed on methodological grounds by the FDA, EFSA and the UK's Food Standards Agency (FSA), but managed to make media headlines.[5] A key political 'risk entrepreneur', meanwhile, is British MP Roger Williams, who has fought for a higher profile for aspartame health concerns, contending that it only managed to obtain regulatory approval corruptly, and that this was subsequently covered up.

Whilst the direct attacks on aspartame are limited and marginal, it does still stand to suffer as an 'additive' in a culture that is now as routinely suspicious of them as it is naive about anything claiming to be 'natural'. This is particularly the case when the issues become high profile and politicized, as they did back in 2007 when the then UK Prime Minister, Gordon Brown, in populist fashion, called on manufacturers and the EU to take action against food additives, following the publication of a study suggesting they might affect children's behaviour.[6]British supermarkets publicly announced a withdrawal of aspartame from colas and other products, in a move announced as 'taking the chemicals out' by one.[7] This was perhaps the most damaging public moment in aspartame's recent history. But there is also more behind-the-scenes regulatory manoeuvring, as indicated by the recent EFSA meeting mentioned at the start. More curious, has been the approach recently taken by the UK's FSA following Brown's pronouncement, at the same time as it continues to maintain that there is no reason to believe that aspartame can cause harm.[8]

Anti-aspartame activists have been active in lobbying bodies like the FSA, and moments such as the 2007 additives alarm have encouraged some concern from members of the public who think it may be causing them harm. The FSA has been taking these perceptions seriously, which means that they, somehow, be analysed by the relevant scientific bodies and procedures – even though it is unclear how this might be done. In October 2007, the FSA Chief Scientist asked the European Food Safety Authority to examine anecdotal reports of adverse effects associated with aspartame, following the Prime Minister's protestations against additives. An expert group was convened and met during 2008 and 2009 to consider data and hear oral evidence from interested parties, including scientists andrepresentatives of anti-aspartame groups. Before this review process was complete, the FSA announced a 'pilot study' in June 2009, explaining: "We know that aspartame can be consumed safely but some people consider that they react badly to it. We've commissioned this research because it's important to increase our knowledge about what is happening. The study will address consumer concerns, including these anecdotal reports. "They also suggested that the pilot might lead to a larger, Europe-wide study, ledby the EFSA.

An interesting dimension of this story is how inter-agency tension appears to have been generated by the decision to have subjective perceptions taken seriously in scientific terms, and, more basically, illustrates the difficulty of doing so. EFSA's expert group reported in May 2010, concluding that no new evidence was identified to suggest that previous EFSA opinions needed to be reconsidered, and that no further consideration of aspartame would take place. The report by the EU Scientific Committee on Food had already considered subjective complaints back in 2002.[9]

They added that the anecdotal information "has proved to have severe limitations preventing effective analysis", that lacked 'a robust initial evidence base' with independent validation. Uncertain of how to advise on citizen complaints, they were more confident in advising that those reporting symptoms should seek medical advice in case the symptoms at-

5 See Felicity Lawrence, 2005, Fresh Fears Raised about aspartame, the Guardian. Available at: <http://www.guardian.co.uk/society/2005/jul/15/health.food?INTCMP=SRCH> (last accessed on 6 August 2013).

6 The study by researchers at the University of Southampton linked additive colours to child hyperactivity; for the European judgement on the study see: <http://www.efsa.europa.eu/en/press/news/ans080314.htm> (last accessed on 6 August 2013).

7 See: <http://www.dailymail.co.uk/news/article-450254/Sainsburys-takes-chemicals-cola.html> (last accessed on 6 August 2013).

8 For the FSA's view on aspartame see: <http://www.food.gov.uk/policy-advice/additives-branch/55174#.UZX-9ODu30A> (last accessed on 6 August 2013).

9 EC Health & Consumer Protection Directorate-General,*supra* note 2.

tributed to aspartame have another, more serious cause. However, the FSA's submission to the public consultation on the report questioned these conclusions, suggesting that further appraisal – of some sort – was appropriate.

Meanwhile, the FSA demonstrated its own, continued commitment to taking anecdotal complaints seriously by commissioning a pilot study from the University of Hull. It is intended to test 50 people who self-report adverse reactions to aspartame, matched by age and sex to 50 volunteers who do not claim to have experienced any problems. Individuals will consume a specially developed food product, which may or may not contain aspartame, in a clinical setting under medical supervision. Any symptoms are to be recorded and a blood sample taken in order to measure various biochemical parameters. The study commenced in mid 2009 and was expected to report in early 2011, but the researchers have had difficulty recruiting participants, particularly from anyone who claims to suffer adverse reactions from aspartame. It is worth repeating that the FSA have made it clear that whilst the object of the study remains unclear, it is not to consider the actual safety of aspartame which remains beyond fundamental question.

The FSA has a general commitment since it's post-BSE inception to open engagement with consumer interests and concerns. Since around 2005 there has been a shift away from embracing 'elite consumer interest representatives' as a participation strategy, towards an emphasis upon looking at consumers as 'objects of enquiry', founded upon an attempt to somehow engage the ordinary consumer beyond self-appointed consumer advocates.[10] Whatever the methodological shortcomings of the proposed pilot study it is at least attempting to proceed in an evidence-based fashion, independent of special interests. Further, the FSA's Chief Scientist explained in his blog, quite reasonably, that anecdotal evidence has a role to play in, at least, stimulating further enquiry.[11]

But, as he further explains, this is in circumstances of 'continuing anecdotal evidence' when 'reports of bad reactions persist.' The number of actual letters written to the FSA complaining of adverse reaction to aspartame appears to be only 46 over a 7 year period, however.[12] I would add that many of them are directly influenced in their terms of reference and language to those circulated by activists. Whilst it remains an open question as to what constitutes *persistent* anecdotal evidence, it is at least debatable whether such a number can reasonably be described in these terms.

What also needs to be made explicit in the equation, which the FSA appears not to have done, are the costs and indirect consequences to such an exercise – costs and consequences that are assured, unlike the uncertain benefits of trying to investigate self reported symptoms associated with something accepted to be essentially harmless. The study is costing public funds (estimated by the FSA as £322k up to 2010). Negative headlines are generated by undertaking such investigations into 'possible side effects'.[13] One of the few mainstream media articles on aspartame then describes 'the persistent controversy that has swirled around.'[14]Perhaps most importantly, it may be *the very act of treating these perceptions seriously, even scientifically, that endows them with a sense of persistence in a self fulfilling exercise*. Certainly, the activist case will be reinforced by the FSA's actions, even as they will continue to complain that nothing is being done whilst aspartame remains available at all.

Returning to the meeting with which we began, EFSA appears to now being more directly entertaining activist perceptions themselves. What surprised industry representatives, at least, was that the format was not the dry scientific review expected, but adopted the 'activist versus industry' format now so familiar in European consumer/environmental lobbying politics. Activist polemics against aspartame were, equivalently, set alongside scientific papers on the meeting webpage and the meeting format operated similarly with a set of activist views ranged against industry, and EFSA science somehow in the middle. Rather than being 'new scientific information', the

10 Henry Rothstein, 2013. Domesticating participation: participation and the institutional rationalities of science-based policy-making in the UK food standards agency, Journal of Risk Research DOI:10.1080/13669877.2013.775180

11 See Andrew Wadge, Anecdotes, Science and Aspartame (22 June 2009). Available at: <http://blogs.food.gov.uk/science/entry/Anecdotes_science_and_aspartame> (last accessed on 6 August 2013).

12 Letters were obtained under a Freedom of Information request to the FSA by commercial lobbyists.

13 Ian Sample, 2009, Sweetener aspartame to be investigated for possible side-effects, the Guardian. Available at: <http://www.guardian.co.uk/science/2009/sep/23/sweetener-aspartame-side-effects?INTCMP=SRCH> (last accessed on 6 August 2013).

14 Felicity Lawrence, 2006, Food safety authority says aspartame not linked to cancer, the Guardian. Available at: <http://www.guardian.co.uk/news/2006/may/15/food.foodanddrink1?INTCMP=SRCH> (last accessed on 6 August 2013).

principal focus of complaint appeared to be the scientifically dismissed concern with the presence of methanol. It will be interesting to see what further developments await. The publication of EFSA's final report has been pushed back to November 2013 on the basis that extra time is needed to evaluate what was said in the April consultation, when activists and industry representatives were set against each other. At the time of writing it has been announced that the FSA sponsored study has been completed, but reportedly too late to inform the EFSA re-evaluation. No indication has been given not only of the results but, more importantly, what *kind of* results might follow from the study. It remains unclear how self diagnosed perceptions of harm in this context can be investigated in a credible and consequential manner. Indeed, it is unclear that investigation can have any consequence at all except creating, arguably unnecessary, uncertainty about a useful and trouble-free product. Meanwhile, parties connected to the issue – industry and activist alike – seem more dissatisfied than ever.

The EU's New Regulatory Framework on Official Controls, Animal Health, Plant Health and Seeds

*Eugenia Laurenza**

I. Introduction

On 6 May 2013, the European Commission (hereinafter, Commission) adopted a package of proposals to consolidate and update the current *acquis* on animal health, plant health and seeds. The package also establishes new rules on official controls in these three sectors, including rules on official controls on the importation of food into the European Union (hereinafter, EU). The current body of EU legislation covering the food chain consists of almost 70 pieces of legislation. The proposed reform is intended to cut this down and includes a proposal for a *Regulation on Animal Health*[1]; a proposal for a *Regulation on protective measures against pests of plants*;[2] a proposal for a *Regulation on the production and making available on the market of plant reproductive material (seeds)*;[3] and a proposal for a *Regulation on official controls and other activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant reproductive material, plant protection products*.[4]

II. Aim and content of the proposals animal health, plant health and seeds

The aim of the proposed reform is to modernise and simplify the regulatory framework of the European Union, to take a more risk-based approach to the protection of health (focussing on the most relevant issues) and to establish more efficient controls to ensure the effective application of the rules in the food chain. In the three sectors covered by the reform (animal and plant health and seeds) a number of issues should be highlighted.

To regulate animal health in the EU, the package introduces a single piece of legislation based on the principle that '*prevention is better than cure*' by improving and harmonising EU Member States' national disease detection and control measures to tackle health, food and feed safety risks in a coordinated way. This enhanced system, with new rules on identification and registration of animals, as well as the introduction of more flexibility into the system, is intended to allow farmers and veterinarians to swiftly react and limit the spread of diseases and minimise their impact on livestock, and on consumers. Furthermore, the proposal on animal health introduces a categorisation/prioritisation of diseases, which requires intervention at EU level, enabling a more risk-based approach and appropriate use of resources.

In relation to plant health, the respective proposal states that the EU's agriculture, forests and natur-

* Senior Associate FratiniVergano, Brussels. A previous version of this report has been published in TradePerspectives, Issue No. 10 of 17 May 2013, http://www.fratinivergano.eu/TradePerspectives.html (last accessed on 17 August 2013).

1 Proposal for a Regulation of the European Parliament and of the Council on Animal Health, COM(2013)260 final.

2 Proposal for a Regulation of the European Parliament and of the Council on protective measures against pests of plants, COM(2013)267 final.

3 Proposal for a Regulation of the European Parliament and of the Council on the production and making available on the market of plant reproductive material (plant reproductive material law), COM(2013)262 final.

4 Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [....] /2013, and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation), COM(2013)265 final.