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CONCLUSIONS OF THE FIRST EUROPEAN ROUNDTABLE ON ASPARTAME: PUTTING BENEFITS INTO PERSPECTIVE

Overweight, obesity and obesity-related diseases, such as diabetes type 2 and cardiovascular disease, are becoming an ever-increasing problem in today's society, which has serious implications for public health not to mention the strain on national health services. Low-calorie sweeteners can play an important role in fighting the problem of overweight by helping consumers reduce their energy intake.

On 30th May 2006, the International Sweeteners Association hosted the "First European Roundtable on Aspartame: Putting Benefits into Perspective" in Paris. This roundtable event, the first of its kind in Europe, brought together eminent professors and professional experts¹ to discuss aspartame and low calorie sweeteners, based on the scientific evidence of their safety and effectiveness. Below are the conclusions of this event.

ASPARTAME IS SAFE

The ADI (Acceptable Daily Intake) is based on animal data, before a food additive can be marketed. The main independent regulatory bodies fixing the ADI include JECFA (WHO/FAO), EFSA (formally SCF) and the FDA. For aspartame, the ADI has been fixed at 40mg/kg body weight/day by JECFA and SCF, while FDA has set it at 50 mg/kg b.w./day.

Since the first approval of aspartame in 1981 a number of clinical data have been accumulated on humans: post marketing surveillance, consumption studies, tolerance studies in volunteers at nearly two times the ADI, clinical studies on specific sub-populations like diabetics, PKUs, overweight/obese people, epileptics etc. Prof. Andrew Renwick, who has refined the ADI setting method to allow for the consideration of human data, presented his findings on applying this principle to the ADI setting of aspartame. He concluded that **the ADI for aspartame could even be double the amount it is today.**

The recent study by Soffritti et al. 2005, published in the journal Environmental Health Perspectives shows, according to the authors, that aspartame is a "multipotential carcinogen". There are several aspects in this study which have been criticised, namely: the methodology used, the conditions under which the experiments have been performed, the potential influence of the commonly occurring spontaneous infectious diseases, differences in survival, very small differences in tumour incidences for several sites over a very large range of doses, low incidences of specific tumours in controls probably related to lower survival and not supported by the high incidences found in historical controls. **This study has also been**

¹ Emeritus Prof. Renwick, School of Medicine, University of Southampton, UK; Prof. La Vecchia, Istituto di Ricerche Farmacologiche 'Mario Negri', Milan, Italy; Dr. Visscher, Vrije Universiteit, Amsterdam, Netherlands; Dr. Bellisle, CRNH, Ile-de-France, Paris, France; Dr. Ashwell, Nutritionist, Advisor to FSA, UK; Prof. Boobis, Imperial College London, UK

evaluated by the EFSA (European Food Safety Authority), who concluded that these data do not provide evidence for a multipotential carcinogenic effect of aspartame.

The role of sweeteners on cancer risk has been widely debated over the last few decades. To provide additional information on saccharin and other sweeteners (mainly aspartame), the Mario Negri Institute (Milan, Italy), under the direction of Prof. Carlo La Vecchia, has been studying data from a large and integrated network of case-control studies conducted in Italy between 1991 and 2004.

The cases included 598 patients with incident, histologically confirmed cancers of the oral cavity and pharynx, 304 of the oesophagus, 1,225 of the colon, 728 of the rectum, 460 of the larynx, 2,569 of the breast, 1,031 of the ovary, 1,294 of the prostate, and 767 of the kidney (renal cell carcinoma). Controls were a total of 7,028 patients (3,301 men and 3,727 women). **This study concludes that there is no association between saccharin, aspartame and other sweeteners, and the risk of several common neoplasms.**

WEIGHT REDUCTION CAN DECREASE THE RISK OF CARDIO VASCULAR DISEASE, DIABETES TYPE 2 AND CANCER

Obesity is closely related to chronic morbidities such as diabetes type 2 and coronary heart disease and also to various disabilities which impair the quality of life and can increase mortality rates. In addition to shorter life-expectancy, obese subjects have increased numbers of unhealthy life-years. Due to the strong relation between obesity and health outcomes, we can expect to see health benefits from small, but sustained changes in a reduction in body weight.

Weight gain is the result of sustained, but subtle changes in energy-intake and/or energy expenditure. The obesogenic environment, an environment in which choices are easily made for too high energy-intake and low energy-expenditure, is crucial in the ongoing obesity epidemic. Subjects are often unaware of their impaired energy-balance. Thus, taking into account the large effect of obesity on health outcomes, environmental interventions have large potential in reducing health risks, even if weight loss is only small but sustained.

Dr. Tommy Visscher concluded that **small reductions in body weight can lead to reduced risks of diabetes type 2. For example, a reduction of 4.3kg in body weight can reduce the risk of diabetes type 2 by 70%.**

ASPARTAME AND OTHER LOW CALORIE SWEETENERS CAN HELP IN A WEIGHT-REDUCING DIET

Humans generally find the taste of sugar very pleasurable and the intake of sweet foods and drinks potentially constitutes an important input to the daily energy intake. Intense sweeteners, e.g. aspartame, were developed in order to allow consumers to enjoy the pleasurable sweet taste of sugar without the calories (4 kcal/g) associated with it. In drinks, practically all the energy can be removed by replacing sugars by intense sweeteners.

Although the sweetener paradox (enhanced appetite and intake following use of intense sweeteners) has been disproved by experimental evidence, a number of physicians still believe that the use of intense sweeteners actually enhances the appeal of sweet foods and drinks especially in children. Dr. France Bellisle concluded that **there is no demonstration of such an effect and all available data indicate that daily sugar intake is actually lower in users of intense sweeteners.** Clinical studies in obese dieters also suggest that the use of food and drinks containing intense sweeteners improves compliance with a diet.

The use of intense sweeteners as a substitute for sucrose potentially offers one way of helping people to reduce the energy density of their diet without any loss of palatability. A recent meta-analysis review of 16 studies looked at evidence for the effect of aspartame on weight loss, weight maintenance and energy intakes in adults and addressed the question of whether the use of aspartame sweetened foods and drinks is an effective way to lose weight.

Dr. Margaret Ashwell presented the results of this study concluding that a significant reduction in energy intakes was seen with aspartame compared to all types of control. This resulted in a

conservative weight loss of around 0.2 kg/week. This could correspond to a 10kg weight loss over a one-year period.

This review has shown that using foods and drinks sweetened with aspartame instead of those sweetened with sucrose is an effective way to maintain and lose weight without reducing the palatability of the diet. **The decrease in energy intakes and the rate of weight loss that can reasonably be achieved is low but meaningful and, on a population basis, more than sufficient to counteract the current average rate of weight gain of around 0.007kg/week.** On an individual basis, it provides a useful adjunct to other weight loss regimes.

PRINCIPLES OF RISK-BENEFIT ANALYSIS APPLIED TO ASPARTAME

For certain classes of chemicals, both the risks and the benefits are evaluated. Risk/benefit analysis seeks to provide a more objective evaluation of the net consequences for human health. In this way, advice to risk managers, consumers and others will be improved, as it will be possible to prioritise the use of resources to address health concerns and improve the transparency and objectivity of the process.

In order to compare risks and benefits objectively, it is necessary to express them in a common metric. In comparing health effects, some measure of impact on quality and duration of life may be appropriate, for example the DALY (Disability Adjusted Life Year) or QALY (Quality Adjusted Life Year). However, if a broader risk/benefit analysis is required, some more generic estimate will be needed, for example monetary value (euros). In adapting a QALY or DALY scale for risks and benefits of chemicals, appropriate weighting factors for severity of effects will need to be developed.

A basic risk/benefit analysis might include parallel evaluation of risk and benefit, followed by their systematic and objective comparison. Prof. Alan Boobis suggested that in the case of aspartame, risk would be evaluated from data in experimental animals and from humans. Benefit would be based on impact on dietary control and consequent improvement in risk factors for nutrition-related diseases, such as cardiovascular disease and diabetes. The assessment should include impact in relevant sub-populations, expression of the uncertainties and sensitivity and consideration of possible interaction with other factors. **Given the huge amount of data accumulated on the safety and benefits of aspartame, it is, among all food additives, the best candidate for this risk/benefit detailed analysis.**

IMPORTANCE OF SOUND RISK COMMUNICATION

Putting benefits and risk into perspective can also help risk communication to be better understood by the wider public and allow for an objective hierarchy of risks to be weighted by the quantified benefits.

A sound risk communication has to be understood and allow the consumer to put the real risk into a proper perspective. Food safety authorities have a very important role to play as independent bodies with responsibilities for risk assessment and risk communication in the area of food safety, as do all members of the risk assessment chain. **Responsible scientists working in the highly regulated area of food safety should be willing to extensively inform food safety agencies of any new data they have regarding food safety, before they communicate to the wider public media with incomplete data or data that they chose to disclose in parts over several months, thus making it impossible for independent risk assessment bodies to deliver an informed scientific opinion.**

For more information about the roundtable on aspartame, please contact the ISA Secretariat