

EFSA to issue statement on two studies on safety of artificial sweeteners

News Story

7 February 2011

EFSA will issue a scientific statement on two recent studies on the safety of artificial sweeteners by the end of February 2011, responding to a request for technical assistance from the European Commission. Guided by the statement of the Panel on Food Additives and Nutrient Sources added to food (ANS) published today, EFSA's scientific evaluation will be carried out in close co-operation with the French agency for food, environmental and occupational health safety, ANSES[1], and will help inform the Authority's ongoing work on artificial sweeteners.

One of the studies published was conducted by the Ramazzini Institute and focuses on the potential carcinogenicity of aspartame in mice (Soffritti et al., 2010[2]). The other is an epidemiological study that examines the association between the consumption of sugar-sweetened and artificially-sweetened soft drinks and the risk of preterm delivery in Danish pregnant women (Halldorsson et al., 2010[3]).

At their plenary meeting on 1 – 3 February 2011, EFSA scientists on the ANS Panel had an initial discussion on these recent publications and highlighted further scientific work which could be considered. The Panel noted that the type and incidence of tumours reported by Soffritti et al (2010) appear spontaneously at high rates in male mice. The Panel also observed that the increased incidence of these tumours in mice exposed to aspartame through feed, whilst statistically significant, remained within the historical control range for these tumours in these mice[4]. EFSA will support the Panel in further analysing the results and conclusions in the Ramazzini paper and will request the complete data set from the authors for possible review.

The ANS Panel also considered the Danish epidemiological study whose findings suggest that the daily intake of artificially sweetened soft drinks may be associated with an increased risk of preterm delivery. These findings are based on a statistical association between the consumption of artificially sweetened soft drinks and preterm delivery observed in a prospective cohort study[5]. This epidemiological study cannot, in and of itself, establish a cause and effect relationship between the intake of artificial sweeteners and risk of preterm delivery. As indicated by the authors, further research (including experimental studies) would be required to confirm or reject these findings. The Panel advised on the need for specialised expertise to provide additional insights on the methodology and statistical aspects of this study, including the implications of possible confounding factors.

EFSA will provide a scientific statement on the two papers by the end of February 2011, responding to a request for technical assistance from the European Commission.

Statement on two recent scientific articles on the safety of artificial sweeteners

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[1] Further information on the work initiated by ANSES

[2] Soffritti M. *et al.*, Aspartame administered in feed, beginning prenatally through life span, induces cancers of the liver and lung in male Swiss mice. *Am. J. Ind. Med.* 2010, 53, 1197-1206.

[3] Halldorsson T.I. *et al.*, Intake of artificially sweetened soft drinks and risk of preterm delivery: a prospective cohort study in 59,334 Danish pregnant women. *Am. J. Clin. Nutr.* 2010, 92: 626-33,

[4] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS): Scientific Opinion on two recent scientific articles on the safety of artificial sweeteners. *EFSA Journal* 2011;9(2):1996. [5 pp.] doi:10.2903/j.efsa.2011.1996.

[5] A **prospective cohort study** is a cohort study that follows over time a group of similar individuals ("cohort") who differ with respect to certain factors under study, in order to determine how these factors affect rates of a certain outcome. This study concerns 59,344 women from the Danish National Birth Cohort (1996-2002).

SCIENTIFIC OPINION

Statement on two recent scientific articles on the safety of artificial sweeteners¹

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Two new articles have been published in the scientific literature, describing potential adverse health effects of sweeteners. The first article by Halldorsson et al. (2010) suggests an association between consumption of artificially sweetened soft drinks and increased risk of preterm delivery. The second article by Soffritti et al. (2010) reports that aspartame is a carcinogenic agent in mice. The Scientific Panel on Food Additives and Nutrient Sources added to food (ANS) of the European Food Safety Authority discussed during its 21st Panel plenary meeting held on 1-3 February 2011 the above mentioned papers and adopted a Panel Statement to advise EFSA on the need for further work.

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KEY WORDS

Artificial sweeteners, aspartame, artificially sweetened soft drinks

¹ On request from the European Commission, Question No EFSA-Q-2011-00068, adopted on 3 February 2011.

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TABLE OF CONTENTS

Abstract	1
Table of contents	2
Background	3
Terms of reference.....	3
Evaluation.....	4
References	5

BACKGROUND

In 2010, two articles have been published in the scientific literature, describing potential adverse health effects of sweeteners. The paper by Soffritti *et al.* (2010)³ reports that aspartame is a carcinogenic agent in mice. The publication by Halldorsson *et al.* (2010)⁴ suggests an association between consumption of artificially sweetened soft drinks and increased risk of preterm delivery.

The European Food Safety Authority (EFSA) has informed the Scientific Panel on Food Additives and Nutrient Sources added to food (ANS) that on 1st February 2011, the European Commission has requested EFSA for technical assistance (in line with Article 31 of Regulation (EC) No 178/2002) to undertake scientific evaluation whether the two above mentioned publications should trigger a revision of the existing opinions of EFSA related to the safety of food additive sweeteners.

TERMS OF REFERENCE

The ANS Panel will produce a Panel Statement on the two above mentioned scientific articles in order to advise EFSA on the need for further work.

³ Soffritti M. *et al.*, Aspartame administered in feed, beginning prenatally through life span, induces cancers of the liver and lung in male Swiss mice. *Am. J. Ind. Med.* 2010, 53, 1197-1206.

⁴ Halldorsson T.I. *et al.*, Intake of artificially sweetened soft drinks and risk of preterm delivery: a prospective cohort study in 59334 Danish pregnant women. *Am. J. Clin. Nutr.* 2010, 92: 626-633.

EVALUATION

Two new articles have been published in the scientific literature, describing potential adverse health effects of sweeteners. The first article by Halldorsson et al. (2010) suggests an association between consumption of artificially sweetened soft drinks and increased risk of preterm delivery. The second article by Soffritti et al. (2010) reports that aspartame is a carcinogenic agent in mice.

In the Soffritti et al., 2010 study, Swiss mice were administered aspartame in feed beginning from gestational days 12 (through pregnant mice) until week 130 of life. The authors of the study reported a higher incidence of hepatocellular carcinoma in animals administered aspartame, statistically significant at the two higher doses tested (approximately 1900 and 4000 mg/kg body weight/day). The authors also reported a statistically significant higher incidence of alveolar/bronchiolar carcinomas at the dose of 4000 mg/kg body weight/day. The increase in liver and lung tumours was observed in male animals only, and no statistically significant change in tumour incidence was reported in female mice. There was no statistically significant increase in the incidence of adenomas of the liver or the lung in either sexes.

Soffritti et al. (2010) conclude that aspartame, administered under these conditions, induces significant dose-related increases in the incidence of carcinomas of both liver and lung in male Swiss mice. The authors suggest that methanol, a metabolite of aspartame, plays a possible role in the hepatocarcinogenic effects observed in male mice. No carcinogenic effects were observed in female mice.

The Panel noted that the type and incidence of the tumours reported by Soffritti et al. (2010) appear spontaneously at high rates in male mice. The Panel also observed that even though statistical significance was reported by the authors for male mice under the experimental conditions of this study, the increased incidence of both liver and lung carcinomas remained in all exposure groups within the historical control range of the tumours in these mice.

The Panel will undertake a detailed analysis of the study results and conclusions reported by Soffritti et al. (2010), including the suggested implication of methanol.

The Panel also discussed the recently published Danish prospective cohort study on the intake of artificially sweetened soft drinks and the risk of preterm delivery (Halldorsson et al., 2010). The Panel advised EFSA on the need for epidemiological expertise to provide additional insights on the methodology and statistical aspects of this study, taking into account confounding factors. EFSA will provide an assessment on the epidemiological and statistical methodology of the Halldorsson et al. study by the end of February 2011.

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- Halldorsson TI, Strøm M, Petersen SB, Olsen SF, 2010. Intake of artificially sweetened soft drinks and risk of preterm delivery: a prospective cohort study in 59,334 Danish pregnant women. *American Journal of Clinical Nutrition* 92, 626-633.