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PRESS RELEASE

EFSA evaluates Southampton study on food additives and child behaviour

Scientists at Europe's food safety watchdog have completed an assessment of a recent study[1] on the effect of two mixtures of certain food colours and the preservative sodium benzoate[2] on children's behaviour. The study, published last year by researchers at Southampton University in the United Kingdom (McCann *et al,* 2007), suggested a link between these mixtures and hyperactivity in children.

The European Food Safety Authority's (EFSA) AFC Panel[3], with the help of experts in behaviour, child psychiatry, allergy and statistics, concluded that this study provided limited evidence that the mixtures of additives tested had a small effect on the activity and attention of some children. However, the effects observed were not consistent for the two age groups and for the two mixtures used in the study.

Considering the overall weight of evidence and in view of the considerable uncertainties[4], such as the lack of consistency and relative weakness of the effect and the absence of information on the clinical significance of the behavioural changes observed, the Panel concluded that the findings of the McCann *et al* study could not be used as a basis for altering the ADI[5] of the respective food colours or sodium benzoate.

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[1] The study conducted by McCann *et al* (2007), commissioned by the UK Food Standards Agency, involved 153 children aged 3 years old and 144 children aged 8-9 years old from the general population, including children with normal to high level activity, but not children medicated for Attention Deficit Hyperactivity Disorder (ADHD). The study is published in The Lancet and can be found at http://www.thelancet.com/journals/lancet/article/PIIS0140673607613063/abstract
The UK's Committee on Toxicology evaluated the study and issued a comprehensive statement which can be found at http://cot.food.gov.uk/statements/cotstatements2007/colpreservechildren

[2] The additives included in the two mixtures given to the children were Tartrazine (E102), Quinoline Yellow (E104), Sunset Yellow FCF (E110), Ponceau 4R (E124), Allura Red AC (E129), Carmoisine (E122) and sodium benzoate (E211).

[3] The Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food.

[4] Lack of consistency in the results with respect to age and gender of the children; the effects of the two mixtures of additives tested and the type of observer (parent, teacher, independent assessor); the unknown clinical relevance of the effects measured; lack of information on dose-response; unknown relevance of the small effect size; the fact that mixtures were used and it is not possible to identify the effects of individual additives; the lack of a plausible biological mechanism that might explain the possible link between the consumption of colours and behaviour.

[5] ADI, or Acceptable Daily Intake, is a measure of the amount of a substance, such as a food additive, which can be consumed over a lifetime without an appreciable health risk. ADIs are expressed by milligrams (of the substance) per kilograms of body weight per day.

Among the limitations of the new study, was the inability to pinpoint which additives may have been responsible for the effects observed in the children given that mixtures and not individual additives were tested.

Although the findings from the study could be relevant for specific individuals showing sensitivity to food additives in general or to food colours in particular, it is not possible at present to assess how widespread such sensitivity may be in the general population.

The Panel assisted by behavioural experts considered that the significance of the effects on the behaviour of the children was unclear since it was not known if the small changes in attention and activity observed would interfere with schoolwork or other intellectual functioning.

Based on surveys conducted from 2002 to 2005 in sweets and soft drinks[6], the colours were shown to be frequently used. Sodium benzoate is also often present in soft drinks. The AFC Panel concluded that children who consume brightly coloured sweets and soft drinks could reach intake levels for some of the additives tested in the study that would be similar to the daily amounts given in that study.

The Panel evaluated the McCann *et al* study against the background of previous studies, going back to the 1970s, on the effect of food additives on behaviour and acknowledged that it is the largest study carried out on a suggested link between food additives and hyperactivity in the general population. The Panel noted that the majority of the previous studies used children described as hyperactive and these were therefore not representative of the general population.

The AFC Panel is currently re-evaluating the safety of all food colours authorised in the European Union on a case-by-case basis and the colours used in the McCann *et al* study are included in EFSA's review. Opinions on some of the colours concerned, such as Allura Red, are expected to be adopted by the end of the year.

The full text of the opinion is available on the EFSA website at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178694648892.htm

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[6] UK Food Standards Agency (FSA) (2002); unpublished survey by the Food Safety Authority of Ireland (FSAI) (2005); Union of European Beverage Associations (UNESDA) (2005).