

Maisons-Alfort, 8 April 2009

# **OPINION**

## of the French Food Safety Agency (Afssa)

on the presence of methyl yellow, a colouring agent not authorised for human consumption, in curry and curry-based spice mixes

THE DIRECTOR GENERAL

On 6 April 2009, the French Food Safety Agency (Afssa) received an emergency request from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) for scientific and technical support regarding the presence of methyl yellow, a colouring agent not authorised for human consumption, in curry and curry-based spice mixes.

Methyl yellow was found in curry powder from India imported by a Belgian company. A European alert (RASFF) was issued on 30 March 2009. The first analyses to be carried out (10 results) revealed levels of methyl yellow of between 16 to  $1,600 \mu g/kg$ .

In Europe, several unauthorised colouring agents considered to be genotoxic and carcinogenic have been found in recent years in foodstuffs, and in spices in particular. Afssa was therefore questioned in 2003 about the presence of Sudan I in Cayenne pepper (at levels of from approximately 1.5 to 16 mg/kg), and in 2005 about the presence of Para Red in ground paprika (at levels of around 13 mg/kg)<sup>1</sup>.

In this context, the EFSA<sup>2</sup> (European Food Safety Authority) issued an opinion in 2005 on a toxicology review of colouring agents (including Sudan I and Para Red) found illegally in food in Europe, and other colourings that have not been found to date in Europe but which present alert profiles in terms of genotoxicity and/or carcinogenicity and which are used in countries outside of the European Union (including methyl yellow).

Methyl yellow (4-dimethylaminoazobenzene, CAS number is 60-11-7) is also known as butter yellow.

In 1987, the IARC placed this substance in its 2B category (possibly carcinogenic to humans)<sup>3</sup>. Recent results have confirmed both *in vitro* (Ames, lymphoma in mice, chromosomal aberration) and *in vivo* (micronucleus) genotoxicity<sup>4</sup>. According to the NTP<sup>5</sup>, methyl yellow induces tumours in mice (lungs, liver), rats (liver) and dogs (bladder) following oral administration in food. The EFSA<sup>1</sup> therefore concluded in 2005 that methyl yellow should be considered genotoxic, carcinogenic and of major health concern.

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<sup>&</sup>lt;sup>1</sup> Afssa opinions dated 9 May 2003 and 13 May 2005.

<sup>&</sup>lt;sup>2</sup> Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission to Review the toxicology of a number of dyes illegally present in food in the EU. Question number EFSA-2005-082. The EFSA Journal 263:1-71, 2005.

<sup>&</sup>lt;sup>3</sup> para-Dimethylaminoazobenzene [60-11-7] (Vol. 8, Suppl. 7; 1987)

<sup>&</sup>lt;sup>4</sup> NTP in EFSA 2005; Suzuki H., Komatsu K., Imamura T., Miyazaki A., Kobayashi T., Nomura M., 2006: Genotoxicity studies of p-dimethylaminoazobenzene (DAB), *J. Toxicol. Sci.*, Vol. 31: No. 4, 399-405.

<sup>&</sup>lt;sup>5</sup> Report on Carcinogens, 11<sup>th</sup> edition, <a href="https://ntp/roc/eleventh/profiles/s078dime.pdf">https://ntp/roc/eleventh/profiles/s078dime.pdf</a>

## Afssa – Request no. 2009-SA-0090

After consulting the "Chemical and Physical Contaminants and Residues" Scientific Panel which met on 8 April 2009, Afssa wishes to emphasise that it is the responsibility of importers to ensure the conformity of imported foodstuffs, and issues the following opinion:

#### Considering

- the similarity of this situation concerning the presence of methyl yellow a colouring agent not authorised for human consumption – in curry, with previous situations in which Sudan I and Para Red were found in other spices;
- the genotoxicity of methyl yellow, defined as a toxic substance with an unknown human toxicity threshold<sup>6</sup>;
- its carcinogenic potential demonstrated in animals and its category 2B classification by the IARC;
- the absence of data enabling human risk assessment;
- the use of curry as a seasoning in a large number of foods;

Afssa cannot exclude the possible risk for human health, even at low levels, and therefore recommends that all possible administrative measures be taken or completed to ensure that consumers are not exposed to methyl yellow.

#### Key words

Methyl yellow, butter yellow, colouring agent, colouring, curry

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<sup>&</sup>lt;sup>6</sup> Exposure to a single molecule may have an effect.