

COMMISSION REGULATION (EC) No 884/2007**of 26 July 2007****on emergency measures suspending the use of E 128 Red 2G as food colour****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽¹⁾ and in particular Article 53(1) thereof,

Whereas:

- (1) Under Article 53(1) of Regulation (EC) No 178/2002 the Commission may suspend the placing on the market or use of a food that is likely to constitute a serious risk to human health, when such risk cannot be contained satisfactorily by means of measures taken by the Member States concerned.
- (2) European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs⁽²⁾ authorises in its Annex I the use of the colour E 128 Red 2G in foodstuffs. Pursuant to Annex IV of that Directive the colour E 128 Red 2G is permitted for use in breakfast sausages with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 %. In both foods a maximum level of 20 mg/kg is allowed.
- (3) The use of that colour has been permitted on the basis of the opinion of the Scientific Committee on Food expressed on 27 June 1975⁽³⁾. That Committee allocated an acceptable daily intake (ADI) of 0,1 mg/kg body weight for E 128 Red 2G.
- (4) Food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. As the original assessments of many of food additives date back over a number of years, the European

Commission considered that there is a need for a systematic re-evaluation of all authorised food additives to verify whether the existing safety assessment remain valid. Therefore, the Commission requested the European Food Safety Authority (EFSA) to re-evaluate all currently permitted food additives in the EU.

- (5) In this context the EFSA Scientific Panel on food additives, flavourings, processing aids and materials in contact with food has re-evaluated the safety of the colour E 128 Red 2G and adopted an opinion⁽⁴⁾ on 5 July 2007.
- (6) EFSA based its evaluation on the conclusions of the European Union risk assessment report⁽⁵⁾ on aniline. That report concluded that aniline should be considered as a carcinogen for which a genotoxic mechanism cannot be excluded. Since the colour E 128 Red 2G is readily and extensively metabolised to aniline, EFSA concluded that it would be prudent to regard that substance as being of safety concern. Consequently, EFSA withdrew the ADI for the colour E 128 Red 2G. EFSA, however, considered that should the tumour inducing mechanism of aniline be further elucidated, shown to be thresholded and/or its relevance for man discounted, the colour E 128 Red 2G could be re-evaluated once again for use as a food additive.
- (7) Considering that a food additive may only be used when there is evidence that its use is not harmful to health, Directive 94/36/EC should be amended to prohibit the use of the colour E 128 Red 2G.
- (8) In the interim, since the colour E 128 Red 2G is likely to constitute a serious risk to human health, it is appropriate, in order to ensure the high level of health protection chosen in the Community, to suspend with immediate effect the use of the colour E 128 Red 2G in food and the placing on the market and import of food containing the colour E 128 Red 2G.
- (9) By virtue of Directive 94/36/EC, the colour E 128 Red 2G is legally authorised for use in all Member States. Therefore, a Community-wide measure is necessary.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

⁽²⁾ OJ L 237, 10.9.1994, p. 13. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽³⁾ SCF (1975). Reports of the Scientific Committee for Food (First series), p. 17, 19, 24.

⁽⁴⁾ EFSA (2007). Opinion of the Scientific Panel on Food Additives, Flavourings, Processing aids and Materials in contact with Food (AFC) on re-evaluation of food colours Red 2G (E 128).

⁽⁵⁾ ECB, 2004, European Chemicals Bureau, Institute for Health and Consumer Protection. European Union Risk Assessment Report on Aniline. Volume 50.

- (10) The Commission will keep this Regulation under regular review taking into account new scientific information.
- (11) Having regard to the nature of the risk, this Regulation should enter into force immediately.
- (12) Taking account of technical and economic reasons, transitional periods should be laid down to cover breakfast sausages and burger meat containing the colour E 128 Red 2G, which have been placed on the market in accordance with Directive 94/36/EC as well as consignments which were dispatched from third countries for the Community before the date of application of this Regulation.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The use of the colour E 128 Red 2G in food, as referred to in Annex IV to Directive 94/36/EC, is suspended.

2. The placing on the market of food containing the colour E 128 Red 2G is suspended.

3. The import of food containing the colour E 128 Red 2G is suspended.

Article 2

1. By derogation to Article 1(2), breakfast sausages and burger meat containing the colour E 128 Red 2G which have been placed on the market in accordance with Directive 94/36/EC before the date of entry into force of this Regulation may be marketed until their 'use by' date or their date of minimum durability.

2. Article 1 shall not apply to consignments of breakfast sausages and burger meat containing the colour E 128 Red 2G where the importer of such foodstuffs can demonstrate that they had been dispatched from the third country concerned and were en route to the Community before the date of entry into force of this Regulation.

Article 3

This Regulation shall enter into force the day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 July 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission
