

EXPLANATORY MEMORANDUM TO
THE FOOD (SUSPENSION OF THE USE OF E 128 RED 2G AS FOOD
COLOUR) (ENGLAND) REGULATIONS

2007 No. 2266

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

- 2.1 This Statutory Instrument provides enforcement measures in England for Commission Regulation (EC) No. 884/2007 on emergency measures suspending the use of E 128 Red 2G as a food colour, following an unfavourable opinion by the European Food Safety Authority (EFSA).

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

- 3.1 These Regulations were made on 30 July 2007, laid before Parliament on 1 August and come into force on 2 August. They therefore breach the 21 day rule. The Food Standards Agency considers this necessary under the circumstances, because the Commission Regulation associated with these Regulations (as to which see further below) contains emergency controls and came into effect on 28 July - the day following its publication in the Official Journal of the European Communities.

4. **Legislative Background**

- 4.1 The Food (Suspension of the Use of E 128 Red 2G as Food Colour) (England) Regulations 2007 are being made to provide for the execution and enforcement of Commission Regulation (EC) No. 884/2007 on emergency measures suspending the use of E 128 Red 2G as a food colour (OJ No. L195, 27.7.2007, p.8) in England.

- 4.2 The Ministerial power under which the Regulations are made is Section 2 (2) of the European Communities Act 1972 as read with paragraph 1A of Schedule 2 to that Act.

- 4.3 Until now, under Directive 94/36/EC, Red 2G has been 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%. The Commission Regulation suspends the use of the colour E128 Red 2G in food, the placing on the market of food containing the colour E128 Red 2G and the import of food containing the colour E128 red 2G. However, the Commission Regulation does not amend Directive 94/36/EC but states that it may be amended in the future.

4.4 Directive 94/36/EC is implemented by the Colours in Food Regulations 1995 (SI 1995/3124). When the Directive is amended, the Colours in Food Regulations will be amended.

5. Extent

5.1 The Regulations apply to England only. Parallel Regulations are being made in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

7.1 The decision to suspend Red 2G was taken as a result of EFSA's recent opinion, which showed that E128 Red 2G may have the potential to damage the genetic material in cells and cause cancer in animals. The opinion by EFSA is the first one in a re-evaluation process of all food additives, which gives priority to food colours as they were among the first food additives to be evaluated under European legislation.

7.2 At a meeting of the Standing Committee on the Food Chain and Animal Health on 20 July 2007 Member States agreed the Commission Regulation. A derogation has been included which permits breakfast sausages and burger meat containing Red 2G placed on the market before the date of entry into force of the Regulation in compliance with Directive 94/36/EC to be marketed until their "use by" date or date of minimum durability. A derogation also applies to consignments of breakfast sausages and burger meat dispatched from third countries and en route to the Community before the date of entry into force of the Regulation.

7.3 Whilst no formal public consultation has taken place because of the need to act quickly to protect public health, the Food Standards Agency met with key stakeholders to determine current use of Red 2G in the UK and also gave them the opportunity to comment on key aspects of the draft Commission Regulation.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact Point

Helen Chapman at the Food Standards Agency (Tel: 0207 276 8000 or E-mail: Helen.chapman@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

Regulatory Impact Assessment

1. Title of proposal

Commission Regulation (EC) No. 884/2007 on emergency measures suspending the use of E128 Red 2G as food colour (the Commission Regulation); and,

The Food (Suspension of the Use of E128 Red 2G as Food Colour) (England) Regulations 2007 (the domestic Regulations).

2. Purpose and intended effect

Objective

To provide for the execution and enforcement of the Commission Regulation by means of domestic Regulations so as to protect public health by suspending the use of Red 2G as a food colour within the UK (equivalent legislation will be adopted in other parts of the UK).

Background

Under EC Directive 94/36/EC, Red 2G is permitted to be used as a food colour in breakfast sausages with a minimum cereal content of 6% and burger meat with a minimum vegetable and/or cereal content of 4%. On re-evaluating Red 2G, the European Food Safety Authority (EFSA) considers the colour may have the potential to damage the genetic material in cells and cause cancer in animals. Risk management decisions fall to the European Commission and EU Member States meeting as the Standing Committee on the Food Chain and Animal Health (SCOFCAH).

Rationale for government intervention.

Under current legislation Red 2G is a permitted food colour. Following the EFSA opinion, this use needs to be stopped. The government needs to act because in the short term some manufacturers and consumers will be less aware of these newly identified possible carcinogenic risks. In addition any potential adverse public health outcomes would incur costs born by the wider public purse thus providing further justification for intervention.

3. Consultation

Within government

The Food Standards Agency (FSA) has sole policy responsibility for ensuring food safety.

Public consultation

FSA consulted key stakeholders concerning the Commission Regulation. FSA officials met with key stakeholders on 10 July, the day after the EFSA announcement. Ahead of a meeting of SCOFCAH on 20 July, FSA informed stakeholders of the significant points proposed for inclusion in a Commission Regulation, giving them the opportunity to

provide feedback. The Agency has also received information in the course of phone conversations with affected stakeholders.

Industry confirmed that Red 2G is used in a small percentage of burgers and sausages on sale in the UK. They also noted that some companies manufacture seasonings to be sold to producers of sausages and burgers who then use this as one of their ingredients; Red 2G is included in the seasoning mixture.

4. Options

Option 1: Do nothing.

Option 2: Put in place the domestic regulations which provide for the execution and enforcement of the Commission Regulation.

5. Costs and benefits

Sectors and groups affected

Food producers manufacturing or importing those specific categories of sausages and burgers are affected. Also companies manufacturing or importing seasonings containing Red 2G to be used for the manufacture of these products (as seasonings with Red 2G have no alternative use). Companies which manufacture or import Red 2G, though there are alternative industrial uses for this colour.

We consider the proposal will have no impact on racial equality, social or environmental issues.

Benefits

Option 1 provides no incremental benefit; doing nothing provides no consumer protection because the requirements of the Commission Regulation cannot be enforced.

Option 2 provides consumer protection by allowing for enforcement and sanctions if Red 2G is used in food.

Costs

Option 1

Doing nothing would mean the UK would be unable to fulfil its Community obligation to enforce the Commission Regulation. This will leave the UK open to infraction proceedings by the Commission for failing to comply with these requirements.

Option 2

There will be costs to producers of the affected types of sausages and burgers who continue to hold stock of seasoning containing Red 2G, as well as to seasoning manufacturers.

The producers will not be able to use any remaining stock of seasonings containing Red 2G, or any stock of packaging/labelling referring to Red 2G. There may be a short period of disruption to production as a company arranges a replacement seasoning mix which does not contain Red 2G.

Seasoning manufacturers will lose the value of any seasoning stock held, along with any stock of packaging/labelling referring to Red 2G. There may also be a short disruption to their supply of seasonings to customers as they arrange for an alternative food colour to be used.

Irrespective of which regulatory option is chosen there may still be costs because many consumers will wish to avoid food products containing Red 2G, so there will be no market for the products. Retailers may wish to return products already supplied and request alternatives. Off-setting some of these costs, some companies may be able to make an insurance claim.

6. Small Firms Impact Test

Seasoning mixes are used by some independent butchers to produce the specific sausages and burgers affected by this legislation. They will be subject to the costs outlined in section 5.

7. Competition assessment

The Regulation will apply uniformly across all food producers, so we do not envisage any impact on competition. The Agency understands that alternative red food colouring agents exist for those food producers to whom this colour is important.

8. Enforcement, sanctions and monitoring

The Food (Suspension of the Use of E128 Red 2G as Food Colour) (England) Regulations 2007 provide for enforcement and sanctions. Local authorities and Port Health Authorities routinely sample food for the presence of illegal additives.

9. Implementation and delivery plan

The Commission Regulation is directly applicable in the UK. We have informed stakeholders of the new legislation.

10. Post-implementation review

The policy will be reviewed if monitoring suggests Red 2G is used illegally in food products.

11. Summary and recommendation

Doing nothing will provide no means of ensuring consumer protection whilst incurring possible infraction costs. Putting in place the domestic regulations will involve costs for the food industry which cannot continue to use stocks of seasoning, but enforcement and sanctions will ensure a greater level of consumer protection. On balance we recommend putting in place the domestic regulations.

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed *Dawn Primarolo*

Date *30th July 2007*

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