



**An Investigation into the Compliance of
Sausages and Burgers available in Ireland
with Regulation 884/2007/EC which
suspended the use of Red 2G (E128) as a
Food Colour**

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The results presented in this report relate solely to the individual samples/batches tested and do not necessarily reflect the general status of the products listed.

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Summary

Red 2G (E128) is the common name for the mono-azo colour disodium 8-acetamido-1-hydroxy-2-phenylazo-naphthalene-3,6-disulphonate and up until July 2007, the use of Red 2G (E128) had been authorised under European Parliament and Council Directive 94/36/EC¹ on colours for use in foodstuffs. In accordance with the Directive 94/36/EC and pursuant to annex IV, Red 2G (E128) was 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 was permitted.

The safety of all additives is kept under continuous observation and is re-evaluated whenever necessary in light of changing conditions of use or whenever new scientific information comes to light. As the original safety assessments for a number of the additives dates back many years the European Commission considered that there was a need to systematically review all of the authorised additives and it was within this context that Red 2G was re-evaluated by the European Food Safety Authority (EFSA).

On the 5th of July 2007, EFSA published its opinion² on the re-evaluation of Red 2G (E128) and concluded that it would be prudent to regard Red 2G as being of safety concern. This conclusion was based on the fact that Red 2G can be extensively metabolised to aniline which is considered to be carcinogenic and for which a genotoxic mechanism cannot be excluded. As a result of this, EFSA withdrew the Acceptable Daily Intake (ADI) for Red 2G. This action prompted the European Commission to invoke emergency measures in order to suspend the use of Red 2G (E128) under Commission Regulation 884/2007/EC³ of the 26th of July 2007. FSAI informed industry about the outcome of the EFSA opinion and instructed manufacturers to stop using Red 2G in their products and to change their product labels accordingly.

Following the publication of the emergency measures, the Food Safety Authority of Ireland (FSAI) in conjunction with the Cork Public Analyst's Laboratory Service carried out a surveillance study on Red 2G (E128) in sausages and burgers available

on the Irish market in order to ascertain the levels of compliance with these new measures.

A total of 26 samples were tested in the 2007 survey (18 different types of sausages and 8 different types of burgers) and out of these two burger samples contained detectable levels of Red 2G, albeit at very low levels. The FSAI followed up these non-compliances and corrective action was taken in both cases.

The results of this study show that most manufacturers had quickly taken action to reformulate any products containing Red 2G following the publication by the European Commission of the emergency measures which suspended its use. The FSAI will continue to monitor products for Red 2G and other additives, in order to safeguard the health of consumers in Ireland.

Introduction

The Food Safety Authority of Ireland (FSAI) has a statutory responsibility to ensure the safety of food consumed, distributed, produced and sold on the Irish market. In order to achieve this aim, the FSAI *inter alia* coordinates the collation of food safety surveillance information from laboratories run by its official agencies, the Health Service Executive, the Department of Agriculture, Fisheries and Food, the Marine Institute, the Sea Fisheries Protection Authority (SFPA) and the local authorities. The FSAI also conducts targeted food safety surveillance in areas where potential safety issues have been identified. This report provides the results of a targeted surveillance study into the presence of the food additive Red 2G (E 128) in sausages and burgers available on the Irish market.

Food Additives

Food additives are substances which are intentionally added to foodstuffs to perform certain technological functions, e.g. to preserve, sweeten or in the case of Red 2G (E128) to colour. The use of food additives in the European Union (EU) is regulated by Framework Directive 89/107/EEC⁴ and three specific Directives on colours (94/36/EC¹), sweeteners (94/35/EC⁵) and on food additives other than colours and sweeteners (95/2/EC⁶). The Community legislation on food additives is based on the principle that only those additives that are explicitly authorised may be used. In order for an additive to be authorised there must be a technological need for its use, it should not mislead the consumer and should not present any hazard to the health of the consumer. Prior to their authorisation food additives are evaluated for their safety by the European Food Safety Authority (EFSA) a task previously carried out by the Scientific Committee for Food (SCF). If an additive is deemed acceptable for food use, an Acceptable Daily Intake (ADI) is normally set. ADI is defined as “*an estimate of the amount of a food additive, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health effects*”. The Framework Directive also requires that 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.

In addition to the requirement for a thorough safety evaluation and a demonstrated technological need all additives used in foods must be declared in the list of ingredients in accordance with Council Directive 2000/13/EC⁷. The labelling must include the purpose of the additive as well as the name of the additive or its assigned E number e.g. Colour, Red 2G or Colour, E128.

Red 2G (E128)

As mentioned earlier this report deals with a surveillance study into the presence of the food colour Red 2G (E128) in sausages and burgers. All colours used in foodstuffs are regulated by Council Directive 94/36/EC¹. The function of colour additives is to restore the original appearance of food whose colour has been affected by processing, storage, packaging and distribution and as a result its visual acceptability may have been impaired. Red 2G is the common name for the mono-azo colour disodium 8-acetamido-1-hydroxy-2-phenylazo-naphthalene-3, 6-disulphonate. The structure of this substance is given in Figure 1 below. Up until the end of July 2007, Red 2G was permitted under European Parliament and Council Directive 94/36/EC¹ on colours for use in foodstuffs. Red 2G (E128) was authorised for use in breakfast sausages with a minimal cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 %. In both foodstuffs a maximum level of 20 mg/kg was allowed.

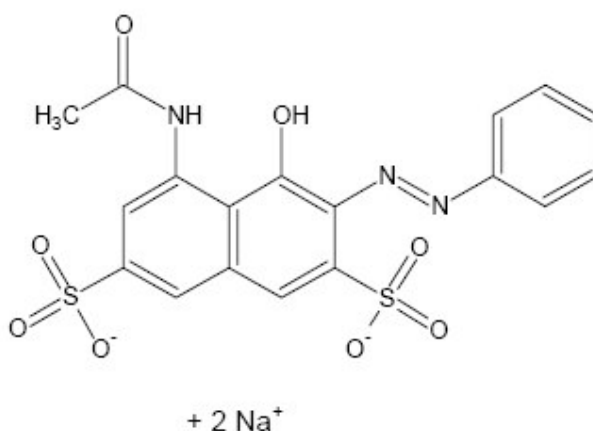


Figure 1: The structure of Red 2G (E 128)

EFSA re-evaluation of Red 2G (E128)

As the original safety assessments for a number of the additives including the synthetic colours date back many years the European Commission considered that there was a need to systematically review all of them to verify whether the existing safety assessment remains valid. Therefore, the Commission has requested EFSA to re-evaluate all permitted additives starting with the colours as a priority and it was within this context that Red 2G was re-evaluated by the EFSA Scientific Panel on food additives, flavourings, processing aids and materials in contact with food.

Red 2G has been evaluated previously by the joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1977⁸ and 1981⁹ and by the EU Scientific Committee for food (SCF) in 1975¹⁰. Both bodies allocated an Acceptable Daily Intake (ADI) for Red 2G of 0.1mg/kg body weight (bw) and it was on this basis that the colour was authorised under Directive 94/36/EC¹. However, on the 5th of July 2007, EFSA published its opinion² on the re-evaluation of Red 2G (E128) and concluded that it would be prudent to regard Red 2G as being of safety concern. This conclusion was based on the fact that Red 2G can be extensively metabolised to aniline, and the EU risk assessment report on aniline¹¹ has concluded that aniline should be considered as a carcinogen for which a genotoxic mechanism cannot be excluded.

These findings were based on the following:

- aniline was genotoxic in vivo in rats and mice,
- there was insufficient mechanistic evidence to discount a genotoxic mechanism for the rodent carcinogenicity
- based on similar metabolism of aniline in animals and humans a carcinogenic risk for man cannot therefore be excluded.

Since Red 2G (E128) is extensively metabolised to aniline in humans its safety could not be guaranteed and as a result EFSA withdrew the ADI for Red 2G. EFSA acknowledged however that should further details be elucidated on the tumour inducing mechanism of aniline, and a threshold level at which tumours are induced can be established, then the situation can be revisited. Secondly if the relevance for human health can be discounted then Red 2G (E128) would be re-evaluated once again for use as a food additive

This opinion by EFSA prompted the European Commission to take the necessary risk management measures in order to suspend the use of Red 2G (E128) as a food colour with immediate effect in order to ensure a high level of human health protection across the Community. These measures were contained in Regulation 884/2007/EC³ and were taken on the basis of article 53 (1) of Regulation 178/2002/EC¹² whereby 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. Transitional measures were also laid down in Regulation 884/2007/EC³ for breakfast sausages and burgers containing Red 2G (E128) which had been placed on the market in accordance with Directive 94/36/EC as well as consignments destined for the Community which were dispatched from third countries before the date of application of the Regulation (26th July 2007).

Following the publication of the EFSA opinion, FSAI informed industry¹³ that the use of Red 2G (E128) was likely to be suspended and requested that they immediately reformulate any products containing Red 2G. In addition, FSAI requested industry to make the necessary changes to product labels in order to take into account any reformulations in recipes that may have taken place. This approach was formalised via the Commission Regulation which suspended the use of Red 2G (E128) with immediate effect from the 26th of July 2007.

Survey Details

26 samples consisting of eighteen different types of sausages and eight different types of burgers were purchased at the end of September 2007 from various retailers and butchers shops and were analysed over the next couple of months. According to the EFSA opinion no formal method for analysis of Red 2G in food has been described but some methods are available from the open literature. In this study Red 2G was extracted from the individual meat samples using a 4% ammonia in methanol solution. Following extraction, Red 2G (E128) was identified and quantified by High Performance Liquid Chromatography (HPLC) coupled with ultra violet (UV)

detection. A reverse phase column was used in the analysis and the mobile phase was made up of a methanol-acetonitrile solution and a phosphate buffer. The injection volume used for the analysis was 10µl and the limits of quantification (LOQ) and detection (LOD) for the method were 10 mg/kg and 1 mg/kg respectively.

Results

The results of this survey are presented in Table 1. From Table 1 it can be seen that none of the sausages tested contained any detectable levels of Red 2G (E128). In contrast however, two out of the eight burger samples tested contained a detectable level of Red 2G (E128) although the levels found were low and below the limit of quantification for the method used by the laboratory performing the analysis.

In the case of these two burger samples the concentrations of Red 2G (E128) detected were 3.9 mg/kg and 2.3 mg/kg. Both of these burger samples were purchased from butcher shops in Co. Louth i.e. Tuites butchers (3.9 mg/kg) and McEvoy's butchers and Farm shop (2.3 mg/kg). Prior to the 26th of July 2007, Red 2G would have been permitted under Directive 94/36/EC¹ at a level of 20 mg/kg in these products. However, as a result of emergency measures taken by the Commission to suspend its use via EU Regulation 884/2007/EC³, these two samples were now deemed non-compliant with the legislation.

Following the request of the FSAI the owner of Tuites Butchers swiftly carried out extensive investigations into the possible source of Red 2G in their burgers. These investigations revealed that Red 2G was present in the burgers as a result of using a spice mix which contained the additive in the preparation of the burgers. This spice mix was purchased by the butchers from McDonnells Ltd. (Queen Street, Dublin) prior to the suspension of Red 2G (E128). Tuites has since notified the FSAI that they had ceased using this particular spice mix at the end of September 2007. Further follow up investigations by the FSAI with McDonnells Ltd. (supplier of the spice mix) revealed that the product specifications for the burger spice mixes no longer contained Red 2G (E128). These mixes were re-formulated to substitute Red 2G

(E128) with an alternative permitted food colour in order to comply with the emergency measures introduced by the Commission in July of 2007.

Follow up investigations into the presence of Red 2G in McEvoy's burgers also revealed that the colour was present in the burgers as a result of using a spice mix in their manufacture. In this case the spice mix was supplied by Kiernans Food Ingredients Ltd, Co. Monaghan. Further follow up investigations by Environmental Health Officers into Kiernans Food Ingredients Ltd. revealed that they had removed all of this particular spice mix from sale in compliance with the emergency measures and subsequently supplied a reformulated burger spice mix to the industry.

Despite these two positive samples, the results overall showed good compliance with the new emergency measure 884/2007/EC³ and revealed that most manufacturers had reacted swiftly to remove Red 2G from their products following its publication at the end of July. It should be noted however that the results presented in this report relate solely to the individual samples/batches tested and do not necessarily reflect the general status of the products listed.

Table 1: Results of Red 2G analysis in sausages and burgers available on the Irish market

FSAI Sample Number	Brand	Product description	Place of Purchase	Red 2G mg/kg
2007/1	Superquinn	Sausages	Superquinn, Swords	n.d.
2007/2	Tesco Value	Sausages	Tesco, Clarehall	n.d.
2007/3	Nice Price	Pork Sausages	Supervalu, Boroimhe	n.d.
2007/4	Hodgins	Traditionally Gluten free Sausages	Supervalu, Boroimhe	n.d.
2007/5	Tom Lynch (Ardee)	Pork Sausages	Staffords Fine Foods, Drogheda	n.d.
2007/6	Mallons	Sausages	Staffords Fine Foods, Drogheda	n.d.
2007/7	Tuites	Sausages	Tuites butchers, Drogheda	n.d.
2007/8	Kennards	Sausages	Kennards butchers, Dorset Street	n.d.
2007/9	Rudd's	Sausages	Dunnes Stores, Pavillions	n.d.
2007/10	Dunnes Stores	Simply better 12 pork Sausages	Dunnes Stores, Pavillions	n.d.
2007/11	Buckleys	Sausages	FX Buckleys butchers, Talbot Street	n.d.
2007/12	McEvoy's	Sausages	McEvoy's butchers and farm shop, Drogheda	n.d.
2007/13	Clonakilty	Sausages	Tesco, Clarehall	n.d.
2007/14	Denny	Sausages	Tesco, Clarehall	n.d.
2007/15	Kearns	Sausages	Tesco, Clarehall	n.d.
2007/16	Galtee	Sausages	Tesco, Clarehall	n.d.
2007/17	Granby	Everyday pork Sausages	Tesco, Clarehall	n.d.
2007/18	Superquinn	Burgers	Superquinn, Pavillions	n.d.
2007/19	Tesco Finest	Jalapeno Burgers x 4	Tesco, Clarehall	n.d.
2007/20	Granby	Individually packed burgers x 10	Tesco, Clarehall	n.d.

n.d. = non-detect (below the limit of detection (LOD))

Table 1 (contd): Results of Red 2G analysis in sausages and burgers available on the Irish market

FSAI Sample Number	Brand	Product description	Place of Purchase	Red 2G mg/kg
2007/21	Tuites	Beef Burgers x 5	Tuites butchers, Drogheda	3.9
2007/22	Dunnes Stores	Irish Quarter Pounders	Dunnes Stores, Pavillions	n.d.
2007/23	Ketty e Irish foods	Traditionally matured beef burgers x 4	Dunnes Stores, Pavillions	n.d.
2007/24	Buckleys	Beef Burgers x 6	FX Buckleys butchers, Talbot Street	n.d.
2007/25	McEvoys	Burgers x 6	McEvoys butchers and farm shop, Drogheda	2.3
2007/26	Oldhausen	Sausages	Tesco, Clarehall	n.d.

n.d. = non-detect (below the limit of detection (LOD))

Conclusion

The FSAI are pleased to report the results of this survey, showing that a range of different sausages and burgers available in Irish retailers and butcher shops were generally in compliance with the recent legislation to suspend the use of Red 2G as a food colourant. However, Red 2G was detected in two samples of burgers where it was present as a result of both butchers using a spice mix containing the colour in their manufacture. It should be stressed that the levels found were below the limit of quantification for the method used by the laboratory but nonetheless should not have been present. In both cases appropriate follow up action was taken by the butchers and the suppliers of the spice mixes concerned and the FSAI are satisfied that the necessary steps have been taken to ensure legal compliance.

However, FSAI emphasises to all manufacturers the need to continue to take every precaution in sourcing raw materials for use in the manufacture of these products and also the need to be vigilant with respect to new legislation which may affect their existing stock. FSAI will continue to monitor such products for Red 2G and other additives, in order to safeguard the health of Irish consumers.

References

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