

REGULATORY APPRAISAL

FOOD, WALES

THE COLOURS IN FOOD (AMENDMENT) (WALES) REGULATIONS 2007

Background

1. At the meeting of the European Commission's Standing Committee on the Food Chain and Animal Health in Brussels on 16 December 2005, Member States agreed to an amendment to the purity criteria set out in Directive 95/45/EC. This amendment was subsequently included in Commission Directive 2006/33/EC.
2. The Colours in Food (Amendment) (Wales) Regulations 2007 are being made to transpose and implement Commission Directive 2006/33/EC, the fourth amendment to Directive 95/45/EC, which lays down specific purity criteria (specification) for colours for the use in foodstuffs throughout the EU.
3. Commission Directive 95/45/EC forms part of a continuing programme to update EU wide specifications for food colours, which are used to ensure the purity of these substances.

Purpose and intended effect of the measure

4. The aim of the Directive is to amend the purity criteria for two colours Sunset Yellow FCF (E110) and titanium dioxide (E 171). Sunset Yellow FCF is a colourant that may be added to foods to induce a colour change. It is a synthetic coal tar and azo dye useful in fermented foods, which must be heated. It is denoted by E number E110, and has the capacity for inducing an allergic reaction. Sunset Yellow FCF may be found in orange squash and soft drinks, marzipan, Swiss roll, apricot jam, sweets, packet soups and some sauce mix. Titanium Dioxide is a natural white mineral that is denoted by E number E171. It is most commonly used as a white food dye, and can be found in tablets and capsules, cottage and Mozzarella cheese, toothpaste and also in sweets where it is often used to provide a barrier between different colours.
5. The proposed legislation will transpose and implement Commission Directive 2006/33/EC, which itself amends Commission Directive 95/45/EC. Changes to the purity criteria for Sunset Yellow and Titanium Dioxide set out in Directive 2006/33/EC were agreed at a meeting of the European Commission's Standing Committee in Brussels on 16 December 2005.
6. Directive 2006/33/EC of 20 March 2006, which was published in the Official Journal of the European Communities (L82/10) on 21 March 2006, amends Directive 94/45/EC for the fourth time. Commission Directive 95/45/EC forms part of a continuing programme to update EU wide specifications for food colours, which are used to ensure the purity of these substances and sets out specific purity criteria (specifications) for individual approved food colours.
7. The main amendments introduced by Directive 2006/33/EC are:
 - To include a new limit of 0.5mg/kg for Sudan 1 in Sunset Yellow;

- Reduce the existing limit of lead in Sunset Yellow from 10mg/kg to 2mg/kg;
- Permit the use of rutile titanium dioxide as an addition to the presently permitted anatase form (Titanium dioxide occurs in four forms: Titania, Rutile, Anatase and Brookite. Rutile is one of the purest forms of the chemical Titanium Dioxide); and
- Amend the description of titanium dioxide to encompass both forms of this colour.

Risk Assessment

8. Sunset Yellow FCF is a colourant that may be added to foods to induce colour change and has the capacity for inducing an allergic reaction. Therefore, the risk of not making these Regulations is that consumer health safety would be compromised and Welsh consumers will not be afforded the same protection measures as the other UK administrations.

Devolution

9. The Regulations will apply in Wales only and will come into force on 10 April 2007. Separate but parallel Regulations will be made in England, Scotland, and Northern Ireland to also come into force by the 10 April 2007.

Options

10. In respect of this legislation, the “Do Nothing” option is not an option, as it would ultimately lead to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the “Make the Legislation” option, to implement the changes required to comply with the European legislation, is being recommended.

Benefits

11. These Regulations are intended to improve food safety in relation to specific colourants, or E numbers in food. Making these Regulations will mean that Wales would become fully compliant with the EU Directive specifying the maximum limits of substances that are potentially hazardous to human health, therefore, improving food safety for the public.

Compliance Costs for Business, Charities and Voluntary Organisations

12. A public consultation was carried out on the draft Colours in Food (Amendment) (Wales) Regulations 2007. No identifiable costs on business, charities or voluntary organisations or to the public have been established.

Costs

13. Enforcement of this legislation is the responsibility of Local Authority Public Protection Departments in Wales. Enforcers will not acquire any additional burdens from these proposals.
14. The public consultation exercise invited comments on any additional costs envisaged in implementing the Regulation. No comments were forthcoming from the Local Authorities Co-ordinators of Regulatory Services (LACORS) (the co-ordinating body for local authority trading standards departments in England

and Wales), or the Welsh Local Government Association. No additional costs to local authorities or the Assembly have been identified.

Consultation

With Stakeholders

15. The Food Standards Agency Wales carried out a consultation with stakeholders between 19 May 2006 and 11 August 2006. Stakeholders included: Assembly Members and consumer and industry representative bodies (a full list of the consultees is attached at Annex A). They were invited to comment on the draft Regulations and any costs associated with the implementation of the Regulations. No comments were received in Wales.
16. Parallel consultations were carried out from 18 May 2006 to 11 August 2006 in England and Northern Ireland and from 19 May to 11 August 2006 in Scotland. The Consultation exercise in Scotland and Northern Ireland produced no comments. In England, the consultation exercise produced three responses; two from industry, and one from a trade association that represents the retail industry, none of which made any substantive comments. All three responses supported the amendment to the Colours in Food Regulations 1995 and demonstrated that there was no disproportionate impact on businesses (including small businesses) as a result of the new Regulations coming into force. Therefore, no issues of significance were raised and no policy changes to the draft Regulations were identified as a consequence of the public consultation.

With Subject Committee

17. These Regulations were notified to the Health and Social Services Committee, via the list of forthcoming legislation, on 11 May 2006 (HSS(2)-08-06 (p.2b), item no: FSA 15(06)) and have remained on the list ever since. The Regulations were not identified for detailed scrutiny.

Enforcement and Sanctions

18. Enforcement of the food additives legislation is the responsibility of Local Authority Public Protection Departments in Great Britain and the Department of Agriculture and Rural Development in Northern Ireland.

Monitoring and Review

19. The Food Standards Agency will consider proposals from stakeholders for any further changes to the rules that they consider necessary in the light of experience, and the effectiveness of the new legislation.

Summary and Recommendations

20. The Food Standards Agency believes that the full implementation of the proposals into The Colours in Food (Amendment) (Wales) Regulations 2007 will provide essential consumer health protection. Support for the adoption of these proposals is therefore recommended.

ANNEX A

Company Name
All Wales Dietetic Advisory Committee
Biotrace Limited
Conwy County Borough Council
National Federation of Womens Institutes - Wales
Peters Food Service Ltd
Tillery Valley Foods Ltd
Welsh Food Laboratories
Graig Farm Organics
Ceredigion County Council
Ceredigion County Council
Monmouthshire CC
Neath Port Talbot CBC
Powys CC
City and County of Swansea
Senior Assistant Trading Standards Officer
Vale of Glamorgan Council
Society of Directors of Public Protection Wales - Trading Standards Group
Bridgend CBC
LACORS (Welsh Officer)
Welsh Consumer Council
Farmers' Union of Wales
Welsh Local Government Association
The Association of Public Analysts
Welsh Food Alliance
UWIC
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Merthyr Tydfil CBC
Clark's Original Pies
ADAS Wales
Ruddock & Sherratt
Torfaen County Borough Council
Chartered Institute of Environmental Health in Wales
Iceland Frozen Foods
Flintshire County Council
G C Hahn & Co Ltd
Brookfield Foods Limited
Halo Foods Ltd
Good Food Distributors
Denbighshire CC
Chartered Institute of Environmental Health in Wales

Gwynedd CC
Gwynedd CC
Co-operative Group (CWS) Ltd
Caerphilly CBC
Caerphilly CBC
Blaenau Gwent CBC
Torfaen County Borough Council
Torfaen CBC
Newport CBC
RCT Trading Standards Dept
Society of Directors of Public Protection
Denbighshire CC
Society of Directors of Public Protection - North Wales
Red Star BioProducts
Department of Food Science & Technology
National Farmers Union (Wales)
British Institute for Allergy and Environmental Therapy
Meridian Foods
Wrexham CBC
Welsh Food Advisory Committee – All Members