

Food Additives Legislation GUIDANCE NOTES

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These guidance notes on food additives legislation have been produced by the Food Standards Agency with the aim of providing informal guidance. They should be read in conjunction with the appropriate legislation and should *not* be taken as an authoritative interpretation of the law, as only the courts have the power to interpret statutory provisions.

A broad overview of the UK provisions is provided in Section 1, General guidance notes. Section 1 also draws attention to points of detail *common* to the three Statutory Instruments discussed. Separate guidance notes for each of the three Statutory Instruments can be found in subsequent sections of this booklet. As these cover only *unique* points of detail, it is important for the separate guidance notes to be read in conjunction with the general guidance notes.

The guidance in Section 2 has been revised to reflect amendments to the principal Regulations by the Sweeteners in Food (Amendment) Regulations 1996, 1997, 1999 and 2001.

The guidance in Section 3 has been revised to reflect amendments to the principal Regulations by the Colours in Food (Amendment) Regulations 2000 and 2001.

The guidance in Section 4 has been revised to reflect amendments to the principal Regulations by the Miscellaneous Food Additives (Amendment) Regulations 1997, 1999, 2001 and 2001 (No. 2)

Chapter 1: General guidance notes on food additives legislation

Introduction

1. In 1995, three sets of Regulations were introduced in England, Scotland and Wales to control the use of the principal classes of food additives. These cover sweeteners, colours and ‘miscellaneous’ additives such as preservatives, antioxidants, emulsifiers, stabilisers and carrier solvents. Similar controls were introduced in Northern Ireland. The relevant Statutory Instruments and their amendments to date are listed below:

- i) the Sweeteners in Food Regulations 1995, as amended by the Sweeteners in Food (Amendment) Regulations 1996, 1997, 1999, 2001* and 2002*
- ii) the Colours in Food Regulations 1995, as amended by the Colours in Food (Amendment) Regulations 2000 and 2001*
- iii) the Miscellaneous Food Additives Regulations 1995, as amended by the Miscellaneous Food Additives (Amendment) Regulations 1997, 1999, 2001 and 2001 (No. 2)*

References to the above Statutory Instruments should also be taken as covering the legislation in Northern Ireland and, from 2000 onwards, the separate Regulations in England, Scotland, Wales and Northern Ireland.

*Separate amending provisions apply in England, Scotland, Wales and Northern Ireland.

2. This section, the General guidance notes, provides a broad overview of the UK provisions as well as drawing attention to points of detail common to the three Statutory Instruments. Separate guidance notes for each of the three Statutory Instruments can be found in subsequent sections of this booklet. As these cover only *unique* points of detail, it is important for the separate guidance notes to be read in conjunction with these general ones. The guidance notes for colours are more substantial than the other two.

3. The Statutory Instruments implement both European Parliament and Council, and Commission Directives controlling specific classes of food additives. These were adopted under Council Directive 89/107/EEC. This so-called Framework Directive sets out the basis for controls on food additives authorised for use in foodstuffs intended for human consumption (OJL 40, 11.2.89, pp. 27–33). The subsequent Directives form part of the Single Market initiative and more fully harmonise member states' national controls on the use of certain classes of food additives, to the benefit of both traders and consumers. Consumer safety is maintained, since safety in use and technological need are prerequisites for all food additives authorised for use by these measures.

Scope of the legislation

4. The principal provisions of each of the Statutory Instruments stipulate:

- which food additives are permitted for use and for sale direct to the consumer
- specific purity criteria (i.e. specifications) for permitted additives
- conditions of additive use including the setting of maximum levels for certain additives

Food additives used primarily for colouring and sweetening are covered by the Colours in Food Regulations 1995 and the Sweeteners in Food Regulations 1995 respectively. The Miscellaneous Food Additives Regulations 1995 cover additives that are used primarily as acids; acidity regulators; anti-caking agents; anti-foaming agents; antioxidants; bulking agents; carriers and carrier solvents for colours, sweeteners and miscellaneous additives; emulsifiers; emulsifying salts; firming agents; flavour enhancers; flour treatment agents; foaming agents; gelling agents; glazing agents; humectants; modified starches; packaging gases; preservatives; propellants; raising agents; sequestrants; stabilisers; and thickeners. The term 'food additive' is defined in each of the three Statutory Instruments. Each class of food additives is defined in the relevant Statutory Instrument.

5. Some solvents and certain classes of miscellaneous additives are not controlled by specific legislation although the general consumer safety provisions contained within the Food Safety Act 1990 apply. This issue is discussed further in paragraphs 12–16 of the guidance notes on the Miscellaneous Food Additives Regulations 1995 in Section 4 of this booklet. The additives Regulations, like the Directives they implement, are applicable generally to all foods, including those intended for particular nutritional uses in accordance with Directive 89/398/EEC (PARNUTS). The amendment to the Food Additives Framework

Directive has, however, allowed member states to maintain national laws prohibiting the presence of certain additives in specific foods considered to be traditional. Non-traditional versions of the same foods are allowed to contain food additives, provided their presence and use is permitted by the additive legislation. No UK products are involved, but of course there are implications for exporters.

6. Apart from a specific provision implemented by the Sweeteners in Food Regulations 1995 concerning additional labelling requirements for table-top sweeteners, the legislation does not contain any provisions for the labelling of the presence of additives in food. It does, however, update the legislation covering the labelling of food additives sold as such.

7. The practice of using substances, such as titanium dioxide, to act as tracers for monitoring purposes is outside the scope of the food additive legislation since this is not an additive function.

8. The Statutory Instruments have been made under the Food Safety Act 1990 and relevant provisions within the Act are applicable. Control of the food additives concerned is by means of a positive list system. Many additives are only permitted in certain foodstuffs, and then only up to specified maximum levels.

9. Enforcement is carried out by local food authorities, with provisions on penalties and condemnation of food included in the legislation. A defence in relation to exports exists, as explained in paragraph 12.

10. Under the legislation, the *purpose* for which the additive is used determines which rules apply. For instance, sorbitol is commonly known for its sweetening properties and, where it is used in that capacity, it is controlled by the Sweeteners in Food Regulations 1995. However, sorbitol may also be used as a humectant and in such instances the requirements of the Miscellaneous Food Additives Regulations 1995 apply.

11. Responsibility for enforcement and interpretation of the law rests with UK enforcement authorities, UK Law Courts and, ultimately, the European Court of Justice (ECJ). The relevant Directives, however, provide for disputes over specific interpretation issues to be resolved, if necessary, by reference to the EC's Standing Committee on the Food Chain and Animal Health (formerly the Standing Committee for Foodstuffs), for example in respect of unresolved queries over the interpretation of food categories. Such action can only be instigated by the European Commission or by appropriate authorities in member states. In the UK, this would normally be the Food Standards Agency. These provisions concerning the Standing Committee on the Food Chain and Animal Health may be found within the principal Directives themselves and not within the UK Regulations, because it is unnecessary for them to be implemented in the UK by national legislation.

12. For products that do not comply with the UK legislation on food additives and which are intended for export, there are two aspects that can be used in defence in any legal proceedings.

- i) For all exports, it will only be a defence if the person charged can prove that the products were intended for export to a country with analogous legislation on food additives, and that the products concerned comply with that legislation. Thus, where no such analogous legislation exists, the legal requirement is for the products concerned to comply with the UK additives legislation.
- ii) For exports to other member states, it will only be a defence if the person charged can, in addition, prove that the legislation of that country complies with relevant Community law on additives. The instances where use of this defence can be made will be very limited, since only in rare and specific cases will other member states have such legislation that differs from that in the UK. This defence is in fact intended to cover instances where a member state has made a temporary authorisation within its own territory in accordance with Article 5 of the Food Additives Framework Directive (89/107/EEC). This provision allows such temporary authorisations while the justifying scientific evidence is considered at Community level in order to allow a decision to be taken on whether or not to apply the authorisation throughout the EC.

Key points of common interest to all three statutory instruments

Implementing legislation

13. Each of the Statutory Instruments implements a European Parliament and Council Directive, which lists the permitted food additives and their condition of use. They also implement Commission Directives laying down the purity criteria for the additives concerned, by a simple reference to the title of those Directives.

14. All three Statutory Instruments include, in Regulation 2, a statement to the effect that expressions not defined in the Regulations have the same meaning as they have in the relevant Directive. Where the expressions are not found in the relevant Directive, they will automatically have the same meaning as in the Food Safety Act 1990 under which the Regulations are made.

Quantum satis

15. There are instances in the Regulations where no numerical maximum level is specified for additive use. This is because there is no need on safety grounds to set a maximum level. Rather, a level of *quantum satis* (QS) is set. QS is defined in the Regulations and means that additives shall be used in the food concerned in accordance with good manufacturing practice. This means that it must not be used at a level higher than is necessary to achieve the intended purpose and must not be used in a way that misleads the consumer.

Carry-over provisions

16. All three sets of Regulations include carry-over provisions. These apply to most foods permitted to contain food additives by those Regulations, but not to those *pecially prepared* for infants and young children. These provisions permit the presence of a permitted food additive in a compound food, to the extent that the food additive is allowed by the relevant Regulations in one of the ingredients of the compound food. They also provide for permitted food additives to be present in foods (such as intermediary products), in which they would not otherwise be permitted, provided that those foods are to be used solely in the preparation of a compound food that will conform to the relevant Regulations.

Food categories

17. All three Statutory Instruments list a number of food categories. Apart from where reference is made to a particular EU food compositional Directive, these have not been defined. This is to allow a necessary degree of flexibility to accommodate differences in the types of food products consumed in different member states. However, as the three Directives were negotiated separately without common categorisation, the food categories are not always directly comparable. While the categories are for the most part self-explanatory, there may be instances where clarification is necessary as regards the position of a certain food product. For example, some foods may meet the description of more than one category. The separate guidance notes for each Statutory Instrument in the later sections of this booklet provide some help here but, if required, further guidance should be sought from local trading standards officers or environmental health officers. A final point to note here is that the food categories have been devised purely to control food additive use and do not have any implications for the labelling of food.

Untranslated food categories

18. There are instances throughout the Directives where some food categories have not been translated into all the various EC languages. This is reflected in the Regulations, for example *saucisses de Strasbourg* and *kippers* in the Colours in Food Regulations 1995 and *mostarda di frutta* in the Miscellaneous Food Additives Regulations 1995. In these instances, the intention is that the relevant additives are only permitted in these speciality products.

Maximum level or maximum usable dose

19. All three Statutory Instruments restrict the level at which certain additives may be present in food. The level is called the 'maximum level' or, in the case of the Sweeteners in Food Regulations 1995, the 'maximum usable dose' and this has two meanings:

- i) The level in the food as ready to eat, taking into account any instructions for use. This rule applies to the entire Sweeteners in Food Regulations 1995, the Colours in Food Regulations 1995 and to three of the Schedules in the Miscellaneous Food Additives Regulations 1995. For example, the quantity (on a weight for volume basis) of a permitted sweetener in a bottle of concentrated squash may be at a higher level than that quoted in the Sweeteners in Food Regulations 1995. This is acceptable provided there are instructions for dilution such that, at the point the product is ready to drink, the level of the permitted sweetener is no greater than the maximum level permitted by the Regulations. It should be noted that in the UK, cooking, where applicable, is considered not to be a further instruction for use. The effect of cooking on the level of additives in a product differs according to a number of variable factors. Therefore, if it were considered to be a further instruction for use, it would make observance and uniform enforcement of the Regulations impossible.
- ii) In all other cases in the Miscellaneous Food Additives Regulations 1995, the level relates to the food as sold.

20. Within a production run of a food, the level of food additives present may vary slightly between individual products. While it is recognised that some variation within a batch might occur, the onus is upon manufacturers to ensure that maximum permissible additive levels are observed for each of the individual products.

Categories of food additives subject to harmonised EC controls that fall outside the scope of the Food Additives Framework Directive 89/107/EC

Flavourings

21. It should be noted that controls also exist for the flavourings category of additives. The Flavourings in Food Regulations 1992 were introduced to implement specific provisions of Directive 88/388/EEC concerning flavourings for use in foodstuffs and to source materials for their production. The Regulations define categories of flavourings to be controlled, lay down limits for certain undesirable substances that are present in some flavourings, and set down labelling requirements for business and retail sales of flavourings sold as such. The Regulations were amended in 1994 when additional labelling requirements were set down relating to retail sales.

22. In addition, EC Regulation 2232/96 (which applies in the UK without the need for further implementation) lays down a Community procedure that will eventually lead to a positive list of permitted flavouring substances following a programme of evaluation. Currently, these substances are being evaluated at European Union (EU) level. This is a developing area and advice on the latest position can be obtained from the Food Standards Agency. See the front of this document for the address of the Food Additives Unit.

Extraction solvents

23. The Extraction Solvents in Food Regulations 1993 implement the provisions of Council Directive 88/344/EEC, which sets out a positive list of extraction solvents. Only those products on the list can be used in the Community. Maximum residue limits for each extraction solvent are laid down and, for some, specific conditions of use apply. The Regulations lay down specifications of purity and prescribe labelling requirements for extraction solvents. These Regulations were amended in 1995 and 1998. Firstly, they were amended to permit the use of an additional substance (cyclohexane) in the preparation of flavourings. Secondly, they were amended to delete two substances (butyl acetate and methylpropan-1-ol) from the positive list, to reduce the maximum residue level for hexane and to clarify its conditions of use, and to add a new extraction solvent (1,1,1,2-tetrafluorethane or 'TFE') to the list.

Chapter 2: Guidance notes on the Sweeteners in Food Regulations 1995 (as amended)

Introduction

1. The notes in this section cover only those aspects of food additives legislation that are specific to the Sweeteners in Food Regulations 1995 as amended. References throughout these notes should be taken as also covering the parallel legislation in Scotland, Wales and Northern Ireland. For a complete overview, these notes should be read in conjunction with the General guidance notes (see Section 1 of this booklet), which cover points common to all additives legislation. Manufacturers should be aware that the use of sweeteners has implications for the labelling of their products. They should therefore also consult the Food Labelling Regulations 1996 and their accompanying guidance notes.

Scope of the regulations

2. The Sweeteners in Food Regulations 1995 implement provisions contained within two EC Directives:
3.
 - i) European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs (OJL 237, 10.9.94, pp. 3–12) as amended by Council Directive 96/83/EC (OJL 48, 19.2.97, pp. 16–19)
 - ii) Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs (OJL 178, 28.7.95, pp. 1–19) as amended by Directives 98/66/EC (OJL 257, 19.9.98, p. 35), 2000/51/EC (OJL 198, 4.8.2000 pp. 41–43) and 2001/52/EC (OJL 190, 12.7.2001 pp. 18–20)

The **Sweeteners in Food Regulations 1995**:

- define ‘sweetener’
- list the permitted sweeteners and, by cross-reference, the purity criteria with which they must comply
- set down conditions of use for sweeteners in food
- control the sale of sweeteners direct to the public (table-top sweeteners) and specify additional labelling requirements for these products
- prohibit the sale and use of sweeteners, and the sale of food containing sweeteners that do not comply with these provisions

The **Sweeteners in Food (Amendment) Regulations 1996** rectify an error in the wording of Regulation 3(2) of the Sweeteners in Food Regulations 1995.

The **Sweeteners in Food (Amendment) Regulations 1997**:

- extend the use of sweeteners already permitted by the principal Regulations to certain additional categories of food
- add certain technical provisions to bring the principal Regulations into line with the Colours in Food Regulations 1995 and the Miscellaneous Food Additives Regulations 1995, for example on ‘carry-over’ (see paragraph 8)
- amend the title of the food category ‘vitamins and dietary preparations’ (see paragraph 22)

The **Sweeteners in Food (Amendment) Regulations 1999**:

- amend a reference to Directive 95/31 so as to cover its amendment by Directive 98/66/EC that changed the specification for isomalt (E953)
- bring up to date references to the 1995 Regulations in other Regulations

The **Sweeteners in Food (Amendment) (England) Regulations 2001**:

- amend a reference to Directive 95/31 so as to cover its amendment by Directive 2000/51/EC that changed the specification for mannitol (E421) and maltitol syrup (E965 (ii))
- bring up to date references to the 1995 Regulations in other Regulations

The **Sweeteners in Food (Amendment) (England) Regulations 2002**:

- amend a reference to Directive 95/31 so as to cover its amendment by Directive 2001/52/EC that changed the specification for mannitol (E421) and acesulfame K (E951). This corrects earlier purity criteria for mannitol in Directive 2000/51/EC that were found to contain an error and were therefore not implemented in the UK.

- give two-year temporary national authorisation to market the sweetener ‘sucralose’ in England
- bring up to date references to the 1995 Regulations in other Regulations

General philosophy of Directive 94/35/EC on sweeteners for use in foodstuffs

4. For sweeteners to be included in this Directive they first had to comply with the general criteria set out in Annex II of the Food Additives Framework Directive 89/107/EEC (OJL 40, 11.2.89, pp. 27–33). Under these criteria, food additives may only be approved if it has been demonstrated that they perform a useful purpose, are safe and do not mislead the consumer. The recitals of Directive 94/35/EC on sweeteners for use in foodstuffs further explain that the use of sweeteners to replace sugar is justified for the production of:

- i) energy-reduced foods
- ii) non-cariogenic foods (i.e. foods that are unlikely to cause tooth decay)
- iii) foods without added sugars, for the extension of shelf life through the replacement of sugar and for the production of dietetic products

Definition of sweetener

(Regulation 2(1))

5. For the purposes of these Regulations, a sweetener is defined as a food additive that is used or intended to be used either to impart a sweet taste to food or as a table-top sweetener. Table-top sweeteners are products that consist of, or include, any permitted sweeteners and are intended for sale to the ultimate consumer, normally for use as an alternative to sugar. Foods with sweetening properties, such as sugar and honey, are not additives and are excluded from the scope of this legislation. The Sweeteners in Food Regulations 1995 do not apply where a substance listed as a permitted sweetener is used for purposes other than sweetening, for example where sorbitol is used as a humectant in accordance with the Miscellaneous Food Additives Regulations 1995 and parallel Northern Ireland legislation.

Permitted sweeteners

(Regulations 2(1), 3(1), 4(a) and Schedule 1)

6. The only sweeteners permitted for sale to the ultimate consumer or for use in or on food are those listed in Schedule 1 to the Regulations whose specific purity criteria are in compliance with that stated in the annex to Directive 95/31/EC.

Foods allowed to contain permitted sweeteners

(Regulations 3(2), 3(3) and Schedule 1)

7. Permitted sweeteners are only allowed to be used in or on foods that fall within one of the categories listed in Schedule 1 to the Regulations. A maximum usable dose for each permitted sweetener, varying according to the food category, is also specified within Schedule 1 and this must be respected. The use of two or more sweeteners in a single food is permitted, provided suitable categories exist and the maximum level for each individual sweetener is observed. The sale of foods that do not comply with these provisions is illegal.

Sweeteners in compound foods – carry-over

(Regulation 2(1) (amended 1997) and Regulation 5A)

8. The Regulations have been amended to include provisions on carry-over (Regulation 5A) to bring them into line with the GB Regulations on Colours and Miscellaneous Food Additives. These provisions allow the presence of a permitted sweetener in a compound food, to the extent that the sweetener is allowed by the Regulations in one of the ingredients of the compound food. However, the definition of ‘compound foods’ in Regulation 2(1) means that permitted sweeteners are only allowed in the following compound foods:

- i) those with no added sugar or that are energy-reduced
- ii) dietary foods intended for a low-calorie diet (excluding those specifically prepared for infants and young children)
- iii) those with a long shelf life

The Regulations also provide for what is commonly known as ‘reverse carry-over’. This means permitted sweeteners can be present in foods (such as intermediary products) in which they would not otherwise be permitted, provided that these foods are to be used solely in the preparation of a compound food that will conform to the Regulations.

Foods not allowed to contain sweeteners

(Regulation 3(4) (amended 1997) and Regulation 5)

9. The use of sweeteners is prohibited in any foods for infants and young children. This is specified in Council Directive 89/398/EEC on the approximation of the laws of the member states

relating to foodstuffs intended for particular nutritional uses (OJL 186, 30.6.89, pp. 27–32) and this prohibition now includes foods for infants and young children not in good health. The sale of such products containing sweeteners is also prohibited. Foods for infants and young children, generally known as ‘baby foods’, include foods specially prepared for infants and young children who are in good health; or whose digestive processes or metabolism is disturbed; or who have a special physiological condition where they would be able to obtain benefit from controlled consumption of certain substances in foods. For the purposes of this prohibition, Regulation 2(1) defines ‘infants’ as children under the age of 12 months and ‘young children’ as children aged between one and three years. These definitions reflect those given in Article 1(2) of Directive 91/321/EEC on infant formulae and follow-on formulae (OJL 175, 4.7.91, pp. 35-49) that are made under Directive 89/398/EEC.

The terms ‘maximum usable dose’ and ‘quantum satis’

(Regulations 2(3)(c) and 2(3)(d))

10. These expressions are explained in the General Guidance Notes, Section 1, paragraphs 19 and 15 respectively.

The terms ‘with no added sugar’ and ‘energy-reduced’

(Regulations 2(3)(a) and 2(3)(b))

11. Many of the categories listed in Schedule 1 to the Regulations are described as ‘with no added sugar’ or ‘energy-reduced’. The final product must comply with the definitions of these terms and the effect is to limit further the type of foods in which sweeteners may be used. However, the actual terms ‘with no added sugar’ or ‘energy-reduced’ are not required by these Regulations to be used in the labelling of such products. Whatever description is used for those products must be in accordance with the Food Labelling Regulations 1996.¹

¹ Guidance notes on the interpretation of the Food Labelling Regulations are available at www.food.gov.uk/multimedia/pdfs/guidnot1.pdf

12. 'Energy-reduced' foods are foods with an energy value reduced by at least 30% compared with the original or a similar food. The legislation does not define the precise basis for this comparison, but wherever possible it should be by reference to one or more products that are currently on the market. If it is not possible to identify a comparable product that is currently on the market, the comparison could be made on the basis of previously marketed products. In an extreme case where it is not possible to identify an actual product, the comparison might be made with a hypothetically equivalent product, the composition of which is based on the use of sucrose rather than permitted sweeteners.

Additional labelling requirements for table-top sweeteners

(Regulation 4(b))

13. The Regulations include labelling requirements that apply to *table-top sweeteners* only. In addition to the requirements contained within existing UK labelling legislation, table-top sweeteners must include on their labels the phrase:

'[Name of sweetener(s)]-based table-top sweetener'

Furthermore, where table-top sweeteners contain polyols and/or aspartame, the following phrases must also be included on their labels:

for polyols – 'excessive consumption may induce laxative effects'

for aspartame – 'contains a source of phenylalanine'

For the purposes of these Regulations, polyols are considered to be sorbitol and sorbitol syrup (E420(i) and (ii)), mannitol (E421), isomalt (E953), maltitol and maltitol syrup (E965(i) and (ii)), lactitol (E966) and xylitol (E967).

Food categories

(Schedule 1 (amended 1997))

14. As the food categories are not defined (see the discussion in paragraph 17 of the General guidance notes, Section 1 of this booklet), there will always be a need for a certain amount of interpretation. The purpose of this section of the guidance notes is to provide an explanation of some of the less obvious food categories.

Energy-reduced fruit and vegetable preparations

15. In addition to covering energy-reduced fruit and vegetable preparations not covered elsewhere, this category would also include baked beans in sauce, but *only* those meeting the energy-reducing definition.

Sauces

16. Dressings would also be included here.

Products intended for particular nutritional uses

17. This would include products specially prepared for diabetics.

Snacks: certain flavours of ready-to-eat, pre-packed, dry, savoury starch products and coated nuts

18. The maximum levels relate to those found in the final snack product as opposed to in the flavouring. In addition to coated nuts, this category would include savoury-flavoured potato products such as crisps, sticks and puffs as well as swollen or puffed cereal products such as maize sticks and popcorn. The flavours covered include those with a sweet/sour flavour profile, such as prawn cocktail, Worcester sauce, tomato sauce, spicy chicken, chilli and tangy sauce.

Essoblaten

19. This untranslated category has been included for a German product very similar to UK ice-cream wafers. UK ice-cream cones and wafers are listed separately as ‘cornets and wafers, for ice-cream, with no added sugar’.

Beers with a minimum acidity content of 30 milli-equivalents expressed as NaOH

Bière de table/Tafelbier/*Table beer (original wort content less than 6%) except for *Obergäriges Einfachbier

Brown beers of the *oud bruin* type

20. The Agency is not aware of any current major production of these beers in the UK. ‘Acid’ beers are produced in Belgium and may contain cherries, cherry juice or cherry extract. *Bière de table* and *Tafelbier* are understood to be low-alcoholic-strength beers produced in Belgium, France and Germany. *Oud bruin* beers are fairly heavy dark-brown Dutch beers.

Feinkostsalat

21. This untranslated category has been included for a German speciality that consists of a prepared salad in a sauce. Use of sweeteners enables the salad to stay crisp for longer, thereby extending its shelf life.

Food supplements/diet integrators based on vitamins and/or mineral elements, syrup-type or chewable

22. This category has been changed from the rather broad category of ‘vitamins and dietary preparations’ to more accurately reflect the needs of the market.

Gaseosa

23. This category was introduced to cover a Spanish carbonated soft drink. Products classified under this category are expected to be labelled as such.

Home-brew kits for alcoholic beverages

24. This category is *not* included in Directive 94/35/EC as amended by Directive 96/83/EC. While some of these types of products may fall within the alcoholic beverage categories, others will not and thus for those there is no legal provision allowing sweeteners to be mixed in with their ‘active ingredients’. This problem was recognised late in the EC discussions. The solution foreseen at the time was for the sweeteners to be in a separate sachet from the other ingredients, thereby being a direct sale of an additive to a consumer. In these instances appropriate labelling rules must be observed, including those on consumer sales of food additives as laid down in the Food Additives Labelling Regulations 1992.

Chapter 3: Guidance notes on the Colours in Food Regulations 1995 (as amended)

Introduction

1. The notes in this section cover only those aspects of food additives legislation that are specific to the Colours in Food Regulations 1995. References throughout these notes are to those Regulations as amended and should be taken as covering the parallel Northern Ireland legislation and, from 2000, separate Regulations in England, Scotland, Wales and Northern Ireland. For a complete overview, these notes should be read in conjunction with the General guidance notes (see Section 1 of this booklet), which cover points common to all the additives legislation.

Scope of the regulations

2. The Colours in Food Regulations 1995 implement provisions contained within two EC Directives:

- i) European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs (OJ L 237, 10.9.94, pp 13–29)
- ii) Commission Directive 95/45/EC (OJ L 226, 22.9.95, pp. 1–45) as amended by Commission Directives 1999/75/EC (GJ No. L206, 5.8.1999, p. 19) and 2001/50/EC (OJ L 190, p.14, 12.7.2001), laying down specific purity criteria concerning colours for use in foodstuffs

The Colours in Food Regulations 1995:

- define ‘colour’
- list the permitted colours and, by cross-reference to the relevant Directives, the purity criteria with which they must comply
- set down conditions of use for colours in food
- control the sale of colours direct to the public and prohibit the sale and use of colours and the sale of food containing colours that do not comply with these provisions

General philosophy on the use of colours in food

3. The colours listed in the Regulations are included on the basis of the general criteria set down in Annex II of the Food Additives Framework Directive (89/107/EEC). As with all other additives used in food, colours may only be used if they perform a useful purpose, are safe and do not mislead the consumer. The recitals of the Colours Directive 94/36/EC state that colour may be used to:

- i) reinforce colours already present in food
- ii) restore the original appearance of food whose colour has been affected by processing, storage, etc.
- iii) make food visually appealing and give colour to otherwise colourless food

There is general agreement that basic and unprocessed food should not be coloured. (For a discussion of the definitions of the food categories, see paragraph 17 of the General guidance notes, Section 1 of this booklet.)

Definition of colour

(Regulation 2(1))

4. Colours add or restore colour in a food. They are not substances that are normally consumed as foods by themselves or used as characteristic ingredients of foods. This Regulation is not intended to catch products such as fruit juices (for example, elderberry juice added to yoghurt) or tomato concentrates. These would be regarded as ingredients, to be labelled as such, even when added principally for colouring purposes.

5. The key to determining whether or not a substance is deemed a colour under the Regulations is whether a substance has undergone 'selective extraction' for the prime function of colouring (Regulation 2(1)(b)). For example, dried spinach used in the manufacture of pasta verdi is not deemed a colour, but is regarded as an ingredient as the colour pigments (the chlorophyll) in the spinach are not selectively chosen. If the chlorophyll pigments are 'selectively extracted' from the spinach to perform a colouring function and added to the pasta, then these are regarded as colours and fall under the scope of the Regulations – chlorophylls (E140) are listed in Schedule 1. Saffron is allowed because it has a primary aromatic effect in addition to its secondary colouring effect and thus is outside the scope of the Regulations. Crocin has to be extracted from saffron by some physical or chemical means and automatically falls under the definition of colour, but is not permitted as it is not listed in Schedule 1 of the Regulations. A further example is that of

malt extracts. Malt extracts used in brewing are not ‘selectively extracted’ but are characteristic natural ingredients. They are, therefore, not caught by this Regulation. Nor are malt extracts used in foods principally for flavouring or nutritional reasons, where the colouring effect is only secondary. If malt extracts were selectively extracted for the primary function of colouring, they would be deemed colours.

Substances not considered colours

(Regulation 2(1))

6. If the primary function of a substance added to food is anything other than as a colour, whether or not it has a secondary colouring effect, then it is not caught by the definition of colour in Regulation 2(1).

7. The Regulations cover some natural extracts such as beetroot red. The status of other natural extracts, such as those obtained from hibiscus, sage, gardenia, nettle and carrot, are being assessed on an *ad hoc* basis by the EU Standing Committee on the Food Chain and Animal Health (formerly the Standing Committee for Foodstuffs). Those natural extracts, which the Standing Committee decides are additives, will have to be evaluated by the Scientific Committee on Food (SCF) and included in an amendment to the Colours Directive 94/36/EC. This will mean a subsequent amendment to the implementing Regulations.

Maximum levels

(Regulation 2(4)(a))

8. The levels in the Schedules to the Regulations refer to the amount of colouring principle in the food. For example, a level of 200mg/kg will mean 200 units of colouring principle for every 1,000,000 units by weight of food.

Marking of meat

(Regulation 4)

9. The restriction on colours provided for here only applies in the case of colours that come into contact with raw meat or raw-meat products. It does not apply to the colour of [the health mark used on] labels or packaging.

Marking of eggs

(Regulation 5)

10. The marking of egg shell is covered by Commission Regulation 1274/91. This states that ‘Egg shell shall be *marked* in an indelible colour resistant to boiling. The product used must comply with the provisions in force in respect of colouring matters that may be used in foodstuffs intended for human consumption.’

All colours listed in Schedule 1 may be used either to decorate egg shells or to stamp egg shells. Migration of colour from the shell to the egg would be negligible and, therefore, even those colours that are listed in Schedule 4, and restricted for certain uses, may be used for this purpose. For example erythrosine, which appears to be the colour most commonly used for this purpose, continues to be permitted.

Colouring of compound foods – carry-over

(Regulation 6)

11. Regulation 6(1) concerns the colouring of a food that is going to be an ingredient in a compound food. It is not the intention to prohibit the use of colour in any compound food that includes as one of its components a food that is not permitted to be coloured, by virtue of it being listed in Schedule 2. For example, the cheese component of a pizza could still be coloured (as some cheeses are permitted to be coloured by being listed in Schedules 3 and 5), even though the pizza might include pieces of meat or other ingredients that are listed in Schedule 2 (see paragraph 27).

12. Regulation 6(2) covers what is commonly known as ‘reverse carry-over’. It allows for the colouring of a food that would not normally be permitted to be coloured under the Regulations, if that food is to be used solely in the manufacture of a compound food, which may be coloured. This is provided the level of colour in the compound food does not exceed the maximum level specified for that food. For example annatto (not normally permitted to be added to seasonings) could be added to a seasoning that is intended solely for use in a snack food. This is provided that the level of annatto does not result in the maximum level permitted in the snack food in Schedule 4 being exceeded (i.e. either 10mg/kg or 20mg/kg, depending on the type of snack).

Colours not permitted to be sold direct to the consumer

(Regulations 7(2) and 7(3))

13. Schedule 4 of the Regulations lists those colours whose use needs to be restricted because of their very low Acceptable Daily Intakes (ADIs). Of the 10 colours listed in Schedule 4, eight may not be sold direct to the consumer – amaranth E123, erythrosine E127, red 2G E128, brown FK E154, canthaxanthin E161g, aluminium E173, litholrubine BK E180 and annatto E160b.

GUIDE TO THE SCHEDULES TO THE REGULATIONS

14. The Regulations have six Schedules.

Schedule 1 – lists the permitted colours.

Schedule 2 – lists those foods that are prohibited from containing colour unless there are specific exemptions provided for in Schedules 3, 4 or 5.

Schedule 3 – lists those foods to which only a very restricted number of colours may be added.

Schedule 4 – lists those colours that can only be used in a very restricted list of foods.

Schedule 5 – Part I lists those colours that can be used at *quantum satis* in foods listed in Part III and in any other food, except for those listed in Schedules 2 or 3.

– Part II lists those colours that can be used, in each case up to the maximum level specified, in the foods listed in Part III.

– Part III lists those foods that are permitted to contain the colours listed in Parts I and II.

Schedule 6 – lists those Regulations that are partially or completely revoked by the Regulations.

Schedule 1

15. The substances listed in this Schedule are the only permitted colours. ‘Aluminium lake’ versions of these permitted colours (i.e. the process whereby water-soluble food colours are precipitated with an aluminium salt to form water-insoluble pigments called lakes) are allowed. They do not have to be listed any differently from other colours in the ingredients list of a food.

Schedule 2

16. This Schedule reflects the philosophy that all unprocessed and basic foods should not be permitted to contain colour. It lists these foods and, unless there are specific exemptions provided by entries in the later Schedules 3, 4 or 5, they are prohibited from containing colour. For example, potato products are included in the entry for fruit and vegetables in this Schedule, and thus not permitted to contain colour, with one exception – ‘dried potato granules and flakes’ that have been allocated an entry in Schedule 3 and thus may be coloured with just one colour. Rice is considered an unprocessed food and is prohibited from containing any colours.

Milk, fermented milk, preserved milks, buttermilk, cream and cream powder

17. These five entries are intended to cover ‘natural’ products such as milk and plain unflavoured yoghurt. They are *not* intended to cover products that have been flavoured, such as milkshakes and other dairy-based drinks or yoghurts, including those that contain added fruit or chocolate-flavoured dairy products. Any flavoured dairy-based drinks are covered by the ‘non-alcoholic flavoured drinks’ entry in Schedule 5 and any flavoured dairy products (other than cheese) by the ‘desserts including flavoured milk products’ in the same Schedule (see paragraphs 77 and 93).

Chocolate milk

18. This covers products made solely of chocolate and milk with no added ingredients or flavouring. There is a subtle difference between these products and those containing chocolate flavouring. The latter involves the addition of chocolate flavouring, but not real chocolate, to milk and is covered by the wide-ranging entry for ‘non-alcoholic flavoured drinks’ in Schedule 5.

Oils and fats of animal or vegetable origin

19. This entry covers all oils, including olive oil, and refined oils such as corn oil, sunflower oil, soya oil and rapeseed oil. It covers all fats *except* those covered by the Schedule 3 entry for butter and the one for margarine, minarine, other fat emulsions and fats essentially free from water (see paragraph 42).

Flour and other milled products and starches

20. This entry does not cover certain breakfast cereals produced by extrusion technology and fruit-flavoured cereals (see paragraph 54). All other breakfast cereals fall under this Schedule 2 entry, including all the raw and stabilised cereal grains, such as those found in muesli. The reference to ‘starches’ in this entry does *not* prevent products such as those found in desserts, biscuits and snack products from containing colour.

21. Examples of products that are caught by this entry include malted wheat grains, cracked grains, kibbled rye, flaked malted wheat, oatflakes, semolina, corn starch, starch soda flour, plain flour, bread-making flour, cake flour and wholemeal flour.

Bread and similar products

22. This entry covers all bread and bread products, including rolls, soda bread, gluten-free bread, baguettes, chappatis and pitta bread, with the exception of malt bread, which is permitted to contain caramel by virtue of a Schedule 3 entry (see paragraph 40).

Sugar, including all monosaccharides and disaccharides

23. This entry includes all monosaccharide and disaccharide sugars including fructose, lactose (which is defined in the Specified Sugar Products Regulations 1976) and maltose. Speciality/decorative sugars and pouring syrups fall under the Schedule 5 entry ‘decorations and coatings’ and are therefore permitted to contain the full range of colours in Schedule 5 Part I and Part II (see paragraph 85(iii)).

Tomato paste and canned and bottled tomatoes

Tomato-based sauces

24. The first tomato entry covers products such as tomato purée, tinned tomatoes and sun-dried tomatoes. The exact coverage of the second entry has never been clarified. The UK takes the view that condiments such as tomato sauce, brown sauce and fruit sauce, which all contain tomato to a varying degree, but which would not be regarded as pure tomato products, are not covered by this entry. Rather they fall under the ‘sauces and seasonings’ entry in Schedule 5 and are thus permitted to contain colour (see paragraph 96). Similarly, a number of dehydrated sauce mixes such as bolognese, barbecue, spaghetti and various cooking sauces (for example, chasseur sauce) are regarded as being permitted to be coloured under the same entry in Schedule 5. Also the Schedule 2 entry does not cover canned tomato-based soups, which may contain colour by way of the ‘soups’ entry in Schedule 5.

**Fruit, vegetables (including potatoes) and mushrooms –
canned, bottled or dried; processed fruit, vegetables
(including potatoes) and mushrooms**

25. There are a number of foods that are exempted from this entry by way of specific entries in Schedules 3 and 5 and, therefore, are permitted to be coloured. These specific entries are:

- i) 'dried potato granules and flakes' in Schedule 3 (see paragraph 63). (Other potato products such as French fries, dumplings, croquettes and tinned potatoes fall under the Schedule 2 entry and are prohibited from being coloured.)
- ii) 'vegetables in vinegar, brine or oil' in Schedule 3. This includes, for example, bottled gherkins and cucumbers, but not olives (see paragraph 53).
- iii) 'sauces and seasonings etc.' in Schedule 5. This includes pickles and chutneys (see paragraph 96).
- iv) 'processed, mushy and garden peas (canned)' in Schedule 3 (see paragraph 64)
- v) 'preserves of red fruits' in Schedule 5. This includes canned or bottled raspberries, blackcurrants, rhubarb, strawberries, etc. (see paragraph 81).

**Extra jam, extra jelly and chestnut purée as mentioned in
Directive 79/693/EEC; *crème de pruneaux***

26. Other jams, jellies and marmalades are covered by an entry in Schedule 3.

**Fish, molluscs and crustaceans, meat, poultry and game, as
well as their preparations, but not including prepared meals
containing these ingredients**

27. The direct colouring of meat is prohibited, except where specifically provided for in Schedule 3 (see paragraphs 59–61). However, the use of colours in a marinade or sauce that subsequently soaks into the meat, thereby colouring it, is allowed by way of the Schedule 5 category of 'sauces, seasonings etc.' using the carry-over provision at Regulation 6. In addition, the breadcrumb coating on fish fingers falls within the Schedule 5 category of 'decorations and coatings', whereas the body of the fish fingers, which is predominantly fish, would be regarded as a fish preparation.

Cocoa products and chocolate components in chocolate products as mentioned in Directive 73/241/EEC

28. While this entry prohibits the use of colour in cocoa products and the chocolate component of chocolate products, it does not extend to the non-chocolate fillings that are allowed to contain colour by way of the ‘confectionery’ entry in Schedule 5 (see paragraph 82).

Roasted coffee, tea, chicory, tea and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products

29. Although it is not clear from this entry heading, products such as lemon tea mixes are excluded from this entry as it has been agreed that they are composite products where the actual tea solids form only a minor part of the product, after glucose and citric acid. They are, therefore, considered as preparations not infusions and are covered by the category ‘non-alcoholic flavoured drinks’ in Schedule 5 (see paragraph 77).

Salt, salt substitutes, spices and mixtures of spices

30. This entry covers only mixtures of spices with no added ingredients. Curry powder, tandoori, etc. are covered in the ‘sauces and seasonings etc.’ entry in Schedule 5 (see paragraph 96).

Wine and spirit entries

31. The four wine and spirit entries in Schedule 2 reflect the situation allowed for by the relevant vertical EC Regulations, i.e. that all the drinks listed are not permitted to contain colour.

32. EC Regulation 822/87 on the Wine Regime referred to in the first entry does not cover de-alcoholised or low-alcohol wine.

33. The actual names of the drinks have not been translated, thus only drink sold under the name ‘London Gin’, for example, may not contain colour. Other gins may be coloured.

34. There are later entries in Schedule 4 and 5 that permit certain alcoholic drinks to be coloured (see paragraphs 50, 66 and 109).

Wine vinegar

35. While wine vinegar is not permitted to be coloured, other vinegars are permitted to contain caramel by way of the specific entry in Schedule 3 (see paragraph 49).

Foods for infants and young children as mentioned in Directive 89/398/EEC, including foods for infants and young children not in good health

36. The use of colours in any foods *specially prepared* for sick or healthy infants and young children as mentioned in the EU PARNUTS (i.e. foodstuffs intended for particular nutritional uses) Directive 89/398 – that is, infant formulae, follow-up milk and other follow-up foods and baby foods – is prohibited. For the purposes of this prohibition, ‘infants’ means children under the age of 12 months and ‘young children’ means children aged between one and three years, as defined in Article 1(2) of the Infant Formulae and Follow-on Formulae Directive 91/321/EEC. Beta-carotene E160a, riboflavin and riboflavin-5'-phosphate E101 are permitted if their primary function is for vitamin fortification, as in that instance they are not considered colours under the Regulations.

Malt and malt products

37. Malt is a natural food that has its own colouring properties. Certain malted beverages require the addition of colour, such as chocolate-malted drinks and banana-flavoured malted drinks. In addition, there is a wide range of dry, powdered malted beverages on the market in which colour is added and where the colour develops when fluid is added. These products are covered by the ‘non-alcoholic flavoured drinks’ entry in Schedule 5 (see paragraph 77(ii)).

Ripened and unripened cheese (unflavoured)

38. This entry prohibits all unflavoured cheeses from being coloured, with the exemptions being covered by the various cheese entries in Schedules 3 and 5. Examples of cheeses that are covered by this entry are Brie, Camembert, Danish blue and *St Paulin*. Cheeses like Cheddar are allowed to contain a restricted number of colours by virtue of a Schedule 3 entry (see paragraph 44).

39. This entry covers quark. While it prohibits colour from being added to unflavoured fromage frais, flavoured fromage frais may still be coloured, as it falls under the ‘desserts including flavoured milk products’ entry in Schedule 5.

Schedule 3

Malt bread

40. Malt bread is the only bread to be permitted to contain colour, the rest being covered by the Schedule 2 entry for ‘bread and similar products’ (see paragraph 22). It is a traditional, small, sticky, fruited bread containing a high level of malt extract and caramel for

colouring and flavouring purposes. Malt bread is in English in all language texts of the Directive to indicate that only the traditional UK and Irish malt bread may contain colour and not similar products sold under different names elsewhere in the Community.

Beer and *Cidre Bouché*

41. *Cidre Bouché* is in French in all language texts of the Directive, to distinguish this product from all other ciders that are permitted to contain the full range of colours by virtue of their Schedule 5 entry (see paragraph 111). All beers, including stouts, are covered by this entry.

Margarine, minarine, other fat emulsions and fats essentially free from water

42. This entry covers solid and semi-solid fats but not liquids. It also covers reduced-fat or low-fat products. The term ‘fats essentially free from water’ covers animal fat products such as lard and tallow and solid and semi-solid vegetable fats. Unlike butter, which is only permitted to contain carotenes E2160a, products under this entry may also contain curcumin E100 and annatto E160b.

Sage Derby cheese

43. Sage Derby is in English in all language texts of the Directive to indicate that only the traditional UK and Irish Sage Derby may contain the two colours chlorophylls E140 and copper complexes of chlorophylls E141.

Ripened orange, yellow and broken-white cheese; unflavoured processed cheese

44. Any of the cheeses meeting the description may contain any of the colours E160a, b and c. The cheeses covered by this entry include Cheddar, Edam, Gouda, Cheshire, Double Gloucester, Wensleydale and unflavoured processed cheese. Flavoured processed cheese has a separate entry in Schedule 5.

Red Leicester cheese

45. Red Leicester is in English in all language texts of the Directive.

***Mimolette* cheese**

46. *Mimolette* is in French in all language texts of the Directive.

***Morbier* cheese**

47. *Morbier* is in French in all language texts of the Directive.

Red marbled cheese

48. This covers cheeses such as Red Windsor.

Vinegar

49. This entry covers only non-wine vinegar, for example malt vinegar and cider vinegar. Wine vinegar is listed in Schedule 2 and thus prohibited from being coloured (see paragraph 35). This entry does not cover non-brewed condiment, a vinegar substitute, which falls under the ‘sauces and seasonings etc.’ entry in Schedules 5 (see paragraph 96).

Wine and spirit entries

50. The five wine and spirit entries in Schedule 3 are included to take account of the position that exists with regard to colour being permitted in certain wines and spirits under the relevant vertical EU Regulations. The actual names of the various alcoholic drinks have not been translated.

51. Although not stated in the Directive or the Regulations, *Americano* is as defined in Regulation No. 1601/91. The entry covering ‘liqueur wines and quality wines produced in specified regions’ reflects a provision in Annex VI of Regulation 87/822 on the Wine Regime.

52. Juniper-flavoured spirit drinks are not covered by these entries in Schedule 3 but fall under the ‘spirituous beverages’ category in Schedule 5 and are thus permitted to contain the full range of colours (see paragraph 110).

Vegetables in vinegar, brine or oil (excluding olives)

53. This entry is intended to cover products such as pickled onions and red cabbage. Products such as sweet pickles, relishes and chutneys, etc. are covered by the ‘sauces and seasonings etc.’ entry in Schedule 5 (see paragraph 96). This entry heading also covers foods such as bottled gherkins, cucumbers, peppers and tomatoes, although these are classified botanically as fruits.

Extruded, puffed and/or fruit-flavoured breakfast cereals

54. Colours are used in two types of breakfast cereal:

- i) extruded cereal products that use colours (mostly caramel) to provide a ‘toasted’ look, like products of the Maillard reaction

- ii) breakfast cereals with flavoured centres where the flavoured centres require colour or where pieces of coloured mallow are mixed with the cereal at the end of production. This type of cereal is regarded as a compound food. Even though the cereal component of the food cannot be coloured because of the Schedule 2 entry 'flour and other milled products and starches', the mallow component is permitted to contain a wide range of colours by virtue of a Schedule 5 entry for 'confectionery' (see paragraphs 14 and 82).

55. The term 'extruded' refers to the direct expansion of a flour-based raw material that has passed through a continuous cooker under pressure, and through a die that gives it a shape. As the material passes through the die to the atmosphere it expands. The material is then dried and can be coated to produce the finished product. A product is said to be 'puffed' if it is first extruded into a pellet. This is made by cooking a flour-based dough and then passing the dough through a die to make a shape. The shape is dried and then puffed by introducing the dried pellet into a system that pressurises and heats the pellet with steam and then passes the pellet into atmospheric pressure or reduced pressure (vacuum) to expand the product.

56. It is only the fruit-flavoured breakfast cereals that may contain cochineal E120, beetroot red E162 or anthocyanins E163.

Jams, jellies and marmalades as mentioned in Directive 79/693/EEC and other similar fruit preparations including low-calorie products

57. Colours are used in standard jams, reduced-sugar jams and marmalades largely to replace colour lost by the use of sulphites and also to add colour when less than fully ripe fruit is used.

58. All reduced-sugar jams are covered in this entry. If some reduced-sugar jams fall outside the term 'low-calorie', they are still allowed to contain colour by virtue of the term 'other similar fruit preparations'. This term also covers mincemeat.

Sausages, pâtés and terrines

59. While there is no Schedule 3 entry specifically listing all speciality products, such as Cornish pasties, haslet and polony, it was agreed during the negotiations on the Directive that this entry covering the use of colours in 'sausages, pâtés or terrines' cover all similar local and national speciality products. A statement to this effect was entered in the Council minutes when the Directive was adopted.

60. By way of this statement it was agreed that there should be a wide interpretation of this entry. Clearly some speciality meat products such as saveloy and polony would be categorised as sausages under this entry. But faggots, haslet, brawn, pork pies, Cornish pasties, Scotch pies, Bridies, Red pudding, meat loaf, meat pastes, spreads and potted meats are also covered by this entry and are permitted to contain the specified colours listed under this Schedule 3 entry. Other member states' speciality products, such as Danish Salami, are also covered.

Breakfast sausages and burger meat

61. Both burgers and sausages (including lorne and sausagemeat) are permitted to be coloured with any one or more of the colours listed in this entry, provided they meet the compositional requirements laid down.

Chorizo, Salchichon, Sobrasada, Pasturmas

62. These entries cover the southern member states' speciality meat products that are untranslated in the Directive.

Dried potato granules and flakes

63. This entry provides for the exemption of dried potato granules and flakes from the Schedule 2 entry covering 'fruit, vegetables (including potatoes) and mushrooms – canned bottled or dried etc.'

Processed, mushy and garden peas (canned)

64. This entry is in English in all language texts of the Directive. 'Canned' relates only to garden peas. All processed and mushy peas are covered.

Schedule 4

65. This Schedule restricts the use of certain colours to ensure that intakes do not exceed the very low Acceptable Daily Intakes (ADIs) that have been set for them.

Amaranth E123

66. This colour is only permitted to be used in fish roe, spirituous beverages, aperitif wines, the aromatised wines *Americano* and Bitter Vino and the aromatised wine-based drink Bitter Soda.

Erythrosine E127

67. This entry restricts the use of erythrosine to cocktail cherries and glacé cherries and to use with one particular kind of cherry – the *Bigarreaux* variety – in syrup and cocktails. The word *Bigarreaux* is in French in all language texts of the Directive.

Red 2G E128

68. The description of the specific sausages and burgers are identical to the ones listed in the Schedule 3 entry (see paragraph 61).

Brown FK E154

69. Kippers are untranslated in all language texts of the Directive.

Canthaxanthin E161g

70. *Saucisses de Strasbourg* remains in French in all language texts of the Directive.

Litholrubine E180

71. The entry 'edible cheese rind' is intended to permit the use of E180 on the rind of cheeses such as *St Paulin* or *Chaume*, even though the cheese itself is prohibited from containing colour by virtue of the 'ripened and unripened cheese' entry in Schedule 2. While the Food Standards Agency is not aware of any use of this colour in the UK, the Dutch use E180 to stamp cheese. They also use it as the red colour on the wax coating of Edam Cheese. This specific use, however, is not controlled by these Regulations as the wax coating is inedible and would be exempt by means of Regulation 2(1).

Annatto E160b

72. Red Leicester and the French cheese, *Mimolette*, are untranslated in all language texts of the Directive.

73. For an explanation of what is covered by each of the food categories, see notes under Schedule 3 and Schedule 5. For example, the entry for desserts includes 'flavoured milk products' and is consistent with the entry in Schedule 5.

Schedule 5

Part I

74. The colours listed in Part I of Schedule 5 are those that have been given a 'non-specified' ADI or, in a few cases, a high ADI. They are permitted to be used in all foods listed in Schedule 5 Part III and all other foods not specifically listed in any of the Schedules, but only in some of the foods listed in Schedule 3 where directly specified. No maximum level is set for any of these colours, as there is no concern over their intake. They are therefore permitted to be used at *quantum satis*.

Part II

75. The colours listed in Schedule 5 Part II all have numerical ADIs, but are not sufficiently low to warrant very tight restrictions in a Schedule 4 entry. Except in the circumstances described in paragraph 76 below, these colours may be used singly or in combination in the food categories listed in Part III up to the maximum level specified for each food.

76. There are four colours within the Part II list – sunset yellow E110, carmoisine E122, ponceau 4R E124 and Brown HT E155 – that have ADIs of less than 5mg/kg/bw/day. The need to restrict the level of these low-ADI colours in foods consumed in large amounts by young children was acknowledged when the Directive was negotiated. Thus for five foods listed in Part III – non-alcoholic flavoured drinks, edible ices, desserts, fine bakery wares and confectionery – each of these four colours is only able to be used up to 50mg/kg or 50mg/l. Note that the 50mg/kg or 50mg/l level is not a total level if the low-ADI colours are used in combination, but is a maximum level applying to *each* low-ADI colour. Clearly though, if non-alcoholic flavoured drinks are taken as an example, use of the low-ADI colours in conjunction with other colours would not be permitted to exceed the overall maximum level of 100mg/l set for this food category.

Part III

Non-alcoholic flavoured drinks

77. This entry is intended to permit colour in a whole range of non-alcoholic drinks including:

- i) dairy-based flavoured drinks, such as flavoured milkshakes and chocolate-flavour milks (but not chocolate milk)
- ii) water-based flavoured drinks – soft drinks, such as squashes*; concentrates for soft drinks*; syrups*; powders for soft drinks* including products such as lemon tea mixes (see paragraph 29) and flavoured malt drinks (see paragraph 37)

*Maximum level of 100mg/l applies to the made-up drink.

78. The entry does not cover the following products as they are prohibited from being coloured by virtue of Schedule 2 entries:

- i) unflavoured milk-based drinks
- ii) fruit juice and fruit nectar
- iii) all bottled or packed water

79. The restriction on the use of the four low-ADI colours applies to this entry.

Candied fruits and vegetables, *mostarda di frutta*

80. This entry covers all fruits or vegetables coated with sugar, such as crystallised fruits. It also covers a traditional Italian product of fruit in a mustard syrup, *mostarda di frutta*, which is untranslated in all language texts of the Directive.

Preserves of red fruit

81. This includes canned red fruits such as strawberries, raspberries, rhubarb, blackberries and blackcurrants (the last two are considered 'red fruits'), where colour is needed to restore colour leached by the canning process. It does not cover red-coloured jams or jellies that are covered under the Schedule 3 entry, or pie fillings that are covered by the 'desserts' entry in this Schedule.

Confectionery

82. This entry includes all sugar confectionery such as liquorice, panned confectionery and chewing gum. It does not cover cocoa and chocolate, which are prohibited from being coloured by way of a Schedule 2 entry. This does not mean that the non-chocolate filling cannot contain colour.

83. The restriction on the use of the four low-ADI colours applies to this entry.

Decorations and coatings

84. Savoury products covered by this entry include:

- i) breadcrumb and batter coatings for fish and meat products. The body of a fish finger, for example, is regarded as a fish preparation and therefore not permitted to be coloured (by way of the Schedule 2 entry). But the breadcrumb coating (i.e. the non-fish component) falls under this entry and is permitted to contain colour up to a maximum level of 500mg/kg (see paragraph 27).
- ii) the colouring of novelty foods produced at certain times of the year, for example brightly coloured cocktail onions used as decorations at Christmas. These products are different from the more standard colouring of pickled onions or gherkins that are covered by the 'vegetables in vinegar, brine or oil' entry in Schedule 3.

85. Sweet products covered by this entry include:

- i) cake icing – this entry covers icings and fillings, with the ‘fine bakery wares’ category in this Schedule covering the cake crumb. Thus, a cake comprising sponge, filling and icing would be deemed a compound food when sold as such. A total limit of 500mg/kg is set for decorations and coatings (which includes the weight of the cake icing and any decorations). As a result, the strength at which some of the colours were previously used in, for example, copyright characters may now have to be diluted.
- ii) bakery jams – these are not covered by the EU Jams Directive 79/693. They are not sold direct to consumers, but are used in cake sandwich fillings, jam tarts, etc. They require higher levels of colour than ordinary standard jams as lower quality/less fruit is used.
- iii) all speciality sugars and pouring syrups, for example sugar toppings, golden syrup, treacle and molasses

Fine bakery wares

86. As mentioned in the previous entry, this category only covers the cake crumb component of a cake, provision being made separately for the icing and filling component under ‘decorations and coatings’.

87. In addition to cake crumb, all baked products other than bread fall under this entry, for example biscuits, pastry, flour confectionery, waffles, wafers, flan bases, Christmas pudding, crispbreads, crumpets.

88. Fine bakery wares will sometimes be components of compound foods. For example, a chocolate-covered shortbread comprises the shortbread (i.e. a fine bakery ware) and the chocolate (i.e. covered by the Schedule 2 entry for chocolate and cocoa products and thus prohibited from containing colour).

89. The restriction on the use of the four low-ADI colours applies to this entry.

Edible ices

90. In addition to ice-cream, sorbets and sherbets are included in this category.

91. The restriction on the use of the four low-ADI colours applies to this entry.

Flavoured processed cheese

92. This entry also covers cheese spreads.

Desserts, including flavoured milk products

93. This covers both dairy-based and non-dairy-based desserts. The latter include fruit pie fillings. Dairy-based desserts include all flavoured milk products such as fruit yoghurts, fromage frais, chocolate-flavour yoghurts and vanilla pudding.

94. Many desserts are compound foods; for example, a fruit pie comprises the fruit pie filling (i.e. 'dessert') and the pastry case (i.e. a 'fine bakery ware').

95. The restriction on the use of the four low-ADI colours applies to this entry.

Sauces, seasonings (for example curry powder, tandoori), pickles, relishes, chutney and piccalilli

96. This entry includes:

- i) sauces – this covers all emulsified and non-emulsified sauces including dressings (full-fat and low-fat varieties), tomato sauce, marinades, gravies, salad cream and custard
- ii) seasonings – this covers ethnic blends, spice blends and seasoning blends, including non-brewed condiment. Curry powder and tandoori (the latter kept untranslated in all language texts of the Directive) are just two examples of the numerous seasoning/ethnic blends that require colour and are covered by this entry.
- iii) pickles, relishes – this covers sweet pickles, corn relish, cucumber relish, etc.
- iv) chutney and piccalilli – this is untranslated in all language texts of the Directive

Fish paste and crustacean paste

97. This entry covers all fish and crustacean pastes, spreads and pâtés, for example salmon pâté and crab paste.

Pre-cooked crustaceans

98. This covers all crustaceans that have been cooked, usually before being frozen, such as cooked ready-to-eat prawns.

Salmon substitutes

99. This entry covers an artificial salmon product, smoked saithe. It is predominantly a German and Danish product. The Agency does not know of any other products that could be described as ‘salmon substitute’.

Surimi

100. This entry covers artificial crab sticks, which may be battered, frozen or heat-preserved.

Fish roe

101. This entry includes artificial caviar.

Snacks: dry, savoury potato, cereal-based or starch-based snack products

102. The ‘extruded or expanded savoury products’ category includes cereal-based and/or potato-based snacks (made from a wide selection of cereal flours, maize grits, tapioca, rice flour, potato granules, grits, flour and starch, gram flour and similar materials) that have been ‘extruded’ or expanded. ‘Extrusion’ refers to the direct expansion of the flour-based raw material that has passed through a continuous cooker under pressure and through a die that gives it a shape. As the material passes through the die to the atmosphere it expands. The material is then dried and can be coated with, for example, flavourings or cheese to produce the finished products. Snack products produced in this way are permitted to contain colour at the higher level of 200mg/kg.

103. ‘Other savoury snack products and savoury coated nuts’ covers all other snack products, such as peanuts and potato crisps, which may contain colour up to a lower maximum of 100mg/kg. This entry includes, for example, snacks coated with a potato or cereal dough.

104. Neither of these entries covers breakfast cereals. Those breakfast cereals that are permitted to be coloured are covered by the Schedule 3 entry ‘extruded, puffed and/or fruit-flavoured breakfast cereals’ (see paragraph 54).

Edible cheese rind and edible casings

105. Edible casings cover the material surrounding, for example, a sausage, a ham, a meat roast or a fish roulade. The skin of a saveloy, for example, contains a red colour.

106. Edible cheese rind is intended to permit the use of colour on the rind of cheeses such as *St Paulin* and *Chaume*, even though the cheese itself is prohibited from containing colour by virtue of the

‘ripened and unripened cheese’ entry in Schedule 2. The Agency regards cheese wax as inedible and, therefore, outside the control of these Regulations.

Soups

107. This entry includes all dehydrated and canned soups. It does not cover broths or stock cubes. As stock cubes are not covered by any specific entry in the Schedules they should be permitted to contain any of the Schedule 5 Part I colours such as caramels.

Meat and fish analogues based on vegetable proteins

108. This entry covers meat analogues, mycoprotein, but also textured vegetable soya protein in such products as snack foods (such as pot noodles) and canned ravioli fillings. Textured vegetable soya protein in vegetarian products (for example, sausage ‘lookalikes’) and vegetable pies is often coloured.

Spirituos beverages (including products less than 15% alcohol by volume), except those mentioned in Schedule 2 or Schedule 3

Aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails as mentioned in Regulation (EEC) No. 1601/91, except those mentioned in Schedules 2 or 3

109. These two entries reflect the position that exists with regard to a wide range of colours being permitted in certain wines and spirits under the relevant vertical EC Regulations.

110. The spirituous beverages category includes liqueurs, as well as flavoured spirits, for example juniper-flavoured spirit drinks and products such as *curaçao*, *crème de menthe*, egg liqueur and spirit coolers. Other spirit drinks are either prohibited from containing colour by way of the Schedule 2 entry or permitted to contain a very restricted range of colours by way of the Schedule 3 entry.

Fruit wines (still or sparkling), cider (except *Cidre Bouché*) and perry-aromatised fruit wines, cider and perry

111. Fruit wines are wines other than those made from grapes, such as ginger wine, apricot wine, cherry wine and raspberry wine. This entry does *not* cover ‘made wines’, such as British wine and British sherry. ‘Made wine’ is made from concentrated grape must, which is imported from other wine-producing countries. As made wines are not listed in Schedule 2, they are not controlled under the Wine Regime. Thus they are not prohibited from containing colour, and are not covered by any other entry in Schedule 3 or 5. They are only permitted to contain the Schedule 5 Part I colours at *quantum satis*.

112. The entry covers low-alcohol and alcohol-free ciders and perries.

Chapter 4: Guidance notes on the Miscellaneous Food Additives Regulations 1995 (as amended)

Introduction

1. The notes in this section cover only those aspects of food additives legislation that are specific to the Miscellaneous Food Additives Regulations 1995. References throughout these notes to those Regulations should be taken as covering the parallel Northern Ireland legislation and, from 2000, separate Regulations in England, Scotland, Wales and Northern Ireland. For a complete overview, these notes should be read in conjunction with the General guidance notes (see Section 1 of this booklet), which cover points common to all the additives legislation.

Scope of the regulations

2. The **Miscellaneous Food Additives Regulations 1995** implement provisions contained within the following European Community (EC) Directives:

- i) European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners (OJL 61, 18.3.95, p.1), as amended by European Parliament and Council Directives 96/85/EC (OJL 86, 28.3.97, p.4), 98/72/EC (OJL 295, 4.11.98, p.18) and 2001/5/EC (OJL 55, 24.2.2001, p.59)
- ii) Commission Directive 96/77/EC (OJL 339, 30.12.96, p.1), as amended by Commission Directives 98/86/EC (OJL 334, 9.12.98, p.1), 2000/63/EC (OJL 227, 30.10.2000, p.1) and 2001/30/EC (OJL 146, 31.5.2001, p.1), laying down specific purity criteria on food additives other than colours and sweeteners

The Miscellaneous Food Additives Regulations 1995 list the food additives other than colours and sweeteners ('miscellaneous additives') that are permitted to be used in food to perform one or more of the functions that fall within the definitions set out at Regulation 2(1). These Regulations:

- specify the purity criteria with which they must comply
- set conditions on their use
- control the sale of miscellaneous additives direct to the public
- prohibit the sale and use of miscellaneous additives and the sale of food containing miscellaneous additives that do not comply with these provisions

The Miscellaneous Food Additives (Amendment) Regulations 1997:

- permit the use of an additional additive, Processed Eucheuma Seaweed (E407a), in most processed foods
- remove the purity criteria for certain additives (mainly preservatives and antioxidants) from the 1995 Regulations
- include a cross-reference to Commission Directive 96/77/EC
- amend the carry-over provision in the 1995 Regulations to bring it more closely into line with the wording used in Directive 95/2

The Miscellaneous Food Additives (Amendment) Regulations 1999:

- add flour treatment agents, previously regulated at national level, to the list of categories of harmonised additives that are controlled as miscellaneous additives
- remove the purity criteria for further classes of additives (mainly emulsifiers and stabilisers) from the 1995 Regulations and include a cross-reference to Commission Directive 98/86/EC
- add four new additives to the list of permitted miscellaneous additives

The Miscellaneous Food Additives (Amendment) Regulations 2001:

- remove the purity criteria for further miscellaneous additives from the 1995 Regulations
- amend the existing purity criteria for butylated hydroxyanisole (BHA)
- include a cross-reference to Commission Directive 2000/63

The Miscellaneous Food Additives (Amendment) (No. 2) Regulations 2001:

- add five new additives to the lists of permitted miscellaneous additives in Schedules 1 and 3: hydrogen (E949); zinc acetate (E650); butane (E943a); isobutane (E943b); and propane (E944). The last three are used as propellant gases in vegetable oil pan sprays and water-based emulsion sprays (see paragraph 43).
- add two additional uses of a permitted additive (glycerol esters of wood rosin (E445))

- allocate an E number (E1520) to the carrier solvent propane-1,2 -diol (propylene glycol) in Schedule 4
- remove most of the remaining purity criteria from Schedule 4 of the 1995 Regulations and include a cross-reference to Commission Directive 2001/30/EC

General philosophy of Directive 95/2/EC

3. For miscellaneous additives to be included in this Directive they first have to comply with the general criteria set out in Annex II of the Food Additives Framework Directive (89/107/EEC). Under these criteria food additives may only be approved if they perform a useful purpose, are safe and do not mislead the consumer.

Definition of an additive

4. 'Food additive' is defined in Regulation 2(1). Any substance, whatever its function, that does not meet this definition is not controlled by these Regulations. Thus, in particular, these Regulations do not apply to normal food/food ingredients, even if they are added to perform a controlled function. The definition includes, for clarification purposes, a list of substances that for the purposes of the Regulations are not considered to be food additives. This list is not, of course, exhaustive.

Definition of food

5. In recognition that the Directive is a Single Market measure, the definition of 'food' has been restricted to that sold or intended for sale, thus making clear that the Regulations do not cover the domestic preparation of food. In addition, in line with the meaning of 'foodstuff' in the Directive, it has also been made clear that 'food' does not cover additive preparations, except where this is necessary (in Regulation 6 and for the purposes of Regulation 9).

Permitted miscellaneous additives

(Regulations 3 and 5)

6. When intended for use, or when used primarily, to perform one of the functions set out in the definition of miscellaneous additive in Regulation 2(1), only additives listed in Schedules 1, 2, 3 and 4 of the Regulations are permitted for sale as carriers in other specified additives or in food sold for human consumption.

Additives categories controlled by the Regulations

(Regulation 2(1))

7. These are identified in the definition of ‘miscellaneous additive’ and defined individually in Regulation 2(1). The definition of ‘stabiliser’ includes all additives used to maintain the physico-chemical state of a food. The definition of ‘glazing agent’ includes mineral hydrocarbons, with the result that the additive uses of these substances in/on dried fruit, citrus fruit, sugar confectionery and eggs, previously permitted by the Mineral Hydrocarbons in Food Regulations 1966 (as amended), but not sanctioned by the 1995 Regulations, are now prohibited. The ‘acidity regulators’ category covers what in previous UK legislation were termed ‘buffers’ and ‘bases’. The ‘carriers’ and ‘carrier solvents’ category covers what were previously termed ‘solvents’ or ‘dilutents’, but with more limited scope (see paragraph 9). The ‘modified starch’ category does not cover all such starches and those excluded from its scope (detailed in Regulation 2(1) under exclusion (iv) in the definition of a food additive) are considered foods and are not subject to additives legislation. Following the harmonisation of EU controls on flour treatment agents (FTAs), previously controlled in the UK under the Bread and Flour Regulations, these substances now fall within the scope of miscellaneous additives legislation. (Enzymes used as FTAs are excluded from the scope of the legislation.)

Additives categories not controlled by the Regulations

8. ‘Liquid freezants’ and ‘release agents’ as processing aids are not included in the Directive and are not subject to specific food additive controls. (It should be noted that ‘glazing agents’ do not include lubricants when these are used as processing aids, for example as ‘release agents’.) The Directive’s controls are based on the primary purpose for which particular additives are added to a particular food (i.e. their intended function), and the Regulations thus control only additives used primarily for the purposes listed under the definition of a miscellaneous additive. The Directive does not include provision for the control of miscellaneous additives in other additives (apart from the provisions relating to carriers and carrier solvents) and there are no controls in the Regulations on such use of additives. This has been effected in the Regulations through the general exclusion of food additives from the definition of ‘food’ in Regulation 2(1). Thus the controls in Regulations 3 and 5 (apart from those on carriers and carrier solvents) on the use of miscellaneous additives in food, and the sale of food containing such additives, do not apply to the use of such additives in other

additives or to the sale of the resultant preparations. Intakes of miscellaneous additives from such uses will be extremely low and will not significantly affect an individual's consumption, so controls are not considered necessary for consumer safety reasons.

9. The 'carriers' and 'carrier solvents' category at Annex V of the Directive encompasses those used with all categories of controlled food additives, i.e. with colours, sweeteners and miscellaneous additives. Schedule 4 provides for these uses. Solvents used for flavourings and for non-controlled additives including processing aids, and also for food ingredients such as spices and vitamins, fall outside the scope of the Directive and these are not controlled under the Regulations. Processing aids are not covered by Directive 95/2/EC or by these Regulations (see the definition of 'miscellaneous additive'), nor is the treatment of food with smoke, pending expected EU proposals on sources of smoke. Flour bleaching agents continue to be controlled by the Bread and Flour Regulations 1998. Colours, sweeteners and flavourings have, of course, their own Regulations. Other additive functions are not subject to specific controls.

10. The addition of any substance to food is subject to the general provisions of the Food Safety Act 1990 (and parallel Northern Ireland legislation) under which it is an offence to render food injurious to health. The absence of specific controls in additive legislation on any particular class of additive does not therefore mean that there are no legal controls.

Foods permitted to contain miscellaneous additives

(Regulations 3(1)–(5), 3(7) and 3(8), Schedules 1, 2, 3, 6, 7 and 8)

11. The miscellaneous additives listed in Schedule 1 can be used in most foods at *quantum satis*. The named packaging gases can be used with *all* foods. However, other Schedule 1 additives may not be used in foods listed in Schedule 6, which include unprocessed foods, except where specifically provided for in Schedule 7. The term 'processed' is defined in the Regulations and examples given of procedures not considered to amount to processing. The list is not, of course, exhaustive. The additives in Schedules 2 and 3 may only be used in the food categories specified. Apart from the packaging gases, only the additives listed in Schedule 8 may be used in foods for infants and young children. In all cases additive use must respect the maximum levels specified. The use of two or more miscellaneous additives in a food is generally permitted, provided suitable food categories exist and the maximum levels for each individual additive are observed. In some cases, however, specific provision is made in the appropriate Schedule concerning combinations of additives and this must be respected.

Maximum permitted levels

(Regulation 2(5)(a), note 3 to Part A of Schedule 2, note 1 to Part B of Schedule 2, heading to Schedule 3 and note 2 to Schedule 8)

12. Unless otherwise specified, all the maximum levels for miscellaneous additives indicated in the Schedules relate to the food as sold. Note 3 to Part A of Schedule 2, the heading to Schedule 3 and note 2 to Schedule 8 state that the maximum levels specified in these parts of the Regulations relate to foods ‘ready for consumption prepared following manufacturers’ instructions’. The Agency accepts that this wording, which is taken from the Directive, is somewhat imprecise. The Agency considers that the condition would only apply to foods such as powdered dessert mixes and powders for drinks that require further preparation (not simply cooking) prior to consumption, and for which specific instructions have been supplied by manufacturers. In these cases, the level of additive would relate to the food ready for consumption after such specific preparation has been carried out. Many of the foods listed in these Schedules do not require such further preparation and, in such cases, the level relates to the food as sold. (See also paragraph 19 in the General Guidance Notes, Section 1.)

13. It is recognised that certain substances, for example phosphates and glutamates, are naturally present in certain foods. The quantitative limits set by these Regulations in nearly all cases relate only to the amount of additive *added*. There is, however, an exception in the case of sulphur dioxide, as the Directive and the Regulations require that the specified quantitative limits include sulphur dioxide available from all sources and therefore take into account any natural occurrence of this substance (see note 1 to Part B of Schedule 2).

Foods for infants and young children

(Regulations 3(7) and 3(8), Schedule 8)

14. Only miscellaneous additives listed in Schedule 8 and certain gases listed in Schedule 1 may be used in foods *specialty prepared* for infants and young children, under the conditions of use specified, and to the maximum permitted levels (see paragraph 54 for additional information). The list currently applies to foods for all infants and young children, including those not in good health. Additional provisions on additives for use in special medical foods intended for infants and young children are set out in Schedule 8, Part 4. Regulation 2(1) defines ‘infants’ as children under the age of 12 months and ‘young children’ as children aged between one and three years. These definitions reflect those given in Article 1(2) of Directive 91/321/EEC on infant formulae and follow-on formulae (OJL 175, 4.7.91, pp. 35–49) that are made under Directive 89/398/EEC.

Food categories

(Schedules 2, 3, 6, 7 and 8)

15. As the food categories in these Regulations are in most cases not defined, there will always be a need for a certain amount of interpretation. The situation is discussed in the General Guidance Notes, Section 1, paragraph 17, and the following section on the Schedules contains some explanations of the less obvious categories. In the case of 'fine bakery wares', the Agency considers that flour confectionery is included in this category, regardless of whether or not this is specifically stated.

The Schedules

16. The Regulations have nine Schedules:

Schedule 1 – lists miscellaneous additives that may be used in most foods, subject to certain exceptions listed in Schedules 6, 7 and 8 and in note 3 to Schedule 1, at *quantum satis*.

Schedule 2 – lists conditionally permitted preservatives and antioxidants that may only be used in the foods and at the maximum levels specified.

Schedule 3 – lists other conditionally permitted miscellaneous additives subject to restricted use.

Schedule 4 – lists additives that may be used as carriers and carrier solvents for colours, sweeteners and miscellaneous additives.

Schedule 5 – lists purity criteria for only one miscellaneous additive (magnesium carbonate (E 504)). The purity criteria for all other miscellaneous additives have now been overtaken by the harmonised provisions in Commission Directive 96/77/EC, as amended by Commission Directives 2000/63/EC and 2001/30/EC.

Schedule 6 – lists foods in the miscellaneous additives listed in Schedule 1, apart from packaging gases, that are generally prohibited (subject to any specific permission provided for in Schedule 7).

Schedule 7 – lists foods in which only a limited number, apart from the packaging gases, of the miscellaneous additives listed in Schedule 1 may be used, and the conditions of their use.

Schedule 8 – lists the only miscellaneous additives permitted in foods for infants and young children, apart from packaging gases.

Schedule 9 – lists the Regulations that are partially or completely revoked.

Schedule 1

17. Schedule 1 lists miscellaneous additives that may be used in food at *quantum satis*. There are two exceptions to this general permission. For foods listed in Schedule 7, only the specified Schedule 1 additives that are listed in Schedule 7 may be used and at the levels specified. For foods listed in Schedule 6, no Schedule 1 additives may be used except where specifically provided for in Schedule 7. The packaging gases listed in Schedule 1 are subject to note 2 of that Schedule, however, and may be used with all foods without exception.

18. Another restriction on the use of Schedule 1 additives is the prohibition on the use of locust bean gum, guar gum, xanthan gum and tara gum to produce dehydrated foods that are intended to rehydrate when ingested (note 3 to the Schedule refers). This prohibition was introduced due to safety concerns about certain slimming products containing large amounts of guar gum, galactomannan, glucomannan or similar substances that were sold in a dehydrated form and were intended to swell in the stomach in order to suppress appetite.

Schedule 2

19. Schedule 2 covers conditionally permitted preservatives and antioxidants that may only be used in the foods and at the maximum permitted levels specified.

Fine bakery wares

20. The UK interprets the entries for fine bakery wares in this Schedule as covering the entire products including any fillings, toppings or coatings, etc.

21. Part A of Schedule 2 covers sorbates, benzoates and p-hydroxybenzoates. These may be used singly or in combination up to the maximum permitted levels specified, with all the levels expressed as the free acid.

Non-alcoholic flavoured drinks (excluding dairy-based drinks)

22. This entry encompasses most products currently considered in the UK as soft drinks, including soft drinks for consumption after dilution, and herbal beverages where the herbal extract is flavouring the product. The category does not include fruit juices or vegetable juices, although it does include soft drinks flavoured with these juices.

Made wine

23. This includes British wine and sherry that is usually made by the fermentation of imported grape must.

Low-sugar jams, jellies, marmalades, and similar low-calorie or sugar-free products and other fruit-based spreads;

Marmalades

24. The European Commission has confirmed that this entry is intended to permit the use of sorbates in all reduced-sugar jams, jellies, marmalades and fruit spreads. Standard jams (i.e. those with 60% or more soluble solids) are not included, given the lack of any technical justification for sorbates in such products.

Processed cheese

25. For the processed cheese category, here and elsewhere, the context requires that the definition of 'processed' in Regulation 2(1) is not applicable. Clearly all cheese would meet this definition, rendering the category of 'processed cheese' unintelligible.

Sauces/emulsified sauces/non-emulsified sauces

26. This includes salad cream and mayonnaise-type emulsified sauces or dressings and non-emulsified vinaigrette-type salad dressings.

27. Part B of Schedule 2 covers sulphur dioxide and the sulphites. The maximum levels relate to the total quantity, expressed as sulphur dioxide, available from all sources (see paragraph 19). A sulphur dioxide level of not more than 10mg/kg or 10mg/l is considered not to be present. This allows for the presence of sulphur dioxide to this level in any food (except those listed in Schedule 8).

Breakfast sausages

28. The Agency considers that this entry also covers sausagemeat.

Vegetable-based and cereal-protein-based meat, fish and crustacean analogues

29. The Agency considers that this entry also covers the use of sulphur dioxide and the sulphites in mycoprotein-based analogues.

30. Part C of Schedule 2 covers other preservatives, including nitrates and nitrites. Although the Regulations require salt or salt substitute to be added to nitrite when sold as a food additive, no specific level for its inclusion has been set. The Regulations also allow for the continuance of the trade practice of selling mixes of nitrite/starch and other additives or ingredients to food manufacturers. While the mixes must now contain some salt, in practice this can be a very small amount.

31. Part D of Schedule 2 covers other antioxidants. When combinations of gallates, butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) are used, the rule of proportionality will apply; for example, if 50% of the maximum permitted amount of BHA is added to a foodstuff, only 50% of that for BHT may also be added (see paragraph 17).

Schedule 3

32. Schedule 3 covers a wide range of permitted miscellaneous additives, including phosphates, glutamates, and waxes used as glazing agents. As with Schedule 2 additives, these additives may only be used in the foods and at the maximum permitted levels specified.

Fine bakery wares and fillings, toppings and coatings for fine bakery wares

33. Throughout this Schedule there are various entries for fine bakery wares and for fillings/toppings/coatings for fine bakery wares. There was no discussion in Brussels on whether or not the maximum levels set for the fine bakery wares categories were intended to cover such wares as complete products, or to exclude their fillings/toppings/coatings. In the UK, the Agency interprets the situation as follows:

- i) where a particular additive/group of additives has an entry covering fine bakery wares but no separate entry for fillings etc., the fine bakery wares entry is taken as applying to the complete product
- ii) where a particular additive/group of additives has an entry covering fillings etc. but no separate entry for fine bakery wares, the additive(s) may only be used in the fillings etc.
- iii) where a particular additive/group of additives has two entries, one for fine bakery wares and another for fillings etc., the level permitted for the fillings etc. applies only to those fillings etc. and the level permitted for the fine bakery wares is taken to apply only to the remainder of the product, for example the crumb

Sugar confectionery

34. This category includes the fondant cream centres of chocolates/chocolate products and sugar glazes for chocolate and other products.

Gel-like desserts

35. This includes mousse dessert mixes.

Processed cheese and processed cheese analogues

36. This category includes all cheese analogues made by processed cheese technology.

Soups and broths

37. This category includes dry soup mixes.

Dried powdered foodstuffs

38. This includes such foods as seasonings and sugars, including icing sugars.

Batters

39. This entry includes the batter mix supplied to food manufacturers with instructions for the addition of specified amounts of water and for beating/mixing to form the liquid batter mix. Despite the fact that it is not at this stage 'ready for consumption', this does complete the preparation (as distinct from cooking) and the Agency considers that it is to the mix at this stage that the maximum phosphate levels apply (see paragraph 13).

Breadcrumbs

40. Although no specific entry exists, the 'soda bread' or the 'flour, self-raising' categories allow for the presence of phosphates in breadcrumbs, by way of the carry-over provision described in paragraph 16 of the General guidance notes, Section 1.

Foodstuffs in tablet and coated tablet form

41. This entry covers the use of talc, and other anti-caking agents specified, on confectionery products that have been formulated by compacting together material to form a tablet. This category does not cover general confectionery products that just happen to be tablet-shaped. This does not, however, mean that talc etc. cannot be used on such products since many such uses would not fall within the definition of an anti-caking agent and/or would be as a processing aid (for example, a release agent to prevent sticking to machinery). Such uses would be outside the scope of the Regulations.

Confectionery (including chocolate)

42. This category includes decorative confectionery for cakes.

Propane, butane and isobutane

43. These entries in the 1995 and 1997 Regulations, which were originally authorised on a temporary national basis under the provisions of Article 5 of the Food Additives Framework Directive, have now been included in Directive 2001/5/EC and are now permitted to be used in the UK (see paragraph 2).

Schedule 4

44. Schedule 4 lists additives that may be used as carriers and carrier solvents for the food additives specified in the definition of carrier and carrier solvent, subject to any restrictions that are specified in the Schedule. Other substances that may be used as carriers, such as those generally considered as foods, and those that have primarily an acid or acidity regulator function, such as citric acid and ammonium hydroxide, are not covered by this Schedule.

Schedule 5

45. Schedule 5 sets out the UK purity criteria applicable to one additive only. EC purity criteria have been agreed for most other permitted miscellaneous additives and are set out in Commission Directive 96/77/EC (as amended).

Schedule 6

46. 'Unprocessed foods' included in this Schedule are defined in Regulation 2(1). However, it was accepted during discussions in the EU that flour is considered a processed food notwithstanding the reference within that definition to 'milled or husked'.

Schedule 7

47. Schedule 7 lists foods in which only a limited number of Schedule 1 additives may be used, apart from the packaging gases, at the maximum permitted levels specified for each. It should be noted that energy-reduced chocolate or that with no added sugar is not covered by the cocoa and chocolate products entry and any Schedule 1 additive may therefore be used. Similarly, most bread or cheeses in the UK do not fall within the categories of specialist products listed in this Schedule and will therefore not be restricted to using only the limited number of Schedule 1 additives listed.

Schedule 8

(See also paragraph 20)

48. Schedule 8 lists additives that may be used in infant formulae, follow-on formulae and weaning foods that are specially prepared for infants and young children. It does not apply to confectionery or other food products that may be targeted at children. Only additives listed in Schedule 8 may be used (or in the case of carriers or carrier solvents be present) in these foods under the specified conditions of use, together with the packaging gases listed in footnote 2 to Schedule 1. Maximum levels of use for Schedule 8 additives relate to foods ready for consumption, where relevant prepared following manufacturers' instructions. It should be noted that, with a few minor exceptions contained in the notes to Schedule 8, no 'carry-over' provision is included in respect of additives used in compound foods specially prepared for infants and young children (see also paragraph 15 of the General guidance notes, Section 1).

Further Information

Copies of UK Regulations and the Official Journals of the European Communities in EC Directives can be purchased from The Stationery Office. For your nearest stockist or for mail, fax and telephone orders, contact:

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