

Food Standards Training Manual



Foreword

The standard and quality of food is important to all consumers and food businesses across Scotland. Consumers must have confidence that food they buy and eat will be what they expect, will not be harmful and that they are protected from fraud. This manual provides information to authorised officers on these areas. The Food Standards Agency in Scotland has worked closely with the Scottish Government to ensure that the reputation of Scottish food and drink is upheld as part of Scotland's National Food and Drink Policy.

The Food Standards Training manual was first issued by the Food Standards Agency Northern Ireland in order to assist authorised officers with the challenging area of food standards. In 2007, the Agency's sector-specific simplification project considered the potential for expanding the use of this manual. In Northern Ireland the manual is now in its third successful year, and evaluation of the manual has further determined the need for this type of resource.

Work began in Scotland to produce a Scottish version of the manual in partnership with local authority authorised officers, based on the positive feedback received on the Northern Ireland manual from District Councils and to address issues raised by audits undertaken in Scotland.

Partnership is key in the development of Agency projects and a working group was established to take this project forward with members of the Scottish Food Enforcement Liaison Committee Food Standards Sub Committee. The group offered invaluable expertise and experience in producing the Scottish edition of this training manual, and kept the main objective in focus, to provide a practical training and reference tool for authorised officers. In addition to input from local authority colleagues, Scottish Public Analysts were also consulted on this document.

The aim of this manual is to provide a reference document for the wide range of food standards legislation in force in Scotland and the associated codes of practice and relevant guidance notes. It is not the intention that the manual will provide a detailed account of each piece of legislation but it is hoped that it will go some way to assisting authorised officers to become more familiar with food standards legislation and associated guidance. It is also intended to give authorised officers an insight into some of the practical applications of food standards enforcement and to identify other sources of useful information.

Food legislation and guidance is ongoing and changes constantly. It is our aim to produce the most accessible and up to date training information. Given the ever evolving nature of food legislation it will be necessary to update the manual. Updates will be issued on a regular basis, and we would welcome comments and suggestions.

Charles Milne Food Standards Agency

¹ http://www.food.gov.uk/multimedia/pdfs/simplifysectorrep.pdf

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1.1 General Introduction and Enforcement

The key pieces of primary legislation dealing with Food Standards Law enforcement are:

Food Safety Act 1990

Responsibility for enforcement of the majority of the food standards, composition and labelling regulations under the Food Safety Act 1990 rests with Local Authorities (Section 26). In Scotland Local Authorities appoint authorised officers specifically in writing to enforce the legislation on their behalf. Food Authorities should be aware that law relating to food is not necessarily made under the Food Safety Act 1990 and that separate authorisation is required. Law that applies to food is also contained in and/or made under the Animal Health Act 1981, the European Communities Act 1972, the Consumer Protection Act 1987, the Consumer Protection from Unfair Trading Regulations 2008, the Weights and Measures Act 1985, the Medicines Act 1968 and directly under EC Regulations.

The Framework Agreement on Official Feed and Food Controls by Local Authorities sets out what the Food Standards Agency expects from local authorities' in their delivery of official controls, and sets out the planning and delivery requirements, based on the existing statutory codes of practice.

Food Authorities are required under the Official Feed and Food Controls (Scotland) Regulations 2009 to have regard to the <u>Food Law Code of Practice (Scotland)</u> when discharging their duties. Food Authorities should take account of <u>Food Law Practice Guidance (Scotland)</u>.

These documents provide detailed guidance to officers on issues such as:-

- Qualifications and experience
- General Enforcement including Powers of entry
- Seizure and detention
- Application of laws to Crown premises etc
- The scope of a food standards inspection

Throughout the manual, where appropriate, references will be made to the Code of Practice and the Practice Guidance to avoid unnecessary repetition.

1.2 Food Standards Intervention Overview

In Scotland, a food standards intervention as outlined in the Food Law Code of Practice (Scotland), is part of system which ensures that food meets the requirements of food standards law, including proper presentation, labelling and advertising, compliance with compositional standards and the absence of non-permitted or excessive levels of additives, contaminants, residues and also includes quality assurance schemes. The food offered for sale should not mislead the consumer.

Interventions are official controls which include inspections, monitoring surveillance, verification, audit, sampling, education, advice and coaching and information and intelligence gathering.

There are principally 6 key areas of investigation in a food standards inspection. They all relate to the ability of the food business to:-

- Meet food standards requirements
- Manage systems in place to ensure that the standards are effective and can be met
- Comply with compositional, labelling, advertising, menus, keep records, claims and recipes
- Be able to demonstrate traceability
- Comply with specifications
- · Consider adhering to industry codes and guidelines

Many authorities use a standard inspection sheet or aide memoire to guide them through the inspection assessment process.

On completion of the intervention an officer is required to carry out a risk rating in accordance with Annex 5 of the Food Law Code of Practice (Scotland)

Qualifications and experience of officers is contained within Chapter 1.2.9 of the Food Law Code of Practice (Scotland)

Before officers can be authorised to carry out food standards interventions they need to be in possession of one of a number of fundamental qualifications. Details of these qualifications, which are outlined in the Food Law (Scotland) Code of Practice, include:-

- The REHIS or EHRB Diploma in Environmental Health (or its antecedents), or Certificate of Registration of EHRB;
- The Higher Certificate in Food Standards Inspection issued by SFSORB;
- The Higher Certificate in Food Premises Inspection issued by EHORB or the IFST with an endorsement to include Food Standards Enforcement
- Diploma in Trading Standards (DTS) or its antecedents;
- Diploma in Consumer Affairs (DCA) provided it includes the Food and Agriculture Paper of Part II, or its antecedents;
- a DCA Certificate of Competence in relation to Food and Agriculture (or its antecedents);
- One of the following Trading Standards Qualifications Framework Certificates with the Food Standards service delivery module (issued by TSI)
 - Module Certificate;
 - Diploma in Consumer Affairs and Trading Standards (DCATS);
 - Certificate of Competence.
- Higher Diploma in Consumer Affairs and Trading Standards (HDCATS) (this certificate must be presented with one of the awards/certificates listed above).

In addition to these qualifications, authorised officers also need to have knowledge of a range of documents including:-

- Relevant food standards and marketing legislation;
- Requirements in Regulation 882/2004 on official controls for competent
- authorities with responsibility for enforcement of food law;
- The Food Law (Scotland) Code of Practice;
- The Practice Guidance accompanying this Code;
- The Food Authority's Enforcement Policy;
- Relevant guidance issued by the Food Standards Agency and by LACORS/SFELC;
- Relevant industry codes of practice.

1.3 Principles of Enforcement

Under the Code of Practice Local Authorities have an obligation to ensure that the actions taken by officers are reasonable, proportionate and consistent with good practice. Except where circumstances indicate a significant risk, officers are advised to operate a gradual and educative approach, giving advice/education and informal action and only moving to more formal action where the informal action does not achieve the desired effect within a reasonable time period.

All officers should have an awareness of:

- Guide for Specialist Reporting Agencies
- Enforcement Concordat
- Local Authority enforcement policies.

When dealing with food business operators, officers need to ensure that they make a clear distinction between actions needed to meet statutory requirements and recommendations relating to good practice.

Correspondence should identify each statutory contraventions and remedial actions needed to secure compliance. The correspondence should also indicate a time scale suggested to achieve compliance.

1.4 Detention and Seizure of Food

Situations may arise where an officer identifies that something has been illegally added to a food during processing. The substance may be prohibited or it may be added at levels at the mixing bowl stage that appear to the officer, to exceed the statutory limits. Under such circumstances the officer would have reasonable grounds to suspect that the foodstuff may fail the food safety requirement and may require detention for the purposes of further inspection/analysis. If the authorised officer decides that the food should be detained then the following considerations are relevant:-

- Has the owner been made aware of the consideration to detain?
- Can the food be detained on site and can its physical condition and security be guaranteed?
- Can the food be properly marked and identified for detention purposes?
- Can arrangements be put in place for periodic monitoring pending a decision about the goods?

It is most likely that grounds for seizure of food will rely heavily on evidence supplied in the form of an analytical certificate, following suitable sampling and analysis by the appointed Public Analyst. The officer needs to consider whether or not the food can be rendered safe and wholesome after processing or make arrangements for the supervision of safe disposal.

Whether or not a food can be seized depends on whether it contravenes the food safety requirement as defined in Article 14 of <u>EC Regulation 178/2002</u>. The food safety requirement will cover both chemical and microbiological hazards, however in food standards enforcement the majority of decisions are more likely to relate to chemical composition.

Circumstances where detention and seizure powers might be exercised under food standards work include:-

- Alcohol adulterated with harmful levels of methanol
- Wine contaminated with di-ethylene glycol
- Foods containing excess additives
- Food containing non permitted colours e.g. Sudan 1.

If an authorised officer opts for voluntary surrender he/she should ensure the following:-

- The owner of the food has suggested this option
- The owner will bear the cost of disposal
- The disposal will be recorded by appropriate documentation

More detailed guidance on voluntary procedures, seizure and detention is contained in the Food Law Code of Practice.

1.5 Sampling of Food and Ingredients

1.5.1 Sampling of food, ingredients and materials and articles in contact with food is often very helpful in the completion of a comprehensive food standards inspection. In some cases it is not possible to assess the fitness or composition of a food or ingredient without having it chemically analysed. Advice can be sought from the Public Analyst as to the most appropriate testing of the food or article. Section 6 (Sampling and Analysis) of the Food Law Code of Practice gives a detailed account of sampling and analysis requirements. Officers should also be aware of sampling guidance issued by Scottish Food Enforcement Liaison Committee and the Food Standards Agency in Scotland.

1.6 Food Control Primary Legislation

1.6.1 The Food Safety Act 1990

<u>The Food Safety Act 1990</u> sets out the framework for most food standards regulation.

The principal provisions of the Act in relation to food standards enforcement are - set out below in paragraphs 1.6.1.1 to 1.6.1.3

1.6.1.1 Part 1 - Preliminary

Section 1 outlines definitions for commonly used terms such as food, food business, food premises, food sources etc. The section was amended by the Food Safety Act 1990 (Amendment) Regulations 2004 to bring the definition of food in line with the definition in Regulation (EC) 178/2002

Section 2(1) extends the meaning of sale to include food supplied in the course of a business.

Section 2(2) deals with food offered as prizes.

Section 3 sets out provisions regarding presumptions relating to food and ingredients, for instance, that food commonly used for human consumption found on certain food premises is presumed to be intended for sale.

1.6.1.2 Part 2 - Main Provisions

Section 7 describes the offence of rendering food injurious to health.

General Enforcement Provisions
 See section 1.6.2.1 regarding Food Safety Requirements.

Section 8 defines the food safety requirements. This section was amended by Article 14 of Regulation (EC) 178/2002, which is concerned with each stage of production, processing and distribution and information on the label). This section also sets out the offence of selling or preparing food which fails to comply with food safety requirements which was removed from the Food Safety Act 1990 by Regulation 4 of the General Food Regulations 2004.

Section 9 gives authorised officers power to inspect any food intended for human consumption and to detain and remove any food suspected of not complying with the food safety requirements. The Article also allows a Sheriff or Justice of the Peace to condemn food failing to comply with the food safety requirement.

Section 10 allows for improvement notices where food hygiene or food processing regulations have been contravened.

Section 11 allows for prohibition orders to be issued by the court where the health risk condition is fulfilled and the proprietor of a food business has been convicted of an offence under food hygiene or food processing regulations.

Section 12 provides emergency prohibition powers for use by authorised officers where there is an imminent risk of injury to health. These powers remain within the Food Safety Act and can be used in relation to offences linked to food standards where there is a risk of injury to health.

Section 13 gives Ministers powers to make emergency control orders prohibiting commercial operations in relation to food, food sources or contact materials where there is an imminent risk of injury to health.

Section 14 relates to the sale of food that is not of the nature, substance or quality expected by the consumer. Each term can be used independently of the others in legal proceedings. There is considerable case law on the terms but the following serves as a useful reference to what each term means:-

- Nature: may be used where a different kind, sort of food or species of food is sold from that requested by the consumer e.g. Haddock sold as cod.
- Substance: tends to include foods that are found to contain substances that are
 not entirely compatible with the food purchased. For example, where the food
 contains foreign bodies such as an insect; or in relation to meat products such as
 sausages or pies where the meat content does not comply with the minimum
 requirements.
- Quality: usually refers to commercial quality. An example of this would be where food does not comply to a standard quality, i.e. a stale cake.

Section 15 is a further consumer protection provision, which creates the offence of falsely describing or presenting food. Food that is claimed to be organic, but which is not may fall within the provisions of this article. Two terms are of particular interest e.g. false and misleading.

False - a label could be interpreted as false if there is a clear factual inaccuracy.

Misleading - a label might be misleading if it relates to an inference or omission.

 An example of where food might be misleadingly presented would be products which are not cream but which are presented in traditional cream cartons and displayed amongst them

For further detailed explanations of the terms refer to the following case law:-

The <u>'CAP Code'</u>: the British code of advertising, sales and promotion direct marketing outlines a self regulatory system of the advertising industry. This code contains specific restrictions on claims such as dieting, health, low calorie and references to vitamins. The Advertising Standards Authority (ASA) administers the code.

The subject of 'presentation' of food is included in <u>Article 16</u> of Regulation (EC) 178/2002 and is enforced by the <u>General Food Regulation 2004</u>.

- Defences

Section 20 enables the enforcement authority to bypass the immediate offender and prosecute the real offender.

Section 21 deals with 'Due Diligence Defence' i.e. where the defendant can prove to the court that they took all reasonable precautions and exercised all due diligence to avoid committing an offence. Although the burden of proof lies with the defendant, they need not establish their case beyond all reasonable doubt. They need only persuade the court that they exercised due diligence on the balance of probabilities.

See Lincolnshire County Council V Safeway stores Plc.

1.6.1.3 Part 3 - Administration and Enforcement

Section 27 deals with the appointment of an appropriately qualified Public Analyst.

- Sampling of Food

Sections 29 and 30 make provision for authorised officers to sample food, ingredients and contact materials and to submit samples to a Public Analyst.

Powers of Entry

Section 32 sets out who may enter premises to enforce the Act and outlines what they can do while on the premises. Unauthorised disclosure of information relating to trade secrets obtained when using these powers is an offence.

Section 33 deals with obstruction of officers

- Offences

Section 34 sets out time limits for prosecution

- 3 years from the commission of the offence or
- One year from its discovery by the prosecution whichever is the earlier.

Section 35 for most offences a High Court may impose a prison sentence of up to 2 years and/or unlimited fines. Sheriff's Courts generally may impose a fine, up to level 5 and/or prison sentence of up to 6 months. In relation to the most serious offences Sheriff's Courts can impose a maximum fine of £20,000.

Section 37 provide for appeals to the Sheriff.

Section 38 provide for appeals to the High Court.

Section 40 allows for Codes of Practice to be issued for the guidance of food authorities

Section 44 allows for the protection of officers who honestly believe they had a duty to do an act which was within their scope of employment.

Section 54 deals with the application of the Act to Crown premises. This section should be read in conjunction with Chapter 1.6 of the Food Law Code of Practice. Officers should note that the crown exemptions do not apply to Health and Social Service or Trusts, as they are not Crown Premises.

1.6.2 The General Food Regulations 2004

These regulations implement the provisions of <u>Regulation (EC) 178/2002</u> in respect of the general principles and requirements of food law.

The regulations amend the interpretation of the food safety requirement of the <u>Food Safety Act 1990</u> to that outlined in **Article 14** of Regulation (EC) 178/2002.

1.6.2.1 Food Safety Requirement (Article 14)

- 1. Food shall not be placed on the market if it is unsafe.
- 2. Food shall be deemed to be unsafe if it is considered to be
 - (a) Injurious to health
 - (b) Unfit for human consumption.
- 3. In determining whether any food is unsafe regard shall be had:
 - (a) To the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - (b) To the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
- 4. In determining whether any food is injurious to health regard shall be had:
 - (a) Not only to the probable immediate and/or short term and/or long term effects of that food on the health of a person consuming it, but also on subsequent generations
 - (b) To the probable cumulative toxic effects
 - (c) To the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

- 5. In determining whether any food is unfit for human consumption; regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
- 6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch lot or consignment is also unsafe, unless following, a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
- 7. Food that complies with specific community provisions governing food safety shall be deemed to be safe in so far as the aspects covered by the specific community provisions are concerned.
- 8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that despite such conformity the food is unsafe.
- 9. Where there is no specific community provision, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

The Food Safety Act 1990 is also amended by the omission of Section 8(2) in relation to selling of food not complying with the food safety requirement.

1.6.2.2 Presentation (Article 16)

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food, including their shape, appearance or packaging, the packaging material used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available through whatever medium, shall not mislead consumers.

1.6.2.3 Traceability (Article 18)

Article 18 of <u>EC 178/2002</u> relates to traceability. The food business operator must have systems and procedures in place to allow information requested to be provided that can identify the businesses to which their products have been supplied and where their ingredients have been sourced. For this purpose food needs to be adequately labelled or identified to facilitate its traceability. Sound traceability ensures food safety and assists in enabling unsafe food to be removed from the market. The traceability process is meant to ensure that targeted and accurate withdrawals or recalls can be undertaken. Appropriate information can be given to consumers and food business operators, risk assessment can be performed by enforcement authorities and unnecessary disruption of trade can be avoided.

Without prejudice to more detailed rules, Article 18, does not compel operators to establish a link between incoming and outgoing products (internal traceability), nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches.

Nevertheless, where appropriate, the food business operator could be encouraged to develop systems of internal traceability designed to reflect the nature of their activities (food processing, storage, distribution etc). The decision on the level of detail of internal traceability should be left with the business operator, commensurate with the nature and size of the food business.

The labelling of beef (and veal) at processor and retail level is governed by the EU Beef and Veal Labelling (Scotland) Regulations 2010. In addition to ensuring traceability, this EU-wide labelling is intended to provide consumers with clear, reliable information about the beef they are buying. Information must be provided on country of birth, rearing and slaughtering at Member State level. Beef imported from outside the EC must indicate that the origin is non-EC and give the country of origin of slaughter.

Under the associated voluntary beef labelling scheme, sellers may provide further information, provided it is approved by the Scottish Government and verified by an independent body.

Local authority environmental health departments have the main responsibility for ensuring enforcement of the Beef Labelling Regulations at retail level, drawing where necessary on the advice of the Scottish Government.

Further information on the scheme can be viewed at the following link: http://www.scotland.gov.uk/Topics/farmingrural/Agriculture/Livestock/Meat/Beef/Labe lling/scheme

1.6.2.4 Product Recall (Article 19)

Under Article 19 of <u>EC 178/2002</u>, responsibilities are placed on food business operators to withdraw from the market food which is not in compliance with the food safety requirement where it has already left their control.

The food business operator must also notify the FSA of foods that have been placed on the market where there is an indication that it may be injurious to health.

Further guidance can be obtained from the following sites:

<u>Europa Website</u> <u>Food Standards Agency Website</u>

Section 2 - Training Notes on Legislation

2.1 Food Labelling Regulations 1996 (as amended)

2.1.1 Introduction

In 1979, the European Community adopted its main legislative document relating to food labelling - Directive 79/112 which established general requirements for food labelling and composition of certain foods. The legislation recognised the need to protect the consumer and included the drafting of a list of information which in principle should be included in the labelling of all foodstuffs. At that time unanimous agreement was required for the Directive to be adopted, the process was difficult and in consequence several 'derogations' were incorporated which allowed countries to maintain slightly different requirements in their national implementing provisions. However, as part of the moves to create the Internal Market (1985-1992) it was recognised that these derogation's would ultimately have to be removed. This was agreed in 1989.

The internal market allowed for products manufactured in one country to be sold in any other member state, but this created problems because it was known that some products were manufactured in certain countries according to defined recipes (national compositional standards). In consequence, a product could be made to a specific standard in one country and yet not meet legal requirements in another Member State. To overcome the problem additional detail was thought necessary to allow consumers to clearly identify the key differences between similar foods. The result was an amendment to 79/112, agreed in 1997, which requires quantitative ingredient declarations (QUID) on many products. The actual requirements go beyond those products which were the particular concern of the Internal Market.

Parallel to the internal market programme many countries were introducing legal requirements relating to nutritional labelling. These were recognised as creating a further potential obstacle to trade and the Commission developed proposals for a European control. A Directive relating to this was agreed in 1990 (Directive 90/496). This, however, was an additional Directive and not an amendment to 79/112.

In 2000, the Directive (79/112) was replaced by a new version which incorporated the various amendments - a process known as 'consolidation'. No changes were included - it just made the legal requirements more obvious. The current Directive is number 2000/13/EC.

The following notes outline how the Food Labelling Regulations 1996 implement the main Directive.

 Food Labelling Regulations 1996 (SI 1996 No. 1499) consolidate and replace the Food Labelling Regulations 1984. They principally implement Council Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs. (Directive 79/112/EEC was superseded by Directive 2000/13/EC)

- 2. They also implement:
- <u>Commission Directive 87/250/EEC</u> on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer;
- <u>Council Directive 2009/39/EC</u> relating to foodstuffs intended for particular nutritional uses;
- Council Directive 90/496/EC on nutrition labelling for foodstuffs; and
- <u>Commission Directive 94/54/EC</u> concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in <u>Council Directive 79/112/EEC</u>.

The Food Labelling Regulations have been progressively amended and updated to take account of new EC Directives on the composition and labelling of food. The amendments are as follows:

- <u>Food Labelling (Amendment) Regulations 1998</u> (SI 1998 No. 1398) Implements EC Directive 97/4/EC (Commonly known as the QUID Directive)
- <u>Food Labelling (Amendment) Regulations 1999</u> (SI 1999 No. 747) Implements EC Directive 1139/98/EC concerning GMO labelling
- <u>Food Labelling (Amendment) (No. 2) Regulations 1999</u> (SI 1999 No. 1483) -Implements EC Directive 1999/10/EC providing for derogations from the provisions of Article 7of EC Directive 79/112/EEC in respect of certain foods.
- Food Labelling Amendment (Scotland) Regulations 2004 (SI 2004 No. 269) Implement EC Directive 2003/120 amending EC Directive 90/496 on nutritional
 labelling of foodstuffs. A conversion factor is specified for salatrims (a group of
 reduced energy fats) to be used in the calculation in the declared energy value of
 foods
- Food Labelling Amendment (No. 2) (Scotland) Regulations 2004 (SSI 2004 No. 472) Implements EC Directive 2003/89 amending EC Directive 2000/13 requiring that food containing allergenic ingredients have to be declared on labels of pre-packed foods
- <u>Food Labelling Amendment (Scotland) Regulations 2005</u> (SSI 2005 No. 222) -Implement EC Directive 2004/77 amending EC Directive 94/54 regarding the labelling of food containing glycyrrhizinic acid and its ammonium salt. This acid occurs naturally in liquorice plants
- The Food Labelling (Declaration of Allergen) (Scotland) Regulations 2008 (SSI 2008 No. 180)
- The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2009 (SSI 2009 No. 374) which amend the Food Labelling Regulations 1996 to provide a temporary exemption from labelling for egg albumin as a fining agent for wine

- and lysozyme (produced from egg) used in wine and for milk (casein) used as a fining agent for wine until December 2010.
- The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2011 due to come into force late March – will further extend the temporary exemption until June 2012.
- The Nutrition and Health Claims (Scotland) Regulations 2007 (SSI 2007 No. 383) amend the Food Labelling Regulations 1996 in respect of overlaps with Regulation 40 and Schedule 6 and 8 which deal with nutrition and claims.

In addition to the above mentioned major amendments there were a number of consequential minor amendments by a range of statutory rules outlined below:

- <u>Miscellaneous Food Additives (Amendment) Regulations 1999</u> concerns a minor amendment to the food labelling regulations by removing of a reference to Schedule 3 of the <u>Bread and Flour Regulations 1998</u> and other minor amendments
- Genetically Modified and Novel Foods (Labelling) (Scotland) Regulations 2000 (SSI 2000 No. 83) - Consequential amendments made to the food labelling regulations with reference to Genetically Modified Organisms
- <u>Food Irradiation (Scotland) Regulations 2009</u> (SSI 2009 No. 261) amends the food labelling regulation references to irradiated foods
- <u>Food Labelling Amendment (Scotland) Regulations 2003</u> (SSI 2003 No. 578) Amends the food labelling regulations in respect of references to Caffeine and Quinine
- Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 (SSI 2001 No.38) - Amends the food labelling regulations in respect of references to Coffee and Coffee Products (Scotland) Regulations 1979
- Condensed Milk and Dried Milk (Scotland) Regulations 2003 (SSI 2003 No. 311)
 Amends the food labelling regulations with reference to Condensed Milk and Dried Milk (Scotland) Regulations 1977
- Specified Sugar Products (Scotland) Regulations 2003 (SSI 2003 No. 527) The amendment removes reference in food labelling regulations to Specified Sugar Products (Scotland) Regulations 1976. This regulation also amends Schedule 3 entry for glucose syrup
- Cocoa and Chocolate Products (Scotland) Regulations 2003 (SSI 2003 No. 291)
 Amends the food labelling regulations by removing reference to Cocoa and Chocolate Products (Scotland) Regulations
 1976

- Honey (Scotland) Regulations 2003 (SSI 2003 No. 569) Amends the food labelling regulations by removal of reference to Honey (Scotland) Regulations 1976
- <u>Fish Labelling (Scotland) Regulations 2010</u> (SSI 2010 No. 90) Consolidated and updated the 2003 regulations. Amends food labelling regulations by removing paragraph 1 of schedule 1 concerning fish names.
- <u>Jam and Similar Products (Scotland) Regulations 2004</u> (SSI 2004 No. 133) -Amendment of Schedule 9 of food labelling regulations by removal of reference to Jam and Similar Products (Scotland) Regulations 1982
- Meat Products (Scotland) Regulations 2004 (SSI 2004 No. 6) (amended by the Meat Products (Amendment) (Scotland) Regulations 2008 (SSI 2008 No. 97)) -Changes the definition of "meat product" and inserts a new Schedule 4A into the Food Labelling Regulations i.e. "Meat Products" not required to bear an indication of the quantity of an ingredient or category of ingredient when sold not pre-packed or pre-packed for direct sale
- Official Feed and Food Control (Scotland) Regulations 2009 (SSI 2009 No. 446)
 (as amended by the Official Feed and Food Controls (Scotland) Amendment
 Regulations 2010 (SSI 2010 No. 5). Removed the export defence in the Food
 Labelling Regulations
- The Drinking Milk Regulations 1998 (SI No. 2424). The Drinking Milk (Scotland)
 Regulations 2011 (SSI No. 84) revoke the Drinking Milk Regulations 1998 for
 Scotland and update EU law references (The sale of raw milk in Scotland is
 prohibited by the Food Hygiene (Scotland) Regulation 2006 (Regulation 32
 Schedule 6))
- The Bread and Flour Regulations 1998 (SI No. 141) these regulations revoke and replace the 1995 regulations
- The Fruit Juices and Fruit Nectars (Scotland) Regulations 2003 (SSI No. 293) implements council directive 2001 /112 EC relating to Fruit Juices and certain similar products

Note: The extent of amendments of the food labelling regulations are considerable and in 2006 it had been the intention of the FSA to consolidate. The process of consolidation was stopped due to the current EU Food Labelling Review. It is anticipated that this process could take several years therefore this document focuses on the current legislation in operation at the time of drafting. The manual will be updated as new legislation comes into operation.

3. The Food Labelling Regulations are arranged into five parts, with eleven schedules supporting and expanding on the main provisions.

Part I (Preliminary)

 Contains the title and commencement date of the regulations, definitions and the exemptions which apply.

Part II (Food to be delivered as such to the ultimate consumer or to caterers); and Schedules 1 to 5

- Defines the scope of the Regulations, including those foods to which this part of the Regulations only do not apply;
- Sets out the detailed rules governing the general labelling requirements;
- Exempts certain foods from some or all of these general requirements:
- Extends additional labelling requirements to certain categories of foodstuffs; and
- Describes the manner in which foods should be marked or labelled, including naming, labelling, ingredient listing, durability, omissions, irradiation, additives, foods sold from catering premises, gas packing, and raw milk.

Part III (Claims, nutrition labelling, and misleading descriptions); and Schedules 6 to 8

- Contains the requirements and conditions attached to the making of nutritional and other claims;
- Controls certain misleading descriptions; and
- Restricts the use of the word 'wine'.
 (NB: See also Nutrition and Health Claims (Scotland) Regulations 2007 SSI. No. 383)

Part IV (Offences and legal proceedings)

- Gives details of the offences which may be committed under the provisions of these Regulations;
- The defences which may be offered in certain circumstances in the event of prosecution; and
- The authorities responsible for their enforcement.

Part V (Revocations, amendments, and transitional provisions); and Schedule

- Gives details of the measures revoked by these Regulations; and
- The transitional arrangements which were made to accommodate the changeover to the requirements in these Regulations.

2.1.2 Principal Provisions

- 1. The principal provisions of the Regulations are to require all food which is ready for delivery to the ultimate consumer or to a catering establishment, subject to certain exceptions (this includes non pre-packed or pre-packed for direct sale foods sold from a catering establishment which are exempt from particulars specified in regulation 5), to be marked or labelled with:-
- The name of the food (regulations 5(a), 6 to 11, and Schedules 1 and 2):
- A list of ingredients (regulations 5(b), 12 to 18, and Schedules 3 and 4);
- The quantity of certain ingredients or categories of ingredients (regulation 19)
- The appropriate durability indication (regulations 5(c), 20 to 22);
- Any special storage conditions or conditions of use (regulation 5(d));
- The name and address of the manufacturer or packer or of a seller established within the European Community (regulation 5(e));

and in certain cases -

- Particulars of the place of origin of the food (regulation 5(f)), and
- Instructions for use (regulation 5(g)).
- 2. The regulations also:
- make special provisions for the labelling of:
 - Food which is not pre-packed and certain similar foods,
 - Fancy confectionery products,
 - Food which is packed in small packages and indelibly marked bottles,
 - Certain foods sold at catering establishments, and
 - Seasonal selection packs (regulations 23 to 28);
- Specify additional labelling requirements for food sold from vending machines and for alcoholic drinks (regulations 29 and 30);
- Products consisting of skimmed milk together with non-milk fat (regulation 32);

- Specify an additional labelling requirement for food packaged in a gas to extend its durability (regulation 33);
- Specify additional labelling requirements for food containing sweeteners, added sugar and sweeteners, aspartame or more than 10% added polyols (<u>regulation</u> <u>34</u>);
- Specify high caffeine levels in drinks be labelled (<u>regulation 34(a)</u>)
- Require that food containing any allergenic ingredient or any derivative (listed in Schedule AA1) must be marked or labelled with a clear reference to the name of the allergenic ingredient concerned. (Regulation 34(b));
- Specify additional labelling requirements for confectionary and drinks containing glycyrrhizinic acid or its ammonium salt. (<u>Regulation 34c</u>)
- Specify requirements as to the manner of marking or labelling of food (Regulations 35 to 39);
- Prohibit a claim in the labelling or advertising of a food that it has tonic or medicinal properties, and imposes conditions for the making of:
 - Claims relating to foods for particular uses and similar foods;
 - Reduced or low energy value claims;
 - Protein claims:
 - Vitamin claims:
 - Mineral claims;
 - Cholesterol claims:
 - Nutrition claims; and
 - Claims which depend upon another food

(Regulations 40 and 41, Schedule 6 and, in relation to nutrition claims, Schedule 7. See also Nutrition and Health Claims (Scotland) Regulations 2007 SSI No. 383)

- Specify labelling requirements for nutritional information, whether or not a nutrition claim is also being made (<u>regulation 41(4)</u> and Schedule 7);
- Specify labelling requirements where voluntary nutritional information is given for a food:
- Impose restrictions on the use of certain words and descriptions in the labelling or advertising of food (<u>regulation 42</u> and Schedule 8);
- Permit the use of the word 'wine' in composite names for drinks other than wine or table wine in accordance with Article 43.2 of Council Regulation (EEC) No. 2392/89 (regulation 43).

- **3.** The Regulations also:
- Create offences, prescribe penalties (<u>regulation 44</u>) and provide for the Regulations to be enforced by Food Authorities (<u>regulation 45</u>);
- Provide a defence in certain cases where the appropriate durability indication for a food is altered (<u>regulation 46</u>);
- Apply various sections of the Food Safety Act 1990 (<u>regulation 48</u>);
- Revoke and make consequential amendments to certain other Regulations (regulation 49).
- **4.** The Regulations do not apply:
- to food imported from a member state in which it was lawfully produced and sold, and which is suitably labelled (regulation 3(1));
- to food imported from a Member State of the European Community in which it was lawfully produced and sold, and which is suitably labelled (regulation 3(1));
- to food produced outside the European Community which is imported from a Member State of the European Community, and which is suitably labelled (<u>regulation 3(1)</u>);
- except insofar as they relate to advertising, to
 - Food which is not intended for sale for human consumption
- Food products, the labelling of which is controlled by specific EC Regulations relating to hen eggs; spreadable fats; wines and grape musts; sparkling wines and aerated sparkling wines; liqueur wines, semi sparkling wines and aerated semi-sparkling wines; spirit drinks; fresh fruit and vegetables; preserved sardines; preserved tuna and bonito (regulation 4(2));

The above mentioned foods are not exempt from provisions in the Food Labelling Regulations 1996, (as amended) relating to claims, prescribed nutrition labelling, misleading descriptions, packaging gases, sweeteners, manner of marking or labelling and intelligibility.

- additives sold as such, the labelling of which is controlled by other Regulations (regulation 4(2));
- apart from the provisions relating to nutrition labelling, claims and misleading descriptions, to
 - Certain food prepared on domestic premises,
 - Food prepared otherwise than in the course of a business (regulation 4(3)).

5. In certain circumstances the provisions relating to nutrition labelling, claims and misleading descriptions do not apply to natural mineral waters (<u>regulation 3(4)</u> and (5)).

The regulations apply to almost all food types. However, the detailed labelling provisions do not apply in respect of: regulation 4 part 2 of the Food Labelling Regulations 1996

- Specified sugar products as defined in the Specified Sugar Product Regulations 1976
- Cocoa or chocolate products as defined in the Cocoa and Chocolate Products Regulations 1976
- Honey as defined in Honey regulations 1976
- Condensed Milk products or Dried Milk products as defined in the Condensed Milk and Dried Milk Regulations 1977. Any condensed milk product or dried milk product which is ready for delivery to a catering establishment other than any such product which is specifically prepared for infant feeding and in the labelling of which there appears a clear statement that such food is intended for consumption by infants and no statement to the effect that such is intended for consumption by any other class or person.
- Hen eggs
- Spreadable fats
- Wine and Grape musts
- Sparkling wines and aerated sparkling wine
- Liqueur wines, semi sparkling wine and aerated semi sparkling wine
- Spirit drinks
- Fresh fruit and vegetables
- Preserved sardines
- Preserved tuna and bonito
- Additives and flavourings labelled and sold as such

2.2 General Labelling Requirements

2.2.1 Name of the Food - (Regulation 5)

The principal provisions of the food labelling regulations are to require that all food which is ready for delivery to the ultimate consumer (i.e. any purchaser of food other than one who intends to resell) or to a catering establishment, subject to certain exceptions, to be marked or labelled with -

- The name of the food (regulations 5(a), 6 to 11, and Schedules 1 and 2);
- A list of ingredients (regulations 5(b), 12 to 18, and Schedules 3 and 4);
- The quantity of certain ingredients or categories of ingredients (regulation 5(ba) and 19)
- The appropriate durability indication (regulations 5(c), 20 to 22);
- Any special storage conditions or conditions of use (regulation 5(d));
- The name and address of the manufacturer or packer or of a seller established within the European Community (regulation 5(e));

And in certain cases -

- Particulars of the place of origin of the food (regulation 5(f)), and
- Instructions for use (regulation 5(g));

Additional labelling requirements such as allergen labelling will be covered later in this document.

Considerations when deciding on a name for a food

(Regulations 6-11, and Schedules 1 and 2)

Where there is a name laid down by law, this must be used. If not, a customary name may be used. If there is no customary name, or it is not used, a descriptive name must be used. The name should be sufficiently precise to inform a purchaser of the true nature of the food and to enable the food to be distinguished from products with which it could be confused. The name of a food may consist of a name, a description, or both and it may contain more than one word.

2.2.1.1 Prescribed Name (Regulation 6 and Schedule 1)

A name may be prescribed by either European Community law or, in the absence of such law, by law in Scotland. Where a name prescribed by law exists (a legal name), that name must be used for a food. The name may be qualified by additional words which make it more precise. For example, some Regulations (e.g. the Fish Labelling (Scotland) Regulations 2010) contain a number of names which are prescribed names, e.g. for certain fish species. Equally, EC Regulations on spreadable fats

require names like 'butter' or 'margarine' to be used for particular product categories. The name 'natural mineral water' must be used to describe this water. The Food Labelling Regulations, as amended, also require the name used for melons and potatoes to include or be accompanied by an indication of their variety e.g. Honeydew melon or Maris Piper potatoes. The name used for vitamins sold as a food must be one of those specified in Table A of Schedule 6 e.g. Niacin, Biotin etc.

2.2.1.2 Reserved Descriptions

Legal names include reserved descriptions i.e. those foods that must meet specific compositional criteria (e.g. such as sausages, coffee, chocolate, jam and sugar for which there are specific regulations).

In addition <u>Schedule 8</u> of the Food Labelling Regulations lists words and descriptions that may only be used to describe a food meeting specified conditions detailed in Column 2 of that schedule e.g. dairy ice-cream, milk.

2.2.1.3 Customary Name (Regulation 7)

Where there is no legal name for a food, a customary name may be used. Customary names are names which, in time, come to be accepted by consumers in the UK, or in particular areas of the UK,. Examples include 'fish fingers' and 'Bakewell tart'. Some names of foreign origin, such as 'muesli' and 'spaghetti' have also become customary names in the UK generally.

A name which is customary in a particular area (e.g. 'bakery products' such as bridie, bap, morning roll) might not be understood on its own if it is used as the name for the same food when it is sold outside that area. Consideration will therefore need to be given to whether or not further supplementary information describing what the food is (see paragraph 2.2.1.4) needs to be provided.

A fancy name, with an accompanying description, may (in time) become acceptable as a customary name (e.g. 'Mississippi Mud Pie'), possibly without the necessity of an accompanying description.

2.2.1.4 Descriptive Name (Regulation 8)

Where there is no customary name, or it has not been used, then the name of the food must be sufficiently precise to indicate the true nature of the product and to distinguish it from other foods with which it could be confused. 'True nature' means a clear and accurate description of the characteristics of the food. A detailed description including all the main ingredients is not required. For example in the case of a 'Cheese and Tomato Quiche', the term 'quiche' is not sufficiently precise to inform the purchaser of the true nature of the food. The name of the food would, therefore, need to be accompanied by the descriptive name 'cheese, tomato with egg encased in short crust pastry'.

2.2.1.5 Protected Food Names

It is important to be aware that certain food names are protected within individual Member States of the European Community. The food must meet certain compositional or manufacturing standards that can be met in the country of origin. The EC rules governing these types of food are

Protected designation of origin / Protected geographical indication

- Regulation (510/2006) on geographical indications and designations of origin
- Implementing Regulation (1898/2006)
- Amending Regulation (417/2008) adding cotton and salt to the list of eligible products
- Amending Regulation (628/2008)

Traditional speciality guaranteed

- Regulation (509/2006) on traditional specialities
- Implementing Regulation (1216/2007)

The rules allow for 3 types of registration-

PDO (Protected Designation of Origin)

PDO means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff: originating in that region, specific place or country, and possessing quality or characteristics which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production, processing and preparation of which take place in the defined geographical area. e.g. Buxton Blue Cheese or Orkney lamb.

PGI (Protected Geographical Indication) means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff: originating in that region, specific place or country, and which possesses a specific quality or reputation or other characteristics attributable to that geographical origin, and the production and/or processing and/or preparation of which take place in the defined geographical area.

The geographic link is deeper for PDOs than for PGIs.e.g. Dorset blue cheese or Scottish farmed lamb or Armagh Brambley apple pie filling.

TSG (Traditional Speciality Guaranteed)

Where this applies a logo is used for products with distinctive features which either have traditional ingredients or are made using traditional methods. Among the product names in this group are *'Kalakukko'* bread, *'Jamón Serrano'* and *'Kriek'* beer. These have been registered following requests from Finland. Spain and Belgium

respectively however they can be used by any producer who follows the same specification. Their 'specific' character refers to the feature or set of features which distinguish them clearly from other similar products or foodstuffs belonging to the same category. This is covered by separate specific Commission regulations.

http://ec.europa.eu/agriculture/publi/fact/quality/2007_en.pdf

The European Commission keeps an up to date register of all products that have been recognised in this way. Details can be found on the <u>Europa website</u>.

2.2.1.6 Additional Specific Requirements with regard to the Name of a Food

- Trademarks, Brand Names or Fancy Names (<u>Regulation 10</u>)
 Trademarks, brand names or any fancy names cannot be substituted for the name of a food, but may be used in addition to it.
- Processes and treatments (<u>Regulations 11</u> and <u>Schedule 2</u>)
 Dried, Frozen, Pasteurised etc

The name of a food must include, or be accompanied by, an indication of its physical condition or treatment e.g. dried, frozen, concentrated or smoked, where a purchaser could be misled by the omission of that information. For example, milk that has been 'pasteurised', 'sterilised', 'condensed', 'UHT' treated, should indicate this on the label. In addition, other descriptions may apply, e.g. 'homogenised'. The omission of information about the previously frozen status of meat and offal, which is sold thawed, could mislead the consumer.

Breaded, Sliced or diced terms

Fish products incorporating minced fish (e.g. 'breaded scampi') may need to carry an appropriate indication on the label in cases where the consumer is likely to be misled, either by the general appearance of the food itself or its labelling, by the omission of such an indication.

Fruit and vegetables (e.g. melon, cucumber, cabbage, pineapple) that have simply been cut in half and sold to the consumer in clear plastic film or other transparent packaging need not indicate this as a treatment. If such products have been sliced, diced or otherwise further processed, this must be indicated (e.g. 'sliced beetroot' or 'shredded cabbage').

Tenderised or irradiated

There are specific requirements for meat tenderised by the use of proteolytic enzymes and irradiated food. The name used for any meat treated with protelytic enzymes must be included in or accompanied by the word 'tenderised' (Regulation 11 (2) and schedule 2).

The name of food that has been irradiated must include or be accompanied by the word 'irradiated' or the words 'treated with ionising radiation' (Regulation 11(2) and schedule 2) (See also Statutory rules dealing with irradiated foods).

Use of terms like 'roasted', 'smoked' etc

<u>FSA Food Labelling Guidance Notes</u> provide practical examples on terms which can be easily abused e.g. smoked and roasted.

Consumers may not necessarily associate roasting with a process involving a high proportion of steam cooking, followed by a short period of flash roasting and then the application of colour to simulate traditional roasting. However, it is important to recognise that many foods are steamed or parboiled before being roasted (e.g. potatoes, poultry). Where such products have been roasted for sufficient time at a sufficient temperature to have the appearance, colour and texture of a roasted product, further elaboration of the cooking processes may not be necessary.

A product which has simply been immersed in, or sprayed with, a solution which imparts flavour and colour has not been 'smoked', although it may be described as 'smoke flavoured'.

Fish which has been de-boned and frozen into blocks before being sliced may need to be distinguished from fish which has been 'filleted' in the traditional manner. Similar issues would arise if a food company used the term 'chargrilled' for an uncooked product which has been branded with grill lines. The word chargrilled implies that the product has been subjected to a specific cooking process.

Where these and other similar terms are used, it is important to ensure that an accurate indication of the process or treatment is given, where not to do so could result in consumers being misled. Alternatively a different or more appropriate indication or description of the process or treatment could be used.

Use of terms such as fresh, pure, natural

FSA have produced guidance notes on a number of specific terms used to describe foods to assist:

- Manufacturers, producers, retailers and caterers to decide when these descriptions could be used
- Enforcement authorities to challenge inappropriate uses
- Consumers, by adopting consistent, transparent labelling Issues

The terms include references to descriptive words including Fresh, Natural, Pure, Traditional, Original, Authentic, Home-made, Farmhouse. Such terms should not be applied to foods that have been subject to some form of processing or treatment.

FSA Guidance Notes - Criteria for the use of the terms fresh, pure, natural etc. in food labelling

2.2.2 List of Ingredients

2.2.2.1 Foods which do not require a list of ingredients

The majority of manufactured foods are required to have a list of ingredients, however, Regulation 18 lists a number of exemptions to this requirement:-

- Fresh fruit and vegetables which have not been peeled or cut
- Carbonated water
- Vinegar derived from fermentation
- Cheese, butter, fermented milk, and fermented cream to which no ingredient has been added other than those essential to its manufacture
- Flour to which no substance has been added other than those permitted by the Bread and Flour (Scotland) Regulations 1998
- Drink with an alcoholic strength by volume greater than 1.2%
- Any single ingredient food where;
 - The name of the food is identical to the name of the ingredient and
 - The name of the food enables the nature of the ingredient to be identified.

Other foods may be exempt from having a list of ingredients because of the conditions in which they are sold e.g. pre-packed for direct sale or in small packages (less than 10cm²) (Regulation 26)

These exemptions do not apply to irradiated ingredients, additives used to serve the fuction of an antioxidant, colour, flavouring, flavour enhancer, preservative or sweetener, genetically modified ingredients or to the allergenic ingredients listed in Schedule AA1 or their derivatives, where the name of the allergenic ingredient is not clearly identified in the sales name of the food. Pre-packed for direct sale foods are exempt from allergen labelling.

Where an ingredient list is provided voluntarily for any of the foods that are exempt, then the list of ingredients must comply with the requirements of the Food Labelling Regulations.

2.2.2.2 Heading of list of ingredients (Regulation 12)

The list of ingredients must be preceded or headed by the word 'ingredients' or a sentence heading which would include the word 'ingredients'. Abbreviations such as 'Ing' are unacceptable.

With vinegar, cheese, butter, fermented milk and fermented cream, if an ingredient is added to any of these foods then it needs to be named in the ingredient list. The heading of the ingredient list must state 'added ingredients'.

2.2.2.3 Order of ingredients (Regulation 13)

Where a food is marked or labelled with a list of ingredients, the ingredients have to be listed in descending order of weight at the time of their use in the preparation of the food i.e. the mixing bowl stage.

The following are a number of exemptions to this requirement:-

- Water and volatile products when used as an ingredient of a food have to be listed in the order of their weight in the finished product. The weight of water or volatile products is calculated by deducting the total weight of the food from the total weight of the other ingredients used.
- Where an ingredient is used in a food in a concentrated or dehydrated form and during the preparation of the food is reconstituted, the ingredient name may be placed in the list of ingredients in the order of weight before dilution or hydration.
- Where a food is in a concentrated or dehydrated form and it has to be
 reconstituted by the addition of water, its ingredients may be listed in descending
 order of weight when reconstituted as directed. The heading of the list of
 ingredients must include or be accompanied by the words 'ingredients of the
 reconstituted product' or 'ingredients of the ready to use product' or another
 similar indication.
- Where a food consists of or contains mixed spices or herbs and no particular spice or herb predominates significantly by weight then these ingredients may be listed as:
 - (a) In the case of food which consists entirely of such a mixture, the heading of the list of ingredients includes or is accompanied by the words 'in variable proportion' or other words indicating the nature of the order in which the ingredients are listed: and
 - (b) In the case of a food which contains such a mixture, that part of the list where the names of these ingredients appear accompanied by the words 'in variable proportion' or other words indicating the nature of the order in which these ingredients are listed.
- Ingredients which form less than 2 per cent of a food may be listed in a different order after the other ingredients.
- In the case of ingredients which are:
 - (a) Similar or mutually substitutable;
 - (b) Are likely to be used in the preparation of a food without altering its nature or its perceived value:
 - (c) Are not additives, allergenic ingredients or ingredients originated from an allergenic ingredient specified in Schedule AA1 and:

(d) Form less than 2 per cent of the finished product,

These ingredients may be referred to in the list of ingredients by the phrase 'contains and/or' where at least one of no more than two of these ingredients are present in the food.

2.2.2.4 Names of ingredients (Regulation 14(1) - (4) and Schedule 3)

Regulation 18 of the Food Labelling Regulations provides exemptions for ingredients that do not need to be in a list of ingredients. These are:

- Components of an ingredient temporarily separated during manufacture and later reintroduced e.g. the yolk and white of an egg need not be identified separately in the ingredient list if they were separated during manufacture. The ingredient list of the food would declare 'egg'. However, additional egg yolk or egg white would need to be separately declared.
- An additive that is present due to the fact that it was contained in an ingredient if
 it serves no significant technological function in the food.
- An additive used solely as a processing aid
- Any substance other than water used as a solvent or carrier for an additive
- Any substance which is not an additive used in the same way and for the same purpose as a processing aid.

These exemptions do not apply to irradiated ingredients. Neither do they apply to the allergenic ingredients listed in Schedule AA1 or their derivatives, where the name of the allergenic ingredient is not clearly identified in the sales name of the food.

Use of abbreviations

Regulation 14 requires the name used for an ingredient to be a name which could be used for it if it was being sold as a food by itself (see previous section on 'name of the food') and should, therefore include an appropriate reference to the physical condition or to any process or treatment which it has undergone, in cases where omission of this information would mislead the purchaser. Abbreviations for ingredients are unacceptable e.g. 'bic soda'. The correct name would be 'bicarbonate of soda'. The use of the term 'flour' or 'plain flour' also needs to be expanded bearing in mind the need to draw attention to allergens e.g. 'Wheat flour'.

Generic names

Certain category or generic terms (e.g. 'vegetable oil', 'cheese', 'sugar' and 'fish') may be used instead of more specific names for the purposes of naming ingredients of foods only. The use of generic terms is subject to certain conditions which are set out in Schedule 3 to the Regulations. Generic names are also subject to the allergen labelling rules (regulation 34B).

Schedule 3 was amended to include the generic name 'meat'.

The generic name 'meat' must be accompanied by the name of the animal species or a word which describes the meat referring to the animal species. 'Meat' excludes mechanically separated meat (MSM). When MSM is included in a food it must be labelled separately and not included as part of the meat content of a meat product.

Maximum fat and connective tissue content for ingredients designated by the term meat is given in the table below.

Species	Fat (%)	Connective Tissue (%)
Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating.	25	25
Porcines	30	25
Birds and rabbits	15	10

Although the category terms 'vegetable oil', 'vegetable fat', 'animal oil' and 'animal fat' all appear as separate entries in schedule 3, this does not prevent the use of indications which combine these terms in a way which makes their intention clear to the consumer, e.g. 'vegetable and animal oils', 'vegetable oils and fats' or 'vegetable and animal oils in varying proportions'. Terms like 'cooking oil', 'Veg fat' would not be acceptable where the source is allergenic. Therefore, the specific source of the vegetable oil needs to be indicated e.g. peanut oil or sesame oil to draw attention to the allergen content.

2.2.2.5 Flavouring

EC Regulation 1334/2008 is enforced by The Flavourings in Food (Scotland) Regulations 2010 (SSI No. 439)

Flavouring as defined in the Regulations means:-

An additive consisting of material used or intended for use in or on food to impart odour, taste or both, provided that such material does not consist entirely of

- (a) any edible substance (including herbs and spices) or product, intended for human consumption as such, with or without reconstitution, or
- (b) any substance which has exclusively a sweet, sour or salt taste and the components of which include at least one of the following:
 - (i) a flavouring substance
 - (ii) a flavouring preparation
 - (iii) a process flavouring
 - (iv) a smoke flavouring

Where flavouring is added or used in a food, it must be identified by either the word 'flavouring' or a more specific name or description of the flavouring. The word 'natural' or another word with the same meaning may be used where the flavouring component of an ingredient consists only of specific naturally derived flavouring substances or a flavouring preparation, or both.

Quinine or caffeine when added to or used in food as a flavouring must be referred to in the list of ingredients as 'flavouring: quinine' and 'flavouring: caffeine'.

Annex 1 of Regulation 1334/2008 on flavourings, authorised flavouring substances list is ongoing and not complete.

2.2.2.6 Additives listing (Regulations 2, 14 and Schedule 4)

Additives are substances not normally consumed as a food or as a characterising ingredient of a food. They are added to food to serve a technological function and thereby become either directly or indirectly a component of the food.

Schedule 4 of the Food Labelling Regulations lists categories of ingredients which must be identified in a list of ingredients by their category name:-

Schedule 4 Categories of Ingredients Food Additive Functional Classes

Acid² Flour treatment agent

Acidity regulator Gelling agent Anti-caking agent Glazing agent Anti-foaming agent Humectant Modified starch³ Antioxidant Packaging Gases Bulking agent Carrier Preservative Colour Propellant gas Raising agent Emulsifier **Emulsifying salts** Sequestrants Firming agent Stabiliser

Firming agent Stabiliser
Flavour enhancer Sweetener
Thickener

Regulation 14(9) of the Food Labelling Regulations requires that, where an additive is added or used in a food to serve the function of one of the categories of additives in Schedule 4, it must be identified by the category name followed by the additives specific name or serial number (e.g. colour E160(a)).

Although the category names listed in Schedule 4 are shown in the singular (e.g. 'preservative'), this does not prevent additives which perform the same function in a food from being grouped together for ingredient listing purposes (e.g. preservatives: x, y and z, colours: a, b and c...).

Any other additive which is added to or used in a food that is not a flavouring and does not serve a function of one of the categories in schedule 4 must be identified by its specific name.

² In the case of an additive which is added to a food to serve the function of an acid and whose specific name includes the word 'acid' it shall not be necessary to use the category name.

³ Neither the specific name nor the serial number is required to be indicated. However, this category name must be accompanied by an indication of its specific vegetable origin, where that ingredient may contain gluten.

'Specific Names' and 'Serial Numbers' for Additives

Details of these can be found in the annexes of the following EC Directives:-

- Council Directive 95/2/EC on food additives other than colours and sweeteners
- Council Directive 94/36/EC on Colours for use in foodstuffs
- Council Directive 94/35/EC on Sweeteners for use in foodstuffs.

Regulation EC 1333/2008 on Food Additives re-enact, on a temporary basis, the Annexes to Directive 95/2/EC, 94/35 and 94/36 the above three directives

Regulation EC 1332/2008 on Food Enzymes

Specific Name used for an Additive

Where the specific name of an additive is to be given in the ingredients list, the name used should be one which is set out in the annexes to the aforementioned directives that are enacted in national legislation by the Food Additives (Scotland) Regulations 2009 (SSI 436/2009).

A summary name which appears in one of the annexes may be used in place of a more specific name provided that the latter does not have its own serial numbers (e.g. 'carotene' may be used for 'mixed carotenes'; 'sorbitol' may be used for 'sorbitol syrup'; 'sodium citrate' may be used for 'disodium citrate'; 'potassium phosphate' may be used for 'tripotassium phosphate').

The FSA Food Labelling Guidance Notes provide recommendations on the wording of certain specific additive names. If a name which appears in one of the annexes is preceded by a bracketed letter or Roman numeral (e.g. (ii) 'Beta carotene'; (i) 'Sorbitol'; (i) 'Monosodium citrate'), this need not be given as part of the name.

In the case of miscellaneous additives, where an alternative to the specific name is given in brackets in one of the annexes this may be used in place of the specific name (e.g. 'polysorbate 20' instead of 'Polyoxyethylene sorbitan monolaurate').

In the case of miscellaneous additives being phosphates, the names 'Diphosphates', 'Triphosphates' and 'Polyphosphates' are acceptable as specific names for the phosphates covered by the serial numbers E450, E451 and E452 respectively. They should not be used for the phosphates covered by serial numbers E338, E339, E340, E341 and E343.

Synonyms or acronyms which are not included in the relevant schedule should not be used as alternatives to the specific name.

Serial Number used for an Additive.

Where the serial number of the additive is to be given in the ingredients list the number used should be one which appears in the column headed 'E No' in the annexes.

Although some ingredients, such as sugar, coffee, salt, banana, concentrated fruit juice, vinegar etc., may serve sweetening, colouring, preserving, flavouring and other 'additive' functions, these do not need to be accompanied by a category name in the ingredients list because they are not 'additives' as defined by the regulations.

Other substances which might appear to fall within the definition of 'additive' but which are not considered to be additives include

- Vitamins, minerals or other nutrients used solely for the purpose of fortifying or enriching food, or for restoring the constituents of food;
- Any substance present in a food as a result of its addition to animal, bird or fish feedingstuff's: and
- Any substance present in food as a result of its use in a process or treatment carried out in crop or animal husbandry, or storage (including any pesticide, fumigant, sprout depressant or veterinary medicine).

2.2.2.7 Compound Ingredients (Regulation 15)

A compound ingredient is an ingredient of the food that is made up itself of two or more ingredients e.g. mayonnaise, bread, biscuit. The name of the ingredients of the compound ingredient must be given in the list of ingredients of the food. The name of the compound ingredient may be given in addition to its ingredients. Where the name of the compound ingredient is given the names of its ingredients must immediately follow in such a way to make it clear that they are ingredients of that compound ingredient (e.g. 'mayonnaise, (eggs, oil, water, salt.').) In this case the compound ingredient will be listed in descending order of weight of the food followed immediately with its ingredients.

Where the names of the ingredients only are given, these ingredients must be listed individually in descending order of weight of the ingredients of the food. In this case there may be repetition of the ingredients in the list of ingredients of the food, e.g. sugar may be an ingredient of the food and it may also be contained in the ingredients of a compound ingredient forming part of that food.

The following categories are where the ingredients of a compound ingredient do not require to be listed:-

- (a) The compound ingredient would not be required to bear a list of its ingredients if it were sold as pre-packed food.
- (b) The compound ingredient has a generic name (schedule 3) e.g.cheese
- (c) The compound ingredient is made up of a mixture of spices and herbs or both and forms less than 2% of the food; or

(d) The composition of the compound ingredient is defined in other specific Community Food Labelling Legislation and forms less than 2% of the food (e.g. spreadable fats, fruit, jams, chocolate)

In the case of (c) and (d) above:

- only additives present must be named (if they perform significant technological functions) immediately following or in close proximity to the name of the compound ingredient.
- However these exemptions do not apply to allergenic ingredients listed in Schedule AA1 or their derivatives, where the name of the allergenic ingredient is not clearly identified in the name of the food.
- If any ingredients within the compound ingredient have been irradiated, the name of the ingredient and the words 'irradiated' or 'treated with ionising radiation' must be given (herbs and spices are permitted to be irradiated).

2.2.2.8 Added Water (Regulation 16)

Water which is added as an ingredient of a food must be identified in the list of ingredients.

However it does not require to be declared if:-

- It is not in excess of 5% of the finished product
- It is used solely for the reconstitution of an ingredient used in concentrated or dehydrated form.
- It is used or forms part of a medium which is not normally consumed.

Water need not be declared in the list of ingredients if it is added to frozen or quick frozen chicken carcasses in accordance with Community Regulation (EEC) No 1538/91, (as amended) and does not exceed the limits specified in that Regulation. Where this is exceeded, the amount of added water will need to be declared on the label, in addition to the words 'water content exceeds EC limit'.

2.2.3 Quantities of Certain Ingredients or Categories of Ingredients

2.2.3.1 Quantitative Ingredient Declarations (QUID)

In 1998, an amendment to the Food Labelling Regulations 1996 brought about the requirement to quantify certain ingredients or categories of ingredients.

2.2.3.2 Scope of the QUID Requirement

QUID principally applies to all food, including drink, with more than one ingredient. The requirements contain some exemptions:-

The requirements do not apply to products not otherwise covered by Food Labelling Regulations 1996, as amended.

- Foods not required to carry an ingredients list are not in principle exempt from QUID declarations.
- The requirements do not affect the labelling of non pre-packed and pre-packed for direct sale foods (including those sold at catering establishments), food sold in small packages or certain indelibly marked glass bottles, or the information provided on the front of vending machines,
- A QUID declaration will not apply to constituents naturally present in foods which have not been added as ingredients. Examples are caffeine (in coffee), vitamins and minerals (in fruit juice),
- A QUID declaration will not apply to foods which, although mentioned in the name of a food, have not been used in its manufacture or preparation, examples are 'cream cracker' - a customary name used to describe a dry biscuit which never contains cream, or 'chicken flavour crisps' - where the chicken flavour comes from one or more ingredients which are not chicken.

<u>Regulation 19</u> requires that the quantity of an ingredient or category of ingredients must be indicated where:

- (a) The ingredient or category of ingredients appears in the name of the food or is usually associated with the name by the consumer.
- (b) The ingredient or category of ingredients is emphasised on the labelling words, pictures or graphics, or
- (c) The ingredient or category of ingredients is essential to characterise a food and distinguish it from products where it might be confused.

2.2.3.3 Products to which the QUID Requirements do not apply

There are exemptions to this requirement. These are:

- (a) In respect of an ingredient or category of ingredients -
 - The drained net weight which is indicated in accordance with Article 8 (4) of Directive 2000/13/EC, e.g. tinned carrots in brine.
 - The quantities of which are already required to be given on the labelling under other EC Measures (i.e. fruit juices and similar products, fruit jams, jellies, marmalades and chestnut puree and spreadable fats).
 - Ingredients which are used in small quantities for the purposes of flavouring
 - Though it appears in the name of the food the quantity of the ingredient does not govern consumer choice as the ingredient is not essential to characterise the food.
- (b) Where specific EC provisions stipulate precisely the quantity of an ingredient or category of ingredients, without providing for the indication of such on the label. Currently there are no foodstuffs in the UK which fall within this category.
- (c) Foods which contain either a mixture of vegetables, fruit or nuts, or mixtures of spices or herbs and not one ingredient predominates significantly by weight.
- (d) The requirements of (1) and (2) given above shall not apply to:
 - Any ingredient or category of ingredients covered by the indication 'with sweetener(s)' or 'with sugar(s) and sweeteners(s)' if that indication is required to accompany the name of the food; or
 - Any added vitamin or mineral if that substance is the subject of nutrition labelling to the food in question, i.e. those vitamins and minerals detailed in schedule 6 of the Food Labelling Regulations.

The indication of quantity of an ingredient or category of ingredients must be expressed as a percentage. The percentage must be calculated at the time of use in the preparation of the food and needs to be indicated in or next to the name of the food or in the list of ingredients adjacent to the ingredient or category of ingredients in question.

2.2.3.4 Formula used to calculate QUID

For foods that require further processing

QUID % = Wt. Ingredients at mix bowl
Total Wt. Of all ingredients at mixing bowl

For foods that have been thermally processed

QUID % = Wt. Ingredients at mix bowl
Total Wt. After product processing

Exemptions to the requirement to express the ingredient as determined at the time of use in the preparation of the food are:

- (a) Where the food has lost moisture as a result of treatment e.g. baking, cooking, the percentage should be calculated as the quantity of the ingredient at the mixing bowl stage expressed as a percentage of the weight of the finished product. Where the total quantity of the ingredient indicated exceeds 100%, the indication of quantity should be based on the weight of ingredient or category of ingredients used to prepare 100 grams of the finished product.
- (b) A declaration for a volatile ingredient must be based on the basis of its proportion by weight in the finished product.
- (c) As with Regulation 13 of the Food Labelling Regulations, as amended, on determining the quantity of an ingredient which has been used in concentrated or dehydrated form and which is reconstituted during preparation of the food, it may be on the basis of its preparation by weight before concentration or dehydration.
- (d) Where the food is in a concentrated or dehydrated form and it is intended to be reconstituted by the addition of water as on the label, the declaration of its proportion by weight in the food when reconstituted as directed, e.g. dried soup mixes.

2.2.3.5 Position of QUID declaration

The declaration must appear either in or next to the name of the food, or in the product ingredient list beside the ingredient or category of ingredient. If the category of ingredient is not listed in Schedule 3 of the Food Labelling Regulations (i.e. it is therefore not a generic name) the QUID may appear in the list of ingredients in association with the category of ingredients provided the constituent ingredients are also listed. A more detailed account of the application of the QUID rules is provided in the Agency guidance.

The official FSA guidance notes on Quantitative ingredient declarations (QUID) The guidance includes details on

- the practical implications of this requirement and provide extensive guidance on their implementation
- when to make QUID declarations
- position of QUID declaration
- circumstances when QUID is triggered
- manner of expressing QUID
- calculations of QUID

2.2.4 Appropriate Durability Indication

2.2.4.1 Date marking provisions (Regulations 20 - 22)

Regulation 22 specifies foods which are exempt from the requirement to carry a date mark. These are:

- Fresh fruit or vegetables (not including sprouting seeds, legume sprouts and similar products) that have not been peeled or cut into pieces.
- Wine, liqueur wine, sparkling wine, aromatised wine and any similar drink.
- Any drink made from grapes or grape musts and coming within codes 2206 00 39, 2206 00 59 and 2206 00 89 of the Combined Nomenclature given in Council Regulation (EEC) No.2658/87 on the tariff and statistical nomenclature and on Common Customs tariff, as amended.
- Any drink with an alcoholic strength by volume of 10% or more.
- Any soft drink, fruit juice or fruit nectar or alcoholic drink sold in a container of more than 5 litres (i.e. intended for catering premises).
- Flour confectionery and bread normally consumed within 24 hours of preparation.
- Vinegar
- Cooking and table salt.
- Solid sugar products and products consisting almost entirely of flavoured or coloured sugars.
- Chewing gums and similar products.

• Edible ices in individual portions.

In addition some foods are exempt from the date marking requirement because they are exempt generally from the labelling provisions of Part II of the Regulations (see regulation 4).

Other foods are also exempt from carrying a date mark because of the conditions in which they are sold e.g. pre-packed for direct sale (see Section 2.2.7 on Omission of Certain Particulars).

There are two types of durability indication:

- Best before: will be appropriate to most foods and indicates the period for which
 a food can reasonably be expected to retain its optimum condition (e.g. it will not
 be stale), if stored properly; and
- Use by: is the required form of date mark only for those foods that are highly perishable from a microbiological point of view and will have a short shelf life after manufacture, after which their consumption would present a risk of food poisoning.

2.2.4.2 Form used for the 'best before' date mark Regulation 20(1) and (2)

The best before date mark consists of the words best before and the date in terms of the day, month and year as shown in the table below:-

Shelf Life	Form of Date Mark
for foods expected to keep for 3 months or less:	the words best before may be followed by the date in terms of the day and month
for foods expected to keep for more than 3 months but no longer than 18 months:	the date mark may be given in the form best before end and the date in terms of the month and year
for foods expected to keep for more than 18 months:	the date mark may be shown as best before end followed by the date in terms of the month and year or the year only

Where appropriate, any storage conditions which need to be observed if the food is to retain its specific properties until the date shown must also be given.

2.2.4.3 Form used for the 'use by' date mark (Regulation 21(1) and (2))

The use by date mark must consist of the words use by and the date in terms of either:

- the day and the month, or
- the day, month and year

and, in either case, should be accompanied by any storage conditions which need to be observed. e.g. 'Keep refrigerated - store at 5 degrees centigrade'

2.2.4.4 Flexibility in application (Regulations 20(3) and 21(3))

The actual date, and/or any storage conditions given as part of the date marking requirement, may appear separately from the words best before, best before end or use by provided these words are followed by a reference to the place where the date and/or any storage conditions appear(s) (e.g. Best before end: see side of pack).

In some cases, it might be more helpful to consumers to have information about the location of the storage conditions given with the date itself rather than with the words best before, best before end or use by. So for example, instead of the indication on the front of the pack consisting of:

for best before date see side of pack and for storage conditions see star marking panel

An alternative might be a declaration on the front of the pack consisting of

for best before date see side of pack

With the information given on the side of the pack consisting of the date, and the declaration 'for storage conditions see star marking panel.'

2.2.4.5 Abbreviation of Indication of Minimum Durability Details

Provided the date is shown in the order required by the regulations (i.e. day, month, year, as appropriate), there is no reason why different forms of expressing the date cannot be used, provided it is given in a form which consumers are going to understand. For example, *1 January 2007*,

31 Mar 07, 1.6.07 and 01.08.07 are all guite clear.

Care should be taken when using abbreviated indications, such as use by 1.6; consumers who might not realise that a use by date must be given in at least day and month form might misread this particular example to mean use by 16th and ask 'use by 16th of what?'. In such cases, it would be preferable to use the form use by 1 June, use by 1 Jun or use by 01.06. Care also needs to be taken when giving year-end date marks, e.g. best before end 2007 or best before end 07, although acceptable, might be misread by consumers to mean best before end July.

2.2.4.6 Foods that should carry a 'Use By' Date

Use by dates are generally applied to foods that are highly microbiologically perishable and in consequence likely after a short period of time to pose an imminent danger to public health.

Foods that need use by dates are those that have to be stored at low temperatures to maintain their safety rather than quality. They tend to have a short product life after manufacture after which their consumption may present a risk of food poisoning.

Foods that need use by dates will fall into one of two groups

- Foods which at ambient or chill temperature are capable of supporting toxin formation or multiplication of pathogens to a level that would lead to food poisoning if they were not properly stored.
- Foods intended for consumption without cooking or after treatment (e.g. reheating) unlikely to be sufficient to destroy food poisoning organisms which may be present.

In consequence, foods that generally need a use by date include

- Dairy products (unless the ph of the product would prevent the growth of pathogens or toxin formation, or some other effective preservative mechanism is in place)
- Cooked products
- Smoked or cured fish
- Smoked or cured ready to eat meat which is not shelf stable at room temperature
- Prepared ready to eat foods
- Uncooked or partly cooked pastry and dough products

2.2.4.7 Storage conditions given with the date mark (<u>Regulations 20(1)</u> (b) and <u>21(1)</u> (b))

Only storage conditions that need to be observed so that the unopened food lasts until the date given in the date mark need be given as part of the date mark (see paragraphs 2.2.4.2 and 2.2.4.3). They should in general be simple and clear, and may vary from indications such as *keep refrigerated* or *keep in a cool, dry place* to indications that incorporate specific storage temperatures or temperature ranges. A maximum temperature should be given at or below which the food should be stored if strict storage temperatures are required to maintain its safety as well as its quality up to and including the date specified. Where various storage conditions are

permissible (e.g. fridge, freezer compartment or freezer) the storage conditions should make clear to which option the date given refers (e.g. *when stored in a refrigerator or if kept frozen*). Both the date and its related storage conditions should apply to the food as bought by the consumer whilst it remains unopened.

2.2.4.8 Sale of Food with expired shelf life (Regulation 44(1)(d))

It is an offence to sell food that has exceeded its 'use by date' however, selling a food after its "best before date" is not. Whilst it may not be an offence under the Food Labelling Regulations, the enforcement officer may wish to point out to a retailer that the food may not possess the required quality outside the shelf life and could result in a complaint being received of food failing to comply with Section 14 of the Food Safety Act.

2.2.4.9 Alteration of Date Marks (Regulations 44(1) (e) and 46)

It is an offence to alter or remove a date mark if the person making the alteration is not the manufacturer, packer or seller within the EC, originally responsible for marking the food.

Regulation 46 provides a defence for anyone so charged to prove that such action was taken with the written authorisation of a person capable of either altering or removing the date mark without contravening Regulation 44(1)(e). In retail shops enforcement officers should check to ensure that the practice of using coloured flash stickers to promote sales and price reductions does not conceal important date coding information.

2.2.5 Special Storage Conditions and Conditions of Use and Instructions for use

2.2.5.1 Meaning of 'Special Storage Conditions or Conditions of Use'

Special storage conditions or conditions of use should be given:

- If the consumer needs to observe certain practices once the packaging of a food has been opened (e.g. 'once opened keep refrigerated and consume within 3 days');
- If various options are available (e.g. 'suitable for home freezing'); or
- If foods are not appropriate or suitable for use in certain circumstances (e.g. 'not suitable for frying' or 'shake well before use').

The storage conditions that are required to be given with the date mark relate specifically to ensuring that the consumer knows how to store the food if it is to last as long as the date indicates while it remains unopened.

2.2.5.2 Instruction for use (Regulation 5)

Instructions for use must be given if it would be difficult to make appropriate use of the food without them.

Any instructions for use given should be sufficiently detailed to enable appropriate preparation or use to be made of the food i.e. the correct time/temperature given for the safe cooking of raw poultry meat or meat products.

The Institute of Grocery Distribution publication 'Voluntary Guidelines for the Provision of Food Safety Advice on Product Labels' provides some useful advice and guidance on:

2.2.5.3 Name and Address (Regulation 5)

Regulation 5 requires the name or business name and address or registered office of either or both of:

- (a) The manufacture or packer or
- (b) A seller established within the EC

The details provided for the address should be sufficient to enable the purchaser to contact the business. Therefore, providing the postcode only would be acceptable if this is sufficient information to reach the addressee.

2.2.6 Origin

2.2.6.1 Origin Labelling - (Regulation 5)

Regulation 5(f) of the **Food Labelling Regulations 1996**, as read with regulation 4, requires food that is ready for delivery to the ultimate consumer or to a catering establishment to be marked or labelled with particulars of **the place of origin or provenance** of the food if failure to give such particulars might mislead a purchaser to a material degree as to the true origin or provenance of the food. Place of origin should not be confused with 'Country of Origin' for which there is separate and specific legislation.

The Food Standards Agency has produce the following Guidance - FSAS Consumer Guide to Country of Origin Information on Food Labels

- Food (other than milk) which is not pre-packed, or which is pre-packed for direct sale, including such foods sold at catering establishments;
- White bread and flour confectionery in certain circumstances;
- Individually wrapped fancy confectionery products not enclosed in any further packaging and which are intended for sale as single items;
- Any pre-packed food (other than milk) contained in an indelibly marked glass bottle intended for re-use that has no label, ring or collar;
- Food contained in packaging the largest surface area of whose packaging has an area of less than 10 square centimetres;
- Food sold or supplied in individual portions which are intended as a minor accompaniment to another food or service; and
- Carcasses and parts of carcasses that are not intended for sale in one piece.

There is no statutory definition of 'place of origin or provenance' in the Food Labelling Regulations 1996 or of 'origin or provenance' in the food labelling Directive 2000/13/EC. The words 'origin' and 'provenance' in the context of this advice should be taken as having the same meaning.

The approach taken in Section 36 of the <u>Trade Descriptions Act 1968</u> is that, for the purposes of that Act, goods are deemed to have been manufactured or produced in the country in which they last underwent a treatment or process resulting in a substantial change.

This is considered to be a reasonable working guide for the purposes of the Food Labelling Regulations 1996. It would ultimately be for a court to decide whether any particular country or place specified is indeed where the last substantial change took

place. Whilst it is likely, for example, that the transformation of pork into bacon, ham or pies might be regarded as a treatment or process resulting in a substantial change, this is less likely to be the case with the simple slicing, cutting and/or packing of meat.

2.2.6.2 Avoiding Misleading Labelling in Relation to Origin Labelling

The true place of origin of a food should always be given if the label, as a whole, would otherwise imply that the food comes from, or has been made in, a different place or area. Consumers are, however, unlikely to expect products such as Chelsea buns, York ham, Madras curry or Frankfurters to come from those areas in the absence of other material on the label suggesting that they do.

Where the label carries other material that may imply origin, the actual country of origin declaration must be sufficiently prominent, precise and compelling to correct any potentially misleading impression to avoid misleading consumers. The sort of information that could lead consumers to attribute a particular place of origin to a food include:

- Use of country or place names in the name of the food or in its trade name, brand name or fancy name;
- Written or illustrative material including maps, flags, emblems (like a shamrock), choice of colour (like the colours of a country's national flag), references to persons associated with a particular place (like 'John Bull', 'Uncle Sam') and famous landmarks (like the Eiffel Tower, Ben Nevis).

Identification marks applied to food to meet the requirements of European hygiene legislation are not in themselves intended to give an indication of place of origin. However, care must be taken to ensure that identification marks do not, by reason of their size, prominence or position, contribute to a misleading impression of the origin of the food.

Assurance scheme logos (like the British Farm Standard 'red tractor') are used to indicate that food has been produced to specified standards; they do not in themselves guarantee the origin of the product. Where the logo may imply origin, it is important that it is accompanied by a clear and equally prominent origin declaration.

The name and address of the manufacturer, packer or seller in the EC is a mandatory labelling requirement under EU rules. This information should not be provided in a way that incorrectly implies origin.

If the place of origin of the food is not the same as the place of origin of its primary ingredients, it may be necessary to provide information on the origin of those ingredients.

For example:

- Bacon or ham made in Britain using Danish pork should not be described as 'British bacon' or 'British ham' but could be described as '(imported) (Danish) pork (cured) (baked) (roasted) in Britain'.
- Pork sausages made in Britain using pork from countries outside the UK should not be described as 'British pork sausages' but could be described as 'made in Britain from (imported) (country of origin) pork (from more than one country)'.
- Salmon smoked in Scotland but made from Norwegian salmon should not be described as 'Scottish smoked salmon' but could be described as '(imported) (Norwegian) salmon smoked in Scotland'.
- Butter churned in England from milk brought in from outside the UK (e.g. Belgium) should not be labelled as 'English' or 'produced in England', but could be labelled as 'produced in England from (imported) (Belgian) milk'.

Other useful terms are 'baked in ...', 'pressed in ...', 'packed in ...', 'sliced and packed in ...' or 'processed in ...'.

Where food that is not pre-packed is presented with tickets, shelf markers or promotional displays indicating origin, care should be taken to ensure the origin claims are clearly worded and that only products to which the claim applies are presented or associated with those indications.

Avoiding Misleading Information in Catering Establishments

In catering establishments, care should be taken to ensure the wording of any origin information on menus etc. is clear and unambiguous. For more detailed information on origin labelling see <u>FSA Country of Origin Labelling Guidance</u>.

2.2.7 Omission of Certain Particulars

2.2.7.1 Pre-packed

Pre-packed, in relation to food, means put into packaging before being offered for sale in such a way that the food, whether wholly or only partly enclosed, cannot be altered without opening or changing the packaging and is ready for sale to the ultimate consumer or to a catering establishment. This description includes food that is wholly enclosed in packaging before being offered for sale, is intended to be cooked without opening the packaging and is ready for sale to the ultimate consumer or to a catering establishment. It does not include individually wrapped sweets, or chocolates that are not enclosed in any further packaging and are not intended for sale as individual items.

It does not include fruit and vegetables individually wrapped in plastic film wrap, provided that the plastic film wrap is used for the purposes of individual protection.

2.2.7.2 Pre-packed for direct sale (Regulation 2) is defined as:

- In relation to a food other than flour confectionery, bread, edible ices, cows' milk, pre-packed by a retailer for sale by him on the premises where the food is packed or from a vehicle or stall used by him;
- In relation to flour confectionery, bread and edible ices, pre-packed by the
 producer of the food for sale by him either on the premises where the food is
 produced or on other premises from where he conducts business under the
 same name as the business conducted on the premises where the food is
 produced; and
- In relation to cows' milk, put into containers on the premises where the milk is
 produced by the person owning or having control of the herd from which the milk
 is produced for sale by him on those premises or from a vehicle or stall used by
 him.

2.2.7.3 Flour confectionery (<u>Regulation 2</u>)

Flour confectionery means any cooked food ready for consumption without further preparation (other than reheating), of which a characterising ingredient is ground cereal, including shortbread, sponges, crumpets, muffins, macaroons, ratafias, pastry and pastry cases, and also includes meringues, petits fours and uncooked pastry and pastry cases, but does not include bread, pizzas, biscuits, crispbread, extruded flat bread or any food containing a filling which has as an ingredient any cheese, meat, offal, fish, shellfish, vegetable protein material or microbial protein material.

2.2.7.4 Labelling Requirement for Food which is not Pre-Packed or which is Pre-packed for Direct Sale - (Regulation 23, 24, 25 and 31)

Foods are exempt from the general labelling requirement of Regulation 5 (except the name of the food. (See section 2.2.1 on name of food)) if they are:.

- (I) Not pre-packed
- (II) Pre-packed for direct sale
 - (III) Any flour confectionery which is packed in a crimp case only or in wholly transparent packaging which may be marked only with the price and the lot mark.
 - (IV) Individually wrapped fancy confectionery products that are not enclosed in any further packaging and which are intended for sale as single items. Such confectionery might take the form of a figure, animal or cigarette.

This regulation does not apply to foods sold at catering establishments.

Milk which is pre-packed for direct sale must be marked with place of origin, if failure to provide this information could mislead the consumer as to the true origin of the food.

Meat products (as defined in Meat Products (Scotland) Regulations 2004) (as amended) sold not pre-packed or pre-packed for direct sale will in addition to the name of the food require an indication to the quantity of the meat ingredients (QUID declaration). Exemptions to this QUID declaration of specified meat products are limited in Schedule 4A of The Food Labelling Regulations 1996 as amended. These exemptions include sandwiches, pizzas, broth and gravy.

However, white bread, flour confectionery, carcasses and parts of carcasses not intended for sale in one piece and any food not exposed for sale that have not been irradiated do not need to be marked or labelled with any of the general food labelling requirements. In addition, they are not required to carry the additional declarations about packaging gases, sweeteners or skimmed milk with non milk fat required by Regulations 32, 33, and 34. It should be noted that flour confectionery and white bread which is not pre-packed, pre-packed for direct sale or is packed in wholly transparent packaging or in a crimp case only (unless irradiated) does not require to be marked or labelled with any of the general food labelling requirements including the name of the food.

Note: the definition of pre-packed for direct sale for the purposes of flour confectionery and bread includes the fact that it is prepacked by the manufacturer for sale either on the same premises of manufacture or on other premises under the same ownership and business name.

All foods within the scope of Regulation 23 that contain ingredients which have been irradiated must be marked or labelled with 'irradiated' or 'treated with ionising irradiation'.

There is no requirement to label non-pre-packed or pre-packed for direct sale foods with information on the presence of allergens as specified in Schedule AA1 of the Food Labelling Regulations. However the definition of food safety requirement (Article 14, 178/2002) must be considered with regard to food safety.

2.2.7.5 Non pre-packed foods and the presence of additives (Regulation 24)

Any food that does not have a list of ingredients because it is exempt from Regulation 23 (see section above) but contains any additive specified in Regulation 24, must be marked or labelled with an indication of the category of additive that is in the food. The specified categories of additives are antioxidant, colour, flavouring, flavour enhancer, flour treatment agents (by virtue of regulation 5b of Bread and Flour (Scotland) Regulations 1998), preservative or sweetener. Only the principal function of the additive present is required to be indicated.

In the case of edible ices and flour confectionery containing additives there is an exemption from the requirement to label the foods if there is a notice displayed in a prominent position stating that the products may contain the above mentioned categories of additives.

Example Notice

Flour confectionery sold in this shop may contain colour and flavourings.

There are a number of premises where officers might expect such a notice to be displayed e.g. bakeries and confectioners.

2.2.7.6 Food sold in small packages (Regulation 26)

This regulation does not apply to any food to which Regulation 23 (food sold non pre-packed or pre-packed for direct sale) or Regulation 27 (sold at catering establishments) applies.

Any pre-packed food, either contained in an indelibly marked glass bottle intended for re-use and having no label, ring or collar, or the largest surface of where packaging has an area of less than 10 square centimetres, needs only to be marked with a product name and if required, an appropriate durability indication (unless irradiated).

The Drinking Milk (Scotland) Regulations 2011 ensure that milk is sold or delivered subject to EU standards. However, the sale of raw milk in Scotland is prohibited by the Food Hygiene (Scotland) Regulation 2006 (Regulation 32 Schedule 6).

2.2.7.7 Certain food sold at catering establishments (Regulation 27)

Any food sold at a catering establishment and is not pre-packed or pre-packed for direct sale need not be marked with any of the particulars laid out in Regulation 5. Irradiated food requires to be marked or labelled with an indication of such treatment and include the word 'irradiated'.

2.2.7.8 Food Sold in Seasonal Selection Packs (Regulations 2 and 28)

Seasonal selection packs are packs that contain two or more different items of food wholly or partly enclosed in outer packaging decorated with seasonal designs. Provided the items of food contained within the seasonal selection pack are individually packed and have been marked or labelled in accordance with the regulations, there is no need for this information to be repeated on the outer packaging of the seasonal selection pack.

2.2.8 Additional Labelling Requirements (Regulation 29, 30, 31, 32, 33, 34)

There are specific additional labelling requirements in these regulations for certain categories of foods: (Regulation 29-34)

- foods containing colours listed in Annex V, EC 1333/2008 (Southampton Six)
- foods sold from vending machines
- pre-packed alcoholic drinks other than Community controlled wine
- products consisting of skimmed milk with non-milk fat
- food, the shelf life of which has been extended by the use of packaging gases,
- foods containing sweeteners, added sugar and sweeteners, aspartame or polyols
- drinks with high caffeine content
- confectionery and drinks containing glycyrrhizinic acid or its ammonium salt
- foods containing allergenic ingredients or their derivatives

Additional Labelling Requirements for the food colours as set out in Regulation 1337/2008

EC Regulation 1333/2008 on food additives (Article 24) and Annex V, contains a labelling requirement for foods containing one or more of the following food colours; sunset yellow (E 110), quinoline yellow (E 104), carmoisine (E 122), allura red (E 129), tartrazine (E 102), ponceau 4R (E 124).

The label must list the 'name or E number of the colour(s)' and that it may have an adverse effect on activity and attention in children.

Exemptions

The above requirements do not apply where the colour(s) has been used solely for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells.

In addition, alcoholic drinks over 1.2% alcohol volume do not need to carry the warning label.

More information is available in the <u>Guidance on the labelling of certain food colours</u> as set out in Regulation 1333/2008 on the FSA website.

2.2.8.1 Additional Labelling Requirements for Foods Sold from Vending Machines (Regulation 29)

Regulation 29 provides requirements in relation to the name of the food, abbreviated nutrition labelling, and re-heating instructions in relation to food sold from vending machines. Unless the name of a food can be clearly read from the outside of the machine then a notice must be displayed indicating the name of the food. In addition, for food that is not pre-packed but a nutritional claim is made, a notice giving the prescribed nutrition labelling should be given. For foods that require to be re-heated before being eaten, a notice must be given of the re-heating instructions if such instructions are not given on the packaging.

2.2.8.2 Additional Labelling Requirements for Alcoholic Drinks (Regulation 30 and Schedule 5)

These relate to alcoholic strength marking and are set out in regulation 30. Every pre-packed alcoholic drink (except EC wine) with greater than 1.2% alcoholic strength must be marked with its alcoholic strength by volume (being a figure of not more than one decimal place followed by '% vol' and which may be preceded with 'alcohol' or 'alc'. Specified positive and negative tolerances are permitted and are listed in schedule 5. See additional notes regarding alcoholic drinks.

For the purposes of this Regulation, the alcoholic strength of any drink must be determined at 20oC degrees celsius

2.2.8.3 Sale of Raw Milk and Raw Cream is not permitted in Scotland

The sale of raw milk and raw cream intended for direct human consumption in Scotland is prohibited by the Food Hygiene (Scotland) Regulations 2006 (Regulation 32 Schedule 6))

2.2.8.4 Additional Labelling Requirements for Skimmed Milk with Non-milk Fat (Regulation 32)

Regulation 32 relates to skimmed milk with non-milk fat which could be used as a substitute for milk and is neither an infant formula nor a follow on formula, nor a product specifically formulated for infants or young children for medical purposes. It must be prominently marked with a warning about its unsuitability as a food for babies. The wording used in the regulation is 'a warning that the food is unfit, or not to be used as food for babies'.

2.2.8.5 Packaging gases (Regulation 33)

The declaration "Packaged in a protective atmosphere" required by regulation 33 need only be given in the label of pre-packed food when that food's shelf life has been extended by the use of any packaging gas authorised by Council Directive 89/107/EEC on food additives. If the packaging gas has been used for some other technological purpose (see examples below), there is no need to include the declaration on the label unless it serves also to extend the shelf life of the food e.g. the gases used to cushion crisps in their packets also keep the crisps dry and aid preservation. This is noted on the packet "packaged in a protective atmosphere".

The following guidance may be helpful: <u>Food Grade Compressed Air - A Code of Practice</u>

Examples

- Gases used as a carrier matrix for granules and pellets etc in a factory would not normally be considered as food contact materials. Compressed air/gas used to blow foods along pipes should not form a constituent of the food, nor should it interact with it. However any equipment such as compressor/regulator/pipe work would have to feature in the HACCP process and any equipment that may come in contact with food must comply with Regulation 1935/2004
- Gases used in freeze drying coffee etc or hot air drying of herbs. It is the
 equipment used with the gas rather than the gases themselves which would
 feature in any inspections for compliance of food contact material legislation.
 This process would not normally feature on the label or packaging, but a
 description of the product would be included "freeze dried coffee"
- Gasses used in the packaging of soft drinks in aluminium cans in order to prevent deforming the packaging
- Where the gas is naturally present in the food, even if operations such as extraction followed by reincorporation are needed at the packaging stage.
- Where the gas is added in order to give the food its particular organoleptic characteristics
- Carbonated water and soft drinks, in which case it will be given in the list of ingredients

2.2.8.6 Additional Labelling Requirements for Foods containing Sweeteners Aspartame or Polyols (Regulation 34)

Regulation 34 requires a declaration if a food contains sweeteners, or sweeteners and sugar. Sugar, in this context, means any added mono- or disaccharide, or any other food used for sweetening purposes. This is consistent with the definition of 'with no added sugar' in the sweeteners Directive. Foods containing an authorised sweetener must be labelled 'with sweetener'. Foods that contain an added sugar and a sweetener must be labelled 'with sugar(s) and sweetener(s)'.

The required indications must accompany the name of the food. There is no requirement that this must be on the front or main label, or that the lettering should be of a particular size. It is therefore sufficient for the information to be given with the legal name wherever this is most convenient (e.g. where the name is given above the ingredients list) provided the information is easily visible, clearly legible and indelible.

Foods that contain the sweetener aspartame must be labelled 'contains a source of phenylalanine'.

A food containing more than 10% added polyols must be labelled 'excessive consumption may produce laxative effects'.

Again, there is no requirement that this information on aspartame and polyols must be on the front or main label, or that the lettering should be of a particular size. It is therefore sufficient for the information to be given wherever this is most convenient, provided it is easily visible, clearly legible and indelible.

2.2.8.7 High Caffeine Content (Regulation 34A)

This regulation does not apply to any drink based on coffee or tea or their extracts where the name of the food indicates the words 'coffee' or 'tea'.

Drinks that contain caffeine in a proportion of more than 150 milligrams per litre and are intended to be consumed must be marked or labelled 'High caffeine content'. The declaration must be in the same field of vision as the name of the drink and the caffeine content expressed in milligrams per 100 millilitres in brackets immediately following the declaration (drinks with an alcohol strength by volume of more than 1.2% do not have to indicate high caffeine content).

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⁴ EC Regultation 1333/2008 on Food Additives

2.2.8.8 Additional Labelling Requirements for Food containing Glycyrrhizinic Acid and its Ammonium Salts

Glycyrrhizinic acid occurs naturally in the liquorice plant. The ammonium salts are produced from liquid extracts from the plant. When present in confectionery or drink the following limits apply:-

Confectionery

Drink with more than 1.2% abv

Drink which does not contain more than 1.2%

abv

100mg/Kg but less than 4g/kg
10mg/L but less than 300mg/L
10mg/L but less than 50mg/L

The label must carry the warning 'contains liquorice'. In cases where the upper limit is exceeded the food must be marked with the warning 'contains liquorice - people suffering from hypertension should avoid excessive consumption'. The warnings must appear after the list of ingredients of the food or, if there is no list, then it should appear near the name of the food.

2.2.9 Allergen Labelling

The provisions for allergen labelling within the Food Labelling Regulations 1996 (SI No. 1499) were amended by the Food Labelling (Declaration of Allergens) (Scotland) Regulations 2008 (SSI No. 180), by inserting a new Schedule AA1 "Allergenic Ingredient". The regulation required that where any food containing any allergenic ingredient or any ingredient originating from an allergenic ingredient referred to in the new Schedule AA1, and did not specify the allergenic ingredient in the name of the food, that food must be marked or labelled with a clear reference to the name of the allergenic ingredient concerned.

Food Labelling (Amendment (No.2) (Scotland) Regulations 2004 (SSI 2004 No. 472)

The Regulations implement new European Union (EU) legislation (Directive 2003/89/EC) deleting the 25% compound ingredient listing exemption and replacing it with the following derogations, which do not apply to a list of specified allergens (see below):

- compound ingredients making up less than 2% of the finished product do not have to list their ingredients if their composition is defined in EU law (e.g. jam and chocolate)
- compound ingredients consisting of mixtures of herbs and spices that make up less than 2% of the finished product do not have to list their ingredients
- ingredients making up less than 2% of the finished product need not be listed in weight order in the ingredients list, and
- similar or mutually substitutable ingredients that make up less than 2% of the finished product may be indicated in the list of ingredients by use of 'contains and/or' in certain circumstances.

The Regulations also introduce a specified list of allergens (Schedule to the draft Regulations). Pre-packed foods (including alcoholic drinks) made using these allergens or their derivatives must declare the relevant ingredient and for derivatives, make a clear reference to the source allergen.

In the case of a drink which has an alcoholic strength by volume of more than 1.2 per cent.

- The presence of any allergenic ingredient must be indicated by marking or labelling the drink with the word 'contains' followed by the name of the allergenic ingredient; and
- The presence of any ingredient originating from an allergic ingredient referred to in paragraphs 1 to 11 of schedule AA1 shall be indicated by marking or labelling the drink with the word "contains" followed by the name of the ingredient including a reference to the allergenic ingredient from which it originates.

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2008 have been amended by the Food Labelling (Declaration of Allergens) (Scotland) Regulations 2009 to exempt the declaration on the labels of wine for the presence of egg and milk as components of wine fining agents.

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2011 are due to come into force in Scotland in March 2011. These Regulations extend the temporary exemptions from allergen labelling requirements for both egg albumin and milk (casein) used as fining agents for wine, and lysozyme (produced from egg) used in wine, until 30 June 2012. This extension will give the wine industry the opportunity to present dossiers to the Commission to support permanent exemptions for these materials.

The requirement to clearly reference a specified allergenic ingredient relates to ingredients that have been intentionally added in the course of preparing pre-packed food and it does not apply to foods sold loose, non-pre-packed or foods sold pre-packed for direct sale.

All added ingredients and components of added ingredients are covered by these requirements, if they are present in the finished product, even in the altered form, including:

- Carry-over additives;
- Additives used as processing aids:
- Solvents and media for additives or flavourings; and
- Any other substances used as processing aids

A detailed description of each ingredient and more information about these requirements is given in the FSA guidance notes and it is recommended that these guidance notes are consulted for further details.

(http://www.food.gov.uk/multimedia/pdfs/publication/allergenlabelguide09.pdf)

Schedule AA1

The ingredients listed in Schedule AA1 include the following:

- 1. Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains), except:
 - (a) wheat-based glucose syrups including dextrose(*);
 - (b) wheat-based maltodextrins(*);
 - (c) glucose syrups based on barley;
 - (d) cereals used for making distillates or ethyl alcohol of agricultural origin or spirit drinks and other alcoholic beverages.
- 2. Crustaceans.
- 3. Eggs.
- 4. Fish,

except:

- (a) fish gelatine used as a carrier for vitamin or carotenoid preparations;
- (b) fish gelatine or isinglass used as a fining agent in beer and wine.
- 5. Peanuts
- 6. Soybeans,

except:

- (a) fully refined soybean oil and fat(*);
- (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from sovbean sources:
- (c) vegetable oils derived from phytosterols and phytosterol esters from soybean sources;
- (d) plant stanol esters produced from vegetable oil sterols from soybean sources.
- 7. Milk (including lactose),

except:

- (a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;
- (b) lactitol.
- 8. Nuts, i.e. almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoiesis (Wangenh.) K.Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia nuts and Queensland nuts (Macadamia ternifolia), except:
 - (a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

- 9. Celery
- 10. Mustard.
- 11. Sesame seeds.
- 12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO2.
- 13. Lupin
- 14. Molluscs

(as amended by SSI 2008/180)

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2008 also repealed the following legislation

- Food Labelling (Amendment No. 2) (Scotland) Regulations 2005 SSI No. 396
- Food Labelling (Amendment No. 2) (Amendment) (Scotland) Regulations 2005 SSI No. 475
- Food Labelling (Declaration of Allergens) (Scotland) Regulations 2007 (SSI. No.498)

"*" The exception only applies to products derived from these products in so far as the process they have undergone is not likely to increase the level of allergenicity assessed by the European Food Safety Authority for the relevant product from which they originated.

2.2.9.1 Form of Allergen labelling

Where an allergenic ingredient or its derivative is not clearly identified on the food (e.g. Malt vinegar), the ingredient should always be identified on the labelling with a clear reference to the name of the allergenic ingredient concerned, for example 'malt vinegar (from barley)'. In order to avoid ambiguity and confusion, this reference should be made in words.

Note that the Agency's Clear Food Labelling Best Practice Advice already recommends the use of simple language and also refers to examples of recommended ingredient names for consistent identification of the presence of food allergens and gluten.

As there is no provision in the Regulations to avoid repetition of listing the same allergenic source for more than one ingredient in an ingredient list, it would seem reasonable to apply the following guidance:-

 Where an allergenic ingredient in Schedule AA1 is already clearly indicated on the label, it would be acceptable not to have to declare it again as the source of a derived allergenic ingredient

- Where several ingredients are derived from the same allergenic ingredient, it
 would be acceptable to asterisk them to a single source allergenic ingredient
 (e.g. from soya), provided that this would not be confused with other uses of
 asterisks (e.g. with reference to GM ingredients). The referenced allergenic
 ingredient could be placed in a separate allergy information/alert box, if used.
- Note that this will only work where there is one allergen source referenced using an asterisk. Where there is more than one, multiple asterisks could make the information confusing.
- If a separate allergy information/alert box is used, best practice dictates that all specified allergens present in the food should be included and that the box be in the same field of vision as the ingredient list.

There is no legal requirement in these labelling Regulations to use 'may contain' or 'trace' warnings to indicate possible allergen cross contamination. Increasingly manufacturers and retailers provide this information voluntarily to indicate the possible presence of unintentional ingredients that people may be allergic to in prepacked food.

Food Standards Agency - Guidance on food allergen labelling legislation

The Food Standards Agency recommends the use of one of two possible phrases to indicate the unintentional presence of an allergen: either "May Contain X" *or* "Not Suitable for Someone with an X Allergy".

Further Guidance

The <u>FSA guidance on allergen management and consumer information</u> provides best practice with particular reference to avoiding cross-contamination and using appropriate advisory labelling (e.g. may contain labelling).

http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/nonprepacked

2.2.10 Manner of Marking and Labelling

Guidance on the issues which need to be considered in designing the layout of a label has been provided by the Institute of Grocery Distribution in Packaging legibility:

2.2.10.1 Additional Manner of Marking Requirements Applying to Pre-packed Food General Requirement (<u>Regulations 35, 37 and 39</u>)

Regulation 35

For all food that is pre-packed and sold to the ultimate consumer, the labelling information required by the Food Labelling Regulations must be:

- on the packaging or
- on a label attached to the packaging, or
- on a label that is clearly visible through the packaging

2.2.10.2 Food Sold Otherwise than to the Consumer (Regulation 35)

Where the food is sold to someone other than to the ultimate consumer e.g. a manufacturer/packer selling to a caterer, the following information must be on the outermost packaging:

- the name of the food
- the appropriate durability indication
- the name or business name and an address or registered office of either or both of :
 - the manufacturer or packer, or
 - a seller established within the European Community.

The remaining labelling requirements e.g. list of ingredients, place of origin, conditions of use, if not provided on the packaging, must be provided on commercial documents relating to the food. The commercial document must either accompany the food or be sent before the delivery of the food.

Therefore all purchased foods accepted and stored in catering premises for preparation must have on its packaging the above mentioned information. If it is not fully labelled, commercial documentation directly relating to the food must be available.

2.2.10.3 Manner of Marking Requirements that Apply to Food which is not Pre-packed or Pre-packed for Direct Sale (Regulation 36)

Food which is sold to the consumer and is:

- Not pre-packed or
- Pre-packed for direct sale or
- Sold from a catering establishment

The labelling requirements must be on a label attached to the food or on a menu, notice, ticket, or label that is readily discernible by an intending consumer at the place where the food is chosen.

Intelligibility

The Food Labelling Regulations 1996, as amended, contain no requirement as to the size and type of letters to be used in labelling.

However, Regulation 38 requires that all food labelling details must be easy to understand, clearly legible and indelible and when a food is sold to the ultimate consumer the information has to be marked in a conspicuous place which is easily visible. The information cannot be hidden, obscured or interrupted by any other written or pictorial matter. For example, the name of the food must not be broken up by other material, nor must the ingredients list, but it is acceptable for the ingredients list to be shown separately from the name of the food.

<u>FSA Guidance Notes on Clear Food Labelling</u> provide detailed guidance and should be referred to for further information.

Regulation 39 requires certain information to be provided in the same field of vision:-

- Name of the food
- Date mark
- Alcoholic strength by volume
- Cautionary words in respect of raw milk
- Warning required on certain skimmed milk with non-milk fat products, and
- Net quantity

This information does not all have to appear on the same face of the product, but consumers must still be able to read the information without having to keep turning the product back and forth to find it.

2.2.11 Claims, Nutrition Labelling and Misleading Descriptions

2.2.11.1 Prohibited Claims (Regulation 40 and Schedule 6)

Schedule 6 of the Food Labelling Regulations prohibits the following types of claims:

- That a food has tonic properties or
- That a food has the property of preventing, treating or curing a human disease or any reference to such a property.

Such claims would be regarded as medical claims and subject to control by the Medicines and Healthcare Products Regulatory Authority.

2.2.11.2 Restricted Claims (Regulation 40 and Schedule 6)

Schedule 6 Part II lists the restricted claims that are permitted by Regulation 40(2) in the labelling or advertising of a food, where the conditions in column 2 of the schedule are met. (Schedule 6)

The types of claim named in schedule 6 Column 1 are under the following headings:

- Claims relating to foods for particular uses
- Reduced or low energy value claims
- Protein claims
- Vitamin claims
- Mineral claims
- Cholesterol claims
- Nutrition claims
- Claims which depend on another food

It should be noted that a substance referred to in the list of ingredients or in nutrition labelling does not constitute a claim. (See also the Nutrition and Health Claims Regulations).

2.2.11.3 Nutrition Claims

The nutrition labelling rules cover foods sold to the ultimate consumer and to foods supplied to catering establishments.

The nutrition labelling rules do not apply to:

- Food supplements
- Natural mineral waters and other waters for human consumption

A nutrition claim is defined in regulation 2 of the Food Labelling Regulations 1996 and means 'any statement, suggestion or implication in any labelling, presentation or advertising of a food that that food has particular nutrition properties, but does not

include a reference to any quality or quantity of any nutrient where such reference is required by law;'

Nutritional labelling in relation to food means '... information appearing on labelling (other than where such information appears solely as part of a list of ingredients) and relating to energy value or any nutrient or to energy value and any nutrient, including any information relating to any substance which belongs to, or is a component of a nutrient'.

The requirements on claims and nutrition labelling are covered in Regulations 40 and 41 and Schedules 6 and 7 of the Food Labelling Regulations, as amended

Nutrition labelling of a food is not compulsory. However, all stated and implied nutrition claims e.g. 'low fat' or 'high in fibre' made in food labelling and advertising, other than those made in generic advertising, and all stated and implied claims that a food is suitable for particular nutritional uses, require compulsory nutrition labelling.

Regulation 41 requires when any claim is made on a food which is detailed in the conditions in Schedule 6, then the food has to be marked or labelled with the prescribed nutrition labelling. However this is not the case for:-

- A food (other than a food sold from a vending machine) which is not pre-packed and sold to the ultimate consumer at a catering establishment
- A claim contained within generic advertising

The definition of a nutrition claim excludes statements required by law. Therefore, such statements, that resemble nutrition claims, do not trigger compulsory nutrition labelling. For instance, the use of the name 'low fat margarine' as defined in Council Regulation 2991/94 on spreadable fats and enforced by The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (Scotland) Regulations 2008, SSI No. 216 does not trigger compulsory nutrition labelling. Energy is not covered by this exclusion, so all reference to it in labelling and advertising, even if required by law will require compulsory nutrition labelling. The Agency is of the opinion that an implied mention of energy e.g. 'diet' or 'calorie' is also subject to this requirement. Claims for ingredients such as fat, sugar and salt which are also nutrients will trigger nutrition labelling.

A claim that a food is free of a nutrient e.g. sugar will also require nutrient labelling. Polyols, if added to replace the sugars, should be declared.

Statements resembling nutrition claims but which do not state or imply particular nutrition properties are not nutrition claims and therefore do not trigger compulsory nutrition labelling, for instance, descriptions of taste such as 'tea without sugar'.

When a nutrition claim is made in advertising, other than generic advertising, nutrition labelling is required on the labels of the products concerned: no information is required to appear in the advertisement itself. When a nutrition claim is made in generic advertising nutrition labelling is not required.

2.2.11.4 Nutritional Rules for Some Foods

There are some variations in the rules for:

- Foods for particular nutritional uses see FLR Schedule 6 Part II Item 1
- Non pre-packed foods sold other than by caterers see FLR Schedule 7 Part II 2-(1)(a)
- Non pre-packed foods sold by caterers see Regulation 41(3)(a)

Unless indicated otherwise, these guidelines cover the requirements for pre-packed foods.

2.2.11.5 Nutrition Declarations (Schedule 7)

Where nutritional labelling is provided for a pre-packed food, it may be given in one of two formats and must include the amount of any nutrient for which a claim has been made.

The minimum declaration permitted is a 'Group 1' declaration which is specified in Schedule 7 part II (1a) (i) of Food Labelling Regulations)

'Group 1' (also known as 'Big 4') Declaration

kJ and kcal
g
g
g

The other standard format is a 'Group 2' declaration which is specified in Schedule 7 part II (1a) (ii)

'Group 2' (also known as 'Big 4 + little 4' and '4+4' Declaration)

Energy	kJ and kcal
Protein	g
Carbohydrate	g
of which:	
- sugars	g
Fat	g
of which:	
- saturates	g
Fibre	g
Sodium	g

The Government recommends that Group 2 information be given on all foods, on a voluntary basis, as this gives consumers information on the key health-related nutrients.

2.2.11.6 Other Nutrients which may be Declared

The following nutrients can be included in a nutrition declaration on a voluntary basis, but must be declared if a claim about them is made. The table is a summary of the requirements of Schedule 7 Part II part 1:

Sugars*
Polyols
Starch
Saturates*
Mono-unsaturates**
Polyunsaturates**
Cholesterol**
Fibre*
Sodium*
Vitamins***
Minerals***

- * If any of these items are declared in the nutrition information, they must all be declared as part of a Group 2 declaration.
- ** When one of these is declared, saturates must also be declared.
- Only vitamins and minerals listed in Schedule 6 Table A and B can be declared, and they must be present in significant amounts. A significant amount means 15% of the recommended daily allowance supplied by 100g or 100ml of a food or per package if the package contains only a single portion.

Nutrients not covered above

Any nutrient not listed above can only be declared if a claim has been made about it, in which case its declaration as part of nutrition labelling becomes compulsory, e.g. fructose or trans fatty acids.

2.2.11.7 The amount of Food the Declaration should relate to

Information must be declared per 100g or 100ml of the food. (If a vitamin and/or mineral claim is made, an additional per serving or portion statement for the claimed vitamins and/or minerals is required, but is not required for any other nutrients). Additional information may be given to the 100g or 100ml declaration. This can include:

- A quantified serving of the food e.g. per 30g serving
- Per portion within a number of portions e.g. one bun
- Any amount as sold to the ultimate consumer or caterer where detailed instructions are given for the preparation for consumption

Part 1 of Schedule 7 states:

The averages should be based on either one, or any combination of:

- Manufacturer's analysis; or
- Calculation from known or actual average values of the ingredients used; or
- Calculation from generally established and accepted data.

Conversion Factors for the calculation of the energy value to be used are also listed in Schedule 7 Part 1

In relation to bullet points (2) and (3), data from analyses carried out by retailers or others can be used. Manufacturers are free to use whichever method, or combination of the above methods, best fits the circumstances.

2.2.11.8 Prescribed layout to be followed

The Agency does not believe it will matter in practice if minor changes are made, to the prescribed layout, provided this would not confuse or mislead consumers or make it more difficult to compare the nutritional content of foods.

Carbohydrate		might be		carbohydrate
of which:	\square	shown as	\square	of which:
- sugars	─ ─ /		——V	sugars

2.2.11.9 Order of Nutritional Information

The regulations do not lay down rules for all cases as this would go beyond what the European Community agreed, but the order specified at Schedule 7, Part I paragraph 1 for energy and the named nutrients must be followed. Please note that this requires sodium to follow fibre. For consistency the Agency suggests the following additional practices be followed:

Energy - Give KJ before kcal

Vitamins and Minerals - Give vitamins before minerals in the order shown in Table

A and B of Schedule 6

Components - State the amount of the named nutrient followed

immediately by the amount of the component. For example, if a fructose claim has been made, it is suggested that the following format be used:

Carbohydrate 28g

of which:
- sugars 17g,
of which:

- fructose 14g

A food business cannot give information on the main nutrients in tabular form followed by vitamin and mineral information in linear form. Information should be either all tabular or all linear.

Information must be in tabular form whenever there is sufficient space for it to be printed clearly. Where there is not enough space, it can be given in linear form.

The Agency believes that 'with the numbers aligned' means that the numbers must be in a column. The Agency does not believe that it necessarily means that the numbers must be aligned around a decimal point, although care should be taken that if numbers are not presented in this way that the relative amounts of nutrients are clear.

Where nutrition labelling is provided on a voluntary basis, the information has to be provided in the same format as that described for prescribed nutrition labelling.

FSA Official Guidance on Nutrition Labelling details guidance on layout, terminology, definitions, conversion factors etc. and it is strongly recommended the guidance is consulted.

2.2.11.10 Health Claims

The Nutrition and Health Claims (Scotland) Regulations 2007 now cover the subject of claims on foods. Guidance on these Regulations is being drafted by the FSA. Training notes are available in Section 2 N of this manual. The Nutrition and Health Claims regulations amend the Food Labelling Regulations 1996 to the extent that 'Nothing in regulation 40 or in Schedule 6 or 8 shall operate to prohibit or restrict a claim made in accordance with the conditions of Regulation (EC) 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food'.

In effect, Regulation (EC) 1924/2006 takes precedence over the Food Labelling Regulations 1996, as amended, in this matter.

In general, only health claims that are listed in the <u>Community Register</u> can be used on food and only if the product meets any specific conditions of use as well as the general requirements of the regulations.

Although the Regulations will apply from the 1st July 2007, transitional measures mean that industry will have anywhere up to 15 years to comply with different aspects of the regulations. During this transitional period, UK legislation will apply.

2.2.11.11 Misleading Descriptions on Food - (<u>Regulations 42</u>, <u>43</u> and <u>Schedule 8</u>)

In addition to the controls on misleading descriptions in the Food Safety (Scotland) Act 1990, the Food Labelling Regulations contain specific controls on the use of descriptions such as ice cream, dairy ice cream, low alcohol, low calorie (to describe a soft drink), Indian/quinine tonic water, and the word wine when used in a composite name. The wording descriptions and specified conditions are in Schedule 8 of the Food Labelling Regulations 1996, as amended. The wording and descriptions may only be used in the labelling and advertising of these foods if the specified conditions named in Column 2 are met.

Conditions are also set out for the use of descriptions or pictorial representations on food labels that imply that a food has the flavour of the food named in the description. It should generally be taken that consumers will assume that the flavour of a food is obtained from the named food in the description, rather than a flavouring, unless the labelling makes clear that this is not the case.

The word chocolate may be used (e.g. in the name chocolate cake), without any further qualification provided the consumer would not be misled by the description.

A pictorial representation of a food, implying that it has the flavour of that food, cannot be used unless the flavour comes wholly or mainly from the food in the picture. Even if the illustrated food cannot be tasted in the product as consumed, provided the flavour of the illustrated food comes wholly or mainly from that illustrated food (rather than, for example, an artificial flavouring), there is no reason why a picture of it should not appear on the product label.

A fruit drink containing orange, mango and passion fruit juices may illustrate all three fruits on the label, even if one or two flavours dominate, provided all three flavours come wholly or mainly from the fruits which are illustrated. In the same way, Indian tonic water with a twist of lemon would only be able to carry a picture of a lemon on it if the lemon flavour comes wholly or mainly from lemons.

Since the controls require that the flavour come 'wholly or mainly' from the illustrated food, this does not prevent the use of illustrations on product labels where the flavour has been mixed with small amounts of synthetic flavouring. In such a case, the flavour must still come wholly or mainly from the illustrated food.

Regulation 42 and Part II and Part III of Schedule 8 list words and descriptions for varieties of cheese and cream, which may only be used when specified conditions are met.

Cheese

The variety of cheese named must not contain more than a specified maximum percentage of water listed in Column 2 of Part II Schedule 8 and all varieties of cheese must have at least 48% milk fat expressed as a percentage of the dry matter.

Cream

The varieties of cream and physical treatment are listed with conditions specified in relation to milk fat content e.g. a single cream must contain not less that 18% milk fat. The milk fat content does not have to be met provided the name used has qualifying words that indicate that the milk fat content is greater or less than specified in column 2 of Schedule 8, Part III. Any ingredient added to a cream must not be accounted for when determining the percentage milk fat.

2.2.11.12 Wine (<u>Regulation 43</u>)

The word 'wine' is defined in Council Regulations (EEC) No 822/87 and must only be used when the definition is met. Regulation 43 permits the word 'wine' to be used in a composite name in the labelling or advertising of a drink, provided it is not likely to confuse the consumer with wine or table wine as defined.

'Non-alcoholic wine' may only be used for a drink derived from unfermented grape juice intended exclusively for communion or sacramental use and which is clearly labelled for such use.

When the word 'wine' is used in a composite drink which is derived from fruit other than grapes, the drink must be obtained by an alcoholic fermentation of that fruit.

2.2.12 Labelling Requirements for Alcoholic Drinks

The requirements mentioned in the following paragraphs apply to most alcoholic drinks intended for sale to the ultimate consumer or to a catering establishment in the UK. The labelling of Community-controlled wine however, is governed by European legislation.

2.2.12.1 The name of the food

The name will generally be the customary name, unless there is a prescribed name laid down in Regulations. Where a prescribed name or a customary name is not used, a precise description or other name which would both indicate the true nature of the product, and distinguish it from others with which it might be confused, is required. Trademarks, brand names or fancy names cannot take the place of the name under which the product is sold but may be used in addition to it.

2.2.12.2 List of ingredients

The ingredients must be given in descending order by weight. This is currently only required for drinks with an alcoholic strength by volume (abv) of 1.2% or less.

2.2.12.3 Appropriate indication of minimum durability (date mark)

Drinks with an alcoholic strength of less than 10% (abv) are required to bear a date mark. Depending on the shelf life of the product, this should be expressed in terms of the day, month and year (in that order) preceded by the words 'best before' or as the month and year (in that order) or the year only, preceded by the words 'best before end'. Exemptions from date marking include: drinks sold in bulk containers of more than 5 litres where these are intended for supply to catering establishments, cider, perry and most wines.

2.2.12.4 Special storage conditions or conditions of use

Details of storage conditions or conditions of use should be provided where necessary.

2.2.12.5 Name and Address

Name or business name and an address or registered office of the manufacturer or packer (who may be located anywhere), or of a seller established within the EU is required to be provided on the label.

2.2.12.6 Place of origin of the product

This must be given if failure to do so would be materially misleading to the purchaser with regard to its true origin.

2.2.12.7 Instructions for use

Instructions should be given if appropriate use could not be made of the product without them.

2.2.12.8 Indication of alcoholic strength by volume

All pre-packed drinks with an alcoholic strength of more than 1.2% (abv) must be labelled with an indication of alcoholic strength by volume. This must be shown as a figure (to not more than one decimal place) preceded by the word 'alcohol' or by the abbreviation 'alc' and followed by the symbol '% vol'. Specified positive and negative tolerances are permitted in respect of the indication of alcoholic strength. These are listed in Schedule 5 of the Food Labelling Regulations 1996, as amended.

Specified descriptions can be used to describe drinks of not more than 1.2% (abv). These descriptions are listed in Schedule 8: (Misleading Descriptions) of The Food Labelling Regulation 1996 as amended.

- 'Low alcohol' a drink with an alcoholic strength by volume of not more than 1.2%;
- 'De-alcoholised' a drink from which the alcohol has been extracted and which has an alcoholic strength by volume of not more than 0.5%; and
- 'Alcohol-free' a drink from which the alcohol has been extracted and which has an alcoholic strength by volume of not more than 0.05%.

The description 'non-alcoholic' must not be used in conjunction with a name commonly associated with an alcoholic drink, except in the composite name 'non-alcoholic wine' when that composite name is used in accordance with regulation 43 of the Food Labelling Regulations 1996.

When these descriptions are used, the drink must be labelled with an indication of its maximum alcoholic strength immediately preceded by the words 'not more than'. The EEC Spirit Drinks Regulation 1576/89 lays down definitions, minimum strengths and certain other labelling requirements for spirit drinks.

The word 'wine' must not be used as part of a composite name for any drink in a way that is likely to cause confusion with products which are covered by the terms 'wine' or 'table wine' as defined in Council Regulation (EEC) No. 822/87

When a composite name including the word 'wine' is used for a drink which has been made from fruit or similar substances other than grapes, the name of the fruit or

substance used must be shown immediately before the word 'wine' in the composite name. If a mixture of fruits and/or other substances has been used, only those which give the wine its character must be shown.

2.2.13 Labelling of Genetically Modified Foods (GM)

All GM foods marketed in the European Union (EU) are regulated under Regulation (EC) No. 1829/2003 (GM Food and Feed Regulation) and Regulation (EC) No. 1830/2003 (Traceability and Labelling of Genetically Modified Organisms (GMOs) Regulation). These foods are subject to rigorous safety assessment before being permitted to enter the food chain.

The current list of authorised GM foods in the EU is available at: http://ec.europa.eu/food/food/food/biotechnology/authorisation/index_en.htm

See also Genetically Modified Foods (Scotland) Regulations 2004

The GM Food and Feed Regulation requires labelling for all food products derived from GM sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used GM ingredient present. The only exemptions to this requirement are listed below.

Regulation EC No 1829/2003 provides the requirement for the labelling of all foods which are to be delivered as such to the final consumer or mass caterers which

- (a) contain or consist of Genetically Modified Organisms (GMO's)
- (b) are provided from or contain ingredients from GMO's

For GM products sold 'non pre-packed', information must be displayed immediately next to the food or on a menu to indicate that it contains GM material.

All food that contains, or are produced from, genetically modified organisms (GMOs) must be labelled as such. Any food product sold by retailers to the final consumer in the UK which is derived from a GMO must also be clearly labelled. For example, bread containing ingredients derived from GM soya must indicate 'this product contains genetically modified organisms' or 'produced from genetically modified soya' to enable the final consumer to make an informed choice.

The main provisions are found in Articles 12 and 13 of the EC Regulation. These are:

- 1) Where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified' (name of the ingredient) must appear in the list of ingredients in parentheses immediately following the ingredient concerned.
- Where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients.

- 3) Where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of ingredient)' shall appear clearly on the labelling.
- 4) Where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm², the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

The indications referred to in (1) and (2) may appear in a footnote to the list of ingredients. In this case, they must be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they must appear on the labelling.

Exemptions to the labelling Requirement

Accidental contamination

There is no need for small amounts of GM ingredients (in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient for GM varieties which have received a favourable assessment from an EC scientific committee and which have been approved in Standing Committee) that are accidentally present in a food or feed to be labelled. Where operators apply this threshold, they must be able to effectively demonstrate to enforcement authorities that appropriate and adequate steps have been taken to avoid the accidental presence of GM material in non-GM supplies.

Processing aids

Processing aids do not fall within the scope of this regulation, for instance foods which have been processed or obtained with the help of GM technology (e.g. bakery products using yeast or cheeses that have been produced with the help of an enzyme) do not have to be labelled.

Products from animals fed GM animal feed

Products from animals fed GM animal feed (e.g. milk, meat and eggs) are also exempt from labelling requirements. In addition, organically produced animal products must be derived from animals fed a non-GM diet.

For further information about GM labelling regulations (including links to the legislation) please go to http://www.food.gov.uk/gmfoods/gm/gm_labelling

Traceability of GMOs

The Traceability and Labelling of GMOs Regulation creates a regime for tracing and identifying GMOs and food and feed products derived from GMOs at all stages of their placing on the market. It also enables products to be withdrawn from the market if any unexpected adverse effects should arise. The Regulation requires food business operators, when using or handling GM products, to transmit and retain information at each stage of the product being placed on the market. For example, where production starts with a genetically modified crop, the company selling the crop (for instance for animal feed) would have to inform any purchaser that the crop is genetically modified. Information on all GM food or feed material must be retained for five years.

'GM Free'

There is no legal basis for the use of the terms 'GM free' or 'non-GM', although these terms can be lawfully used on a voluntary basis if this is appropriate to the particular product. The scope of Regulation (EC) No. 1829/2003 only includes the labelling of food that is genetically modified. Any food on sale labelled 'GM-free' is subject to the general requirements of food law.

The Food Safety Act 1990 makes it an offence to sell food that is not of the nature, substance or quality demanded by the consumer or that is falsely or misleadingly described or labelled.

Under Article 16 of <u>EC Regulation 178/2002</u> the labelling, advertising and presentation of food, including its shape, appearance or packaging, the materials used, the manner in which they are arranged, the setting in which they are displayed and the information which is made available about them through whatever medium, shall not mislead customers.

The Agency's view is that GM free should mean GM free - food that is completely free from the use of GM technology and without a threshold for the accidental presence of GM material in a non-GM source. The use of this term would clearly be limited to a small range of products.

LACORS, now known as Local Government Regulation (LGR) advice for non-GM labelled products

A statement that a food is 'Non-GM' can be made, provided that the following conditions are satisfied:

- A fully documented traceability and testing system is in place;
- The traceability and testing system is regularly audited by an independent third party;
- Accidental contamination (in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient for GM varieties which have received a favourable assessment from an EC scientific committee and which have been approved in Standing Committee); and
- All these measures combined prove that a "due diligence defence" can be satisfied.

Products consistently 100% free from GM material can be labelled as such but its use is discouraged for practical purposes.

2.2.14 Scottish Government Beef Labelling Regulations

The Beef and Veal Labelling (Scotland) Regulations 2010
The Beef and Veal Labelling (Scotland) Regulations 2008

Section 3 - Legislation Guidance - Alphabetical Order

Legislation under A

Arsenic in Food (Scotland) Regulations 1959 (SI No. 928)

Legislation under B

Beef and Veal Labelling (Scotland) Regulations 2008 (SSI No. 418)

Beef and Veal Labelling (Scotland) Regulations 2010 (SSI No. 402)

Bread and Flour Regulations 1998 (SI No. 141)

Legislation under C

Caseins and Caseinates Regulations 1985 (SI No. 2026) (as amended)

Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (SSI No. 230)

Chloroform in Food (Scotland) Regulations 1980 (SI No 289)

Cocoa and Chocolate Products (Scotland) Regulations 2003 (SSI No. 291)

Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 (SSI No. 38)

Condensed Milk and Dried Milk (Scotland) Regulations 2003 (SSI No. 311)

Contaminants in Food (Scotland) Regulations 2009 (SSI No. 215)

Legislation under D

Drinking Milk (Scotland) Regulations 1998 (SI No. 2424)

Legislation under E

Erucic Acid in Food (Scotland) Regulations 1977 (SI No. 1028) Extraction Solvents in Food (Scotland) Regulations 1993 (SI No. 1658) (as amended)

Legislation under F

Fish Labelling (Scotland) Regulations 2010 (SSI No. 90)

Flavourings in Food (Scotland) Regulations 2010 (SSI No 439) (as amended)

Food Additives (Scotland) Regulations 2009 (SSI No. 436)

Food Enzymes (Scotland) Regulations (amendment) 2010 (SSI No. 26)

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009 (SSI No 427)

Food intended for Use in Energy Restricted Diets for Weight Reduction (Scotland) Regulations 1997 (SSI No. 2182)

Food Irradiation (Scotland) Regulations 2009 (SSI No. 261)

Food Labelling (Nutrition Information) (Scotland) Regulations 2009 (SSI No. 328)

Food Supplements (Scotland) Regulations 2003 (SI No. 273) (as amended)

Food with Added Phytosterols and Phytostanols (Labelling) (Scotland) Regulations 2005 (SSI No. 1)

Food (Jelly Mini-Cups) (Emergency Control) (Scotland) Regulations 2009 (SSI No. 437)

Food (Suspension of Use of E128 Red 2G as food Colour) (Scotland) Regulations 2007 (SSI No. 363)

Fruit Juices and Fruit Nectars (Scotland) Regulations 2003 (SSI No. 293)

Legislation under G

The Genetically Modified Food (Scotland) Regulations 2004 (SSI No. 432)

Legislation under H

Honey (Scotland) Regulations 2003 (SSI No. 569) (as amended)

Legislation under I

Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (SSI No. 549) (as amended)

Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008 (SSI No. 322)

Legislation under J

Jam and Similar Products (Scotland) Regulations 2004 (SSI No. 133)

Legislation under K

Kava Kava in Food (Scotland) Regulations 2004 (SSI No. 244)

Legislation under L

Food (Lot Marking) Regulations 1996 (SI No. 1502)

Legislation under M

Material and Articles in Contact with Food (Scotland) Regulations 2007 (SSI No. 471)

Meat Products (Scotland) Regulations 2004 (SSI No. 6)

Medical Foods (Scotland) Regulations 2000 (SSI No. 130)

Mineral Hydrocarbons in Food (Scotland) Regulations 1996 (SI No. 200)

Legislation under N

Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (SI No. 420)

Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 (SI No. 60)

Novel Foods and Novel Food Ingredients (Scotland) Regulations 2004 (SI No. 33)

Nutrition and Health Claims (Scotland) Regulations 2007 (SSI No. 383)

Legislation under O

Legislation under P

Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 (SI No. 56)

Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990 (SI No. 194)

Preserved Tuna and Bonito (Marketing Standards) (Scotland) Regulations 1994 (SI No. 425)

Processed Cereal Based Baby Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2003 (SI No. 530)

Legislation under Q

Quick Frozen Foodstuffs (No2) (Scotland) Regulations 2007 (SI No. 110)

Legislation under R

Rice Products from the United States of America (Restriction on First Placing on the Market) (Scotland) Regulations 2008 (SI No. 99)

Legislation under S

Smoke Flavourings in Food (Scotland) Regulations 2005 (SI No. 76)

Specified Products from China (Restriction on First Placing on the Market (Scotland) Regulations 2008 (SI No. 171)

Specified Sugar Products (Scotland) Regulations 2003 (SI No. 301)

Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (Scotland) Regulations 2008 (SI No. 239)

Legislation under T

Tryptophan in Food (Scotland) Regulations 2005 (as amended)

Legislation under U

Legislation under V

Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (SI No. 301)

Legislation under W

Legislation under XYZ

Arsenic in Food (Scotland) Regulations 1959 (SI No. 928)

Scope

These regulations provide that, subject to certain exceptions, it will be an offence to sell, consign or deliver any food which contains more than one part per million (1mg/Kg) of arsenic.

Lower limits are specified for beverages, some soft fruit concentrates and ice cream. Higher limits are specified for some products which are either food essences or ancillary foods.

The primary regulations were amended in 1973 by the Arsenic in Food (Scotland) Amendment Regulations 1973 SI No. 1039 which allow for a maximum permitted arsenic content in food to be prescribed by other regulations.

Arsenic is present in food in various chemical forms, with inorganic forms being the most toxic. In the UK, fish is the main contributor of arsenic in the diet.

Ingredients/Products

The regulation applies to any food or ingredient intended for use in food.

Labelling Requirements

None.

Public Analyst Observation

Can be found in American rice, Bangladesh Rice and is naturally occurring.

No issues in shellfish/fish.

Associated Regulations

Arsenic in Food (Scotland) Amendment Regulations 1973 (SI No. 1039)

Further Information

Survey work: - The FSA completed a survey of total and inorganic Arsenic in fish in 2005.

The survey concluded that shellfish tended to accumulate higher levels of the more toxic inorganic form of arsenic than the composite fish samples, but the levels of inorganic arsenic were low. The maximum intake of inorganic arsenic was below 5 per cent of the safety guideline set previously by the World Health Organisation.

The data indicated that exposure is as low as is reasonably practicable.

Arsenic in fish and shellfish 2005
Total diet study 2000

Bread and Flour Regulations 1998 (SI No. 141)

Scope

The key provisions of the regulations deal with laying down rules on the composition and labelling of wheat flour, and bread.

Ingredients/Products

- **1. Bread:** This includes any size, shape and form which is usually known as bread and consists of dough made from flour and water, with or without other ingredients, which has been fermented by yeast or otherwise leavened and subsequently baked or partly baked. It excludes buns, bunloaves, chapattis, pitta bread, potato bread or bread specially prepared for coeliac sufferers.
- **2. Flour:** The product which is derived from, or separated during, the milling or grinding of cleaned cereal whether or not the cereal has been malted or subjected to any other process, and includes meal, but does not include other cereal products, such as separated cereal bran, separated cereal germ, semolina or grits.
- **3. Flour bleaching agent:** Any food additive primarily used to remove colour from flour.
- **4. Flour treatment agent:** Any food additive other than an enzyme preparation which is added to flour or dough to improve its baking quality.

Fortification of Wheat Flour

The regulations specify in Schedule 1 the amount of essential ingredients to be added to flour derived from wheat. There are exceptions in the case of wholemeal flour, self raising flour which has a calcium content of not less than 0.2per cent, and wheat malt flour. The permitted ingredients are:-

- Calcium carbonate
- Iron (Specifications for iron are set out in Schedule 2)
- Thiamin (Vitamin B1)
- Nicotinic acid or nicotinamide

Added Ingredients

The regulations were amended by the Miscellaneous Food Additives (Amendment) (Scotland) Regulations 1999 which require that no person can use any flour bleaching agent in the preparation of any flour or bread. Schedule 3 in the Bread and Flour Regulations was also deleted. The Miscellaneous Food Additives Regulations also control the addition of additives to bread and flour.

Labelling Requirements

The food must be labelled with its name.

Bread may be described as

(a) 'Wholemeal' only if:-

All the flour used as an ingredient in the preparation of the bread is wholemeal; or

(b) 'Wheatgerm': Where the bread has an added processed wheatgerm content of not less than 10%. This percentage being calculated on the dry matter of the bread.

If none of the aforementioned names apply, the name of the bread may be one that is customary in the area where it is sold, or a name which is sufficiently precise to describe the food. (Food Labelling Regulations 1996 as amended). For example 'White', 'Brown' or 'Soda bread'.

Bread which has been 'aerated' or 'partially baked' must include this in the name of the food.

Trade names e.g. Hovis or Granary cannot be used on their own, but may be included with other words in the name.

Bread on Display

Bread, which contains any of the following types of additives:- antioxidant, artificial sweeteners, colour, flour improvers, flavour enhancer, flavouring, preservative, must have a notice in close proximity to it, which clearly tells customers which of these additives are present in that bread.

Public Analyst Observation

Sampling provisions are contained in the Regulations.

Flour mills need to be checked in relation to descriptions of flour products (wholemeal and brown).

Associated Regulations

Bread and Flour Regulations 1998 SI No. 141 (as amended)

Food Labelling Regulations 1996 SI No. 1499 (as amended)

Further Information

Bakers Federation web page

FSA Bread and Flour Guidance Notes

Caseins and Caseinates Regulations 1985 (SI No. 2026)

Scope

These regulations implement <u>Commission Directive 83/417/EEC</u> relating to certain lacto proteins (casein and caseinate) intended for human consumption.

Regulations

- Prescribe reserved descriptions, composition and manufacturing characteristics for casein products.
- Impose labelling and advertising provisions.
- Impose additional labelling requirements.
- Require heat treatment of casein before sale of casein products. The heat treatment must be at least equivalent to pasteurisation unless the casein product is itself subjected to such heat treatment during its preparation.

Ingredients/Products

Casein is defined as the principal milk constituent, washed and dried, insoluble in water and obtained from skimmed milk by precipitation by the addition of acid, by micro-biological acidification, by using rennet or by using other milk coagulating enzymes, without prejudice to the possibility of prior use of ion exchange processes and concentration processes.

Caseinate means a product obtained by drying casein treated with neutralising agents.

Caseinate product means edible acid casein, edible rennet casein or any edible caseinate.

What are Caseinates?

Since casein itself will not dissolve in water it will more likely be seen as caseinates, which are the salts of casein, on ingredients labels. They are made by dissolving acid casein in a suitable hydroxide and drying it to make a water soluble product.

- Ammonium caseinate is used mainly in bakery products.
- Calcium caseinate is used as a nutrient supplement. It is used in creamed cottage cheese, powdered diet supplements, nutritional beverages, processed cheese, and frozen desserts because it has a milky appearance and smooth feel in the mouth.
- Potassium caseinate is used in frozen custard, ice cream, ice milk, and fruit sherbets.
- Sodium caseinate is highly soluble and is used as an emulsifier in coffee
 whiteners, cottage cheese, cream liqueurs, yogurt, processed cheeses, and
 some meat products. It is also used to improve the whipping properties of
 dessert whips.

Labelling Requirements

The additional labelling provisions include:

- The Reserved descriptions specified for that product, in the case of caseinates an indication of the cation or cations.
- Use of the term 'mixture of' as appropriate followed by the reserved descriptions in descending order in weight as well as protein content calculated on dried extract expressed as a percentage of total weight of product sold.
- Name and Address of the packer, manufacturer or seller within the EEC.
- 'Country of Origin' if the product originates from a third country.
- Date of manufacture or some marking to identify the batch.

Schedule 1 part 1 deals with the casein products and their reserved descriptions whilst part 2 deals with technological adjuvants and bacterial cultures. Part 3 deals with standards.

The primary regulations were amended by Caseins and Caseinates (Scotland) Amendment Regulations 1989 SI No. 2321 and again by The Caseins and Caseinates (Scotland) Amendment Regulations 1990 SI No. 1 which implement provisions relating to:

- Analysis of Casein Products Commission Directive 85/503/EEC.
- Method of Sampling Commission Directive 86/424/EEC.

The amendment also reinstates caseinates as the generic name for use in ingredient lists.

Public Analyst Observation

These substances may be found in meat products as additional sources of protein.

Associated Regulations

Caseins and Caseinates (Scotland) Regulations 1986 (SI No. 2026)

Caseins and Caseinates (Scotland) Amendment Regulations 1989 (SI No. 2321)

Caseins and Caseinates (Amendment) (Scotland) Regulations 1990 (SI No. 37)

The Food Enzymes (Scotland) amendment Regulations 2010 (SSI No. 26)

<u>Commission Directive 83/417/EEC</u> relating to certain lacto proteins (casein and caseinate) intended for human consumption.

<u>Commission Directive 85/503/EEC</u> on methods of analysis for edible caseins and caseinates.

<u>Commission Directive 86/424/EEC</u> methods of sampling for chemical analysis of edible caseins and caseinates

Further Information

Health Issues: Milk allergy and intolerance

The Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (SSI No. 230)

Scope

These Regulations apply to ceramic articles which are intended to come into contact with food and set limits on the amount of lead and cadmium which may migrate from such articles. The regulations also lay down requirements for testing ceramic articles and require them to be accompanied at the marketing stages by certificates of compliance.

These Regulations implement <u>Council Directive 84/500/EEC</u> on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs as amended by <u>Commission Directive 2005/31/EC</u> regarding a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs. The former Directive was previously implemented by the Ceramic Ware (Safety) Regulations 1988 (SI 1988/1647) which have been revoked.

Ingredients/Products

Regulation 2 defines 'ceramic article' as an item made from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. The item may be glazed, enamelled or decorated.

Regulation 3 limits the quantities of lead and cadmium which may be transferred by a ceramic article. The levels of lead and cadmium permitted are set out in Schedule 1 which refers to 3 categories of ceramic ware.

Schedule 2 sets out how an article is to be tested.

Labelling Requirements

Regulation 4 requires a written declaration of compliance to accompany a ceramic article which is not yet in contact with food at all marketing stages up to the retail stage. The details of the declaration are set out in Schedule 3. The written declaration must contain the following information:

- The identity of the manufacturer and if applicable the importer
- The identity of the ceramic article
- Date of the declaration
- Confirmation that the ceramic meets the standard specified in the regulations and Council Directive 84/500/EEC, Regulation (EC) 1935/2004
- The declaration must be renewed if the article undergoes substantial change which alters the lead and cadmium migration

The Regulation also requires the manufacturer or importer of ceramic articles into the Community to keep documentation showing that the requirements of Schedule 1 have been met and the tests in Schedule 2 have been carried out.

Requirement for documentation

This applies to manufacturers and importers of ceramic products intended to come into contact with food. Manufacturers would be expected to generate this documentation in the course of establishing (through testing etc) compliance with the migration limits. Importers of products originating outside of the EU would be expected to obtain the documentation from the overseas producer. If the documentation was not available the importer would be expected to test as much of the imported consignment as was necessary to indicate that it complied in its entirety with the migration requirements before the goods could be released on to the market.

A Distributor who did not have a declaration of compliance and was unable to obtain one from the manufacturer/importer, would be expected to produce his own after having first tested the product for compliance with migration limits.

Requirement for Declaration of Compliance

This requirement applies to manufacturers, importers, distributors and retailers of ceramic products intended to come into contact with food.

The declaration is not intended for consumers its purpose is to provide the enforcement authorities and distributors with the means to check that ceramic products comply with lead/cadmium migration requirements.

Manufacturers and importers would be expected to produce a declaration and to provide this with every consignment released on to the market.

Distributors (including retailers) should ensure that they obtain a valid declaration(s) with every delivery, and should provide a copy of this when supplying to other distributors or retailers.

Smaller retailers who obtain their stock from cash and carry businesses should take reasonable steps to ensure that the products are compliant (e.g. asking to see declarations) and kept records of where they obtained the goods. The latter would enable the enforcement officers to follow a document trail back to the manufacturer.

Other instances when a declaration would not be needed include where a declaration for the same product (or product range) was already held, and within a retail chain the documents were held centrally.

Enforcement Issues

Issues may arise in respect of ceramic articles that do not comply with the legal requirements. Clearly the power to seizure which relates to food cannot be applied.

Powers to deal with defective goods supplied to a consumer are to be found in the provisions of the General Product Safety Regulations 2005 e.g. Regulation 3(2)(b) allow for certain obligations/provisions to apply along with enforcement powers e.g.

- Suspension notices (Regulation 11)
- Forfeiture (Regulation 18)

Officers availing of these powers must be appropriately authorised.

Public Analyst Observation

Checks can be made to ensure that the glazes used are not high in lead or cadmium. If there are heavy metals in the glaze then the levels should not be excessive.

In catering establishments checks should be made to ensure that the ceramics are food grade and not merely ornamental wear e.g. Chinese ornamental ceramic ware or similar items sold in budget stores.

Samples to be submitted must not have been used before. Some products are sold with ceramic ware e.g. jam, pate and sometimes honey. The test on migration cannot be done on these products but tests can be done on the ceramic containers as supplied to the manufacturer. With dry ingredients there is little risk from migration of components from the glaze.

Associated Regulations

The Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (SSI No. 230)

<u>Council Directive 84/500/EEC</u> on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs as amended by <u>Commission Directive 2005/31/EC</u> regarding a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs

Further Information

FSA Food contact materials 'Questions and Answers'

Guidance on Ceramic articles in contact with food

Chloroform in Food (Scotland) Regulations 1980 (SI No. 289)

Scope

These regulations prohibit the sale and export of food containing chloroform in or on that food.

Ingredients/Products

Chloroform: This substance is colourless, volatile, non-flammable, and only slightly water-soluble. It is a pungent and sweet-tasting liquid. It is usually derived from acetone, acetaldehyde, or ethyl alcohol by the reaction of chloride of lime: used chiefly in medicine as a solvent and formerly as an anaesthetic.

Chloroform is one of the trihalomethanes and is a known carcinogenic substance.

For the purposes of the regulations food found to contain chloroform may be treated as failing the food safety requirement of the EC Regulation 178/2002 as enacted by the General Food Regulations 2004.

Public Analyst Observation

Chloroform is not currently found in foods.

Associated Regulations

General Food (Scotland) Regulations 2004

EC Regulation 178/2002

Further Information

Cocoa and Chocolate Products (Scotland) Regulations 2003 (SSI No. 291)

Scope

The regulations implement the European Directive 2000/36/EC relating to cocoa and chocolate products intended for human consumption.

The regulations do not apply to composite foods containing such a product as an ingredient. However where a cocoa or chocolate product (designated product) is used as an ingredient in another food, it must meet the compositional requirements.

The compositional requirements are contained in Schedule 1 and a QUID declaration of the amount of the designated product will be required when contained in a composite product such as a pre-packed chocolate chip cookie (normal QUID rules apply to designated products).

Ingredients/Products

The products covered by the regulations include

- Cocoa butter
- Cocoa and powdered chocolate (including reduced fat and non fat)
- Chocolate, milk chocolate, (including family milk chocolate, white chocolate, filled chocolate, 'Chocolate a la taza' and chocolates or pralines

The central requirement of the Regulations is to provide 'reserved descriptions' for 'designated products'. Schedule 1 of the Regulations states the reserved descriptions with the minimum compositional requirements for each. A reserved description cannot be used to describe a product unless it meets the relevant compositional requirements. Where the compositional requirements are met, the reserved description must be used in the name of the food.

Schedule 1 is provided in the annex to this document.

Schedule 1 permits additional ingredients to be added to designated products (other than cocoa butter and powdered cocoa products) but must not exceed 40% of the weight of the finished products e.g. nuts, fruit, honeycomb. The regulations prohibit the addition of:

- animal fats and their preparations not derived solely from milk
- flour, granular and powdered starch (other than in chocolate a la taza and chocolate familiar a la taza : see Schedule 1 of the regulations). Flour includes all types of flour i.e. cereal flours as well as ingredients such as soya flour.

Flavour

Flavouring may also be added to a designated product except cocoa butter provided the flavouring does not mimic the taste of chocolate or milk fat. However, flavourings that significantly characterise the food product will have to indicate this in the name of the food e.g. orange flavoured milk chocolate.

The Food Labelling Regulations provide controls for the use of the word 'chocolate' to foods that are not designated products, but have a chocolate flavour. Schedule 8 of the Food Labelling Regulations 1996 as amended requires that a food is not described as having a chocolate flavour unless that flavour is derived wholly or mainly from either chocolate or (where the purchaser would not be misled by the description) from non-fat solids. Therefore the use of the word 'flavour' e.g. 'chocolate flavour sauce' may be used provided the purchaser is not misled by the description,

The Regulations require that a food cannot include any reserved description set out in Schedule 1 unless:

- a) the food is the designated product to which the reserved description relates.
- b) the description is used to indicate explicitly that the substance to which it relates is only an ingredient of that food.
- c) the description is used to indicate explicitly that the food in question is not and does not contain a designated product.

Use of Vegetable Fats other than Cocoa Butter

Regulation 3 permits the addition of authorised vegetable fats other than cocoa butter to specific designated products - i.e. in column 2 of Schedule 1 items 3, 4, 5, 6, 8 and 9. The addition of these fats must not exceed 5% of the finished product, after the deduction of the total weight of any other edible substance permitted, without reducing the minimum content of cocoa butter or total dry cocoa solids. The authorised vegetable fats are listed in Schedule 2 of the Regulations.

Chocolate Products

Schedule 1 of the Regulations describes the various chocolate products as being obtained from cocoa products and sugars i.e. the products <u>must</u> contain <u>added</u> sugars.

Use of Sweeteners

Artificial sweeteners may be used in accordance with the rules in the Sweeteners in Food Regulations⁵. These provide restrictions on the specific sweeteners that may be used and the Food Labelling Regulations 1996 require additional labelling to indicate their presence.

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⁵ EC Regulation 1333/2008

FSA advice on the use of sweeteners and amount of added sugars is summarised as follows:

- a) 'Chocolate' including some added sugars with sweeteners used to replace part
 of the sugar is a chocolate product and must comply with Cocoa and Chocolate
 Products Regulations.
- b) 'Chocolate' with no added sugars and no added sweeteners is not a chocolate product and does not have to comply with the Cocoa and Chocolate Products Regulations labelling requirements. The term 'chocolate' or any of the reserved descriptions in their labelling may be used provided that the term is used with sufficient context to indicate clearly that the food is not and does not contain chocolate. The name of the food and the use of the word 'chocolate' on the labelling must therefore be put into appropriate context.
- c) 'Chocolate' where there are no added sugars but with added sweeteners. This is not a chocolate product and is not required to carry Cocoa and Chocolate Products Regulations labelling requirements. The product has to comply with the Sweeteners in Food Regulations and additional labelling requirements in the Food Labelling Regulations 1996, as amended. FSA guidance recommends that the use of the word 'chocolate' on the labelling of such products must be put into context so as not to confuse the consumer e.g. 'no added sugar chocolate with sweetener(s)'.

Labelling Requirements

Regulation 6 specifies requirements with regard to labelling and marking of designated products.

Where a product contains vegetable fats other than cocoa butter, the products labelling must include the words 'contains vegetable fats in addition to cocoa butter'. The declaration must be in the same field of vision as the list of ingredients, in bold lettering at least as large as that of the list of ingredients and located near to the reserved description in at least one place on the packaging, but not necessarily each time the reserved description appears. It should be noted that this statement is required in addition to the listing of the vegetable fats in the product list of ingredients.

Milk Solids Declaration

Milk chocolate made from either 14/25 recipe or the 20/20 recipe must give an indication of the milk solids content in the form 'milk solids x % minimum'.

Cocoa Solids Declaration

Designated products (except cocoa butter, white chocolate, filled chocolate, chocolates and pralines) must be labelled with a declaration of the cocoa solids content as 'cocoa solids x % minimum'. For those products containing additional ingredients such as nuts or honeycomb it should be clear that the declared percentage relates to the weight of the chocolate part and not the whole product.

Regulation 6 (4) states how the percentage of cocoa solids in the product must be calculated. An example can be found in the <u>FSA guidance</u>:

The designated products require that 'fat-reduced cocoa powder' and 'fat -reduced drinking chocolate' as well as products described using any of the permitted reserved descriptions for these products are required to be labelled with an indication of the cocoa butter content.

No specific wording is stipulated for the declaration. The FSA guidance recommends the words 'contains cocoa butter x % minimum' be used.

Calculation of cocoa solids

Sugar 48
Cocoa solids content
Cocoa solids declared
Milk solids 820g/80g =25%
Is calculated on Cocoa solids 2020g/98g=20%
Vegetable fats 4
Hazelnut 18
Lecitin 1
Vanillin 1
Total 100g

Assortments

Where the designated products are sold in assortment, the reserved description may be replaced by 'assorted chocolates', 'assorted filled chocolates' or similar statement. The list of ingredients may cover all the products in the assortment, instead of a separate list of ingredients for each product.

Manufacturers may choose to supplement the reserved descriptions 'chocolate', 'milk chocolate' and 'couverture chocolate' with further descriptions that emphasise the quality of the chocolate e.g. extra fine milk chocolate. Where such descriptions are used, the product must meet the following additional requirements:

- Chocolate not less than 43% dry cocoa solids, including not less than 26% cocoa butter
- Milk chocolate not less than 30% dry cocoa and not less than 18% dry milk solids
- Couverture chocolate -not less than 16% dry non-fat cocoa solids.

Seasonal Selection Packs

If designated products are sold in a seasonal selection pack, the outer packaging is not required to carry any labelling information provided each item in the pack is properly labelled.

Minimum Durability

All chocolate food products sold pre-packed are subject to the indication of minimum durability requirements of the Food Labelling Regulations.

Public Analyst Observation

Inadvertent allergen ingredients can occasionally turn up in Chocolate products e.g. traces of nuts.

No other issues as there are few manufacturers in the United Kingdom.

Authorised officers should be aware of chocolate flavour coatings being described as chocolate.

Associated Regulations

Cocoa and Chocolate Products (Scotland) Regulations 2003 (SSI No. 291)

EC Directive 2000/36/EC relating to cocoa and chocolate products intended for human consumption relating to cocoa and chocolate products intended for human consumption

Further Information

The FSA guidance notes (Revised May 2006) on The Cocoa and Chocolate Products Regulations 2003 should be consulted for further guidance

Quick Guide to Chocolate

SCHEDULE

Annex 1

SCHEDULE 1

Regulations 2, 3 and 6

COCOA AND CHOCOLATE PRODUCTS AND THEIR RESERVED DESCRIPTIONS

Colur	nn 1	Column 2
Reserved descriptions		Designated products
1.	Cocoa butter	The fat obtained from cocoa beans or parts of
		cocoa beans with the following characteristics:
		- not more than 1.75 per cent free fatty acid
		content (expressed as oleic acid); and
		- for press cocoa butter, not more than 0.35
		per cent unsaponifiable matter (determined
		using petroleum ether); or
		31
		- for other cocoa butter, not more than 0.5 per
		cent unsaponifiable matter (so determined).
2.		
(a)	Cocoa powder or Cocoa	The product obtained by converting into
		powder cocoa beans which have been
		cleaned, shelled and roasted, and which
		contains not less than 20 per cent cocoa
		butter, calculated according to the weight of
		the dry matter, and not more than 9 per cent
		water.
(b)	Fat-reduced cocoa or	Cocoa powder containing less than 20 per
	Fat-reduced cocoa	cent cocoa butter, calculated according to the
	powder	weight of the dry matter.

(c)	Powdered chocolate or	The product consisting of a mixture of cocoa
	Chocolate in powder	powder and sugars, containing not less than
		32 per cent cocoa powder.
(d)	Drinking chocolate or	The product consisting of a mixture of cocoa
	Sweetened cocoa or	powder and sugars, containing not less than
	Sweetened cocoa	25 per cent cocoa powder.
	powder	
(e)	Fat-reduced drinking	The product consisting of a mixture of cocoa
	chocolate or Fat-	powder specified at item 2(b) and sugars,
	reduced sweetened	containing not less than 25 per cent of such
	cocoa or Fat-reduced	cocoa powder.
	sweetened cocoa	
	powder	
3.		
(a)	Chocolate	(a) The product obtained from cocoa
		products and sugars which, subject to item
		3(b), contains not less than 35 per cent total
		dry cocoa solids, including not less than 18
		per cent cocoa butter and not less than 14 per
		cent of dry non-fat cocoa solids.
(b)	If "Chocolate" is	The product presented in the form of granules
	supplemented by	or flakes containing not less than 32 per cent
(i)	"vermicelli" or "flakes"	total dry cocoa solids, including not less than
		12 per cent cocoa butter and not less than 14
		per cent of dry non-fat cocoa solids.
(ii)	"couverture"	The product containing not less than 35 per
		cent total dry cocoa solids, including not less
		than 31 per cent cocoa butter and not less
		than 2.5 per cent of dry non-fat cocoa solids.
(iii)	"Gianduja" <i>or</i> one of the	The nut chocolate product obtained (1) from
	derivatives of	chocolate having a minimum total dry cocoa
	"Gianduja"	solids content of 32 per cent including a
		minimum dry non-fat cocoa solids content of 8

per cent, and (2) from finely ground hazelnuts in such quantities that 100 grams of the product contain not less than 20 grams and not more than 40 grams of hazelnuts; and to which may have been added:

- milk or dry milk solids obtained by evaporation or both, in such proportion that the finished product does not contain more than 5 per cent dry milk solids;
- almonds, hazelnuts and other nut varieties, either whole or broken, in such quantities that, together with the ground hazelnuts, they do not exceed 60 per cent of the total weight of the product.

4.

(a) Milk chocolate

The product obtained from cocoa products, sugars and milk or milk products which, subject to item 4(b), contains:

- not less than 25 per cent total dry cocoa solids
- not less than 14 per cent dry milk solids obtained by partly or wholly dehydrating whole milk, semi-skimmed or skimmed milk, cream, or from partly or wholly dehydrated cream, butter or milk fat
- not less than 2.5 per cent dry non-fat cocoa solids
- not less than 3.5 per cent milk fat

- not less than 25 per cent total fat (cocoa butter and milk fat). (b) If "Milk chocolate" is The product presented in the form of granules supplemented by or flakes containing not less than 20 per cent "vermicelli" or "flakes" (i) total dry cocoa solids, not less than 12 per cent dry milk solids obtained by partly or wholly dehydrating whole milk, semi-skimmed or skimmed milk, cream or from partly or wholly dehydrated cream, butter or milk fat and not less than 12 per cent total fat (cocoa butter and milk fat). "couverture" (ii) The product containing a minimum total fat (cocoa butter and milk fat) content of 31 per cent. (iii) "Gianduja" or one of The nut milk chocolate product obtained (1) the derivatives of from milk chocolate having a minimum content "Gianduja" of 10 per cent dry milk solids, obtained by partly or wholly dehydrating whole milk, semiskimmed or skimmed milk, cream, or from partly or wholly dehydrated cream, butter or milk fat and (2) from finely ground hazelnuts in such quantities that 100 grams of the produce contain not less than 15 grams and not more than 40 grams of hazelnuts; and to which may have been added almonds, hazelnuts and other nut varieties, either whole or broken, in such quantities that, together with the ground hazelnuts, they do not exceed 60 per cent of the total weight of the product. (c) If "Milk" is replaced by -The product containing a minimum milk fat "cream" content of 5.5 per cent. (i)

(ii)	"skimmed milk"	The product containing a milk fat content not
_	Family mills absolute or	greater than 1 per cent.
5.	•	The product obtained from cocoa products,
	Milk chocolate	sugars and milk or milk products which contains:
		Contains.
		-not less than 20 per cent total dry cocoa
		solids;
		-not less than 20 per cent dry milk solids
		obtained by partly or wholly dehydrating whole
		milk, semi-skimmed or skimmed milk, cream,
		or from partly or wholly dehydrated cream,
		butter or milk fat;
		-not less than 2.5 per cent dry non-fat cocoa
		solids;
		-not less than 5 per cent milk fat;
		-not less than 25 per cent total fat (cocoa
		butter and milk fat).
6.	White chocolate	The product obtained from cocoa butter, milk
		or milk products and sugars which contains
		not less than 20 per cent cocoa butter and not less than 14 per cent dry milk solids obtained
		by partly or wholly dehydrating whole milk,
		semi-skimmed or skimmed milk, cream, or
		from partly or wholly dehydrated cream, butter
		or milk fat, of which not less than 3.5 per cent
		is milk fat.
7.	Filled chocolate or	The filled product, the outer part of which
	Chocolate with filling	consists of a product specified in column 2 of

or Chocolate with ... item 3, 4, 5 or 6 and constitutes not less than centre 25 per cent of the total weight of the product, but does not include any filled product, the inside of which consists of bakery products, pastry, biscuit or edible ice. 8. Chocolate a la taza The product obtained from cocoa products, sugars, and flour or starch from wheat, rice or maize, which contains not less than 35 per cent total dry cocoa solids, including not less than 18 per cent cocoa butter and not less than 14 per cent dry non-fat cocoa solids, and not more than 8 per cent flour or starch. Chocolate familiar a la 9. The product obtained from cocoa products, taza sugars, and flour or starch from wheat, rice or maize, which contains not less than 30 per cent total dry cocoa solids, including not less than 18 per cent cocoa butter and not less than 12 per cent dry non-fat cocoa solids, and not more than 18 per cent flour or starch. 10. A chocolate *or* A praline The product in single mouthful size, consisting of:-(a) the product specified in column 2 of item 7; or (b) a single chocolate or a combination or a mixture of chocolate within the meaning of any of the definitions specified in column 2 of items 3, 4, 5 and 6 and any other edible substance, provided that the chocolate constitutes not less than 25 per cent of the total weight of the product.

Notes

1. (1) Subject to regulation 3 and paragraph (2) of this Note, other edible substances may also be added to the designated chocolate products specified in column 2 of items 3, 4, 5, 6, 8 and 9:

Provided that this paragraph does not authorise the addition -

- (a) of animal fats and their preparations not deriving solely from milk; or
- (b) of flours, granular and powdered starch other than in accordance with the definitions specified in column 2 of items 8 and 9; or
- (c) of other edible substances in a quantity exceeding 40 per cent of the total weight of the finished product.
- (2) Only those flavourings which do not mimic the taste of chocolate or of milk fat may be added to the designated products specified in column 2 of items 2, 3, 4, 5, 6, 8 and 9.
- 2. (1) The minimum contents of the designated chocolate products specified in column 2 of items 3, 4, 5, 6, 8 and 9 shall be calculated after deduction of the weight of other edible substances provided for in Note 1.
 - (2) In the case of the designated chocolate products specified in column 2 of items 7 and 10, the minimum contents shall be calculated after deducting the weight of other edible substances provided for in Note 1, as well as the weight of the filling.
 - (3) The chocolate contents of the designated chocolate products specified in column 2 of items 7 and 10 shall be calculated in relation to the total weight of the finished product, including its filling.
- 3. In this Schedule, 'sugars' includes sugars covered by Council Directive 2001/111/EC (21) and other sugars.

Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 (SSI No. 38)

Scope

The Regulations implement <u>Directive 1999/4/EC</u> and apply to coffee and chicory extracts which are ready for delivery to the ultimate consumer or to a catering establishment. The Regulations do not apply to the product known as café torrefacto soluble. The Regulations prescribe definitions and reserved descriptions for coffee extracts and chicory extracts and restrict the sale of such foods which must be labelled with a reserved description.

Ingredients/Products

The regulations apply to coffee and chicory extracts which are defined as follows:-

Coffee extract: The concentrated product obtained by extraction from roasted coffee beans using water as the only means of extraction (excluding any process of hydrolysis involving the addition of a acid or base) and which contains only the soluble and aromatic constituents of coffee apart from the insoluble substances which it is impossible to remove and insoluble solids derived from coffee.

Chicory extract: The concentrated product obtained by extraction from roasted chicory using only water as the method of extraction (excluding any process of hydrolysis involving the addition of an acid or base).

The use of the reserved descriptions is restricted in the labelling of foodstuffs unless:

- a) The food is the designated product to which the reserved description relates
- b) The description is used in such a context as to indicate explicitly or by clear implication that the substance to which it relates is only an ingredient of that food
- c) The description is used in such a context as to indicate explicitly or by clear implication that such food is not and does not contain a designated product.

Annex 1 of the Regulations states the reserved descriptions and designated products of both coffee extracts and chicory extracts. (See attached Schedule)

Labelling Requirements

There are specific labelling requirements for the designated products in addition to the general requirements of the Food Labelling Regulations 1996 as amended. These are:

- A reserved description of the product
- The word 'decaffeinated' for coffee extracts which have been subjected to a
 decaffeination process and in which the residual anhydrous caffeine content
 does not exceed 0.30% of its coffee-based dry matter content
- In the case of coffee and chicory extracts in liquid form in which sugar has been used, the words 'with x', 'preserved with x', 'with added x' or 'roasted with x' as

appropriate, x being the name of the sugar product used. The name of the sugar product used must be the reserved description from Specified Sugar Products (Scotland) Regulations 2003 or if no reserved description the name of the product as if it were itself being sold as a food

- In the case of coffee/ chicory extracts in paste or liquid form a declaration of the minimum coffee/ chicory based dry matter content expressed as a percentage
- In the case of coffee extracts in liquid form containing more than 25% coffee based dry matter and for chicory extracts in liquid form containing more than 45% chicory based dry matter the word 'concentrated' may be added to the reserved description
- The information required by these regulations must be in a conspicuous place so as to be clearly visible, clearly legible and indelible and easy to understand.

Public Analyst Observation

There tend to be very few issues regarding composition and labelling of these products.

Associated Regulations

Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 (SSI No. 38)

Directive 1999/4/EC relating to coffee extracts and chicory extracts.

SCHEDULE

Annex 1

Table

Coffee Extracts and their Reserved Descriptions

Column 1	Column 2
Reserved descriptions	Designated Products
Coffee extract or Soluble coffee extract or Instant coffee or Soluble coffee	Coffee extracts in powder, granular, flake, cube or other solid form, of which the coffee-based dry matter content is not less than 95%, containing no substances other than those derived from the extraction of coffee.
2. Coffee extract supplemented in or Soluble coffee each case by the extract or Instant word "paste" or the coffee or Soluble words "in paste form" coffee	Coffee extracts in paste form, of which the coffee-based dry matter content is not more than 85%, and not less than 70%, containing no substances other than those derived from the extraction of coffee.
3. Coffee extract supplemented in or Soluble coffee each case by the extract or Instant word "liquid" or the coffee or Soluble words "in liquid form" coffee	Coffee extracts in liquid form, of which the coffee-based dry matter content is not more than 55%, and not less than 15%. NOTE:
	The product may contain added sugar products, whether or not roasted, in a proportion not exceeding 12%.

Part II

Chicory Extracts and their Reserved Descriptions

Column 1		Column 2
Reserved descriptions		Designated Products
1. Chicory extrac	t or Instant chicory or	Chicory extracts in powder,
Soluble chicor	у	granular, flake, cube or other solid
		form, of which the chicory-based
		dry matter content is not less than
		95%.
		NOTE.
		NOTE:
		This product may contain not
		more than 1% of substances not
_		derived from chicory.
2. Chicory	supplemented in each	Chicory extracts in paste form, of
extract or Instant	case by the word "paste"	which the chicory-based dry
chicory or	or the words "in paste	matter content is not more than
Soluble chicory	form"	85%, and not less than 70%.
		NOTE:
		This product may contain not
		more than 1% of substances not
		derived from chicory.
3. Chicory	supplemented in each	Chicory extracts in liquid form, of
extract or Instant	case by the word "liquid"	which the chicory-based dry
chicory or	or the words "in liquid	matter content is not more than
Soluble chicory	form"	55%, and not less than 25%.

NOTE:
This product may contain added sugar products, whether or not roasted, in a proportion not exceeding 35%.

The Condensed Milk and Dried Milk (Scotland) Regulations 2003 (SSI No.12)

Scope

These regulations implement the provisions of <u>EC Directive 2001/114</u> relating to certain partly or wholly dehydrated preserved milk for human consumption. EC Directive 2001/114 was amended by <u>Council Directive 2007/61/EC</u> and these amendments are addressed by the Condensed Milk and Dried Milk (Amendment) (Scotland) Regulations 2008.

In addition all products covered by the Regulations must also comply with the general provisions of <u>The Food Safety Act 1990</u>, <u>The Food Labelling Regulations</u> 1996 (as amended) and all other relevant legislation.

Ingredients/Products

Interpretation Article 1 and Annex I of 2001/114/EC Regulation 2, 3, 4 & 10 and Schedule 1 & 2 of SI 2003

The Regulations are intended to make rules governing the labelling of certain preserved milk, and the manufacturing specifications to be adhered to if products are to be described by certain reserved descriptions. As the name implies, these Regulations apply to condensed milk and dried milk, intended for human consumption and ready for delivery

to the ultimate consumer or to a catering establishment. A full list of these products with their specification is in Annex I of the schedule to these notes.

The products subject to these Regulations are grouped in two classes, partly dehydrated milk and totally dehydrated milk. Partly dehydrated milk can be sweetened (sweetened condensed milk) or unsweetened (unsweetened condensed milk). The two classes are further subdivided by their fat content. This is outlined in Annex I as reproduced in the schedule to these notes.

Labelling Requirements Reserved Descriptions

Reserved descriptions are used for certain foods which must meet specific product criteria. The reserved descriptions listed in column 1 of Annex 1 are to be used to name all products which comply with the product requirements as described in column 2 of Annex 1 of these notes.

Alternative descriptions, with their respective product requirements are listed in Annex 2 of these notes.

ADDED VITAMINS ARTICLE 3 OF 2001/114/EC Regulation 2 and Notes to Schedule 1 of SI 2003 Added vitamins:

Any condensed milk product or dried milk product may contain any added vitamin as a permitted miscellaneous additive, provided the final product complies with the Food Safety (Scotland) Act 1990, as amended.

LABELLING ARTICLE 3 OF 2001/114/EC Regulations 5, 6 and Schedule 1 of SI 2003

Condensed milk and dried milk products within the scope of these Regulations are subject to the general rules set by the Food Labelling Regulations 1996, with particular respect to Regulations 35, 36 (1) and (5) and 38 (which relate to the manner of marking or labelling of food). In general, these products should be labelled with the percentage of milk fat expressed by weight in relation to the finished product and the percentage of fat-free milk extract. This information should appear on the label near

the trade name of the product. However, there are exceptions.

Totally dehydrated milk (dried high-fat milk or high-fat milk powder, dried whole milk or whole milk powder, dried partly skimmed milk or partly skimmed-milk powder, dried skimmed milk or skimmed-milk powder) must also have the following information on the label:

- details of the fat content of the product when diluted or reconstituted
- recommendations as to the method of dilution or reconstitution
- the product is "not intended as a food for infants under 12 months"

Exceptions

- Skimmed products, that is condensed skimmed milk, sweetened condensed skimmed milk, and dried skimmed milk or skimmed milk powder which do not contain more than 1% fat. Do not need to be labelled with the percentage of milk fat, expressed by weight in relation to the finished product
- Totally dehydrated milk, that is dried high-fat milk or high-fat milk powder, dried whole milk or whole milk powder, dried partly skimmed milk or partly skimmedmilk powder, dried skimmed milk or skimmed milk powder: Do not need to state the percentage of fat-free dried milk extract
- Products caught by these Regulations in pack sizes of less than 20 grams per unit must be labelled with the required designation but all other labelling requirements need only appear on the outer packaging.

LABELLING OF MILK PRODUCT OR DRIED MILK PRODUCT WITH ADDED VITAMINS USED IN THE PRODUCTION OF A COMPOUND FOOD, E.G. INSTANT HOT CHOCOLATE

Under the current Food Labelling Regulations 1996 (as amended) (FLR), if the fortified milk product or dried milk product constitutes 2% or more of the finished product then the vitamins would need to be included in the ingredients list of the final product.

Additives

Notes for Schedule 1 of SI 2003

Additives that are listed as permitted currently by the Food Additives (Scotland) Regulations 2009 for use in the designated products may continue be used for the foreseeable future.

Public Analyst Observation

Very few issues arise in respect of these products as they are manufactured at specified sites and no longer at dairies.

Associated Regulations

<u>EC Directive 2001/114</u> relating to certain partly or wholly dehydrated preserved milk for human consumption.

The Condensed Milk and Dried Milk (Scotland) Regulations 2003 (SSI No. 311)

Food Safety Act 1990

Food Labelling Regulations 1996

Specified Sugar Products (Scotland) Regulations 2003

Condensed Milk and Dried Milk (Amendment) (Scotland) Regulations 2008

The Food Additives (Scotland) Regulations 2009

Further Information

Guidance on condensed milk and dried milk

On 26 September 2007, the European Commission published amendments to Directives relating to the Dairy Industry:

Council Directive 2007/61/EC amends Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption

Currently, the Agency is responsible for implementing Directive 2001/114/EC through domestic legislation; The Condensed Milk and Dried Milk (Scotland) Regulations 2003 (SSI No. 12)

The main features of Directive 2007/61/EC are:

- Protein Standardisation Allowing the standardisation of the protein content of preserved milk (dried and condensed milk) in line with internationally agreed standards (<u>CODEX</u>)
- Definition of partially and totally dehydrated milk Removal of the word "directly" from the current definitions
- Council Regulation 1925/2006/EC on the addition of vitamins and minerals and of certain other substances to foods - Addition of reference

SCHEDULE

Annex I

PARTLY OR WHOLLY DEHYDRATED PRESERVED MILK PRODUCTS AND THEIR RESERVED DESCRIPTIONS

Column 1	Column 2
Reserved description	
1. Partly dehydrated milk	
- Types of unsweetened	
condensed milk	
(a) Condensed high-fat milk	Partly dehydrated milk containing, by weight, not less than 15% fat, and not less than 26.5% total milk solids.
(b) Condensed milk	Partly dehydrated milk containing, by weight, not less than 7.5% fat, and not less than 25% total milk solids.
(c) Condensed, partly skimmed milk	Partly dehydrated milk containing, by weight, not less than 1% and less than 7.5% fat, and not less than 20% total milk solids.
(d) Condensed skimmed milk - Types of sweetened condensed milk	Partly dehydrated milk containing, by weight, not more than 1% fat, and not less than 20% total milk solids.
Typos of sweeteriou condensed mink	
(e) Sweetened condensed milk	Partly dehydrated milk with an admixture of sucrose* (semi-white sugar, white sugar or extra white sugar) and containing, by weight, not less than 8% fat and not less than 28%

	total milk solids.
(f) Sweetened condensed, partly skimmed milk	Partly dehydrated milk with an admixture of sucrose* (semi-white sugar, white sugar or extra white
	sugar) and containing, by weight, not less than 1% and less than 8% fat, and not less than 24% total milk solids.
(g) Sweetened condensed skimmed milk	Partly dehydrated milk with an admixture of sucrose* (semi-white sugar, white sugar or extra white sugar) and containing, by weight, not more than 1% fat and not less than 24% total milk solids.

*as defined by the Specified Sugar Products (Scotland) Regulations 2003.

2. To	tally dehydrated milk	
Reserved description		Designated product
(a)	Dried high-fat milk or high-fat milk powder	Totally dehydrated milk containing, by weight, not less than 42% fat.
(b)	Dried whole milk or whole milk powder	Totally dehydrated milk containing, by weight, not less than 26% and less than 42% fat.
(c)	Dried partly skimmed milk or partly skimmed-milk powder	Totally dehydrated milk with a fat content of more than 1.5% and less than 26% by weight.
(d)	Dried skimmed milk or skimmed- milk powder	Totally dehydrated milk containing, by weight, not more than 1.5% fat.

Notes

- 2. Authorised additions and raw materials:
- (a) Any designated product may contain—
 - (i) any substance permitted pursuant to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives, and
 - (ii) vitamins and minerals in accordance with the requirements Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods
- (b) Authorised raw materials for protein adjustment purposes referred to in Note 4 are:
 - (i) Milk retentate, which is the product obtained by concentrating milk protein by ultra filtration of milk, partly skimmed milk or skimmed milk;
 - (ii) Milk permeate, which is the product obtained by removing milk proteins and milk fat from milk, partly skimmed milk or skimmed milk by ultra filtration; and
 - (iii) Lactose, which is a natural constituent of milk normally obtained from whey with an anhydrous lactose content of not less than 99.0% m/m on a dry basis. It may be anhydrous or contain one molecule of water of crystallisation or be a mixture of both forms.
- **3.** An additional quantity of lactose, not greater than 0.03% by weight of the finished product, may be added in the manufacture of any designated product specified in paragraph 1(e) to (g).
- 4. Without prejudice to Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin as corrected by a corrigendum published on 25 June 2004 and amended by Commission Regulation (EC) No. 2074/2005 of 5 December 2005, Commission Regulation (EC) No. 2076/2005 of 5 December 2005, Commission Regulation (EC) No. 1662/2006 of 6 November 2006 and Council Regulation (EC) No. 1791/2006 of 20 November 2006, the preservation of the designated products shall be achieved—".
- 5. Without prejudice to the compositional requirements set out in the table above, the protein content of milk may be adjusted to a minimum content of 34% by weight (expressed on fat-free dry matter) by the addition and/or withdrawal of milk constituents in such a way as not to alter the ratio of whey protein to casein in the milk being adjusted.
- **6.** The levels of dry matter, moisture content, fat, sucrose, lactic acid and lactates and phosphatase activity in the designated products shall be determined in accordance with the methods set out in Directive 79/1067.

Annex II

ALTERNATIVES TO THE RESERVED DESCRIPTIONS SPECIFIED

- 1. The term "evaporated milk" may be used instead of the term "condensed milk" in the case of partly dehydrated milk containing, by weight, at least 9% fat and 31% total milk solids.
- 2. The term "evaporated semi-skimmed milk" may be used instead of the term "condensed partly skimmed milk" in the case of partly dehydrated milk containing, by weight, between 4% and 4.5% fat and not less than 24% total milk solids.
- 3. The term "semi-skimmed milk powder" or "dried semi-skimmed milk" may be used instead of the term "dried partly skimmed milk" or "partly skimmed-milk powder" in the case of totally dehydrated milk with a fat content of between 14% and 16%.

The Contaminants in Food (Scotland) Regulations 2009 SSI No 215

Scope

These Regulations implement <u>European Commission Regulation 1881/2006</u> setting maximum levels for contaminants in food. The regulation as amended sets maximum permitted levels for certain contaminants in foodstuffs.

Ingredients/Products

The rules apply to all foodstuffs including those that are used as ingredients.

Purpose of the regulations

<u>Commission Regulation 1881/2006</u> (as amended) provides consumers with an increased level of protection through the setting of maximum EC levels for

- specific mycotoxins
- undesirable process
 and
- environmental contaminants

in those foods that are significant contributors to the total dietary exposure by the consumer. The levels are set so that they are toxicologically acceptable and exclude grossly contaminated food from entering the food chain.

Article 1 of Regulation 1881/2006 specifies by means of an annex foods that must not be placed on the market if they contain a listed contaminant in excess of the maximum level. Maximum levels apply to the edible portion of the food.

The annex is divided into different sections covering the following contaminants.

Section 1 – Nitrites

Section 2 – Mycotoxins - Aflatoxins

- Ochratoxin A

- Patulin

DeoxynivalenolZearalenoneFumonisins

- T-2 and HT-2 Toxin

Section 3 – Metals - Lead

- Cadmium - Mercury

- Tin (inorganic)

Section 4 – 3-monochloropropane-1, 2-diol (3-MCPD)

Section 5 - Dioxins and PCB's

Section 6 – Polycyclic aromatic hydrocarbons – Benzo(a)pyrene

In addition, the Contaminants in Food Regulations also enacts amendments brought about by <u>Commission Regulation EC No. 124/2009</u> setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non target feed.

The following substances are listed in the Annex to EC Regulation No. 124/2009

- Lasalocid sodium
- Narasin
- Salinomycin sodium
- Monensin sodium
- Semduramicin
- Maduramicin
- Robenidine
- Decoquinate
- Halofuginone
- Nicarbazin and
- Diclazuril

<u>The Contaminants in Food (Scotland) Regulations 2009</u> create the following offences:

- Placing on the market certain foods that contain contaminants at levels exceeding those specified in the <u>EC Regulation 1881/2006</u> as amended.
- Using products that do not comply with maximum levels as food ingredients for the production of compound foods.
- Mixing foods that do not comply with the maximum levels.
- In relation to afflatoxins, to mix foods intended for direct consumption with foods that are intended to be sorted or otherwise treated prior to consumption or
- In relation to mycotoxins, to detoxify by chemical treatment food not complying with the maximum limits.

Public Analyst Observations

It is important to note that there is separate EU legislation which covers the sampling and sample storage (and analysis) of some of these contaminants (e.g. Commission Regulations (EC) Nos 33/2007 and 1883/2006. It is important to check if any such provisions exist before samples are taken.

Associated Regulations

Contaminants in Food (Scotland) Regulations 2009

Commission Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

<u>Commission Regulation (EC) No. 466/2001 setting maximum levels for certain contaminants in foodstuffs.</u>

Commission Regulation (EC) No. 565/2008 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCB's in fish liver.

Commission Regulation (EC) No. 629/2008 amending Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

Commission Regulation (EC) No. 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from unavoidable carry-over of these substances in non-target feed.

Further Information

FSA Guidance on the Contaminants in Food (Scotland) Regulations 2009

Drinking Milk (Scotland) Regulations 2008 (SI No. 237)

Scope

These Regulations made provisions for the enforcement of Article 114(2) of, and Annex XIII to, Council Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products.

Ingredients/Products

Milk is defined in the directive as the produce of milking one or more cows and as such the standards would not apply to milk from any other source.

Labelling Requirements

If a food business operator sells milk for drinking, or imports milk into the European Union, they must describe it using one of the following terms, and it must meet the standard for the fat content:

- Raw milk, which must not have been heated above 40°C or equivalent treatment
- Whole milk, heat treated and with a fat content of at least 3.5 per cent
- Non-standardised whole milk, heat treated and with a fat content less than 3.5 per cent
- Semi-skimmed milk, heat treated and with a fat content reduced to between 1.5 and 1.8 per cent
- Skimmed milk, heat treated and with a fat content reduced to 0.5 per cent or below

If a food business operator sells milk for drinking, it must not have been modified, except in the following ways:

- By the addition or removal of cream, whole milk, or semi-skimmed milk, in order to meet the fat content standards
- By enrichment with milk proteins, minerals or vitamins, as long as it is clearly labelled.
- By having the lactose reduced by conversion to glucose and galactose, as long as it is clearly labelled.

In addition, all milk must meet specific technical criteria for:

- Freezing point
- Mass per litre
- Protein content

Public Analyst Observation
Dairies do sometimes have difficulty regulating the fat content of semi-skimmed milk

Associated Regulations

Council Regulation (EC) No. 2597/97

Drinking Milk (Scotland) Regulations 2011 SSI No. 84

Erucic Acid in Food (Scotland) Regulations 1977 (SSI No. 1028)

Scope

These regulations implement <u>European Directive 76/621/EEC</u> which sets the maximum levels of erucic acid in oils and fats intended for human consumption and in foods containing added oil and fat.

Ingredients/Products

Erucic acid is a substance naturally found in some oils derived from plants, primarily in some varieties of mustard seed oil and rapeseed oil. Although there have been no confirmed cases of erucic acid toxicity in humans, high levels of erucic acid have been linked to the formation of fatty deposits in heart muscle in animals.

Erucic acid is defined in the regulations as *cis-docos-13-enoic acid*.

Prior to 1st July 1979 the limit was set at 10% calculated on fatty acid content of the oil or fat component. In respect of any oil or fat or food made thereafter the limit was set at 5% calculated by weight.

Exemptions

The regulations do not apply to:

- Food containing not more than 5% oil or fat unless it is described as specially prepared for infants or young children.
- Food intended for manufacturing or catering purposes.

A breach of the Erucic Acid in Food (Scotland) Regulations 1977 may occur when:

- (a) Erucic acid is more than 5% of the fatty acid content of any oil or fat or mixture of the two.
- (b) For foods with more than 5% total fat content, the erucic acid comprises more than 5% of the fatty acid content of all the oil or fat in the case of a food to which oil and/or fat has been added.
- (c) Where a product to which oil and/or fat have been added is aimed explicitly or implicitly at young children and infants, the same conditions in (b) apply except there is no minimum fat level, all such foods must comply irrespective of total fat content.

The regulations were amended in 1982 by Erucic Acid in Food (Amendment) (Scotland) Regulations 1982 (SSI No. 18) implementing Commission Directive 80/891/EEC laying down the method of analysis for determining the erucic acid content of oils and fats and foods intended for human consumption.

Public Analyst Observation

Can be found in oily foods from Far East, Asia subcontinent and China.

There may be imported food issues regarding rape seed oils.

Associated Regulations

Erucic Acid in Food (Scotland) Regulations 1977 (SSI No 1028)

Erucic Acid in Food (Amendment) (Scotland) Regulations 1982 (SI No. 184)

<u>European Directive 76/621/EEC</u> which sets the maximum levels of erucic acid in oils and fats

<u>Commission Directive 80/891/EEC</u> laying down the method of analysis for determining the erucic acid content of oils and fats

Further Information

In 2004 the Food Standards Agency advised people not to eat particular pickles, sauces and preserved vegetables imported from Bangladesh, China, Pakistan and India, following a survey that showed that some products contained illegally high levels of erucic acid.

Eight out of 71 samples of pickles, sauces and preserved vegetables were found to contain levels of erucic acid exceeding the UK legal limit.

Erucic acid in food preserved in oil

FSA alerts

<u>European Directive 76/621/EEC</u> relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats.

European Directive 80/891/EEC laying down the method of analysis for determining the erucic acid content of oils and fats and foods intended for human consumption

Extraction Solvents in Food (Scotland) Regulations 1993 (SI No. 330)

Scope

These Regulations which implement the provisions of EC Directive prohibit the sale or importation into Scotland from outside the EC of extraction solvents (other than permitted extraction solvents which are listed in Schedule I of the Regulations), or any food having in or on it any extraction solvent other than a permitted extraction solvent.

Ingredients/Products

An extraction solvent is defined as any solvent which is used or intended to be used in an extraction procedure. Examples of extraction solvents include propane, butane, ethanol, and methanol. A full list is reproduced in Schedule 1 of the regulations. The Regulations also require that certain information be given with permitted extraction solvents on sale or imported into Scotland from outside the EC.

Labelling Requirements

The labelling information required includes:

- prescribing the name of the permitted extraction solvent;
- a clear statement that the solvent is of suitable quality;
- a batch or lot number for identification purposes;
- name and address of manufacturer or packer;
- net quantity by volume;
- any special storage conditions or conditions for use.

Schedule 2 of the Regulations defines foods in which only certain extraction solvents may be used and the certain purposes for which they can be used.

Schedule 3 gives maximum permissible residue levels for named extraction solvents.

The primary regulations were amended in 1993 by Extraction Solvents in Food (Scotland) Regulations 1993 (SI No. 330).

Public Analyst Observation

Extraction solvents tend not to present many issues regarding food composition.

The solvents can be used to take caffeine out of decaffeinated coffee. Today it is more likely that high pressure carbon dioxide would be used to remove caffeine and in consequence there tends to be no residue issues.

Associated Regulations

Extraction Solvents in Food (Scotland) Regulations 1993 (SI No. 330)

Extraction Solvents in Food (Amendment) (Scotland) Regulations 1995 (SI No. 263)

Extraction Solvents in Food (Amendment) Regulations 1998 (SI No. 2257)

EC Directive 88/344 on extraction solvents used in the production of food and food ingredients

EC Directive 97/60 on extraction solvents used in the production of food and food ingredients

Further Information

The Fish Labelling (Scotland) Regulations 2010 (SSI No. 90)

Scope

These regulations implement the provisions of European Council Regulation 104/2000 on the common organisation of the markets in fishery and aquaculture products, and Commission Regulation 2065/2001 laying down detailed rules for application of Council Regulation 104/2000 as regards consumer information.

These Regulations require fish sold at retail to be labelled with all of the following information:

- Commercial name of the fish species (but scientific (Latin) name is optional at retail sale). It requires Member States to establish a list of commercial designations of fish species which are names prescribed by law. These are established in the Schedule to The Fish Labelling (Scotland) Regulations 2010.
- Method of Production (i.e. whether caught at sea, or inland waters or farmed)
- Catch area or Country of Production (i.e. European Member State or third country of origin)

Ingredients/Products

The regulations apply to the following products:

- Fish pre-packed at retail sale: live fish; fresh, chilled or frozen fish; smoked fish; dried, salted or brined fish; fish fillets (whether minced or not); crustaceans (except crustaceans which are both cooked and peeled); and molluscs (except cooked molluscs).
- Apply also to fish (in the aforementioned presentations) which is sold loose from fish counters or pre-packed for direct sale to the final consumer.

It should be noted that the regulations do not apply to

- fish that has been further processed, preserved treated or cooked e.g. tinned tuna:
- fish to which other ingredients have been added e.g. fish fingers; fish with colouring;
- crabsticks, fish sticks or similar;
- recipe dishes/fish ready meals e.g. fish pies;
- smoked fish with additional ingredients e.g. smoked salmon fillet treated with honey, salmon sandwiches;
- cooked molluscs e.g. cockle meat out of shell or winkle meat with or without shell.

Traceability requirements

Traceability information on the commercial designation including scientific name of the fish species, production method and catch area must be available at each stage of marketing of the species (i.e. at all stages of production / first landing, distribution, etc., where the ownership of the produce changes hands). It is generally understood that commercial documentation rather than labelling of the product per se is the usual means of providing traceability information.

Exemptions

The Regulations do not apply to sales of <u>small quantities</u> of fish (to the value of less than £17(€20)) sold directly to the final consumer by either fisherman (e.g. from the quayside) or aquaculture producers (e.g. from lakes, ponds, etc.).

Labelling Requirements

Labelling of Production method

The production method (which specifies the manner in which the fish was harvested) should to be given in one of the following ways:

- (a) For products caught at sea or in freshwater the terms 'caught' or 'caught in freshwater' should be used.
- (b) For products of aquaculture the terms 'farmed' or 'cultivated' should be used to indicate that the fishery and aquaculture products have been farmed. In order to ensure that accurate and meaningful information is provided to the consumer, the Agency recommends that the method of production be given prominently with the commercial designation (e.g. 'farmed Scottish trout').

Circumstances where the production method need not be indicated

For fish caught at sea, the terms 'caught' or 'caught in' do not have to be used if it is obvious from the commercial designation or the catch area that species have been caught at sea e.g. Sea bass, Pacific sand dab, However, if there is any doubt about the production method, then omitting the terms 'caught' or 'caught in' is not permitted.

Labelling of catch area

The catch area must be indicated as follows:

- (a) For products caught at sea, the origin <u>must be</u> indicated by reference to one (or more, if appropriate) of 12 catch areas based on FAO statistical classifications. These are specified in the Annex to 2065/2001.
- (b) For products caught in freshwater, the origin <u>must give</u> a reference to the Member State or third country of origin. For example, for trout caught in freshwaters of Spain or Norway, reference would need to be made to Spain or Norway respectively.
- (c) For farmed and cultivated products, the origin <u>must</u> indicate the Member State or third country in which the product underwent final development. So, for example, if a fish started its life farmed in France and Denmark but was 'finally farmed' in Iceland, the labelling is required to state 'Farmed Icelandic fish'.

However, consistency with separate advice on country of origin labelling would suggest that <u>all</u> countries be indicated on the labelling to give consumers accurate and meaningful information on the true place(s) of origin of the fish. So in the above example, the Agency *recommends* the product is labelled as 'Farmed Icelandic fish reared in France and Denmark'.

Meaning of 'final development' for farmed products?

The term 'final development' should be taken to mean the stage when the fish is finally 'harvested' from the water where it reaches its final size.

Rules for farmed products coming from more than one Member State or third country

The Fish Labelling Regulations (at Regulation 7) permit an indication of the various Member States or third countries for a product that has been farmed in various countries.

Labelling of products containing a mixture of different species

The Regulations apply in full to each of the species that go to make up the product combination, that is the commercial name, production method and catch area for each and every species must be given.

Labelling of products containing mixtures of fish of the <u>same</u> species with different production methods and/or obtained from different catch/production areas

- (1) For mixtures of fish of the <u>same species</u> coming from a <u>variety of production</u> <u>methods</u>, the Regulations require that the labelling must state each production method. For example, 'a mix of farmed Scottish cod and cod caught in the N.E. Atlantic', in the order in which origin predominates.
- (2) For mixtures of fish of the <u>same species</u> coming from <u>different catch areas or fish-farming countries</u>, the origin that is most representative of the batch in terms of quantity must be stated. Processors must decide whether the basis of the labelling is representative and not misleading to the consumer. Hence a batch of 'farmed salmon steaks' may originate predominantly in Scotland but also Norway or Chile and could be described as 'farmed salmon steaks originating from Scotland, Norway and Chile'.

Labelling of products sold loose (non-prepacked e.g. at supermarket fish counters, fishmongers, etc.)

The manner of marking for food which is not pre-packed and sold loose should be consistent with general labelling requirements (Regulation 36 of Food Labelling Regulations). That is the name of the food on a label attached to the food or a ticket or notice should be 'readily discernible by the purchaser at the place where he chooses that food'.

In terms of best practice, the *Agency recommends* that where farmed fish/shellfish is offered for sale, an indication of this production method be indicated on the ticket/label next to the product. This will provide consumers with accurate and meaningful information about the production method and help consumer choice as to whether they wish to purchase a farmed fish product or not.

With regard to the catch area, it is possible for an in-store notice, wall chart/poster, etc., near the fish counter which is 'readily discernible' by the purchaser at point of sale to carry this information. For example, 'all our Icelandic fish is caught in the North-East Atlantic'.

Labelling of products sold in catering establishments

Fish/shellfish sold in catering establishments such as restaurants are outside the scope of the EC fish labelling rules. Provided the product is ready to eat without the need for further preparation, it is regarded as a catering sale and, therefore, does not need to be labelled according to the EC fish labelling rules.

Nevertheless, where a product is specifically named in the catering establishment and there is a name for it prescribed by law, such as a commercial designation laid down in the Regulations, then it must be used to describe the product.

Controls in place for checking traceability

Traceability checks will normally be carried at the point of sale by Enforcement Officers when checking the required information. In addition, DARD Sea Fisheries Inspectorate may also check traceability information in carrying out their responsibility for fish marketing for products at landing, wholesale chain and transit up to the point of retail sale.

Public Analyst Observations

Authenticity Issues.

Origin - farmed/wild sea bass, salmon, sea bream can be analysed.

Associated Regulations

The Fish Labelling (Scotland) Regulations 2010 (SSI No. 90)

<u>European Council Regulation 104/2000</u> on the common organisation of the markets in fishery and aquaculture products, and <u>Commission Regulation</u> <u>2065/2001</u> laying down detailed rules for application of Council Regulation 104/2000 as regards consumer information.

Further Information

FSA Quick Guide

CN Codes for fish

Flavourings in Food (Scotland) Regulations 2010 (SSI No 439)

Scope

These regulations implement EC Regulation 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation EEC 1601/91, Regulations EC 2232/96, EC 110/2008 and Directive 2000/13/EC(1)

Ingredients/Products

Flavouring is defined in the EU Regulation as 'material used or intended for use in or on food to impart odour, taste or both'. The regulations also define 'relevant flavourings' which include flavouring substances, flavouring preparations, process flavouring, thermal process flavourings, flavour precursors and smoke flavouring.

Only permitted flavourings may be used in food. To be regarded as a permitted flavouring the relevant flavouring must comply with the specified purity criteria (Schedule 1): In general permitted flavouring should contain

- No element in a toxicologically dangerous quantity.
- No more than 3mg/kg of arsenic.
- No more than 10mg/kg of lead.
- No more than 1mg/kg of cadmium.
- No more than 1 mg/kg of mercury.

The Regulations prohibit the sale of food containing relevant flavourings resulting in certain substances in the food exceeding specified limits. These substances and the limits are listed in Schedule 2.

Regulation 3 prohibits the sale and advertisement for sale, for use as an ingredient in the preparation of food, of any relevant flavouring other than a permitted one. In addition the word 'natural' and similar expressions must not be used in a business sale to describe a relevant flavouring unless the relevant flavouring meets specific requirements.

Labelling Requirements

Regulation 4 and Schedule 3 prescribe labelling requirements for Business sales and Consumer sales. The requirements are as follows:

Business sale (Sale other than to the ultimate consumer)

- The name and address of the manufacturer, packer or seller within the EC.
- The word 'Flavouring' or more specific name or description.
- Either the words 'for foodstuffs" or a more specific reference to the intended food.

Trade documents to contain the following information:

- A list in descending order of weight of the ingredient components using the following classifications:
 - Natural flavouring substance.
 - Flavouring substance identical to natural substances.
 - Artificial flavouring substances.
 - Flavouring preparations.
 - Process flavourings.
 - Smoke flavourings.
- Name and or E number of other substances where appropriate

Consumer sale (Sale to the ultimate consumer)

- The name and address of the manufacturer, packer or seller within the EC.
- The word 'Flavouring' or more specific names or descriptions.
- Indication of minimum durability.
- Special storage conditions or conditions of use.
- Instructions for use if omission would prevent appropriate use of the flavouring.
- A list setting out in descending order of weight components of the flavouring and where appropriate its E number.

Food Additives (Scotland) Regulations 2009 (SSI No. 436)

Scope

These regulations give effect to Regulation (EC) No. 1333 / 2008 on food additives, which replaces previous directives and decisions concerning food additives permitted for use in food. The regulation ensures efficient functioning of the internal market and a high level of protection of human health including protection of consumer interests.

The regulation continues to harmonise the use of food additives in foods in the community, including the use of additives in PARNUTS and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs. The rules also cover the use of additives in food additives and food enzymes and carriers in nutrients. The regulations also deals with the purity of additives used in food. The purity criteria set out in Commission Directives 2008/60/EC (sweeteners), 2008/84/EC (miscellaneous additives) and 2008/128/EC (colours) will continue to apply.

Regulation 1333/2008 will be required, from 20 July 2010, the labelling of the six "Southampton" colours with a warning that they may have an adverse effect on activity and attention in children.

The Food Additives (Scotland) Regulations 2009 also re-enact, on a temporary basis, the Annexes to Directives 95/2/EC, 94/35 and 94/36. The provisions in these Annexes will continue to apply until they are transferred, in the form of a consolidated list of foods in which additives can be used, into Annex II of Regulation 1333/2008. This process must be completed by June 2011.

Ingredients / Products

The regulations apply to all food additives but do not apply to the following substances processing aids

- Substances used for the protection of plant and plant products
- Substances added to foods as nutrients
- Substances used for the treatment of water for human consumption
- Flavouring coming under Regulation(EC) No. 1334/2008
- Food enzymes coming under Regulation (EC) No. 1332/2008

A food additive is defined as

"...any substance, whether or not it has nutritive value, that is not normally consumed as a food in itself or used as a characteristic ingredient of food, and which, if added intentionally for a technological purpose to food in its manufacture, processing, preparation, treatment, packaging, transport or storage, results or may reasonably be expected to result, in the substance or its by-products becoming directly a component of the food concerned..."

The definition does not include:

- Substances used for the treatment of drinking water
- Products containing pectin from dried apple pomace or citrus peel or a mixture of both, treated with dilute acid and part neutralised with sodium or potassium salt
- Chewing gum bases
- White or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alcohol, bleached starch, physically modified starch and starch treated by amylolytic enzymes.
- Ammonium chloride
- Blood plasma, edible gelatine, protein hydrolysates and their salts, milk protein and gluten.
- Amino acids and their salts other than glumatic acid,glyciene, cysteine and cystine and their salts and having no additive function.
- Caseinates and casein and
- Inulin

The regulations also include colour which is defined in EC Directive 94 / 36, an additive whose primary purpose is adding or restoring colour in a food. This includes:

- a) Any natural constituent of food and any natural source not normally consumed as food and not normally used as a characteristic ingredient of food and
- Any preparation of pigment that has been selectively extracted from food or other natural sources

Colours may only be used to:

- Restore the original appearance of food where colour has been affected by processing, storage etc
- Giving colour to food otherwise colourless
- Making food more visually appealing

Sweeteners are also covered by the regulations and are defined as any food additive which is used or intended to be used to

Impart a sweet taste to food or in a table-top sweetener

The Food Additive (Scotland) Regulations 2009 are enforced by Local Authorites. The regulations implement the EC Regulation and also introduce powers to enforce the rules including provisions relating to seizure and condemnation. The principal provisions are

- Use of Colours in or on food (Regulation. 3)
- Health marking of meat and meat products (Regulation 4)
- Use of colour on eggshells (Regulation 5)
- Sale of colour and food containing colours (Regulation 6)
- Use of miscellaneous additives (Regulation 8)
- Sale of food additives and food containing miscellaneous additives (Regulation
 9)
- Placing on the market and the use of sweeteners (Regulation 11)
- Sale of food containing sweeteners (Regulation 12)
- Condemnation of food (Regulation 17)

Use of colours in or on food (Regulation 3)

Only a permitted colour may be used in or on food. Permitted colours are listed in Annex II to Directive 94/36. Foods to which colours may be added are specified in Annex III directive 94/36 (Foodstuffs to which only certain permitted colours may be added) along with the maxim permitted levels.

Annex IV dealing with colours permitted for certain uses only indicates the maximum levels of particular colours in food.

There are 18 permitted colours that can be used to a maximum level as specified for specific food categories. These are identified in the table in Part 2 of Annex V colours in permitted foodstuffs other than those mentioned in Annex II or III.

Health Marking of certain meat and meat products. (Regulation 4)

The regulation requires that only the following colours may be used for health marking:

- (a) E155 Brown HT
- (b) E133 Brilliant Blue FCF
- (c) E129 Allura Red AC or

An appropriate mixture of (b) and (c) above.

Use of colours on Egg Shells (Regulation 5)

Only permitted colours can be used for decorative colouring of egg shells or marking of egg shells (as stipulated in Regulation (EC) No. 1234 / 2007)

Sale of colours and food containing colours (Regulation 6)

Only permitted colours may be sold or used in or on food.
Only specified permitted colours may be sold directly to a consumer:
Specified permitted colours are any permitted colours except:

- E123 Amaranth
- E127 Erythrosine
- E128 Red 2G⁶
- E154 Brown FK
- E160b Annatto, Bixin, Norbixin
- E161g Canthaxanthin
- E173 Aluminium and
- E180 Litholrubine BK

Use of miscellaneous additives (Regulation 8)

Only permitted miscellaneous additives can be used in or on food; and these are set out in Annex 1 of Directive 95/2. Foodstuffs in which a limited number of additives may be used are set out in Annex II

Foods which should not contain a miscellaneous additive as specified in Article 2a of Directive 95/2 include:

- Unprocessed foodstuffs
- Honey (See EC Directive 2001/110)
- Non-emulsified oils and fats of animal or vegetable origin
- Butter

- Pasteurised and sterilized (including UHT) milk (including plain, skimmed and semi-skimmed) and plain pasteurised cream
- Unflavoured, live fermented milk products

⁶ Commission Regulations (EC) No. 884/2007 suspended the marketing and import of food containing E128 (Red 2G) in July 2007, this was subsequently enforced by all EU member States including the UK. Although 94/36/EC was not amended to remove E128 from the list of permitted colours, Commission

- Natural mineral water and spring water
- Coffee(excluding flavoured instant coffee) and coffee extracts
- Unflavoured leaf tea
- Sugars
- Dry pasta, excluding gluten free and/or pasta intended for hypoproteic diets.
- Natural unflavoured buttermilk (excluding sterilized buttermilk)

Where there is no limit indicated in the Annex to the Directive 95/2 the term "Quantum satis" is used, meaning that the additive must be used in accordance with good manufacturing practice at a level that is not higher than is necessary to achieve the intended purpose and provided that such use does not mislead the consumer.

Conditionally permitted preservatives and antioxidants are listed in Annex III and other permitted additives as set out in Annex IV.

Annex V lists the permitted carriers and carrier solvents, their E-Number and restrictions on use.

Annex VI lists the additives permitted in foods for infants and young children.

Sale of food additives and foods containing miscellaneous additives (Regulation 9)

A person cannot sell any miscellaneous additive for use in or on food unless it is a permitted miscellaneous additive, nor is it permissible to sell any miscellaneous additive for use primarily as a carrier or carrier solvent earlier listed in Annex V to Directive 95/2.

A person cannot test sell direct to a consumer any miscellaneous additive that is not permitted.

A person cannot sell any food having in or on it any miscellaneous additive unless it is permitted, nor sell any relevant food additive in combination with a miscellaneous additive which has been used primarily as a carrier or carrier solvent.

Placing on the market and use of sweeteners (Regulation 11)

Only permitted sweeteners may be placed on the market for sale to the ultimate consumer or for use in or on food. (A list of permitted sweeteners, the foods they are permitted in, and maximum usable doses are listed in the Annex to EC Directive 94/35.

Sale of Food containing sweeteners (Regulation 12)

A person must not sell any food having in or on it any sweetener other than a permitted sweetener.

Condemnation of Food (Regulation 17)

Where the Public Analyst certifies food as contravening these regulations that food may be treated for the purposes of Article 8 of the Food Safety (Scotland) Act 1990 (under which the food may be seized and destroyed under an order of the justice of the peace) as failing to comply with the food safety requirement.

Public Analyst Observations.

- 1. Sweeteners: In general limits are being complied with but labelling issues can arise where food business operators fail to indicate it in the name of the food when being used as an ingredient. Officers who are inspecting premises that utilise sweeteners should take this into account when undertaking inspections. Officers need to consider use of sweeteners in foods which also contain sugars e.g. soft drinks.
- 2. Miscellaneous Additives: Issues can include
 - a) Carry-over of ascorbic acid preservative in bakery products not declared
 - b) 100% steak burgers containing sulphur dioxide
 - c) Revised (lower) limits for nitrate/nitrite preservative in cured meat and meat products were introduced prior to these Regulations coming into force. Higher maximum limits are still applicable if certain defined "traditional" curing processes have been used. For this reason it is important for sampling officers to record and transmit to the lab details of the process used whenever possible (i.e. sampling in factory, this would likely be impossible when sampling from retail premises).
- 3. Colours: Note that Annex V to 1333/2008 introduces the additional labelling provisions which will become applicable to foods containing the colours identified in the "Southampton" study and which are listed in that Annex.

There can be labelling issues for trade sales and trade documents. Officers may wish to pay particular attention to delivery ingredients held in the dry goods stores of food premises such as bakeries, butchers and other food processing factories.

Associated Regulations

Food Additives (Scotland) Regulations 2009 SSI No. 436

Regulation EC 1333/2008

Regulation EC 1234/2007

Regulation EC 884/2007

EC Directive 94/36

EC Directive 95/2

EC Directive 94/35

Directive 74/409/EEC

The Food Enzymes (Scotland) amendment Regulations 2010 (SSI No. 26)

Scope

The regulations implement the provisions of Regulation EC No. 1332/2008 on food enzymes amending Council Directive 83/417, Council Regulation EC No 1493/1999, Directive 2000/13/EC, Council Directive 2001/12/EC and Regulation EC No. 258/97.

Food enzymes (other than those used as food additives) are not subject to specific harmonisation controls across the EC, but are regulated as processing aids under the national legislation of some Member States.

This regulation therefore introduces harmonisation controls for enzymes whether used as food additives or processing aids in the production of food stuffs and provides a high level of protection by introducing a positive approval system for all food enzymes.

Ingredients/Products

Enzymes are substances (usually proteins) that can increase the rate of chemical reactions. They are useful in food production achieving results that might be too time consuming by other methods.

Through Regulation EC 1332/2008 the following controls are introduced

- Restriction on placing on the market and use of food enzymes not on the approved list.
- Restriction on placing on the market of non-compliant food enzymes or foods containing such enzymes.
- Introduction of labelling requirements for food enzymes and preparations intended for sale to the final consumer.

The regulations are enforced by Local Authorities.

The following provisions of the Food Safety (Scotland) Act 1990 apply to these regulations

- Offences due to the fault of another person
- Defence of due diligence
- Documentary evidence
- Punishment of offences
- Powers of entry
- Presumptions regarding food intended for Human Consumption
- Obstruction
- Time limits for prosecution.

Condemnation of Food

Where the Public Analyst certifies that food to which this regulation applies has been placed on the market in contravention of the regulations the food may be treated for the purposes of Article 8 Food safety (Scotland) Act as failing the food safety requirement.

Public Analyst Observations

Officers would need to pay particular attention to ensure that enzymes are used in practice strictly for the purpose for which they have been approved.

Associated Regulations

The Food Enzymes (Scotland) amendment Regulations 2010 (SSI No. 26)

Regulation EC No 1332/2008

Council Directive 83/417

Council Regulation EC No 1493/1999

Directive 2000/13/EC

Council Directive 2001/12/EC

Regulation EC No. 258/97

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009 SSI No. 427

Scope

These regulations implement Commission Regulation (EC) No. 953/2009, which **consolidate** and **repeal** Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in food for particular nutritional uses.

A number of nutritional substances such as vitamins, minerals, amino acids and others may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the persons for whom they are intended are fulfilled and also conform to requirements of EC Directive 2009/39/EC.

New substances have been evaluated by EFSA and as such the list has been updated. In addition specifications are introduced for some vitamins and minerals for their identification.

A food for a particular nutritional use (a 'parnuts') is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional purpose.

A particular nutritional use means the fulfilment of the particular nutritional requirements of certain categories of persons

- a) whose digestive processes or metabolism are disturbed or
- b) whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs or
- c) of infants or children in good health.

The regulations do not apply to infant formula, follow on formula, processed cereal based foods and baby foods for infants and young children as nutritional aspects for these foods are covered by Commission Directive 2006/141/EC, Directive 2006/141/EC, Directive 2006/125/EC.

Ingredients/Products

The range of foods for particular nutritional uses is very wide and diversified. The widest possible choice of substances that can be safely used in the manufacture of foods for particular nutritional uses should be available for the categories of nutritional substance listed.

Offences: Regulation 3

It is an offence for a person to fail to comply with the specified provisions which are detailed in the Schedule to the regulation.

Specified provisions

- 1. Article 2(1) Eligible substances: Only the substances listed in the Annex to the Commission Regulation (EC) No. 953/2009 complying with the relevant specifications as necessary may be added for specific nutritional purposes for Parnuts as covered by Directive 2009/39.
- 2. Article 3(1) General Requirements: The use of substances added for specific nutritional purposes must result in safe food that fulfil the particular nutritional requirements as established by generally accepted scientific data.
- 3. Article 3(2): General Requirements: Upon request by the competent authority FSA Scotland a manufacturer or as appropriate an importer must produce the scientific work and the data establishing that the use of the substances complies with Article 3(1) of Commission Regulation (EC) No. 953/2009. (The information may be readily available through a publication in which case a reference to the publication will suffice.
- 4. Article 4(2): Specific requirements for substances listed in the Annex to Commission Regulation (EC) No. 953/2009: Purity criteria which apply to the substances listed when they are used in the manufacture of foodstuffs for purposes other than those covered by the Commission Regulation shall also apply to those substances
- 5. Article 4(3) Specific requirements for substances listed in the Annex to Commission Regulation (EC) No. 953/2009: In respect of substances listed for which there is no established purity criteria generally accepted purity criteria recommended by international bodies must apply.

Public Analyst Observations

There are no major issues identified with these regulations. Officers may want to check that the label correctly reflects the nutritional criteria. Special precautions may be required if samples are taken and submitted for checks on vitamin(s) content; please seek advice before sampling.

Associated Regulations

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009 SSI No. 427

Further Information

Commission Directive 2006/141/EC

Directive 1999/21/EC

Commission Directive 2006/125/EC

EC Directive 2009/39/EC

Commission Directive 2001/15/EC

Food Intended for Use in Energy Restricted Diets for Weight Reduction (Scotland) Regulations 1997 SSI No. 2182

Scope

These Regulations implement <u>Commission Directive 96/8/EC</u> dealing with composition and labelling requirements on food intended for use in energy-restricted diets for weight reduction.

Ingredients/Products

The legislation essentially deals with foods for use in energy-restricted diets for weight reduction that are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet. They are divided in two categories collectively referred to as relevant food in the regulations:

- (a) products presented as a replacement for the whole of the daily diet;
- (b) products presented as a replacement for one or more meals of the daily diet.

Composition

The relevant foods must meet certain compositional requirements and be described only as

- (a) 'Total diet replacement for weight control' or
- (b) 'Meal replacement for weight control'

Labelling RequirementsThe labelling requirements for the relevant food can be generally summarised as set out in the following table

A Total diet replacement foods	B Meal Replacement foods
Energy value in kJ and K cal	Energy value in kJ and K cal
Protein	Protein
Carbohydrate	Carbohydrate
Fat	Fat
Average quantity of each mineral and	The average quantity as a percentage
vitamin specified in the directive	of the values in Table A and B of Part
	11 of Schedule 6 of Food Labelling
	Regulations 1996 as amended
Instructions for appropriate	Instructions for appropriate
preparation and importance of	preparation and importance of
following the instructions	following the instructions
Where 20g or more polyols will be	Where 20g or more polyols will be
provided as part of the daily diet when	provided as part of the daily diet when
used according to instructions there	used according to instructions there
should be a statement of laxative	should be a statement of laxative
effects	effects
A statement of the importance of	A statement of the importance of
maintaining an adequate daily fluid	maintaining an adequate daily fluid
intake	intake
A statement that the product provides	A statement that the product is useful
adequate amounts of all essential	as part of an energy restricted diet
nutrients and a statement that the	and that other foods should be a
produce should not be used for more	necessary part of the diet.
than 3 weeks without medical advice	

General provisions on labelling, advertising and presentation

The labelling, advertising or presentation of relevant foods must not refer to the rate or amount of weight loss that may result from its use.

The regulations also prohibit sale of relevant food intended as a replacement for the whole of the daily diet unless all the components are contained in the same package.

Public Analyst observations and comments

There tend to be few analytical problems; however, checks should be made for compliance with labelling requirements.

Associated Regulations

Food Intended for Use in Energy Restricted Diets for Weight Reduction (Scotland)
Regulations 1997 SSI No. 2182

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 SI No. 408

Further Information

Commission Directive 96/8/EC

The Advertising Standards Authority have references to the above legislation in their CAP Code.

The Food Irradiation (Scotland) Regulations 2009 SSI No. 261

Scope

These regulations deal with the treatment, storage, transport and sale of food that has been irradiated. The regulations implement the European Directives 1999/2/EEC and 1999/3/EC.

The regulations do not apply to

- 1. irradiation by measuring or inspection devices at a maximum level of
 - a. 10 MeV in the case of X-rays
 - b. 14 MeV in the case of neutrons or
 - c. 5 MeV in other cases

Where the dose of ionising radiation absorbed does not exceed 0.01 Gy in the case of inspection devices which utilise neutrons and 0.5 Gy in other cases.

2. irradiation of food prepared under medical supervision for patients requiring sterile diets.

Ingredients/Products

Not all foods can be irradiated. The regulations identify the following foods that may be irradiated and the maximum dose which they may receive.

Table

Food Type	Further qualification	Level deemed to be over irradiated *
Fruit	Includes fungi, tomatoes and rhubarb	2kGy
Vegetables	Excludes fruit, cereals, bulbs and tubers, and dried aromatic herbs, spices and vegetable seasoning but includes pulses	1kGy
Cereals		1kGy
Bulbs and tubers	Means potatoes, yams, onions shallots and garlic.	0.2 kGy
Dried aromatic herbs, spices and vegetable seasoning		10kGy
Fish and shellfish	Includes eels, crustacean and molluscs	3kGy
Poultry	Includes domestic fowl, geese, ducks, guinea fowl, pigeons, quails and turkeys	7kGy

*(Food is deemed to be over irradiated when the "overall average dosage" calculated for a batch of food exceeds that given in the table; or when the maximum dose of ionising radiation absorbed by any food in a batch of which it forms a part is when so measured a dose of kGy higher than the lower of 3X and 1.5 Y where "X" is the minimum dose absorbed by any of the food in the batch in kGy and "Y" is the overall average dosage in kGy given in the table.).

Regarding the table, an average dose is calculated for the whole batch of food (called the "overall average dose") and this overall average dose must not exceed the values given. However, there are also constraints on the minimum and maximum doses received by any part of that batch, namely that the maximum dose received by any part of the batch must not be

- more than 3 times the minimum dose received by any other part of the batch or
- more than 1.5 times the dose values given.

For information, the first of the bullet points above is actually a constraint on the minimum dose to ensure no part of the food is under irradiated but it is stated the other way for consistency.

Prohibition on Treatment without a licence (Regulation 4)

The regulation prohibits any person from subjecting food to treatment by ionising radiation unless the person

- Holds a licence to do so
- Food is in a wholesome state and
- Treatment is in accordance with licence conditions

Restrictions on Importation (Regulation 5)

The regulations restrict the import of irradiated foods unless

- It falls within a permitted category
- It was irradiated in one of the approved facilities
- It was properly irradiated

If the food comes from another Member State of the EU it must be accompanied with the following details

- Name and address of irradiation facility and Official Reference Number
- For each batch
 - Nature and quantities
 - Batch number
 - Name and address of consignors and consignees
 - Date irradiated
 - Overall average dose applied

If the food comes from a 3rd Country it must be accompanied with the following

- Name and address of irradiation facility
- Nature and quantities
- Batch number
- Name and address of consignors and consignees
- Date irradiated

Overall average dose applied

- Microbiological information relating to the batch
- Type of food packaging used during irradiation
- Temperature of food before irradiation (where appropriate)
- Maximum, minimum and overall dose of ionising radiation
- Type of ionising radiation
- Data used for control of the irradiation

For foods other than dried aromatic herbs, spices and vegetable seasoning, they must be irradiated by

- A person approved under a reference by which the approval can be identified by the competent authority in the country in which it was irradiated.
- The approval requires the method of measurement specified in Schedule 1.
- Legislation in the originating 3rd Country is of equivalent standard as the EU.
- Complies with conditions applied to the food.

The requirement applies to food which has (as well as has not) become an ingredient of another food.

Storage and Transportation restrictions (Regulation 6)

Only persons holding a licence may store or transport irradiated food, however, storage and transport is permitted for irradiated food that has been imported and is accompanied with the necessary documentation. The provision applies to food which has (as well as has not) become an ingredient of another food.

Restrictions on Sale (Regulation 7)

Irradiated food cannot be sold in Scotland unless

- It was irradiated in a UK facility complying with the licence provisions
- It was imported and was accompanied with the required information set out in regulation 5 and
- It was stored and transported in accordance with regulation 6
- In the case of both of the latter two bullet points it was stored and transported in accordance with regulation 6

Documentation for food not ready for a final sale (Regulation 8)

Documentation for irradiated foods, or food with an irradiated ingredient or food ingredients that have been irradiated which are not ready for delivery to the ultimate consumer or catering establishment must bear

- The words "Irradiated" or "Treated with ionising radiation"
- Name and address of facility or Official Reference Number of the facility that conducted the irradiation

Enforcement (Regulation 9)

The FSA and Local Authorities have different roles and responsibilities in relation to enforcement of the regulations. In general it will be the FSA who licence irradiation facilities in the UK.

Labelling Requirements

The Food Labelling Regulations 1996 as amended by Food Irradiation Provisions (Scotland) Regulations 2000 required that a food or food ingredient must bear the treatment description e.g. "Irradiated" or "Treated with ionising radiation".

Public Analyst Observations

Officers may consider checking sources of herbs and spices including supplements in premises that specialise in health products.

It is possible that imported sources of shellfish such as fresh/frozen prawn may have been irradiated. As part of routine monitoring of the microbiology of such materials it may be possible to correlate unusually good microbiological results with potentially irradiated foods that warrant further investigation.

Associated Regulations

Food Irradiation (Scotland) Regulations 2009 SSI No. 261

Directive 1999/2/EC Food ingredients treated with ionising radiation

<u>Directive 1999/3/EC Establishment of Community list of irradiated foods and food ingredients</u>

Further information

Europa Website

At present there are 7 EC approved facilities in 3rd Countries that can irradiate foods i.e 3 in South Africa, 1 in Turkey, 1 in Switzerland and 2 in Thailand.

The Food Labelling (Nutrition Information) (Scotland) Regulations 2009 SSI No. 328

Scope

The regulations implement Commission directive 2008/100 amending Council directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions. The purpose of the regulations is to amend the Food Labelling Regulations 1996 and bring clarity about the legal requirements for industry and enforcement officers with regard to fibre which has previously not been defined.

Ingredients/Products

Applies to foods that are pre-packed and bear nutritional labelling information

Nature of amendments

The Food Labelling Regulations contain specific provisions regarding nutritional information and specify energy conversion factors, needed to calculate the energy present in food. Advances in analytical technology mean that new and more accurate energy conversions are required to ensure that the consumer is not misled as to the overall energy content for some foods. The regulations therefore add energy conversion factors for

Fibre (2 Kcal/g or 8 Kj/g) and

Erythritol (0 Kcal/g)

In addition the regulations give lists of vitamins and minerals which may be declared as part of the nutrition labelling and specify the recommended daily allowance (RDA). The regulations update the list to take account of other legislation on Food Supplements, vitamins and minerals fortification and health claims.

Vitamins in respect of which claims can be made in Schedule 6 Food Labelling Regulations 1996

Vitamin	RDA
Vitamin A	800 µg
Vitamin D	5 μg
Vitamin E	12mg
Vitamin K	75 μg
Vitamin C	80mg
Thiamin	1.1 mg
Riboflavin	1.4mg
Niacin	16mg
Vitamin B6	1.4 mg
Folic acid	200ug
Vitamin B12	2.5 µg
Biotin	50 μg
Pantothenic acid	6mg

Minerals in respect of which claims can be made in Schedule 6 of Food Labelling Regulations 1996

Mineral	RDA
Potassium	2000 mg
Chloride	800 mg
Calcium	800 mg
Phosphorus	700 mg
Magnesium	375 mg
Iron	14 mg
Zinc	10mg
Copper	1 mg
Manganese	2 mg
Fluoride	3.5 mg
Selenium	55 μg
Chromium	40 μg
Molybdenum	50 μg
Iodine	150 µg

Public Analyst Observations

The provision now made for the contribution made to dietary energy by fibre is small in most cases. The main significance of these Regulations is the expansion of the lists of vitamins and minerals which may be declared in nutrition information, subject to a significant amount being present. Special precautions may be required if samples are taken and submitted for checks on vitamin(s) content; please seek advice before sampling.

Associated Regulations

The Food Labelling (Nutrition Information) (Scotland) Regulations 2009 SSI No. 328

Food Labelling Regulations 1996 SI No 383

Commission directive 2008/100

Council directive 90/496/EEC Nutrition labelling of foodstuffs discussion paper

Food Supplements (Scotland) Regulations 2003 (SI No. 273)

Scope

The Regulations implement the provisions of <u>EC Directive 2002/46/EC</u> and Commission Regulation (EC) No.1170/2009, which amends Directive 2002/46/EC. The regulations apply to the sale of food supplement products sold as a food and do not apply to medicinal products as defined by <u>Directive 2001/83/EC</u>.

The control of medicinal products is the responsibility of the Medicine and Healthcare Products Regulatory Agency (MHRA).

The Regulations prohibit the sale of food supplements to the ultimate consumer unless pre-packed. However, they may be sold to catering establishments not pre-packed.

Ingredients/Products

A food supplement is defined as a food <u>sold in dose form</u> whose purpose is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination.

Dose form means a form such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, capsules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities.

Where food supplements contain vitamins and or minerals, these must be listed in Annex I of the amending Commission Regulation 1170/2009, and be in a chemical form as listed in Annex II of the amending Commission Regulation 1170/2009 and meet the relevant purity criteria. E.g. vitamin A listed in Annex I may be used in the manufacture of a food supplement in the form of either, (a) retinol, (b) retinyl acetate, (c) retinyl palmitate, or (d) beta-carotene. Relevant purity criteria may be specified by EC Legislation or generally acceptable purity criteria for the substance as recommended by international bodies.

Labelling Requirements

The labelling of food supplements which are ready for delivery to the ultimate consumer or to a catering establishment require:

- The name under which it is sold is 'food supplement'. Food supplement is a
 prescribed name for the purposes of the Food Labelling Regulations 1996 as
 amended
- The name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product
- The portion of the product recommended for daily consumption e.g. the number of tablets or capsules recommended
- A warning not to exceed the stated recommended daily dose

- A statement that food supplements should not be used as a substitute for a varied diet
- A warning that the product should be stored out of reach of young children
- The amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product. The amount must be given in numerical form, Annex I to Directive 2002/46 sets out the forms of measurement that must be used for the vitamins and minerals either milligrams or micrograms; the use of international units (i.e. for fat soluble vitamins is no longer a valid unit of measurement for food supplements in the EU). The amount given must be per portion of the product as recommended on the label and be an average amount based on the manufacturers' analysis.

The Regulations state that details on labels of food supplement must not mention, express, or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

The specific labelling requirements must be on the packaging, or on a label attached to the packaging, or on a label which is clearly visible through the packaging. Where the sale is otherwise than to the ultimate consumer, the specific details may be on commercial documents where it can be guaranteed that such documents either accompany the food supplement or were sent before or at the same time as the delivery.

The outermost packaging requires (as per The Food Labelling Regulations 1996 as amended) at all times to be labelled with name of food, minimum durability and name or business name of manufacturer or packer or seller in the EU. The details must be easy to understand, clearly legible and indelible and when a food supplement is sold to the ultimate consumer the details must be marked in a conspicuous place in such a way to be clearly visible.

Where the food supplement is delivered to a catering establishment and is not prepacked the details must be on a label attached to the food supplement, or on a ticket or notice which is readily discernable by the purchaser at the place where he chooses the food supplement or in commercial documents relating to the food supplement.

The regulations were amended by Food Supplements (Amendment) (Scotland) Regulations 2007 SI No. 116 which add another form of the vitamin folate and another form of the mineral iron to the positive list in Annex II to Directive 2002/46. The regulations were further amended by the Food Supplements and the Addition of Vitamins, Minerals and Other Substances (amendment) (Scotland) Regulations 2009 SI No. 407 which incorporates requirements set out in Regulation 1170/2009/EC.

Public Analyst Observations

There tends to be very few food supplements being submitted for analysis.

Traditional Chinese Medicine Shops - At present there is an exemption for herbal remedies and if dispensing to individuals after consultation. (Herbal medicines / herbs other than those used purely for culinary purposes are regulated under the Traditional Herbal Medicines Directive, which is administered by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK).

In relation to herbal remedies there may be issues of heavy metals or pesticides contamination.

There is no registration process for food supplements in the UK therefore there is no method to verify what is actually on the market. It is not possible to confirm if any brand is from an approved source.

Health Food Shops – authorised officers should check vitamin and mineral level on products through submission of samples for analysis.

Associated Regulations

Food Supplements (Scotland) Regulations 2003 SI No. 278

Food Supplements (Amendment) (Scotland) Regulations 2007 SI No 78

EC Directive 2002/46/EC relating to food supplements

EC Directive 2001/83/EC relating to medicinal products for human use

Commission Directive 2006/37/EC amending 2002/46/EC

Commission Regulation (EC) No. 1170/2009

Further Information

FSA Guidance Notes on Food Supplement (Scotland) Regulations 2003

Medicines and Healthcare Products Regulatory Agency (MHRA)

Report of Expert Group on Vitamins and Minerals Safe Upper Level Report 2003

The Food with Added Phytosterols or Phytostanols (Labelling) (Scotland) Regulations 2004 (SI No. 515)

Scope

These Regulations provide for the enforcement of <u>Commission Regulation (EC) No.</u> 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters.

Ingredients/Products

'Plant sterols occur naturally and are minor components of various plant derived foods, including vegetable oils, such as rape seed oil and soya bean oil, nuts, grain and seeds. They are also present in other plant materials such as wood and leaves. The sterols can be extracted from these sources and used as food ingredients'.

'Plant sterols have a similar molecular structure to cholesterol. This means that when they are eaten they partially block the uptake of cholesterol from the gastrointestinal tract, thus reducing the cholesterol levels in the blood stream - particularly the more dangerous LDL cholesterol'. Advisory Committee on Novel Foods and Novel Food Processes (ACNFP).

Labelling Requirements

The Regulations require such foods and food ingredients to be labelled with additional information, including the words 'with added plant sterols/plant stanols' in the same field of vision as the name.

In addition the labelling must make reference to the following information:

- The food is intended exclusively for those who wish to lower their blood cholesterol.
- Patients on cholesterol lowering medication should only consume them under medical supervision.
- Consumption of plant sterols is not appropriate for people with special dietary needs (i.e. pregnant and breast feeding women and children under 5).
- Foods with added plant sterol should be consumed as part of a balanced diet.
- Consumption should not exceed 3 grams of added sterols a day. (In same field of vision as the first bullet point).
- Phytosterols should be quantified in percentage or gram/100grams in the list of ingredients.

The regulation requires that the manufacturer must also clearly define the portion size. The products covered by Regulation 608/2004 are foods and food ingredients which are to be delivered as such to the ultimate consumer or which are intended for supply to mass caterers. By virtue of Article 13(4) of the Directive, certain small packages and indelibly marked bottles are exempt from the labelling requirements of regulation 608/2004. There is a transitional provision in Article 3 of that Regulation.

Pursuant to Articles 14 and 15 of the Directive, these Regulations contain an exemption from the need to be labelled with some of the particulars required by Regulation 608/2004 in the case of food which is not pre-packed, certain similar foods and fancy confectionery products. In such case the particulars required are:

- 'With added plant sterols/plant stanols'.
- Consumption of plant sterols is not appropriate for people with special dietary needs (i.e. pregnant and breast feeding women and children under 5).
- These Regulations make provision as to the manner of labelling in the case of the required particulars.

Public Analyst Observations

These are not easy to analyse. Substances can be found in products such as yoghurts, low fat spread, yoghurt drinks.

Associated Regulations

<u>The Food Labelling (Added Phytosterols or Phytostanols) (Scotland) Regulations</u> 2005 SSI No. 1

<u>Commission Regulation (EC) No. 608/2004</u> concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters.

Further Information

Advisory Committee on Novel Foods and Novel Food Processes

The Food (Jelly Mini-cups) (Emergency Control) (Scotland) Regulations 2009 SSI No 437

Scope

The regulations re-enact the existing emergency controls, required by <u>Commission</u> <u>Decision 2004/374/EC</u> suspending the placing on the market and import of jelly minicups containing any of the following food additives E400, E401, E402, E403, E404, E405, E406, E407, E407a, E410, E412, E414, E415, E417 and E418.

The need for an emergency control order arises from the fact that jelly mini-cups combine several risk factors due to their consistency, shape, size and manner of ingestion, giving rise to the risk that they remain blocked in the throat and provoke choking.

The risk also originates from the chemical and physical properties of the additives. In addition, warning through labelling would not be sufficient to protect human health especially with regard to children.

The legislation has been introduced to provide legal continuity with respect to changes introduced by Regulation EC 1333/2008 which impact on earlier national provisions on jelly mini cups.

Ingredients/products

The regulations apply to "controlled jelly mini-cups" defined as jelly mini cups containing any of the relevant additives listed above.

The regulations which are enforced by Local Authorities prohibit a person from carrying out any commercial operation with respect to any controlled jelly mini-cups, and prohibit the use of any of the relevant food additives in the manufacture of any jelly mini—cups which are intended for human consumption.

The regulations also apply certain provisions of the Food Safety (Scotland) Act 1990 to facilitate enforcement. The provisions include

- Extended meaning of sale
- Offences due to fault of another person
- Defence of due diligence
- Analysis of samples
- Power of entry
- Obstruction
- Punishment of offences
- Inspection and seizure of suspect food and
- Procurement of samples

Public Analyst Observations

These products have (thankfully) largely disappeared from the market, however they do re-appear from time to time, so continued vigilance is required.

Associated Regulations

The Food (Jelly Mini-cups) (Emergency Control) (Scotland) Regulations 2009 SSI No 437

Commission Decision 2004/374/EC

Regulation EC 1333/2008

The Food (Suspension of the Use of E128 Red 2G as Food Colour) (Scotland) Regulations 2007 (SI No. 352)

Scope

The regulations make provision for the enforcement of Commission regulation EC No. 884/2007 which suspends the use of the colour E128 Red 2G in food and suspends placing on the market or importation of food containing E128 Red 2G.

Ingredients/Products

The regulation applies specifically to the colour known as **E128** or **Red 2G**. There are no exemptions.

Public Analyst Observations

Red 2G may degrade on cooking. There are no issues regarding detection in raw meat or meat preparations.

Associated Regulations

The Food (Suspension of the use of E128 Red 2G as Food Colour) (Scotland) Regulations 2007 SSI No. 363

Further Information

The colour E128 Red 2G is readily and extensively metabolised into aniline. The European Food Safety Authority (EFSA) concluded from an EU Risk Assessment report that aniline should be considered as a carcinogen for which a genotoxic mechanism could not be excluded and as such it was deemed prudent to regard the substance as a safety concern. In consequence the acceptable daily intake (ADI) for E128 Red 2G was withdrawn.

EFSA however also indicated that should the tumour inducing mechanism of aniline be further elucidated, shown to be thresholded and/or its relevance to man discounted the colour E128 Red 2G could be re-evaluated once again as a food additive.

EC No. 884/2007 on emergency measures suspending E128 Red 2G.

The Fruit Juices and Fruit Nectars (Scotland) Regulations 2003 (SSI No. 293)

Scope

The Regulations implement the provisions of <u>Council Directive 2001/112/EC</u>. The Regulations give specific definitions of juices and nectars and apply only to designated products and their reserved descriptions as detailed in Schedule 1. Products which are not listed in Schedule 1 are not covered by these Regulations. With compound foods where designated products such as fruit juices are an ingredient, then the ingredient fruit juice is covered by this legislation.

With the exception of Regulation 5(g), enforcement applies to fruit juice once it has been sealed in the pack and labelled. Regulation 5(g) and 5(2) covers the labelling of concentrated fruit juice not intended for delivery to the final consumer.

Ingredients/Products

The five reserved descriptions are found in Schedule 1 of the Regulations (Annex 1) and are; <u>fruit juice</u>, <u>concentrated fruit juice</u>, <u>fruit juice from concentrate</u>, <u>dehydrated or powered fruit juice and fruit nectar</u>.

Raw Materials and Additional Ingredients

Schedule 2 and 3 respectively list the permitted raw materials and additional ingredients that are permitted in the preparation of the designated products. The permitted raw materials are fruit other than tomatoes, fruit puree, sugars, honey and pulp or cells. It should be noted that sugars as defined in Council Directive 2001/111/EC includes white sugar, glucose syrup, dextrose and fructose.

Addition of sugar

Sugars can be added to fruit juice, concentrated fruit juice, fruit juice from concentrate and dehydrated/powdered fruit juice, other than any prepared from grapes and pears, for sweetening purposes in an amount not exceeding 150 mg/litre of fruit juice. In this case the sales name must include the term 'sweetened' or 'with added sugar' followed by an indication of the maximum quantity of sugars added. The amount of added sugar for sweetening purposes must also be declared in the list of ingredients.

Sugars may also be added for regulating acidic taste up to 15g and this must be indicated in the list of ingredients. In either case, the total amount of such added sugars for either purpose must not exceed 150g per litre of fruit juice. The addition of artificial sweeteners to fruit juice is not permitted by these Regulations.

Addition of vitamins and minerals

Vitamins and minerals may be added in accordance with EC Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. All of the additives in the Miscellaneous Food Additives (Scotland) Regulations 1996 that are identified as being suitable for use in fruit juice production can be used, for example, malic acid can be used to balance acidity in pineapple juice.

Schedule 4 and 5

Schedule 4 lists physical treatments that are permitted in the manufacture of the juice and a list of additional substances which may be used as processing aids during manufacture. The addition of these permitted substances does not have to be declared in the ingredient list.

Schedule 5 list the minimum juice and puree content for specific fruits in the manufacture of fruit nectars.

Labelling Requirements

All designated products are also subject to the Food Labelling Regulations 1996.

If the product falling within the 5 reserved descriptions is manufactured from one kind of fruit then the name of that fruit must be substituted for fruit, e.g. orange juice.

- Where two or more kinds of fruit are used the name of the product must be supplemented by the names of the fruit in descending order of the volume in the unconcentrated form.
- Where three or more kinds of fruit are used the reserved description may be supplemented by the words 'several fruits' or by similar wording or by the number of fruit used, e.g. five fruit juice.

In all cases quantitative ingredient declaration must be applied.

Regulation 11 of the Food Labelling Regulations 1996 requires, where the fruit juice has been subjected to treatment for preservation purposes, then the name of the juice must include, or be accompanied by an indication of the treatment. FSA guidance suggests: "In practice this is likely to apply to freshly squeezed fruit juices, where consumers may not expect them to be pasteurised. If such juices have been pasteurised or treated under pressure, there must be an indication of this along with the name (e.g. 'juice subject to high pressure')".

With regard to the term 'freshly squeezed' FSA guidance suggests it should only be used to describe juice obtained direct from the fruit (not prepared from concentrates) where there has been a short time between extraction and packaging and the 'use by' date given on the product is within 2 weeks of juice extraction. The names of the fruits used should be listed in descending order of the volume of the juice or puree included from each kind of fruit. Volume is calculated as unconcentrated juice or puree.

The water which is added to the fruit juice from concentrate to return the product to its original state does not need to be declared in the ingredient list.

The added ingredients must be declared in the ingredient list in descending order of volume. Added ingredients include sugars, vitamins and minerals.

Ascorbic acid, if added to perform a technological function is an antioxidant and must be labelled as ascorbic acid. If added to fortify the product with Vitamin C, it must be labelled as such. There is no legal definition of the term 'freshly squeezed'. Fruit juice must not contain preservatives (with the exception of lemon juice, lime juice and bulk dispensed orange juice, grapefruit juice, apple juice and pineapple juice which can contain sulphur dioxide).

In lemon juice and lime juice, under Part B of the Miscellaneous Food Additives (Scotland) Regulations 1996, sulphur dioxide is permitted to a maximum level of 350mg/litre. In bulk dispensed orange juice, grapefruit juice, apple juice and pineapple juice, sulphur dioxide is permitted to a maximum of 50mg/litre. Other than the exceptions above, where preservatives are used, another product name be used e.g. fruit juice drink.

Fruit juice from concentrate

Fruit juice made from concentrate must be labelled with the declaration '<u>made with concentrated X juice</u>' (X is the named fruit) and when reconstituted is 100% juice. Where fruit juice is mixed with fruit juice from concentrate(s), the product is labelled as fruit juice and the additional wording '<u>partially made with concentrates(s)</u>'. This additional wording should be close to the product name standing out well from any background and in clearly visible characters. The same requirement applies where fruit nectars have been produced partly, or wholly from fruit juice concentrate.

Public Analyst Observations

Typical issues in relation to composition and labelling include:

- Claims such as juices described as from concentrate but are not.
- Sales of pasteurised or high pressure treated juice being described as fresh.

Adulteration issues

- Product described as x juice but not in fact a fruit juice
- Concentrate not correctly hydrated
- Range of fruit not declared
- Percentage of fruit not as declared
- Fruit juice attributed to a geographic region which is incorrect
- Excess preservative in certain juice
- Excess added sugar to fruit juice above specified limits.

Associated Regulations

The Fruit Juices and Fruit Nectars (Scotland) Regulations 2003 (SSI No. 293)

Council Directive 2001/112/EC on fruit juices and similar products

The Food Enzymes (Scotland) amendment Regulations 2010 (SSI No. 26)

The Food Additives (Scotland) Regulations 2009 (SSI No. 436)

Further Information

The British Soft Drinks Association provides guidance to their members on a range of fruit juice issues.

The British Fruit Juice Importers Association provides advice and guidance on juice.

British Soft Drinks Association

FSA Guidance on Fruit Juices and Nectars Regulations 2003

SCHEDULE

Annex 1

1. Fruit Juice

This is pressed directly from the fruit and the juice is not concentrated, may additionally be described as 'direct' or 'not from concentrate'. It can be fresh or preserved by chilling and is often subjected to pasteurisation or high pressure treatment.

Fruit juice may be from one or more kinds of fruit having the characteristic colour, flavour and taste of the juice of the fruit from which it comes.

In the processing flavour, pulp and cells will become separated from the juice; these are permitted to be added back to the same juice to ensure its characteristic smell and taste.

In the case of citrus fruits other than limes, the juices must come from the endocarp and with limes the juice can be obtained from the whole fruit however, the outer part must be reduced to a minimum.

2. Concentrated Fruit Juice

This product is obtained from the fruit juice as defined above by the physical removal of water. Where it is intended for direct sale to the consumer, the proportion of the water content removed must be at least 50%

3. Fruit Juice from Concentrate

This product is produced by replacing the water extracted from the concentrated fruit juice. Flavours, pulp and cells, which were recovered during the manufacture of the fruit juice in question or fruit juice of the same kind, have to be restored to produce an end product, which displays organoleptic and analytical characteristics at least equivalent to those of an average fruit juice obtained from fruit or fruits of the same kind.

The quality of the water added must display appropriate characteristics to guarantee the essential qualities of the juice.

If a fruit juice is from concentrate, then the concentrate must be reconstituted to the same concentration as normal juice.

4. Dehydrated or Powdered Fruit Juice

This product is obtained from fruit juice by the physical removal of virtually all of the water content.

5. Fruit Nectar

Fruit nectar is a product made by combining fruit juice, fruit juice from concentrate, concentrated fruit juice, dehydrated/powdered fruit juice, fruit juice, fruit puree or a mixture of these products with water and adding sugar and/or honey and/or sweeteners. The Regulations require minimum quantities of fruit juice, fruit puree, or a mixture of such juice and puree for these products, depending on the type of fruit used.

The Genetically Modified Food (Scotland) Regulations 2004 (SSI No. 432)

Scope

These Regulations provide for the enforcement and execution of certain specified provisions (relating to food and feed) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified (GM) food and feed.

In particular these Regulations formally designate the Food Standards Agency as the national competent authority to receive applications for the authorisation of new genetically modified organisms for food use, food containing or consisting of genetically modified organisms, or food produced from or containing ingredients produced from genetically modified organisms (GMO).

The regulations:

- 1. Prohibit the placing on the market of a GM food unless it has received an appropriate authorisation.
- 2. Require that products without authorisation be withdrawn from the market.
- 3. Require an authorisation holder to comply with conditions or restrictions imposed on an authorisation and post marketing requirements.
- 4. Authorisation holders must inform the Commission if scientific information raises doubts on the safety of the product.
- 5. Stipulates certain labelling requirements.

Under these regulations, authorised officers have power to detain food which fails to comply with this EC Regulation. The officer may also seize the food and apply for an order from a justice of the peace for it to be condemned and destroyed or disposed of to prevent its use in food or animal feed.

In the case of incorrectly labelled food, the justice of the peace may at their discretion order that the food be properly labelled and released to the operator.

Public Analyst Observations

Anyone selling soya, maize or rice can encounter issues surrounding cross contamination. Officers may wish to consider sampling such products if encountered in manufacturing premises.

Associated Regulations

Regulation (EC) No. 1829/2003

The Genetically Modified Food (Scotland) Regulations 2004 SSI No. 432

Further Information

European Food Safety Authority EFSA

Register of GM Food and Feed

GM Food Debate

Guidance note for sampling food and feed to determine the presence of genetically modified material.

The Honey (Scotland) Regulations 2003 (SSI No. 569)

Scope

The Honey (Scotland) Regulations 2003 implement the provisions of <u>EC Directive</u> 2001/110 relating to honey by laying down specifications with which a product must comply in order to be described as 'honey' and providing additional labelling requirements for these products. The Regulations revoke and replace the Honey (Scotland) Regulations 1976.

Ingredients/Products

The Regulations apply to 'specified honey products', i.e. a food covered by the reserved descriptions in Schedule 1, and which contains no added ingredients.

The labelling provisions (including the use of the reserved descriptions) apply to specified honey products offered for sale to the ultimate consumer or a catering establishment. The provisions relating to the labelling of baker's honey and filtered honey sold in bulk containers (Regulation 5) apply at all stages of the supply chain.

Reserved descriptions - General

Regulation 3; Regulation 4(1)(a); Schedules 1 and 2

Reserved descriptions are controlled sales names that apply to specified honey products. The Regulations provide that a food offered for sale to the ultimate consumer or a catering establishment may not be described using one of the reserved descriptions unless it meets the relevant specifications laid down in Schedules 1 and 2.

The reserved descriptions may also be used in the name of a food in the following circumstances:

- a) Where it is clear that the specified honey product to which the reserved description relates is only an ingredient of the food. (e.g., 'honey cake', 'honey roast ham', 'honey and bran muffin')
- b) Where it is clear that the food is not, and does not contain, the specified honey product to which the reserved description relates. (e.g., 'honey substitute').

Reserved descriptions - Added ingredients

Regulation 2(2)(ii)

A food may only be considered a 'specified honey product' if it has not had any other ingredient added to it. In effect therefore, honey that contains added ingredients may not be described as 'honey' (or by any of the reserved descriptions).

Substances such as residues of veterinary drugs, contaminants such as heavy metals or additives should not be present in honey. This provision does not preclude the sale of honey with declared ingredients, provided that a suitable 'name of the food' is used. For example 'honey with cherries', or 'honey and x'. This type of food is effectively a product containing honey as an ingredient. As such, the flexibility described in point (a) allows a reserved description (such as 'honey') to be used in the name of the food.

Reserved descriptions - Filtered honey

Schedule 1, item 8

Filtered honey is defined as 'honey obtained by removing foreign inorganic or organic matters in such a way as to result in the significant removal of pollen'. Where fine filters are used such that a significant amount of pollen is removed, e.g. where honey is finely filtered to improve the shelf-life and clarity, the product will need to be described as 'filtered honey' and not simply 'honey'.

Reserved descriptions - Baker's honey

Schedule 1, item 9

Baker's honey is defined as honey that is 'suitable for industrial uses or as an ingredient in other foodstuffs which are then processed; and may have a foreign taste or odour; have begun to ferment or have fermented; or "have been overheated".

Baker's honey will normally be subjected to further processing for use in bakery products or other processed products. Therefore, the specific criteria laid down for moisture content, free acid, diastase activity and Hydroxy Methyl Furfuraldehyde (HMF) content are more generous for baker's honey. There are also additional labelling provisions specific to baker's honey. These are described further on in this guidance note.

Specifications for specified honey products Reserved descriptions - specific requirements

Schedule 1: Schedule 2

Schedule 1 provides the reserved descriptions for specified honey products. The various reserved descriptions relate to the source, processes and way in which the honey is presented.

Schedule 2 provides the detailed specifications with which the honey must comply and also provides general quality criteria for honey. Honey that is sold as such, as well as honey that is used as an ingredient in another food (with the exception of baker's honey) must not -

- have any foreign tastes or odours
- have begun to ferment
- have an artificially changed acidity
- have been heated in such a way that the natural enzymes have been either destroyed or significantly inactivated. In addition, no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter (see also paragraph above relating to finely-filtered honey).

Schedules 1 and 2 are reproduced in Annexes I and II respectively of this guidance.

Application of Schedule 2 in the supply chain

The specifications laid down in the Schedules apply when a specified honey product is sold to the ultimate consumer or a catering establishment. Therefore, where honey is sold other than to these consumers, in theory the specific criteria relating to the use of the reserved descriptions do not apply. This also has the effect that the specifications do not apply to honey at the point of import - if that honey is not ready for delivery to the ultimate consumer or a catering establishment.

However, it is quite possible that the specific criteria laid down in Schedule 2 will continue to be relevant where honey is used as an ingredient of another food. Where honey is used as an ingredient, it must be described appropriately in the product's list of ingredients. Such honey may only be described using a reserved description, if the honey complied, at the time of its use as an ingredient, with the relevant compositional criteria.

Labelling Requirements

As well as the specific labelling provisions of the Regulations, specified honey products are also subject to the general labelling rules of the Food Labelling Regulations (FLR). In particular, this includes the requirement to give a 'best before' date and any special storage instructions on the label of specified honey products (see Regulation 5 of FLR).

General labelling requirements

Regulation 4 requires that specified honey products must be labelled with the following information when offered for sale to the ultimate consumer or a catering establishment:

- (i) A reserved description: Regulation 4(1)(a) requires that a specified honey product is labelled with an appropriate reserved description. However, in the case of blossom honey, nectar honey, honeydew honey, drained honey and pressed honey, the Regulations permit, the simple description 'honey' to be used as an alternative to the reserved description.
- (ii) The country or countries of origin: country or countries in which the honey was harvested. Where the honey is a blend of honeys from more than one country, one of the following statements may be used:
- 'blend of EC honeys'
- 'blend of non-EC honeys'
- 'blend of EC and non-EC honey

It is not enough simply to provide a manufacturer's address on the label as this is not sufficient as a declaration of country of origin. It is the Agency's view that country could represent the UK or the individual country Scotland, NI, England, Wales. Similarly a precise form of words is not laid down. So statements such as produce of Scotland, Scotland honey or made from honey harvested in Scotland would be acceptable.

Labelling provisions specific to baker's honey and filtered honey Regulations 4 and 5

- (i) Baker's honey and filtered honey may not be labelled with additional information relating to its floral or vegetable origin; its regional, territorial or topographical origin; or its specific quality criteria (see also paragraph below on 'Optional labelling information').
- (ii) Where baker's honey or filtered honey is sold in bulk containers or packs, the full product name must appear on both the container and on any accompanying trade documents. In effect, this means that baker's honey and filtered honey sold in this way may not simply be labelled as 'honey'. The term 'trade documents' includes all documents relating to the sale, transportation, storage or delivery of the product. The term 'bulk containers or packs' is not defined as such in the Regulations, but this provision is understood to cover the sale of honey in any container, which is later filled into consumer packaging and not honey in the consumer packaging itself. As such the provisions will usually apply to the sale of honey to food processors and manufacturers etc. (NB this provision applies at all stages of the supply chain, not only to sales to the ultimate consumer or a catering establishment).
- (iii) When baker's honey is sold as food in its own right, it must be labelled with the words 'intended for cooking only'. This declaration must appear close to the name of the food.
- (iv) In the case of a food product containing baker's honey as an ingredient, the 'name of the food' may include a reference to simply 'honey' rather than 'baker's honey', the full reserved description. Hence a product may be called 'honey cake' rather than 'baker's honey cake', but 'baker's honey' must appear on the list of ingredients. It is the view of the Agency that in cases where honey does not appear in the product name then the ingredients list may then refer simply to 'honey'.
- **Example 1:** 'Honey cake' prepared with baker's honey. Honey may be used in the product name but the ingredients list must specify that "baker's honey" has been used (Regulation 4(3) and Note 2 to Schedule 1).
- **Example 2:** 'Coconut cake' prepared with baker's honey. In this case the Agency's view is that Baker's honey used as an ingredient could be labelled as simply 'honey' in the ingredient list. All other types of honey, except filtered honey can be labelled as "honey" in the ingredient list.

Optional labelling information

The Regulations contain further rules to cover certain labelling information that can be provided on a voluntary basis. The Regulations allow honey (with the exception of baker's honey and filtered honey) to be labelled with the following information, where certain requirements are met:

- (i) Floral or vegetable origin: provided that the honey is derived wholly or mainly from the indicated source, and that it meets the specifications relevant to the floral or vegetable source in question (i.e. as contained in Schedule 2).
- (ii) Regional, territorial or topographical origin: provided that the honey comes entirely from the indicated source.
- (iii) Specific quality criteria: this provision relates to additional descriptions that emphasise the quality of the product.

Voluntary labelling

Since 1996 the British Honey Importers and Packers Association (BHIPA) have adhered to a voluntary labelling code whereby all honey on retail sale includes a warning statement that 'honey should not be given to infants under 12 months of age'. This is as a precautionary measure against possible infant botulism which could potentially arise from the presence of Clostridium botulinum spores in honey.

Public Analyst Observations

Adulterations of honey can arise from addition of sucrose or cane sugar, beet sugar or high fructose corn syrup.

There can be origin issues, e.g. samples from Turkey have been found to be misdescribed. Country of origin can be determined based on a range of analytical techniques.

Analytical procedures are accurate enough to trace antibiotic residues in honey. There have been residues in honey produced in China and South America.

Officers should also be aware of the differences between retail and baker's honey and the potential for adulteration. Analytical tests can distinguish between them.

Associated Regulations

EC Directive 2001/110 relating to honey

Honey (Scotland) Regulations 2003 (SSI. No 569)

Honey (Scotland) (Amendment) Regulations 2005 (SSI No. 307)

Further Information

FSA Guidance on Honey Honey Association

SCHEDULE

ANNEX 1 SCHEDULE 1 Regulation 2(1) SPECIFIED HONEY PRODUCTS AND THEIR RESERVED DESCRIPTIONS

Column 1	Column 2
Reserved Descriptions	Specified honey product
1(a) blossom honey	Honey obtained from the nectar of
1(b) nectar honey	plants
2. honeydew honey	honey obtained mainly from excretions
	of plant sucking
	insects (Hemiptera) on the living part of
	plants or secretions
	of living parts of plants
3. comb honey	honey stored by bees in the cells of
	freshly built broodless combs or thin
	comb foundation sheets made solely of
	beeswax and sold in sealed whole
	combs or sections of such
	combs
4 (a) chunk honey or	honey which contains one or more
4 (b) cut comb in honey	pieces of comb honey
5. drained honey	honey obtained by draining de-capped
	broodless combs
6. extracted honey	honey obtained by centrifuging de-
	capped broodless combs
7. pressed honey	honey obtained by pressing broodless
	combs with or without
	the application of moderate heat not
	exceeding 45°C
8. filtered honey	honey obtained by removing foreign
	inorganic or organic
	matters in such a way as to result in
	the significant removal

	of pol	len
9. baker's honey	honey which is —	
	(a)	suitable for industrial uses or as
		an ingredient in other
		foodstuffs which are then
		processed; and
	(b)	may —
		(i) have a foreign taste or
		odour,
		(ii) have begun to ferment or
		have fermented, or
		(iii) have been overheated

Annex II SCHEDULE 2 Regulation 2(2) SPECIFICATIONS FOR SPECIFIED HONEY PRODUCTS

1.	Sugar Content	
1(1)	Fructose and glucose content	
	(sum of both)	
_	blossom honey	not less than 60 g/100 g
_	honeydew honey, blends of	not less than 45 g/100 g
	honeydew honey with blossom	
	honey	
1.2.	Sucrose content	
_	in general	not more than 5 g/100 g
_	false acacia (Robinia	not more than 10 g/100 g
	pseudoacacia), alfalfa	
	(Medicago sativa), Menzies	
	Banksia (<i>Banksia menziesii</i>),	
	French honeysuckle	
	(Hedysarum), red gum	
	(Eucalyptus camaldulensis),	
	leatherwood (Eucryphia lucida,	
	Eucryphia milliganii), Citrus spp.	
_	lavender (Lavandula spp.),	not more than 15 g/100 g
	borage (Borago officinalis)	
2. Mo	isture content	
_	in general	not more than 20%
_	heather (Calluna) and baker's	not more than 23%
	honey in general	
_	baker's honey from heather	not more than 25%
	(Calluna)	
3. Wa	ater–insoluble content	
		1

-	In general	not more than 0.1 g/100 g
_	pressed honey	not more than 0.5 g/100 g
4. Electrical conductivity		
_	honey not listed below and	not more than 0.8 mS/cm *
	blends of these honeys	
_	honeydew and chestnut honey	
	and blends of these except with	not less than 0.8 mS/cm
	those listed below	
_	exceptions: strawberry tree	
	(Arbutus unedo), bell heather	
	(Erica), eucalyptus, lime (Tilia	
	spp.), ling heather (Calluna	
	vulgaris), manuka or jelly bush	
	(Leptospermum), tea tree	
	(Melaleuca spp.)	
5. Fre	e acid	
_	in general	not more than 50 milli-equivalents acid
		per 1000 grammes
_	baker's honey	not more than 80 milli-equivalents acid
		per 1000 grammes
6. Dia	stase activity and HMF content	
detern	nined after processing and	
blendi	ng	
(a)	Diastase activity (Schade scale)	
-	in general, except baker's honey	Not less than 8
-	honeys with low natural enzyme	Not less than 3
	content (e.g. Citrus honeys) and	
	an HMF content of not more	
	than 15mg/kg	
(b) HM	//F	
-	in general, except baker's honey	Not more than 40mg/kg (subject to the

		provisions of (a), second indent
-	honeys of declared origin from	Not more than 80mg/kg
	regions with tropical climate and	
	blends of these honeys	

^{*} The reading given in the table has been reproduced from EC legislation that has been amended to correct the drafting defect. The reading should actually read "not less than 0.8 mS/cm"

Infant Formula and Follow-on Formula (Scotland) Regulations (SSI No. 322)

Scope

These Regulations implement <u>Commission Directive 2006/141/EC</u> on infant formulae and follow-on formulae, which lays down rules about the composition, labelling and advertising of these products. The regulations also take advantage of the flexibility provided in the Directive to further restrict the advertising of infant formula such that infant formula can only be advertised in a scientific journal or for trade purposes prior to the retail stage. These Regulations also implement <u>Council Directive 92/52/EEC</u> which requires that any infant formula exported from the EU must comply with various provisions of the EC regime.

Ingredients/Products

Manufacturer

An infant formula and follow on formula may only be manufactured from:

- The protein sources and food ingredients specified in Annex I and Annex II of Commission Directive 2006/141/EC
- Other food ingredients whose suitability for use by infants from birth has been established by generally accepted scientific data

Composition

Annex I of Commission Directive 2006/141/EC lists the essential ingredients, including specific criteria of infant formula when reconstituted. The Annex sets minimum and maximum limits on:

Energy Mineral substances
Protein Lipids and phospholipids
Taurine & Choline Vitamins
Carbohydrates Nucleotides
Oligosaccharides Inositol

Annex I must also be read in conjunction with Annex V: Indispensable and conditionally indispensable amino acids in breast milk

Annex II lists the ingredients with minimum and maximum limits for follow on formula and these are:

Energy Mineral substances
Protein Lipids and phospholipids
Taurine Vitamins
Carbohydrate Nucleotides
Oligosaccharides

Annex II must be read in conjunction with Annex V 'Amino acids composition of casein and breast milk protein'

Only water may be added to either of the above in preparing them ready for consumption.

The Regulations also state that infant formula and follow-on formula must not contain any substance at such levels that would endanger the health of the infants.

Labelling Requirements: Requirements

Infant Formula

Must be named 'infant formula' except when manufactured entirely from cows' milk protein, in which case it must be named 'infant milk'. Statement confirming suitability for infants from birth when not breast fed

Nutrition data per 100ml of product as ready to use: i.e.

Energy kj or kcal

Proteins Lipids

Carbohydrates

Average quantity of each mineral and vitamin as per Annex I of the Commission Directive 2006/141/EC and where applicable per 100mls of the product ready for use

- Choline
- Inositol
- Carnitine

Average quantity of nutrients mentioned in Annex III per 100mls of the product ready for use:

- 1. Vitamins
- 2. Mineral substances
- 3. Amino acids and other nitrogen compounds
- 4. Other nutritional substances Preparation, storage and disposal instructions and a warning against health hazards from inappropriate preparation and storage

The words 'Important Notice' or their equivalent followed by details about:

- 1. Superiority of breast feeding
- 2. Product only to be used on

Follow on Formula

Must be named 'follow-on formula' except when manufactured entirely from cows' milk protein, in which case it must be named 'follow-on-milk'. Statement confirming suitability for infants over 6 months and not to be used as a substitute for breast feeding during the first 6 months of life.

Any decision to begin complementary feeding, particularly if that decision is made before 6 months of age, should be made only by a professionally qualified person as outlined in regulation 18(1)a (iv)

Nutrition data per 100ml of product as ready to use: i.e.

Energy kj or kcal

Proteins

Lipids

Carbohydrates

Average quantity of each mineral and vitamin as per Annex II of the Commission Directive 2006/141/EC and where applicable per 100mls of the product ready for use

- Choline
- Inositol
- Carnitine

Average quantity of nutrients mentioned in Annex III per 100mls of the product ready for use:

- 1. Vitamins
- 2. Mineral substances
- 3. Amino acids and other nitrogen compounds
- 4. Other nutritional substances Preparation, storage and disposal instructions and a warning against health hazards from inappropriate preparation and storage

advice of a medical person Must not contain:

- 1. Picture of an infant
- 2. Picture or text that idealises the use of the product

Only nutrition claims listed in Annex IV of Directive 2006/141/EC can only be made if the conditions warranting the claim are fulfilled.

The permitted nutrition claims are:

- 1. Lactose only
- 2. Lactose free
- Added long chain poly unsaturated fatty acids (LCP) or equivalent nutrition claim related to the addition of docosahexaenoic acid
- 4. Nutrition claims on the addition of the following optional ingredients:
 - Taurine
 - Nucleotides
 - Fructo-oligosaccharides and galacto oligosaccharides

Health Claims: only the health claims listed in Annex IV of Directive 2006/141/EC can be made if the conditions warranting the claim are fulfilled, the permitted claim is:

Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties Nutrition claims on follow-on formula are controlled by the <u>Nutrition and</u> <u>Health Claims Regulation 1924/2006</u>

Health claims on follow-on formula are controlled by the <u>Nutrition and</u> Health Claims Regulation 1924/2006

Information on vitamins and minerals included in Annex VII, expressed as a % of the reference values given in Annex VII, per 100ml of the product ready for use.

The labelling of infant formula and follow on formula must be designed to provide necessary information about the appropriate use of the product and must not discourage against breast feeding or contain terms such as "humanised", "maternalised", "adapted" or any similar term.

Infant formula and follow on formula must be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow on formula.

Restrictions on advertising infant formula

Regulations place a restriction on the advertising of infant formula except in:

- Scientific Publication
- Purposes of trade prior to retail stage
- The advertisements cannot include any nutrition and/or health claims other than those in Annex IV of Commission Directive 2006/141/EC
- The advertisements must include the important notice and should not discourage breast feeding or contain references to terms such as "humanised", "materialised" or "adapted"
- The advertisement may only contain information of a scientific and factual nature and may not imply that bottle feeding is equivalent or superior to breast feeding.

Restrictions on advertising follow-on formula

Follow on formula may not be advertised in a way that would discourage breast feeding or contain references to terms such as "humanised", "maternalised" or "adapted". Nor should it create confusion in the mind of the consumer regarding the differences between infant formula and follow on formula.

Restrictions on promotion of infant formula

In the case of a retail sale, it is not permitted to:

- Advertise or make a display designed to promote sales of infant formula.
- Give free samples or coupons for discount
- Promote sales through premiums, special sales, loss leaders etc.
- Undertake promotional activity to induce sales

A manufacturer or distributor of any infant formula must not offer infant formula products at a reduced or discounted price or provide any gift designed to promote its sale to:

- General Public
- Pregnant women or mothers or the family members either directly or indirectly through the health care system or health workers.

The regulations also contain restrictions on provision of information and education regarding infant and child feeding.

Amendments to Regulations

Infant Formula and Follow-on Formula (Amendment) (Scotland) Regulations 1997 SI. No. 213

These regulations update the primary regulations by taking account of amendments to EC Directive 91/321/EEC by Directive 96/4/EEC and insert a new schedule no. 8

"Reference values for nutrition labelling for foods intended for infants and young children".

Infant Formula and Follow-on Formula Amendment (Scotland) Regulations 2000 SSI No. 217

These regulations update the primary regulations by taking account of amendments made by Commission Directive 1999/50/EC amending Directive 91/321/EC. The amendments extend the prohibition on sale or export to 3rd countries of food containing individual pesticide residues above a level of 0.01 mg/kg measured when ready for use or when re constituted.

Infant Formula and Follow-on Formula Amendment (Scotland) Regulations 2004 SSI No 7

These regulations amend the primary regulations by taking account of the Commission Directive 2003/14/EC amending Directive 91/321/EC. The amendment requires the insertion of new Schedule 7a "Pesticides whose residues must not be present in infant formula or follow on formula at a level exceeding 0.003mg/kg. Schedule 7b "Specific maximum residue levels of certain pesticides in infant formula or follow on formula" is also inserted.

Public Analyst Observations

Generally there tend to be few problems concerning product composition.

Associated Regulations

Infant Formula and Follow-on Formula Regulations 1995 (SI No. 77)

Infant Formula and Follow-on Formula Amendment (Scotland) Regulations 2000 (SSI No 217)

Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (SSI No. 549)

Infant Formula and Follow-on Formula Amendment (Scotland) Regulations 2008 (SSI No. 322)

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 SSI No. 424

<u>Food Standards Agency Guidance on Infant Formula and Follow on</u> Formula 2008

The Jam and Similar Products (Scotland) Regulations 2004 (SSI No. 133)

Scope

The Regulations implement the provisions of <u>EC Directive 2001/113</u> relating to fruit jams, jellies and marmalades and sweetened chestnut puree intended for human consumption. The Regulations also contain national measures to control mincemeat and fruit curds which are not covered by the Directive.

Ingredients/Products

The Regulations apply to a specified jam or similar product that is intended for human consumption and ready for delivery to the ultimate consumer or to a catering establishment.

A 'specified jam or similar product' means a food covered by the reserved descriptions in Schedule 1 to the Regulations. The Regulations do not apply to specified products intended for use in the manufacture of fine bakery wares, pastries and biscuits as they normally require the addition of certain additives and flavourings to enable them to withstand food processing in bakeries.

Reserved descriptions - General

Reserved descriptions are controlled sales names that apply to specified products and include descriptions of the composition of e.g. 'jam', 'extra jam', 'jelly' etc. A food may not be described using one of the reserved descriptions unless it meets the relevant compositional criteria laid down in the Schedule. Reserved descriptions are 'names prescribed by law' for the purposes of Regulation 6(1) of the Food Labelling Regulations (FLR). The name under which a specified product is sold must be (or include) a reserved description.

The reserved descriptions may also be used in the name of a food in the following circumstances:

- (a) Where it is clear that the specified product to which the reserved description relates is only an ingredient of the food. (e.g., 'jam sandwich').
- (b) Where it is clear that the food is not, and does not contain, the specified product to which the reserved description relates.
- (c) Where the reserved description is used in a customary name for another food product, including relishes and savoury foods, and its use is not liable to mislead the consumer (e.g., 'aspic jelly', 'jelly beans' etc.).

Point (c) above will also allow the name 'jelly' to be used to describe table jelly - i.e., the type of fruit flavour jelly commonly used for desserts

Reserved descriptions - Fruit curds and mincemeat

These products are not controlled by Directive 2001/113 and because they are a different kind of product to jam, jelly and marmalade and some of the general provisions of the Regulations affect them in a slightly different way, as described below:

- (i) Permitted ingredients and treatments: The restrictions on the ingredients and treatments that may be used in the preparation of specified products do not apply to fruit curds and mincemeat.
- (ii) Soluble solids content: The minimum required soluble solids content for fruit curds and mincemeat is 65% (this compares with 60% for the rest of the specified products).
- (iii) Labelling: Fruit curds and mincemeat are exempt from some of the labelling provisions such as the requirement to label their fruit and sugar content, but are still subject to general labelling provisions.

The compositional requirements for fruit curds and mincemeat do not apply to foods imported from other EU Member States. However, if a product made elsewhere in the EEA and sold here is substantially similar to mincemeat so that it could be confused with mincemeat by a consumer, it should make clear (by its labelling) that it is something other than mincemeat as understood in the UK.

Reserved Descriptions - 'conserve' and 'preserve'

The terms 'conserve' and 'preserve' can still be used with an appropriate reserved description i.e. 'jam' or 'extra jam', if the product meets the relevant specifications for jam and extra jam, but where the terms 'conserve' and 'preserve' are used without a reserved description there are no longer any compositional requirements relating to the use of these terms.

Compositional Requirements for specified products

Reserved descriptions - compositional requirements
The compositional requirements for specified products are set out in Schedules 1 and 2. The requirements fall into three categories:

(i) Minimum content requirements: Schedule 1 stipulates the minimum amounts of certain ingredients that must be used in the manufacture of specified products (e.g. fruit, sugar etc). Where jam, extra jam, jelly and extra jelly are produced from two or more types of fruit, the minimum content for each fruit type must be adjusted to take account of this and a quantitative declaration for each of the fruits may be necessary on the label.

Extra jam is required to be made from fruit pulp only. However, an exception is made to permit seedless extra jams, whereby such jams made from raspberries, blackberries, blackberries or redcurrants may be made using only fruit puree (see Schedule 1, item 2).

- (ii) Permitted additional ingredients: Only those ingredients specified in Schedule 2 may be added to jam, extra jam, jelly, extra jelly, marmalade and jelly marmalade in addition to the 'core' ingredients of fruit, sugar and water. However, if ingredients other than those specified in Schedule 2 are added to jam etc. rendering it unable to meet the compositional requirements for a specified product, the name of the food could include the words 'conserve' or 'preserve'. For example, a product made of raspberry jam and cider (which is not covered in the list of permitted additional ingredients) could be called 'raspberry and cider conserve'. Manufacturers must take care to ensure that the labelling does not mislead consumers into believing that these products are specified products.
- (iii) Permitted treatments: Only the treatments set out in items 2-4 of Schedule 2 may be used in the production of jam, extra jam, jelly, extra jelly, marmalade and jelly marmalade. Citrus peel is permitted to be subjected to these permitted treatments but may also additionally be preserved in brine.
- **NB** -The provisions relating to permitted additional ingredients, and permitted treatments do not apply to mincemeat and fruit curds i.e. any added ingredient may be used in those products (subject to the general provisions of food law).

Required fruit content in mixed fruit products

In the case of jam, extra jam, jelly and extra jelly, the minimum required amount of fruit ingredients differ depending on the type of fruit used. The Regulations require that where a mixture of fruits is used, these minima must be 'reduced in proportion to the relative quantities of the types of fruit used'.

Reduced Sugar Products

Jam, extra jam, jelly, extra jelly, marmalade, jelly marmalade and sweetened chestnut puree should have a sugars content (expressed as soluble dry matter content) of at least 60%. However, there are two exceptions:

- (i) For products where the sugar has been wholly or partly replaced by permitted sweeteners and
- (ii) For products labelled as 'reduced sugar': The total soluble dry matter in reduced sugar jams must not be less than 25% and must not exceed 50%.

Labelling Requirements

Labelling of Specified Products

Regulation 5 provides the labelling requirements for specified products. In addition, the FLR provide further labelling requirements for specified products containing permitted sweeteners.

Required Labelling Information

Regulation 5 requires that specified products must be labelled with the following information:

All specified products:

- A reserved description this will be the 'name prescribed by law' (i.e. the legal name) of the product for the purposes of Regulation 6 of the FLR.
- Sulphur dioxide content where a specified product has a residual sulphur dioxide content of more than 10mg per kg, this must be declared as 'sulphur dioxide' in the products list of ingredients. The general rules relating to the ordering of the ingredients list will still apply, i.e. its position in the list must be determined according to the weight of the residue in the final product.

All specified products other than fruit curds and mincemeat:

• The total sugar content - this declaration must be given in the form 'total sugar content: Yg per 100g'. The proportion of sugar declared represents the total soluble solids content determined by refractometer at 20 centigrade (accurate to +/- 3 refractometric degrees).

In the case of a nutritional claim such as 'reduced sugar' and the product is labelled with nutritional information in accordance with Schedule 7 of the FLR, the total sugar content declaration required by the Jams Regulations need not be provided. Products which provide nutritional information on a voluntary basis will still be required to contain a sugar content declaration as required by the Jam Regulations in the form of total sugar content: Xg/100g.

It should be noted that in products where the nutritional information is provided on a voluntary basis, the numerical sugar value given in the table of nutritional information might appear different from the value given under the Jam Regulations i.e. Xg/100g.

As a result two different values may appear on the product label and enforcement officers should note this possible anomaly.

Jam, Extra jam, Jelly, Extra jelly, Marmalade, Jelly marmalade:

- The type of fruit used in the preparation of the food where the product contains two or more types of fruit, the fruit in question must be declared in descending order of weight used in the preparation. Where three or more types of fruit have been used, the words 'mixed fruit' (or a similar wording) may be used or alternatively the number of types of fruit used.
- The proportion of fruit used in the preparation of the product this declaration must be given in the form 'prepared with Xg of fruit per 100g'. It is important to note that this proportion relates to the amount of fruit from which the fruit ingredients are derived. For example in the case of a product made using fruit pulp, the declaration should relate to the weight of whole fruit used to make the fruit pulp not the weight of the fruit pulp itself.

NB - in the case of jam made from stone fruits, the fruit content calculated for the purposes of the labelling declaration required under regulation 52(b) may not be the same as the fruit content calculated to ensure that product meets the compositional requirements of Schedule 1. This is because the former relates to the amount of whole fruit used (including the stones), while the latter relate to the minimum amount of edible fruit (i.e. puree or pulp), which will no longer contain any peel or stones.

The declarations of both the fruit and sugar contents must appear in the same field of vision as the name of the product in clearly visible characters. The name of the product may also appear elsewhere on the labelling, and it is not necessary for the total fruit and total sugar content declarations to accompany the name of the product where it is in the largest type.

Specified products containing permitted sweeteners

The Sweeteners in Food Regulations allow a range of sweeteners to be used in the manufacture of jams, jellies and marmalades, where those products are:

- (i) 'Energy reduced' An energy-reduced product must have an energy value reduced by at least 30% in comparison with the original food or a similar food.
- (ii) 'No added sugar' A product with 'no added sugar' may not contain any added monosaccharide or disaccharide, or other food added for its sweetening properties.

The FLR requires that a specified product containing a permitted sweetener must be labelled with the following information:

- (i) The words 'with sweetener(s)'. This declaration must accompany the name of the food. e.g. "strawberry jam, with sweeteners".
- (ii) Where the specified product contains aspartame, the <u>words 'contains a source of phenylalanine'</u>.
- (iii) Where the specified product contains more than 10% added polyols, the words 'excessive consumption may produce laxative effects'.

Pre-packed for direct sale

Regulation 23 FLR

Products which fall within this category will be subject to certain exemptions by virtue of Regulation 23 of the FLR. This applies to jams and similar products prepared at home and sold at the farm gate or in market stalls and those homemade products sold by charitable institutions. Therefore the above products may be exempt from the requirement to include the declaration 'X grams of fruit per 100g' and 'Y grams of sugar per 100g' on the label.

Public Analyst Observations

From an analytical view point most jam samples from the major manufacturers tend to have correct fruit contents.

Officers might consider sampling a small manufacturer requesting analysis for sugar content. Inadequate sugar levels will have an impact on the keeping quality of the end product. Small manufacturers have difficulty regulating the sugar content.

Manufacturers check sugar content at room temperature using a refractometer. Please note that with a small manufacturer who pre-packs for direct sale, there is no requirement to declare sugar/ fruit content.

With fruit picked at the roadside officers might consider submitting samples for analysis for contaminants of platinum (used as a catalyst) and lead.

Associated Regulations

The Jam and Similar Products (Scotland) Regulations 2004 (SSI No. 133)

The Food Additives (Scotland) Regulations 2009 (SSI No. 436)

<u>EC Directive 2001/113</u> relating to fruit jams, jellies and marmalades and sweetened chestnut puree intended for human consumption

Further Information

FSA Guidance note 'The Jam and Similar Products Regulations 2003'

Quick Guide to Jam

Kava Kava in Food (Scotland) Regulations 2004 (SSI No. 244)

Scope

These Regulations revoke and replace the Kava-kava in Food (Scotland) Regulations 2003.

These Regulations prohibit the sale, possession for sale, offer, exposure or advertisement for sale of any food consisting of, or containing Kava-kava (regulation 3). Any such food may be treated as being unfit for human consumption and liable to be seized and destroyed (regulation 5(3)).

These Regulations provide for an exception to the prohibition imposed above where the food is imported from an EEC state, if it originates from such a state but is in free circulation in member states (within the meaning of Article 23.2, as read with Article 24, of the EC Treaty), and is being or is to be exported to an EEA state other than the United Kingdom (regulation 3(2)).

Ingredients/Products

Kava-kava is a plant, or an extract from such a plant, belonging to the species Piper methysticum.

The majority of products that Kava-kava was used in are classed as herbal medicines and are regulated in the UK by the <u>Medicines and Health Care products</u> <u>Regulatory Agency (MHRA)</u>. However, there were some food products containing kava kava, for example herbal tea bags, 'smoothie' drinks, cereal bars and vodka products. In addition, internet sites offered Kava-kava root and root powder for sale.

Evidence has mounted that in rare cases the use of products containing Kava-kava (mostly in the form of herbal medicines) has been associated with severe liver damage. The occurrence of liver damage is unpredictable and the mechanism is unclear.

To date, the Agency is aware of 110 cases of severe liver damage (hepatoxicity), possibly associated with the use of Kava-kava containing products. Eleven patients have suffered irreversible liver failure and received a liver transplant. Overall, nine patients have now died, including two who had received liver transplants.

Public Analyst Observations

Since this product has been banned there has been nothing found on sale in retail outlets.

Associated Regulations

Kava Kava in Food (Scotland) Regulations 2004 (SSI No. 244)

Further Information

Kava Kava

Food (Lot Marking) Regulations 1996 (SI No. 1502)

Scope

These Regulations revoke and replace the Food (Lot Marking) (Scotland) Regulations 1992 and implement Council Directive 89/396/EEC as amended by Council Directives 91/238/EEC and 92/11/EEC.

The Regulations require that food which has been produced, prepared or packaged as part of a lot is so marked or labelled as to enable the lot to be identified.

The following are useful definitions contained in the Regulations:

- Lot: a batch of sales units of food produced, manufactured or packaged under similar conditions.
- Lot marking indication: an indication which allows identification of the lot to which a sales unit of food belongs.

Ingredients/Products

The regulations apply to the sale of all foodstuffs intended for sale for human consumption, including wines and spirits Subject to the exemptions specified below, the sale of food forming part of a lot is not permitted unless it is accompanied by a lot mark.

Size of lot

The producer, manufacturer, packer or first seller within the EC must determine the size of lot most appropriate to the operational pattern. It will be necessary to consider the production, practicality and implications of a lot mark based on a large run to avoid having to recall more food than is necessary.

Labelling Requirements

The lot marking indication must appear in such a way as to be easily visible, clearly legible and indelible, however, it does not have to be understood by the consumer provided that the indication can be clearly identified. If the lot identification is not clearly distinguishable from other information it should be prefixed by the letter 'L'. Code edging, another form of lot identification is permitted provided a reader key would not be necessary to identify the mark clearly. It is possible that another mark appearing on the package could serve a secondary purpose as a lot mark, in which case this would need to be made clearly distinguishable by prefixing it with the letter 'L'.

In the case of pre-packed food, the lot mark is required to appear on the prepackaging or on a label attached. Pre-packaging includes bottles and the lot mark could appear on the rear of the label if clearly visible through the bottle (as in the case of some bottles of alcoholic spirit), or on a seal. Manufacturers, packers, etc., may need to consider whether there are any circumstances whereby removal of the seal would impede a product recall.

It would not be acceptable for a lot mark to appear on a cork or any other part of the packaging which was enclosed and thus not easily visible.

Exemptions

The following foods do not require a lot mark:

- Agricultural products which, on leaving the agricultural premises of production, are either sold or delivered to temporary storage, preparation or packaging stations or to producers' organisations; or collected for immediate use in an operational preparation or processing system. The term 'agricultural product' applies only to primary agricultural products (i.e. products of the soil, stock farming or fisheries which have not undergone initial processing). Examples could be harvested vegetables delivered to grading or packing stations, fresh fruit provided for canning operations.
- Individual items of food which at point of sale to the ultimate consumer are not pre-packed, such as loose sweets, fruit and vegetables.
- Foods sold to the ultimate consumer which are pre-packed for direct sale (for example bread baked on the premises for direct sale) or which are pre-packed at the request of the purchaser.
- Individual goods not intended to be sold separately, such as single tea bags or chocolates.
- Foods which are in a package or container, of which the largest side has a surface area of less than 10 square centimetres.
- Individual portions intended as an accompaniment to another food provided at a
 catering establishment for immediate consumption, such as sachets of salt,
 sauce or sugar. Also excluded are tea bags, coffee etc. provided as part of
 another service, for example drink making facilities in hotel rooms.
- Individual portions of ice cream and other edible ices.

Use of a date mark as a lot mark

A date mark ('best before', 'best before end' or 'use by') which appears on a product may be used as a lot mark whether or not the Food Labelling Regulations 1996 require the product to carry a date mark. For the date mark to qualify as a lot mark, it must be given in accordance with the requirements of the Food Labelling Regulations 1996.

However, it may be necessary to consider whether the size of the resulting batch is suitable. For example, using a 'best before end' date as a form of lot mark could result in a batch consisting of at least one month's production being withdrawn. 'Best before end' dates are acceptable as lot marks as the indication of the day and month (as required by the Regulations) is implicit (e.g. 'best before end October 1997' means best before 31 October 1997).

Bulk packaging

The lot mark of a sales unit contained in bulk packaging, for example retail packs enclosed in a wholesale pack, should appear on the outer container in addition to those retail packs. A lot mark for items exempt by virtue of the provisions and identified by an asterisk '*' only should be indicated on any outer container, for example it should appear on the outer catering pack which contains catering sachets. Goods that are not pre-packed that are supplied in bulk containers are required to carry a lot mark, but this may appear on the container in which the sales units are contained or on a commercial document accompanying the container.

Where a pre-package is enclosed in an outer container, such as bottles within a presentation box or tins inside a cardboard sleeve, consideration should be given as to whether the mark should also appear on the outer container. This arrangement would assist product recall as the entire stock of outer cartons would not have to be opened in order to identify the lot mark on the enclosed pre-package. This approach would seem particularly practical in circumstances when only a small number of items of the total stock need to be withdrawn. In some circumstances it may be possible to narrow the batch down in the event of recall if there was a 'broader' indication on the outer package

- such as a seasonal package or date mark.

Associated Regulations

Food (Lot Marking) Regulations 1996 (SI No. 1502)

<u>Council Directive 89/396/EEC</u> as amended by <u>Council Directives 91/238/EEC</u> and 92/11/EEC.

Further Information

FSA Guidance on Lot marking

Materials and Articles in Contact with Food (Scotland) Regulations 2007 SSI No. 471

Scope

The regulations implement the provisions of Commission Regulation EC No.
1935/2004 on materials and articles intended to come into contact with food;

Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food and Commission Directive 2007/42/EC relating to materials and articles made from regenerated cellulose film intended to come into contact with food. The regulations also deal with presence and migration of vinyl chloride monomer out of materials and articles.

The purpose of the regulations is to ensure that materials and articles are sufficiently inert to preclude substances from which they are made transferring into food in which they come into contact at levels that would endanger human health, or bring about unacceptable changes in the composition of food or its organoleptic properties. Some contact materials can be formulated to contain certain additives that are not inert and are intended to improve the condition of food or to monitor its condition. Such contact materials are known as "Active" or "Intelligent" should not change the composition or organoleptic properties or give information about the food that could mislead the consumers.

Ingredients/Products

The regulations apply to all materials and articles which in their finished state

- Are intended to be brought into contact with food or
- Are already in contact with food and were intended for that purpose or
- Can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal foreseeable conditions of use.

The regulations also contain specific requirements concerning vinyl chloride monomer and regenerated cellulose film.

The regulations do not apply to

- Materials and articles supplied as antiques
- Covering or coating materials such as cheese rinds, prepared meat products or fruits which form part of the food and may be consumed together with the food.
- Fixed public or private water supply equipment

EC Regulation 1935/2004

The EC Regulation provisions are enacted in Regulation 4.

Article 3:- Materials and articles whether active or intelligent must be made in accordance with Good Manufacturing Practice (GMP) to prevent danger to human health from migration of constituents into food or changes to food composition or organoleptic characteristics. The labelling, advertising and presentation or these materials must not mislead the consumer.

Article 4: Active and intelligent materials and articles must not bring about changes in composition or organoleptic characteristics of food that might mask food spoilage, nor give information about food that might mislead the consumer. These Active and intelligent materials need to be adequately labelled to identify what they are and to allow identification of the inedible parts.

Article 11: Business operators must comply with any conditions or restrictions identified for substances authorised by Community procedures. The article also places a duty on business operators to notify the Competent Authority to verify new scientific or technical information relating to use of authorised substances and human health.

Article 15: Labelling requirements

Materials and articles not yet in contact with food when placed on the market must be accompanied by the following information

- The words "for food contact" A symbol like the cup and fork may also be used although this is not strictly necessary where the intended use of the material are article is obvious.
- Instructions to be observed for safe use
- Name and address or registered office of the manufacturer, processor or seller responsible for placing the material or article on the market.
- Adequate labelling or identification to ensure traceability
- In the case or "active" or "intelligent" materials and articles, information on the permitted use of such materials.

The labelling data must be conspicuous, clearly legible and indelible and in a language easily understood.

At retail the above information must be displayed

- On packaging or
- Labels affixed to packaging or
- On a notice in the vicinity of the material or article

At marketing stages other than retail the information must appear

- On accompanying documents or
- The materials and articles themselves

Article 16: Declaration of compliance.

A written declaration of compliance stating that the materials and articles comply with the provisions of Article 5 must be provided. Provisions mentioned in article 5 include matters relating to

- Use only of authorised substances
- Use of only authorised substances incorporated into active or intelligent materials and articles
- Purity standards

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- Special conditions of use for authorised substances
- Specific limits of migration
- Overall limits of migration
- Provisions aimed at protecting human health against hazards arising from oral contact with materials and articles.
- Rules relating to sampling and analysis.
- Rules regarding traceability
- Additional labelling provisions regarding active and intelligent materials and articles.

Article 17: Traceability

Traceability of materials and articles must be ensured in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

The regulations also implement the provisions of EC Regulation 2023/2006 which places a duty on business operators to make materials and articles in accordance with GMP which includes a requirement for

- Quality assurance systems
- Quality control
- Documentation

Including specific controls to prevent printing inks applied to non-food contact side of materials and articles are not transferred to the food contact side. In addition printed surfaces must not come in contact with food.

Controls in relation to Vinyl chloride monomer (VCM)

Regulation 8 requires that a material or article must not contain more than 1 mg/kg of VCM and must not transfer more than 0.01 mg/kg of VCM to food. It is an offence to sell, import or use in the course of a business in connection with the storage, preparation, packaging selling or service of food materials and articles that do not meet this standard.

Controls in relation to regenerated cellulose film (RCF)

The regulations implement the provisions of Commission Directive 2007/42 which lays down details of authorised substances and restrictions for the manufacture of RCF.

It is an offence to sell, import or use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food which does not meet with the standard specified.

Regulation 11 sets the migration limit for RCF coated with plastic as not more than 10mg/square decimetre. In cases where a container is between 500 millilitres and 10 litres, or where the container surface cannot be established or in the case of caps, gaskets or stoppers the migration limit is 60 mg/kg of food.

In addition conversion factors are referred to in the legislation in respect of authorised monomers and starter substances referred to in Annex 11 of the Commission Directive 2002/72/EC.

Sampling Procedures

Where an enforcement officer decides that a sample of a material or article should be procured in accordance with article 29 of the Food Safety (Scotland) Act 1990 it should be divided into 3 parts or where this might impede analysis must divide the sample by putting the containers into 3 lots where each lot can be treated as being a part of the sample.

Enforcement Issues

Issues may arise in respect of materials and articles in contact with food that do not comply with the legal requirements. Clearly the power to seizure which relates to food cannot be applied.

Powers to deal with defective consumer goods are to be found in the provisions of the General Product Safety Regulations 2005 e.g. Regulation 3(2)(b) allow for certain obligations/provisions to apply along with enforcement powers e.g.

- Suspension notices (Regulation 11)
- Forfeiture (Regulation 18)

Officers availing of these powers must be appropriately authorised.

Public Analyst Observations

Recently officers have encountered unexpected types of material in contact with food in the form of food baskets intended to contain chips to which vinegar would be added. In one case a basket was lined with a zinc/tin plate which had reacted with the acid, releasing potentially harmful substances.

In another incident, officers encountered salt and pepper containers with metal lids being used to dispense vinegar in foods served in catering premises. The metal lids were found to be corroded as a result of reaction with the vinegar. In routine inspections officers should try and establish the nature and type of food coming into contact with a range of available contact materials.

Officers should not assume that:

- materials used in contact with food were originally intended for such a purpose, and
- 2. even if they were intended for contact with certain foods, they may not be suitable for the purpose to which they have been put.

Associated Regulations

The Materials and Articles in contact with Food (Scotland) Regulations 2007 SI No. 471

The Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2009 SSI No. 426

General Product Safety Regulations 2005

Further Information

Commission Regulation EC No. 1935/2004

Commission Regulation EC No. 2023/2006

Commission Directive 2007/42/EC

Commission Directive 2002/72/EC

Commission Regulation (EC) 450/2009

Meat Products (Scotland) Regulations 2004 (SSI No. 6)

Scope

These regulations replace the Meat Products and Spreadable Fish Products (Scotland) Regulations 1984 and implement the provisions of EC Directive
2001/101/EC The main differences are that the 2004 Meat Products Regulations (MPR) simplify the labelling of meat products, bring the regulations into line with the European definition of 'meat' and have fewer reserved descriptions.

The Meat Products Regulations apply to food which is ready for delivery to the ultimate consumer or to a catering establishment. The regulations do not apply to any food not intended for sale for human consumption or labelled clearly that it is intended exclusively for consumption by babies or young children.

The Regulations cover the following:

- Compositional requirements i.e. the prohibition on the use of some parts of the carcase in uncooked meat products.
- Reserved descriptions i.e. the minimum compositional criteria that meat products must meet in order to be described using the reserved descriptions (e.g. sausages, etc.).
- Labelling 'name of food' requirements for meat products having the appearance
 of a cut, joint, slice, etc. of meat i.e. declarations in the name of the food for such
 products of the presence of added water and certain other added ingredients.
- A QUID requirement for meat ingredients of foods sold loose.

Quantity declarations for the labelling of meat products are now covered solely by the general rules contained in the QUID parameters of the Food Labelling Regulations. FSA guidance recommends that to avoid confusion the QUID requirements are considered separately from the requirements relating to the reserved descriptions in the meat product regulations.

Generic Definition of Meat for the purposes of labelling meat ingredients in meat products Commission directive 2001/101/EC introduced a European generic definition of meat for the purposes of labelling meat ingredients in meat products.

The new definition as summarised in FSA guidance:

- Restricts the generic term 'meat' (as well as the species name such as 'beef',
 'pork', 'chicken' etc.) to skeletal muscle with naturally included or adherent fat
 and connective tissue.
- Introduces maximum numerical limits for associated fat and connective tissue, depending on the species of the meat. Any fat or connective tissue in excess of these limits cannot be counted towards the meat content and must be declared separately in the ingredients list (although a QUID declaration will not be required for this fat and connective tissue).

- Excludes mechanically recovered meat (MRM), which must already be declared separately in the ingredients list. MRM may not be counted towards the 'meat' content.
- Requires other parts of the carcase such as liver, kidney, heart etc to be labelled as such. The generic term 'offal' may not be used. In addition, these parts of the carcase may not be counted towards the QUID declaration for any meat ingredient.

Percentage Limits on Fat and Connective Tissue

Species% Fat %Connective Tissue Pork 30 25 Birds and Rabbits 1510 All other red meats and mixtures 2525

The definition does not in itself prohibit the use of any meat ingredients. It should be noted the European definition does not apply to raw meat and cuts of meat which are not ingredients of composite meat products.

Ingredients/Products

What is a Meat Product?

Regulation 2 of the MPR defines a meat product as 'any food which consists of meat or which contains as an ingredient any of the following:

Meat, mechanically recovered meat; or from any mammalian or bird species recognised as fit for human consumption, heart, tongue, the muscles of the head (other than the masseters), the carpus, tarsus or the tail.'

Schedule 1 to the Regulations states that the following foods are not meat products for the purposes of these Regulations, i.e:

- Raw meat to which no ingredient, or no ingredient other than proteolytic enzymes has been added.
- Poultry meat falling within the scope of Council Regulation 1906/90 as read with Commission Regulation 1538/91 (as amended), which lay down certain marketing standards for poultry.
- Any product containing the fat, but no other meat, of any animal or bird.

Compositional requirements

Specific parts of a carcase cannot be used in the preparation of uncooked meat products. The specific parts are: brains, feet, large and small intestine, lungs, oesophagus, rectum, spinal cord, spleen, stomach, testicles and udder.

Large or small intestines can be used solely to produce skin for sausages. 'Sausage' in this context includes frankfurters, salami, black pudding and any similar products.

Labelling Requirements

Reserved Descriptions

The regulations require that a meat product offered for sale to the ultimate consumer or to a catering establishment may not be described using one of the reserved descriptions unless it meets the relevant compositional criteria laid down in schedule 2 of the MPR. The schedule lays down minimum required meat contents for products described using the reserved descriptions. The minimum meat content for the reserved description products is based on the EC definition of meat. (Schedule 2 of the Regulations can be found in Annex 1).

Note: The meat or cured meat content requirements specified in this Schedule are calculated by weight. In relation to items 1 to 6 and 11 they are based, subject to regulation 4(2)(a)(ii), on the weight of the food concerned as it is labelled or, as the case may be, advertised.

Labelling Requirements for Name of Food of Meat Products Having the Appearance of a Cut, Joint, Slice, etc.

Regulation 5 of MPR requires that where certain meat products, that is those with the appearance of a cut, joint, slice, portion or carcase of meat or of cured meat (whether cooked or uncooked), contain added water and/or other added ingredients then, subject to certain exemptions, these ingredients must be declared in the name of the food.

- However it is not necessary to give a quantitative declaration of added water in the product name.
- Any added ingredients of animal origin from a different species to the rest of the meat, e.g. pork protein in chicken breast fillets, regardless of whether or not they serve a technological function must be declared in the product name.
- There are exemptions to the 'name of food' requirements in relation to other added ingredients which must be declared in the name of the food. The exemptions are listed in schedule 3 of the meat product regulations and are:
- 1. Any additive
- 2. Any curing salt
- 3. Any ingredient used solely as a garnish or decorative coating
- 4. Any ingredient (not being an additive) that is added only in order to impart odour or taste or both
- 5. Any salt, herb or spice used as seasoning
- 6. Any sugar that is added only in order to impart a sweet taste

7. In the case of meat (whether cooked or uncooked) or cooked cured meat, added water making up not more than 5% of the weight of the product. In the case of uncooked cured meat, added water making up not more than 10% of the weight of the product.

QUID Requirement

The quantifying of meat in the labelling of meat products falls within the provisions of the Food Labelling Regulations 1996 (as amended) and is based on the EC meat definition. Therefore, the quantitative ingredient declaration (QUID) will be required for meat products sold pre-packed; any excess fat or connective tissue present in the product cannot count towards the QUID declaration of meat content and must be declared separately in the list of ingredients.

The MPR provide an amendment to Regulation 23 of Food Labelling Regulations requiring that meat products sold loose or pre-packed for direct sale (e.g. by butchers, delicatessens, etc.) are marked with the QUID declaration of the meat ingredient(s). QUID declarations are required only for those ingredients that fall within the EC definition of 'meat'. There is

no requirement to mark or label the meat content of meat products sold loose or prepacked for direct sale from catering establishments.

For foods sold loose, the QUID declaration will be given in the form 'x% pork' and will appear alongside the name of the food either on a ticket or notice or on the food itself. However, Schedule 4a of the Food Labelling Regulations specifies foods which do not require any QUID declaration for the meat content of meat products sold loose.

These are:

- a) Sandwiches, filled rolls and similar products
- b) Pizzas and similar topped products
- c) Soup, broth and gravy
- d) Ready to eat individual portions assembled from two or more ingredients. E.g. salads that are made up from self service counter or to order by serving staff. However, when sold pre-packed these products will require a QUID declaration.

Public Analyst Observations

Officers need to pay particular attention to the food composition, ingredient listing etc. Examination of specifications outlining composition of the ingredients, particularly with regard to non-meat nitrogen which will inflate the meat content e.g. milk protein, soya, blood plasma, collagen. The composition of seasoning mixes used in butcheries and meat manufacturing plants should be examined for such information and the product and or ingredients sampled if necessary.

Associated Regulations

Meat Products (Scotland) Regulations 2004 SSI No. 6

Food Labelling (Scotland) Amendment Regulations 2003 SI No. 578

Meat Products (Scotland) Amendment Regulations 2008 SSI No. 97

Commission Directive 2001/101/EC

Food Additives (Scotland) Regulations 2009 (SSI No. 436)

Further Information

<u>Labelling and Composition of Meat Products (September 2003) - FSA Guidance Notes</u>

The Meat Products Regulations 2003- FSA Summary Guidance Notes for Bakers

The Meat Products Regulations 2003- FSA Summary Guidance Notes for Butchers

Eurofins meat calculator (for pre-packed meat products)

FSA Meat content calculator

<u>Labelling of 'Added Ingredients' in Meat Product covered by</u> MPR Regulation 5

Annex 1

SCHEDULE 2

Regulation 4(1) and (2)

RESERVED DESCRIPTIONS

Column 1	Column	. ?		Column 2
	Column		Column 3	
Name of Food	Meat or Cured Meat Content			Additional
	Requirements			Requirements
	The food shall contain not less			
	than the indicated percentage of			
	meat, where the meat ingredient			
	consists of the following:			
	Meat	Meat or, as	Meat or,	
	or, as	the case may	as the	
	the	be, cured	case may	
	case	meat from	be, cured	
	may	birds only,	meat from	
	be,	rabbits only,	other	
	cured	or a	species or	
	meat	combination	other	
	from	of birds and	mixtures of	
	pigs	rabbits only	meat	
	only			
1. Burger - whether or not	67%	55%	62%	1. Where the
forming part of another				name "hamburger"
word, but excluding any				is used, the meat
name falling within items 2				used in the
or 3 of this schedule.				preparation of the
				food must be beef,
				pork or a mixture
				of both.
				2. Where either of
				the names

"burger" or "economy burger" is qualified by the name of a type of cured meat, the food must contain a percentage of meat of the type from which the named type of cured meat is prepared at least equal to the minimum required meat content for that food.

3. Where any of the names "burger", "economy burger" or "hamburger" is qualified by the name of a type of meat, the food must contain a percentage of that named meat at least equal to the minimum required meat content for that food.

4. Where any of the names "burger", "economy burger" or "hamburger" are used to refer to a compound ingredient consisting of a meat mixture and other ingredients, such as a bread roll, these requirements shall apply only to the meat mixture, as if the meat mixture were the meat product in the labelling or advertising of which the name was used as the name of the food. 47% 2. Economy Burger -50% 41% whether or not "burger" forms part of another word. **3. Hamburger** - whether or 67% Not 62% not forming part of another applicable word. **4. Chopped X**, there being 75% 62% 70% No additional inserted in place of "X" the requirement

name "meat" or "cured				
meat" or the name of a				
type of meat or cured meat,				
whether or not there is also				
included the name of a				
type of meat				
5. Corned X, there being	120%	120%	120%	1. The food shall
inserted in place of "X" the				consist wholly of
name "meat" or the name				meat that has
of a type of meat, unless				been corned.
qualified by words which				
include the name of a food				2. Where the
other than meat				name of the food
				includes the name
				of a type of meat,
				the meat used in
				the preparation of
				the food shall be
				wholly of the
				named type.
				3. The total fat
				content of the food
				shall not exceed
				15%.
6. Luncheon meat	67%	55%	62%	No additional
				requirement
Luncheon X, there being				
inserted in place of "X" the				
name of a type of meat or				
cured meat				
7. Meat pie				1. Where the
				name "Melton

Meat pudding				Mowbray pie" is
				used, the meat
				used in the
The name "pie" or				preparation of the
"pudding" qualified by the				food must be meat
name of a type of meat or				from pigs only.
cured meat unless qualified				
also by the name of a food				
other than meat or cured				
meat				
Melton Mowbray pie				
Game pie				
Based on the weight of the	12.5%	12.5%	12.5%	
ingredients when the food				
is uncooked				
But if the food weighs -				
not more than 200 g. and	11%	11%	11%	
not less than 100 g.				
less than 100 g.	10%	10%	10%	
8. Scottish pie or				No additional
Scotch pie				requirement
Based on the weight of the	10%	10%	10%	
ingredients when the food				
is uncooked				
9. The name "pie" or				No additional
"pudding" qualified by the				requirement
words "meat" or "cured				
meat" or by the name of a				
type of meat or cured meat				
and also qualified by the				
name of a food other than				
meat or cured meat -				
Where the former (meat-	7%	7%	7%	

related) qualification				
precedes the latter				
Where the latter (non-	6%	6%	6%	
meat-related) qualification				
precedes the former				
Based on the weight of the				
ingredients when the food				
is uncooked				
10. Pasty or Pastie				No additional
				requirement
Bridie				
Sausage roll				
Based on the weight of the	6%	6%	6%	
ingredients when the food				
is uncooked				
11. Sausage (excluding				No additional
the name "sausage" when				requirement
qualified by the words				
"liver" or "tongue" or both),				
link, chipolata or sausage				
meat.				
Where the name is	42%	Not	Not	
qualified by the name		applicable	applicable	
"pork" but not by the name				
of any other type of meat				
In all other cases	32%	26%	30%	

Medical Food (Scotland) Regulations 2000 (SSI No. 130)

Scope

These regulations implement the provisions of <u>Commission Directive 1999/21/EC</u> on dietary foods for special medical purposes.

Notification of medical foods to the Food Standards Agency is a statutory requirement under Medical Food (Scotland) Regulations 2000 (SI 2000 No. 187).

Notification is required when a medical food is first placed on the market in the UK.

Ingredients/Products

The term 'medical food' means food coming within the classification of dietary foods for special medical purposes for which the compositional and labelling requirements are laid down in Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Article 1 of the directive defines 'dietary foods for special medical purposes' as a category of food for particular nutritional uses specially processed or formulated and intended for the <u>dietary management of patients</u> and to be used <u>under medical supervision</u>. They are intended for the exclusive or partial feeding of patients with a limited impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

The foods are classed into 3 categories:

- Nutritionally complete foods that provide the sole source of nourishment.
- Nutritionally complete foods specifically <u>adapted for a particular disease</u>, disorder or medical condition that provide the sole source of nourishment.
- Nutritionally complete foods specifically adapted for a particular disease, disorder or medical condition that are <u>not suitable as the sole source of</u> nourishment.

The duty to notify falls on:

- The manufacturer if the product is manufactured in the UK; or
- The importer if the product is manufactured abroad and imported into the UK.

It is an offence to sell a medical food in the UK if it has not been so notified. An application form can be downloaded from the FSA web site.

Medical foods are foods specially processed or formulated for the dietary management, under medical supervision, of patients who require a special diet.

Articles 3 and 4 of the directive set out the requirements for formulation, composition, and instructions for use of such food, and for its naming and labelling. It is an offence to sell medical foods that fail to meet these requirements.

Labelling Requirements

In addition to the labelling provisions of the Food Labelling Regulations 1996, medical products must carry the following information:

- Energy value in KJ and Kcal and the content of protein, carbohydrate and fat expressed in numerical form per 100g or 100ml as appropriate
- Average quantity of each mineral substance and each vitamin mentioned in the annex expressed in numerical form per 10g or 100ml as appropriate
- Selectively the contents of components of protein, carbohydrate and fat and or/of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use expressed in numerical form per 100g or 100ml as appropriate
- Information on the osmolality or osmolarity of the product
- Information on the origin and the nature of the protein and or protein hydrosylates contained in the product.

Mandatory labelling

The following mandatory information must be provided on the label:

- "...Product must be used under medical supervision..."
- Whether the product is '...suitable for use as the sole source of nourishment...'
- As appropriate '...product is intended for a specific age group...'
- As appropriate '.product poses a health hazard when consumed by persons who
 do not have the diseases, disorders or medical conditions for which the product
 is intended...'
- '...For the dietary management of ...' (Blank space indicating the nature of the medical condition)
- Adequate precautions and contra-indications
- Description of the properties and or characteristics that make the product useful in particular, as the case may be relating to the nutrients
- Warning that the product is not for paternal use
- Instructions for the appropriate preparation, use and storage of the food.

Public Analyst Observations

Unless there is a producer in the authority region there are unlikely to be issues. Manufacturing company issues tend to focus on labelling rather than composition.

Associated Regulations

Medical Food (Scotland) Regulations 2000 SSI No. 130

<u>The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland)</u> <u>Regulations 2007</u> SSI No. 424

Further Information

Commission Directive 1999/21/EC on dietary foods for special medical purposes

Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (SI No. 200)

Scope

These regulations prohibit, subject to certain exemptions, the use of mineral hydrocarbon in the composition or preparation of food, the sale of food containing mineral hydrocarbon and the consignment or delivery of food containing mineral hydrocarbon.

Ingredients/Products

A mineral hydrocarbon is defined as any hydrocarbon product, whether liquid, semi liquid or solid derived from any substance of mineral origin, and includes liquid paraffin, white oil, petroleum jelly, hard paraffin and micro crystalline wax.

The regulations set out specifications for mineral hydrocarbons the use of which is regulated in relation to the permitted exemptions, including a test for limits of contents of polyaromatic hydrocarbons.

The primary regulations above were amended by the Miscellaneous Food Additives (Scotland) Regulations 1996 (SI No. 50) (now repealed). These regulations outline the exemptions e.g.

- Presence of mineral hydrocarbon as a lubricant or greasing agent to which food has come into contact (0.2 parts/100 parts food)
- Chewing gum (60 parts/100 parts chewing compound)
- Rind of any whole pressed cheese
- A food containing mineral hydrocarbon as a miscellaneous additive as defined in the Food Additives (Scotland) Regulations 2009.

Public Analyst Observations

There are currently no issues.

Associated Regulations

Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (SI No. 200)

Miscellaneous Food Additives Regulations 1995 (SI No 3187)

Food Additives (Scotland) Regulations 2009 (SSI No. 436)

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (SSI No. 420)

Scope

The regulations control the exploitation and marketing of natural mineral waters spring water and bottled drinking water. These Regulations revoke the requirements of SI1999/301, 2003/182 and 2004/115 and re-enact provisions for natural mineral waters as laid down in the parent Directives, (80/777/EEC, as amended by 96/70/EC and 2003/40/EC), 2009/54/EC (recast of Directive 80/777/EEC) and Commission Regulation EU 115/2010. The regulations also implement the provisions of Council Directive 2003/40/EC and Council Directive 98/83/EC. However, the European Parliament consolidated the latter directive into Directive 2009/54/EC of 18th June 2009. The consolidated text is implemented in Scotland by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulation 2010 (SSI. No.89), the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment (No.2) Regulations 2010 (SSI No. 127) and the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2011 (SSI No. 94)

Ingredients/Products

The regulations cover the exploitation and marketing of three distinct types of bottled product e.g.

Natural Mineral Water: A well or bore hole source that officially recognised and bottled at source and characterised by its stable chemical and microbiological composition.

Spring Water: An underground water bottled at source and satisfies most of the exploitation conditions, microbiological criteria and some of the labelling requirements that apply to natural mineral water other than stability.

Bottled Drinking Water: Water which is bottled, and is neither spring nor natural mineral water from a variety of sources, including municipal water supplies.

Exemptions

Exemptions apply to water licensed or authorised for medicinal or veterinary use, or for curative purposes in thermal and hydrotherapy establishments. Packed ice used for cooling food, water not intended for human consumption and natural mineral water exported to a country other than an EEA State are also excluded.

Recognition of Natural Mineral Water (Regulation 4)

Information to be supplied to the district council for purpose of recognition as set out in Schedule 3 Part 3 include:-

- a hydrogeological description of the source,
- the physical and chemical characteristics of the water,
- microbiological analyses and analyses for toxic substances.
- Proof that the water is protected from all risk of pollution and is free from parasites and pathogenic organisms.

 the composition, temperature and other essential characteristics of the water remain stable. Stability of the source is assessed over 2 years.

Recognition of a Natural Mineral Water is confirmed by publication of the details in the Edinburgh Gazette. Such an announcement should include, among other things,

the trade name, name of the spring and the place of exploitation to allow these
details to be reported in the Official Journal of the European Communities.
Copies of such announcements should be sent to the FSA. (Recognised
Sources)

Natural Mineral Waters from other EU Member States (Regulation 4)
Water originating in other Member States of the European Union may only be sold as natural mineral water in the UK if it has been officially recognised.

The Local Authority or FSA can withdraw recognition on the grounds that the minimum requirements are not being met or the producer no longer wants to retain recognition. To withdraw recognition an advertisement needs to be placed in the Edinburgh Gazette and the FSA in Scotland should also be informed. The Local Authority can also facilitate the change in a named source by placing an advertisement in the Edinburgh Gazette and informing the FSA in Scotland.

Exploitation of natural mineral water springs and treatment (Regulation 5 & 6) Only water recognised as a natural mineral water can be so described and can only be exploited after permission is granted and the requirements of Schedule 4 are met. In general treatment of Natural Mineral Water is not permitted other than, oxygenation and ozone enrichment. Treatments that alter the microbiological compositions (e.g. membrane filtration and UV radiation) are not permitted.

Bottling of natural mineral water (Regulation 7)

Maximum limits for certain constituents as set out in Schedule 6 must not be exceeded at time of bottling. Natural mineral water cannot be tankered (unless it was tankered for the purpose of exploiting the source before 17th July 1980.

Labelling, Marketing and Advertising of natural mineral water (Regulation 8) A trade description is the description under which the natural mineral water is sold, and may include brand names, trademarks and other descriptors.

If the name of the source or the name of the place of exploitation is not the name of the product then either of these must appear on the label in letters one and a half times larger than any other text on the label. Once the producer has identified either the name of the source or the place of exploitation to use on the label, only this labelling format can be used. The term 'sales description' describes the name of a natural mineral water product.

Mandatory labelling requirements for natural mineral waters (Regulation 8(2))

- Statement of the analytical composition
- Name of the spring and the place of its exploitation on the label.

And where applicable:

- Indication of partial/total elimination of free carbon dioxide regulation 8(2)(c)
- Indication of the use of authorised ozone-enriched air oxidisation techniques should be placed on the label in proximity to the analytical composition. See Regulation 8(2)(d).
- Specific requirements for fluoride concentrations > 1.5 mg/l, including "not suitable for infants and children under 7 years of age" and the presentation of actual fluoride content. (See Regulation 8 (2)(e))

Bottled water from a natural mineral water source can only be marked with the following sales descriptions which are defined in the regulations:-

- natural mineral water
- naturally carbonated natural mineral water
- natural mineral water fortified with gas from the spring
- carbonated natural mineral water

Restrictions (Natural Mineral and Spring water) (Regulation 10)

A recognised natural mineral water can only be marketed within the European Union under the designated name. It cannot also be marketed as a spring water. The wording of the trade description must not be misleading as to the nature of the water and the place of exploitation of the spring.

Permitted indications on the label of natural mineral water (Regulation 8)

The indications 'may be diuretic', 'may be laxative', 'stimulates digestion' and 'may facilitate hepato-biliary functions' are permitted if the natural mineral water has been properly assessed. (See Schedule 8)

Natural mineral water used as an ingredient in a soft drink (Regulation 6) Regulation 6(2) permits the use of natural mineral water in the manufacture of soft drinks.

Sale of natural mineral water

The microbiological criteria that natural mineral water is required to meet when placed on sale is set out in Regulation 9(2) and Schedule 4

Brand names and sources (Regulation 9(4))

It is forbidden to sell natural mineral water from one and the same spring under more than one trade description. <u>The Natural Mineral Water, Spring Water and Bottled Drinking Water Guidance Notes</u> provides further clarification on trade descriptions, proximity of boreholes and catchment areas.

SPRING WATER

Bottling of spring water (Regulation 10)

Spring water must meet stringent analytical requirements but is not required to have essential characteristics of constant chemical composition. Spring water may be transported from spring to bottling plant in containers not for distribution to the ultimate consumer if water from the spring was so transported before 13th December 1996. The right to tanker is linked to the spring, not the bottler.

Microbiological tests for spring water (Regulation 10; Schedule 2 & 4) Spring water must comply with the requirements in Schedule 2.

Spring water composition and protected against all risk of pollution (Regulation 11; Schedule 4)

The term 'spring water' is reserved for water which is extracted from a spring, bottled at source and meets the exploitation and bottling requirements of Schedule 4, as if it were a natural mineral water.

Maximum limits for certain constituents of spring water

Schedule 2 lays down the requirements for spring water (and drinking water) including properties, elements, substances and organisms contained within it.

Labelling of spring water (Regulation 11)

Spring water can only be so marked and labelled if, when bottled at source, it is intended for consumption without treatment, other than authorised treatments. Spring waters are required to state the name of the spring and the place of its exploitation on the label. The name of the source or the place of exploitation must be in letters one and a half times larger than the height and width of any other text. The Regulations also contain a requirement stating that the wording of the trade description must not be misleading as the nature of the water and the place of exploitation of the spring.

Spring water treatment (Regulation 11(3c))

Where the water has undergone authorised ozone-enriched air oxidation, specific text is provided in the Regulations.

Sale of spring water

Trade description for spring water (Regulation 11 & 12)

Water from the spring must not be sold under more than one trade description. If the name of the source or the name of the place of exploitation is not the trade description then either of these must appear on the label in letters one and a half times larger than any other text on the label.

BOTTLED DRINKING WATER

Bottling of bottled drinking water (Regulation 13)

There are no restrictions on treatments of bottled drinking water provided that they do not make the water unsafe. However, bottled drinking water must satisfy the requirements of Schedule 2.

Labelling, marketing and trade description of bottled drinking water (Regulation 14)

There are no restrictions on the selling of bottled drinking water under more than one trade description. However, these descriptions should not mislead the consumer to believe that the product is a spring or natural mineral water. The labels must also comply with The Food Labelling Regulations 1996 (as amended).

Removal of hardness from a spring or bottled water (Regulation 10 & 13) The requirement is intended to ensure that if softening or desalinating water (essentially any scenario where you remove the hardness from water) there is a limit on how much you can reduce the hardness level by. The calcium concentration is there as an indicator of the hardness level present in the water.

Public Analyst Observations

Sources of recognised natural mineral water need to be regularly assessed for compliance with stability requirements including evidence of freedom from pollution. Officers who have sources that require to be tested need to inform the Public Analyst of their intention to sample as it may be necessary to obtain specially prepared sample containers especially when tests are to be done for evidence of organic contaminants.

Associated Regulations

Directive 2009/54/EC on the exploitation and marketing of natural mineral waters

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No 2) Regulations 2007

<u>The Natural Mineral Water, Spring Water and Bottled Drinking Water Amendment</u> (Scotland) Regulations 2009

<u>Commission Regulation EU 115/2010</u> on the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

Further Information

FSA Guidelines on Natural Mineral Water, Spring water and bottled drinking water.

Zam Zam water

EC Recognised Natural Mineral Water Sources

The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 SI No. 60

Scope: These regulations implement the provisions of Commission Directive 2009/39 of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses.

Ingredients/Products

The rules relate to food which because its special composition or manufacture are clearly distinguishable from foods for normal consumption and which are marketed as suitable for categories of consumers with disturbed digestive processes or metabolism or in special physiological condition or for infants or young children in good health and which are not covered by other directives. Foods that fall under this category are referred to as "PNU" foods or "PARNUTS", Dietetic or Dietary foods. Examples include very low calorie diets and lactose free foods.

The category does not cover the following foods

- infant formulae and follow-on formulae,
- processed cereal-based foods and baby foods for infants and young children,
- foods intended for use in energy-restricted diets for weight reduction,
- dietary foods for special medical purposes,
- foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, and
- foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

Foods which have been specially manufactured to ensure that they are for example gluten-free are considered to be foods for particular nutritional uses under the Directive and are therefore subject to the notification requirements. It should be noted that Infant Formula, Follow on Formula and Food for Special Medical Purposes require notification under separate regulations.

Legislative requirements

Restriction of sale (Regulation 3): A manufacturer or importer cannot sell a PARNUT food unless the appropriate notification procedure as set out in Directive 2009/39 has been followed involving notification of the Competent Authority. In Scotland the Competent Authority is the Food Standards Agency.

Declarations (Regulation 4): Where the Agency has detailed grounds for establishing that a foodstuff is intended for a particular nutritional use but does not belong to one of the groups in Annex 1 of the directive, does not comply with Article 1 (2) and (3) or endangers human health, the Agency may by written declaration suspend or restrict trade in that product.

The declaration issued by the Agency must be published and may impose conditions on trade.

Where a declaration is in force suspending trade in any product, no person may trade in that product.

Where a declaration is in force imposing conditions on trade in any product, no person shall trade in that product unless it complies with the conditions specified.

The regulations are enforced by Local Authorities.

Enforcement issues

If there is doubt about whether a "PNU" food has been correctly notified the officer investigating could contact the FSA for clarification.

Public Analyst Observations

Associated Regulations

The Notification of Marketing of Food for Particular Nutritional Uses (Scotland)
Regulations 2007 SI No. 37

<u>The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland)</u> Regulations 2010

EC Directive 2009/39 on foodstuffs intended for particular nutritional uses

Further information

FSA Notification guidance notes

Novel Foods and Novel Food Ingredients Regulations 1997 (SI No. 1335)

Scope

These Regulations provide for the enforcement and execution of certain specified provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients.

Ingredients/Products

Under the Novel Foods Regulation a novel food is defined as a food that does not have a significant history of consumption within the EU prior to 15th May 1997.

The definition will include new products obtained from natural sources (animals, plants, micro-organisms) and by chemical synthesis. Regulation (EC) 258/97 does not apply to food additives, flavourings, extraction solvents or processing aids.

A company wishing to market a novel food or novel food ingredient in the EU must submit an application to the Competent Authority in the Member State where it first intends to market their product. Novel foods are subject to a pre-market safety assessment before a decision is made on EU-wide authorisation.

These Regulations designate the Food Standards Agency as the food assessment body for the purposes of Regulation (EC) No. 258/97 and appoint Local Authorities to enforce the provisions of Regulation (EC) No 258/97 and these Regulations.

Full application - Initial assessment

A company wishing to market a novel food must submit an application dossier to one of the 27 Member States (MS) consisting of a request accompanied by a summary. Information on manufacturing process may be kept confidential, as stated in Regulation 1852/2001. A copy of the request is sent to the European Commission (EC). (Guidance on presentation of data required for the safety assessment was published by the European Commission Recommendation 97/618/EC). An initial assessment report will be compiled in 90 days. This timescale may be extended if the evaluation raises questions, which require the submission of further information from the applicant.

The EC will distribute to other Member States the initial assessment report for comment (60 days). If all Member States are agreed, the applicant is informed by the EC of the decision and if not, a decision is taken by majority vote. Before any vote, any outstanding technical or scientific issues are examined by the European Food Safety Authority (EFSA).

Substantial equivalence - simplified procedure

This procedure applies to novel foods that are very similar ('substantially equivalent') to existing foods in terms of (a) composition, (b) nutritional value, (c)metabolism, (d) intended use, and (e) the level of undesirable substances.

Commission Recommendation 97/168/EC includes a section on substantial equivalence and offers general guidance (section 3.3).

In this procedure an application dossier is submitted to one of the 27 Member States and an opinion on substantial equivalence is issued to the applicant (no timescale). The applicant notifies the European Commission when the product is first marketed. The UK has published national guidance on data requirements (see Advisory Committee on Novel Foods and Novel Food Processes (ACNFP) report 2004 - Annex XIV). There is no EU guidance on the procedure.

UK practice

The Food Standards Agency (FSA) is the responsible body in the UK for the purpose of novel food applications. The fees for a full application are £4000 whilst a request for a substantial equivalence will cost £1725.

The risk assessment is conducted by the Advisory Committee on Novel Foods and Processes (ACNFP). The FSA will discuss with the applicant before the dossier is submitted and each application will be published for public comment (28 days). Committee papers and minutes are also published and a draft assessment report is also published for public comment (10 days).

Public Analyst Observations

Issues arise in relation to new food types that have not been on the European market. Questions were raised concerning Goji berries but market checks revealed that there was evidence of its presence in Europe prior to 15th May 1997.

Associated Regulations

Novel Foods and Novel Food Ingredients Regulations 1997 (SI No. 1335)

Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients

Food Enzymes (Scotland) amendment Regulations 2010 (SSI No. 26)

Further Information

European Food Safety Authority (EFSA)

Advisory Committee on Novel Foods and Processes

More than 60 applications have been made for novel foods since 1997; the majority of the applications were for non GM foods. About a third have been accepted, another third have been rejected or withdrawn by applicants and the remainder are currently under evaluation.

ACNFP Full Application List

Examples of products refused approval by the European Commission include:

- Betaine
- Nangai Nuts and
- Stevia Rebaudiana Bertoni

The Nutrition and Health Claims (Scotland) Regulations 2007 (SSI No. 383)

Scope

The regulations implement the provisions of the <u>EC Regulation 1924/2006</u> on nutrition and health claims made on food. The regulation controls the use of nutrition and health claims in the advertising, labelling and presentation of all foods including food supplements. The FSA view on advertising, labelling and presentation includes labels, print and broadcast media, statements made on the internet, posters, explanatory leaflets and in-store promotion including commercial communications.

Where there are specific requirements regarding claims in other EC legislation e.g. PARNUTS then these specific rules take precedence over the Nutrition and Health Claims Regulations.

The regulations ensure that any claim made on a food label is clear, accurate and substantiated so that consumers may make informed and meaningful choices when it comes to food and drink.

Ingredients/Products

The rules apply to all food including supplements sold directly to the consumer and also to foods intended for supply to restaurants, hospitals, schools, canteens and other mass caterers. It applies to food ready for consumption in accordance with manufacturer's instructions.

Labelling Requirements

Nutrition Claims

A nutrition claim is defined as any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- The energy (calorific value) it
 - provides
 - provides at a reduced or increased rate or
 - does not provide and/or
- The nutrients/other substances it
 - contains
 - contains in reduced or increased proportions or
 - does not contain.

Examples include 'Low Fat', 'Low Sugars' and similar claims as set out in the Annex to the regulations.

Only claims listed in the Annex to the EC Regulation can be made on food and only if the product meets with the specific conditions of use for the claim. In addition the nutritional claim must not be false, ambiguous, misleading, condone excessive consumption or imply that a balanced diet cannot provide the nutrients.

Nutrient claims cannot be put on alcoholic beverages although there are some exceptions relating to reduced energy and low alcohol content.

The table in schedule 1 to these notes summarises current recognised claims as set out in the EC Regulation.

Where a claim is made it is obligatory to provide nutritional labelling. In addition the Commission is also working on 'Nutrient Profiling' of foods. These are expected in January 2009. In consequence where a food is high in more than two nutrients e.g. fat and sugar only 'Reduced' claims can be made.

Health Claims

The EC Regulation defines a health claim as 'any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health'.

The regulation also defines 'Reduction of disease risk claim' as 'any health claim that states, suggests or implies that the constituents of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.'

Examples include 'Calcium helps build strong bones' or 'Omega 3 may help maintain a healthy heart'. In general only 'Health Claims' which are listed in the community register (to be established by the European Commission) can be used on food and only if the product meets with any specific conditions of use as well as the requirements of the regulations.

Health claims cannot be made where any nutrient does not meet the criteria set by the nutrient profile.

Only authorised claims can be put on the community register.

There are three ways a claim could go on the Community Register:

- Member States have until 31 Jan 2008 to submit claims based on scientific evidence to the European Commission. EFSA will decide if the claim is permissible.
- Claims based on new science with supporting dossiers sent to FSA for onward transmission to EFSA. The Commission will have 8 months to decide whether to register the claim.
- Disease risk reduction or claims relating to child health/development supported by dossiers submitted to FSA for onward transmission to EFSA.

Health Claims that are prohibited
The following health claims are prohibited:

- Any health claim on alcoholic beverage
- Claims that health could be affected by not consuming the food
- Claims that make reference to the rate or amount of weight loss
- Claims that make reference to recommendations of individual doctors or health professionals.

To use any 'Health Claim' the regulations require the product to:

- Meet the criteria for the claim
- Comply with 'Nutrient profiles'
- Conform to the following labelling requirements:
 - Present full nutritional labelling.
 - Include a statement about the importance of a varied and balanced diet and healthy life style.
 - Include details of quantities of food to be eaten to achieve claimed benefit.
 - Statement for persons who may need to avoid such foods.
 - Warning about health risks arising from excess consumption.

In 'disease risk reduction claims' state that the disease has multiple risk factors and altering one of these may or may not have a beneficial effect.

The regulations apply from 1st July 2007 but there are transition measures to allow industry time to comply. For products on the market or labelled before 1st July 2007 the regulation generally apply from the food expiry date on the product bearing the claim or 31st July 2009. A detailed breakdown of transitional arrangements is given in Section 6 of the FSA Guidance on Nutrition and Health Claims. During the various transitional periods the nutrition and health claims provisions of the Food Labelling Regulations 1996 (as amended) apply.

Public Analyst Observations

Associated Regulations

The Nutrition and Health Claims (Scotland) Regulations 2007 (SSI No. 383)

Food Labelling Regulations 1996 (SI 1996 No. 1499)

Food Safety Act 1990

EC Regulation 1924/2006 on nutrition and health claims made on food

Further Information

FSA Draft Guidance on Nutrition and Health Claims

SCHEDULE 1

Summary table

Nutrition Claim	Condition
Low Energy	Product not to contain > 40Kcal (170 kJ/100g{solid} or 20Kcal
	(80kJ/100 ml {liquid}
	Table top sweeteners not > 4Kcal (17kJ) per portion with
	equivalent sweetening properties of 6 g sucrose
Energy	Reduction must be at least 30%. There must be an indication
Reduced	of the characteristics which make the food "reduced"
Energy Free	Product contains not > 17kJ/100ml
	Table top sweeteners 0.4Kcal(1.7 kJ) per portion with
	equivalent sweetening properties of 6g sucrose.
Low Fat	Not > 3g fat/100g{solids} 1.5g fat/100ml {liquid} [1.8g
	fat/100ml for semi skimmed milk]
Fat Free	Not > 0.5g/100g or 100ml
	The term "X% fat free" is prohibited.
Low Saturated	The sum of saturated fatty acids and trans fatty acids must
Fat	not be > 1.5g/100 or 0.75g/100ml
	The sum must also not exceed 10% of energy provided.
Saturated Fat	The sum of saturated fat and trans fatty acids must not be >
Free	0.1 g/100g or 100ml
Low Sugars	Not > 5g sugar/100g {solid} or 2.5g/100ml {liquid}
Sugars Free	Not > 0.5g sugar/100g or 100 ml
With No Added	Product must not contain added mono or disaccharides or
Sugars	any other food for sweetening. If natural sugars are present
	the claim must state "CONTAINS NATURALLY OCCURRING
	SUGARS"
Low	Not > 0.12g sodium or equivalent/100g or 100ml. For water
Sodium/Salt	other than Natural Mineral Water not > 2 mg/100ml
Very Low	Not > 0.04g sodium or equivalent/ 100g or 100 ml. Can not be
Sodium/Salt	used on waters or Natural Mineral Waters.
Sodium Free or	Not > 0.005g sodium or equivalent per 100g

Salt Free	
Source of Fibre	Food to contain at least 3g fibre/100g or 1.5g fibre / 100Kcal
High Fibre	Food to contain at least 6g fibre/100g or 3g fibre /100Kcal
Source of	12% of energy value of the food must come from protein.
Protein	
High Protein	20% of energy value of the food must come from protein
Source of	Significant amount as defined in EC Directive 90/496 or as
named vitamin	per Article 6 EC Regulation 1925/2006
and or mineral	
High named	Must contain twice the level of that for a "source"
vitamin or	
mineral	
Contains a	May only be made where the product complies with all
named nutrient	requirements of EC Regulation 1924/2006
or substance	
Increased	Must meet the conditions for the claim "Source of" and the
Named Nutrient	increase is at least 30% compared to similar food
Reduced	Reduced by 30% compared with similar foods.
named nutrient	Micronutients as set in Directive 90/496 10% difference is
	acceptable.
	For sodium a 25% difference is acceptable
Light/Lite	Must meet the conditions specified for "Reduced" and be
	accompanied with an indication of the characteristics that
	make the food Light or lite.
Naturally or	Can only be used when the food meets the conditions for the
Natural	nutrient claim

The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 (SSI 2009 No. 30)

Scope

The purpose of these regulations is to ensure that any plastic material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

The regulations implement various provisions of the following European Law:

- Council Directive 82/711/EEC concerning testing migration of the constituents of plastic materials and articles in contact with food as amended by Commission Directive 93/8/EEC
- Council Directive 85/572/EEC laying down lists of simulants to be used in testing migration of constituents of plastic materials and articles in contact with food.
- Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuff as amended by Commission Directive 2004/1/EC, 2004/19/EC, 2005/79/EC and 2007/19/EC.
- Commission Directive 2008/39/EC amending Commission Directive 2002/72/EC. This directive:
 - introduces a positive Community list of additives approved for use in the manufacture of plastic materials and articles intended to come into contact with foods;
 - makes amendments to the lists of approved monomers (including starting substances) and additives annexed to the Directive; and
 - provides for appropriate transitional arrangements.

Ingredients/Products

Within the context of the regulations materials and articles are defined in Article 1(2) of EC Regulation 1895/2005 as:

- (a) Materials and articles made of any type of plastics.
- (b) Materials and articles covered by surface coatings.
- (c) Adhesives.

Plastic materials and articles are defined in the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 as –

"Anything which for the purposes of the directive is included among those plastic materials and articles and parts thereof which the directive applies".

Plastic is defined in Commission Directive 2002/72/EC as the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules of lower molecular weight or by chemical alteration of natural macromolescules.

None of the plastic materials or articles may be used for:

- (a) Handling food in the course of a business.
- (b) Sold for the purpose of handling food.
- (c) Imported for the purpose of handling food.

If they fail to meet the required standards laid down in EC legislation.

Labelling Requirements

At marketing stages other than the retail stage a person who places on the market any plastic materials or articles or any substance intended for the manufacture of a plastic material or article must ensure that it is accompanied by a written declaration which conforms to:

- (1) Article 16(1) of Regulation EC No. 1935/2004. The written declaration must state that the materials and articles comply with the rules applicable to them as set out under Article 5.
- (2) Requirements as set out in Schedule 4 of the regulations.
- (3) The written declaration must be renewed when substantial changes in the production of the plastic material and article for which the declaration is issued bring about changes in the migration or when new scientific information is available.

Note: Officers can request for appropriate documentation to demonstrate that the plastic material, article or substance intended for manufacture complies with the regulations i.e. conditions and results of testing, calculations and other analysis and evidence on the safety or reasoning demonstrating compliance.

The regulations also prohibit the use of and/or presence of bis (hydroxyphenyl) methane bis (2, 3-epoxypropyl) ethers (BFDGE) and other novolac glycidyl ethers (NOGE) in materials and articles.

Transitional matters relating to PVC gaskets containing epoxidized soya bean oil

Regulation 3 imposes restrictions on use, sale and import of a plastic material or article which fails to meet the required standard set out in the regulations, however Regulation 20 allows for a defence in relation to sale of glass jars which contained

- 1. Infant formula or follow on formula or
- 2. Processed cereal based foods for infants and young children the lids of which were sealed with a PVC gasket containing epoxidised soya bean oil. However there are defences available in the Regulation.

Enforcement Issues

Issues may arise in respect of plastic contact materials that do not comply with the legal requirement for food contact. Clearly the power to seizure in the Food Safety (Scotland) Act 1990 which relates to food cannot be applied.

Powers to deal with defective plastic food contact materials supplied to consumers are to be found in the provisions of the General Product Safety Regulations 2005 e.g. Regulation 3(2)(b) allow for certain obligations/provisions to apply along with enforcement powers e.g.

- Suspension notices (Regulation 11)
- Forfeiture (Regulation 18)

Officers availing of these powers must be appropriately authorised.

Sampling Procedure

Where an enforcement office decides that a sample of a material or article should be procured in accordance with Article 29 of the Food Safety (Northern Scotland) Act 1990 it should be divided into 3 parts or where this might impede analysis must divide the sample by putting the containers into 3 lots where each lot can be treated as being a part of the sample.

Public Analyst Observations

The enforcement officers need to take into consideration the following matters if they consider that a plastic contact material warrants testing:

- The sample should be taken from unused materials
- The analyst needs to know the type of material to be tested e.g. an area of a sheet of film or polystyrene trays
- Sample size is significant. If bottle caps are to be tested a considerable number will be required to facilitate the test
- The officer should establish what type of food the plastic material will be in contact with e.g. oils, fats, water or acid type foods including details of the shelf life of the food and storage conditions
- The material should also be suitable for the purpose

In the course of routine food standards inspections officers need to consider the nature and type of containers being used to store ingredients. Some food businesses may be recycling plastic containers for storage of ingredients that are different in composition from the original contents.

It may be acceptable to use food grade liners in bulk plastic containers e.g. plastic liners can often be found in bulk drums used to store apple pulp.

Officers should not overlook the composition of spatulas and similar cooking implements that are of plastic composition.

In general there are few samples of plastic materials submitted for examination. Samples that have been submitted in the past tend to comply.

Associated Regulations

<u>Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009</u> (SSI No. 30)

General Product Safety Regulations 2005

Further Information

Council Directive 82/711/EEC

Commission Directive 93/8/EC

Council Directive 85/572/EEC

Commission Directive 2002/72/EC

Commission Directive 2004/1/EC

Commission Directive 2004/19/EC

Commission Directive 2005/79/EC

Commission Directive 2007/19/EC

Commission Directive 2008/39/EC

Food Standards Agency Guidance notes

The Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990 (SI No. 1139)

Scope

This regulation implements the provisions of <u>EC Directive 2136/89</u> relating to the marketing of preserved sardines.

Ingredients/Products

A preserved sardine is described as a product:

- Covered by CN codes 1604 13 10 and ex 1604 20 50
- Exclusively from the species Sardinia Pilchardus Walbaum
- Pre-packed in an appropriate cover medium and hermetically sealed
- Sterilised by appropriate treatment

In accordance with good manufacturing practice sardines must be trimmed of head, gills, caudal fin, and internal organs other than the ova, milt, kidney and according to the marketing presentation concerned, the backbone and skin.

Labelling Requirements

There are 6 marketing presentations described in Article 4 of the Directive.

- 1. Sardines (basic)
- 2. Sardines without bones
- 3. Sardines without skin and bones
- 4. Sardine Fillets
- 5. Sardine Trunks
- 6. Any other form of presentation not covered in 1-5 above

For the purpose of trade descriptions Article 5 sets out different descriptions for cover media:

- 1. Olive oil
- 2. Refined vegetable oil
- 3. Tomato sauce
- 4. Natural juice, saline solution or water
- 5. Marinade with or without wine
- 6. Other cover media not covered by 1-5 above.

Cover media may be mixed but olive oil may not be mixed with other oils.

The final appearance for preserved sardines is set out in Article 6. Without prejudice to other EC rules the trade descriptions on pre-packed preserved sardines must correspond to the ratio between the weight of sardines in the container after sterilisation and the net weight expressed in grams.

The ratio between cover media and sardine is given in the table below.

Cover media	Ratio
Olive oil, vegetable oil, natural juice or	70%
marinade	
Tomato sauce	65%
Cover media not described in 1-5 of	50%
Article 5	
Presentations other than set out in	35%
points 1-5 of Article 4	

The designation of the cover medium must form an integral part of the trade description. Oil media must be described as one of the following:

- 'in olive oil'
- 'in vegetable oil'
- 'in ...oil' indicating the nature of the oil

Preparations using homogenised sardine flesh involving the disappearance of muscle structure may contain flesh of other fish which have undergone the same treatment provided that the proportion of sardines is at least 25%.

Public Analyst Observations

Generally the issues relate to quality as measured against the marketing standards. The checks are sometimes very subjective. It is more likely to be an issue in respect of products that fall within the lower end of the market.

Associated Regulations

Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990 (SI No. 194)

EC Directive 2136/89 on provisions relating to marketing of preserved sardines.

Further Information

<u>The Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990</u> (SI No. 1139)

The Preserved Tuna and Bonito (Marketing Standards) Regulations 1994 (SI No.)

Scope

The regulations implement the provisions of <u>Council Regulation No. 1536/92</u> relating to the marketing of preserved tuna and bonito.

The EC regulation sets out specific compositional standards and outlines how tuna and bonito should be described when preserved.

Ingredients/Products

The definitions for each species are as follows:

Tuna	Bonito
Falls within CN code 1604 14 10	Falls within CN code 1604 14
ex 1604 20 70	90, ex 1604 20 50, 1604 19 30
Prepared from the species	ex 1604 20 70, ex 1604 19 99
genus thunnus	and 1604 20 90
Albacore or longfin	Prepared from the species
Yellow fin	genus Sarda
Blue fin	Atlantic bonito
Big eye	Pacific bonito
Skip jack	Oriental bonito
	Prepared from the species
	genus euthynnus
	Atlantic little tuna
	Eastern little tuna
	Black skip jack
	 Prepared from the species
	genus auxix
	Frigate mackerel
	Auxis Rochei

Different species may not be mixed in the same container, however, culinary preparations using tuna and bonito flesh without muscle structure may contain the flesh of other fish provided 25% of the net weight consists of tuna or bonito.

Labelling Requirements

Forms of 'Commercial Presentation' are set out in Article 3 as follows:

- Solid 18% presence of flake is tolerated but when canned raw the presence of flake is prohibited
- Chunks Fragments of flesh not less than 1.2 cm. 30% flake can be tolerated
- Fillets Consist of longitudinal strips of flesh taken from along the vertebral column or strips of muscle from the abdominal wall
- Flakes Fragments of flesh with muscle structure maintained
- Grated/shredded tuna Separate particles that do not constitute a paste.

Any presentation falling outside these definitions may be used provided it is clearly identified in the Trade Description.

Terms used to describe the cover medium as used in the Trade Description are set out in Article 4 and include:

- 'in olive oil'
- 'Natural' (reserved for product using the natural juice, saline solution or water)
- 'in vegetable oil'
- If some other medium is used it must be clearly indicated.

Article 5 Trade Descriptions

The trade description should state:

- The type of fish (tuna, bonito)
- The presentation in which marketed e.g. solid, chunk, flake etc
- The description of the cover medium.

In all other cases of presentation:

- The type of fish (tuna, bonito)
- The nature of the culinary preparation

Trade descriptions must not associate the words Tuna and Bonito.

Article 6 sets out additional compositional requirements for product presented as 'solid' (article 3(1)). The ratio between the weight of fish after sterilisation and the net weight in grams must be as follows:

Type of media	Ratio
In olive oilIn vegetable oilNatural	70%
Other media	65%

In the case of culinary preparations the ratio is 25%.

Public Analyst Observations

Issues can arise in respect of the description of the product and the differences between tuna steaks and flakes etc. It may be beneficial looking at products that fall into the lower end of the market.

Associated Regulations

The Preserved Tuna and Bonito (Marketing Standards) Regulations 1994 (SI No 2127)

Council Regulation No 1536/92 relating to the marketing of preserved tuna and bonito.

Further Information

Processed Cereal - Based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004

Scope

These Regulations implement <u>EC Directive 96/5/EC</u>, as amended by EC Directive 1998/36/EC, 1999/39/EC and 2003/13/EC.

The Regulations define 'baby foods' as foods for particular nutritional use fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned and by young children as a supplement to their diet or for their progressive adaptation to ordinary food, but excludes processed cereal based foods.

Ingredients/Products

Processed cereal based foods are foods for particular nutritional use in categories of processed cereal based foods in part 1 of Schedule 1 i.e. simple cereals which are reconstituted with milk, cereals with an added protein food which have to be reconstituted with water, pastas which have to be boiled in water and rusks and biscuits which may be used directly or pulverised with the addition of water of milk.

Infants are defined as children under the age of twelve months and young children are aged between 1 and 3 years.

The Regulations do not apply to any milk which is a baby food intended for young children.

The Regulations prohibit the sale of processed cereal based foods and baby foods for infants and young children unless they comply with the manufacturing and compositional requirements in regulations 3 to 7 and the labelling requirements in regulation 8.

Manufacture and Composition

Such foods must be prepared from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data. Such foods must not contain any substance in a quantity as to endanger their health.

The Regulations detail in Schedule 1, 2 and 3 the criteria with regard to composition which must be complied with for processed cereal based foods and baby foods.

The schedules detail requirements concerning nutrients and permitted quantities in products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

Nutrients include protein, carbohydrates, fat minerals and vitamins.

Schedule 4 lists nutritional substances which may only be added during the manufacture of such foods.

Schedule 5 Part 1 provides maximum limits for added vitamins, minerals and trace elements e.g. vitamin B6 0.35mg.

Part II of Schedule 5 specifies foods and the maximum limit per 100kcal for specific nutrients when added to processed cereal based and baby foods. e.g. fruit-based dishes, fruit juices must not contain vitamin C exceeding 125mg per 100kcal.

The Regulations restrict the presence of pesticide residues in such foods. Schedule 6 lists pesticides where residues must not be present at a level exceeding 0.003mg/kg. All other pesticide residues of any individual pesticide not specified must not exceed 0.01mg/kg.

Labelling Requirements

Regulation 8 provides specific labelling requirements for processed cereal based foods and baby foods. These are the appropriate age (not less than 4 months) from which the food may be used the presence or absence of gluten if the appropriate age indicated is less that 6 months

- the available energy value expressed in KJ and Kcal, and the protein, carbohydrate and fat content per 100g or 100ml of the food sold. Where appropriate, per serving information may be given
- the average quantity per 100g or 100ml of minerals and vitamins as specified in Schedule 1 and 3
- appropriate instructions for preparation if necessary and a statement as to the importance of following these instructions
- The nutrients listed in Schedule 4 may be expressed as an average per 100g or 100ml of the food or per quantified serving as consumed
- In the case of a mineral or vitamin, it is a mineral or vitamin other than one listed in part II of Schedule 1
- Vitamins and/or minerals specified in Schedule 8 which are indicated per 100g or 100ml cannot be expressed as a percentage of the reference value unless 15% or more of the reference value is present in 100g or 100ml.

Public Analyst Observations and Comments

As a general rule the major manufacturers will be aware of and comply with the rules concerning food composition.

Associated Regulations

<u>Processed Cereal- Based foods and Baby Foods for Infants and Children</u> (Scotland) Regulations 2004 SSI No 8

<u>The Food for Particular Nutritional Uses (Scotland) (Miscellaneous Amendments)</u> Regulations 2007 SSI No. 424

Further Information

EC Directive 96/5/EC

EC Directive 98/36/EC

EC Directive 1999/39/EC

EC Directive 2003/13/EC

Quick Frozen Foodstuffs Amendment (Scotland) Regulations 2007

Scope

The regulations replace and consolidate the previous such regulations and came into force on 1st March 2007. The regulations implement the provisions of <u>Commission</u> <u>Regulation 37/2005</u>, <u>Council Directive 89/108</u> and <u>Commission Directive 92/2</u>.

The purpose of the regulations is to protect the quality of quick frozen foods (QFF) throughout the distribution chain. The regulations apply to all businesses that manufacture, transport (including rail), store and retail quick frozen foods (but see exempted businesses below).

Ingredients/Products

What is a Quick Frozen Food?

A quick frozen foodstuff is defined in the Regulations as a food which has undergone a freezing process known as 'quick freezing' whereby the zone of maximum crystallisation is crossed as rapidly as possible, depending on the type of product and it is labelled to indicate that it has undergone that process. QFF does not include ice cream or any other edible ice. 'Quick frozen' is an optional description, so legal requirements only apply to foods that have undergone a quick freezing process and if they are labelled as 'quick frozen'.

Conditions required for QFF to be placed on the market for human consumption

Schedule 2 of the Regulations specifies conditions that have to be satisfied for a quick frozen food to be placed on the market for human consumption. Conditions are:

- The quick frozen food must be made from raw materials of sound, genuine and merchantable quality
- The preparation and quick freezing of the product must be carried out promptly and by the use of appropriate technical equipment to minimise any chemical, biochemical and microbiological changes to the food
- The authorised cryogenic medium must be one or more of air, nitrogen, or carbon dioxide
- The temperature on thermal stabilization must be -18oc or colder. This temperature has to be maintained, except for brief periods during transport (including local distribution) where it may reach not warmer than -15oc, and when in retail display cabinets where it may reach not warmer than -12oc.

Other conditions that have to be satisfied for QFF are specified in regulation 4 of the Regulations, namely that any QFF intended for the ultimate consumer must have been packed by its manufacturer or packer in such pre-packaging as to protect it from microbial and other forms of external contamination and against dehydration, and the QFF must remain in such pre-packaging up to the time of placing on the market.

Labelling Requirements

Quick frozen foods that are to be supplied (without further processing) to the ultimate consumer or a catering establishment must show the following information (in addition to the name of the food) on the label:

- The description 'quick frozen'
- The date of minimum durability a 'best before date'
- An indication of the maximum advisable storage period
- An indication of the temperature and /or the equipment that should be used to store it
- A batch or lot mark
- A message such as 'do not refreeze after defrosting'

Other QFF products destined for further processing must be labelled with:

- The description 'quick frozen'
- A batch or lot mark
- The name (or business name) and address of the manufacturer, packer, or seller in the EU

Temperature Monitoring - Schedule 1

All new temperature monitoring instruments used in transport (including rail), warehousing and storage of quick frozen foods must comply with relevant European standards (EN 12830, EN 13485 and EN 13486) from 1st January 2006.

Existing instruments (installed before 1 January 2006) complying with previous legislation may continue to be used until 31st December 2009. All instruments must comply with the European Standards from 1st January 2010. Food operators must keep all relevant documents permitting verification that equipment/ instruments conform to the relevant European Standard(s).

Temperature recording details must be dated and kept by the food operator for at least one year or for longer depending on the nature and shelf-life of the QFF.

Exemptions

There are exemptions to this requirement of air temperature monitoring during storage in retail display cabinets and during local distribution. In these cases, the air temperature needs to be measured by at least one easily visible thermometer only. For open retail display cabinets, the maximum load level line must be clearly marked and the thermometer must measure the air temperature at this line at air return side. The cabinet should not be filled above the load line.

In addition, the air temperature of cold store facilities of less than 10m3 for stock in retail outlets can continue to be measured by an easily visible thermometer. Where the above exemptions apply, there is no requirement to keep temperature records.

Enforcement

The regulations are enforced by the Local Authorities. The Regulations require that where there are reasonable grounds to believe that quick frozen foods have not been kept at the required temperatures, the quick frozen food and temperatures must be further inspected in accordance with the provisions of Directive 92/2. Specific procedures for this inspection are included in the existing Food Law Code of Practice and associated Practice Guidance for Scotland which is due to be reviewed shortly. The Food Law Code of Practice and associated Practice Guidance are produced for enforcers.

The review of the Food Law Code of Practice and Guidance will include any necessary revisions to reflect changes introduced by the 2007 QFF Regulations but there are unlikely to be significant changes relating to inspection procedures.

Associated Regulations

Quick Frozen Foodstuffs Amendment (Scotland) Regulations 2007 (SSI 106)

European Commission legislation:

Council Directive 89/108/EEC Quick Frozen Foodstuffs for human consumption

<u>Commission Directive 92/2/EEC Sampling procedures for quick frozen foodstuffs intended for human consumption</u>

Commission Regulation (EC) No. 37/2005 Monitoring of temperatures in the means of transport, warehousing and storage of quick frozen foodstuffs intended for human consumption.

Further Information

EN Standards

EN12830

EN13485

EN13486

The Rice Products from the United States of America (Restrictions on First Placing on the Market) (Scotland) Revocation Regulations 2010

Scope

These regulations implement Commission Decision 2006/601/EC on emergency measures regarding non authorised genetically modified LL Rice 601.

These regulations implement <u>Commission Directive 2006/601/EC</u> as amended by <u>Commission Decision 2006/754/EC</u> and <u>Commission Decision 2008/162/EC</u>.

These Regulations implement Commission Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism "LL RICE 601" in rice products (O.J. No. L 244, 7.9.2006, p.27), as last amended by Commission Decision 2008/162/EC. Commission Decision 2006/601/EC, as amended, was repealed by Commission Decision 2010/315/EU (O.J. No. L 141, 9.6.2010, p.10).

Regulation 3 implements Article 2(1) of the Commission Decision by requiring that the first placing on the market of any rice is prohibited unless the consignment is accompanied by:

- a) a statement from the Food Business Operator responsible for the consignment that the products only contain rice from the 2007 or a subsequent harvest, that was subject to the USA Rice Federation plan to remove "LL Rice 601" and
- b) the original of an analytical report issued by one of the approved laboratories (see <a href="http://archive.gipsa.usda.gov/rdd/llriceprof.pdfhttp://archive.gipsa.usda.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llriceprof.gov/rdd/llricepr

The analytical report must also be accompanied by an official document issued by the Grain Inspection, Packers and Stockyards Administration (GIPSA) of the United States Department of Agriculture (USDA).

If a consignment is split copies of the documents must accompany each part of the spilt consignment up to and including the wholesale stage. These copies must be certified by the competent authority of the Member State on whose territory the splitting has taken place.

The regulations also apply with some modification the following articles of the Food Safety (Scotland) Act 1990 19, 20, 33, 34(1), 34(2), 36(1) and 36(2) and (3).

The regulations repeal The Rice Products (Restriction on First Placing on the Market) (Scotland) Regulations 2006.

Public Analyst Observations

Sample size needs to be sufficiently large to make the test valid.

Associated Regulations

The Rice Products from the United States of America (Restriction on First Placing on the market) (Scotland) Regulations 2010

Commission Decision 2006/601/EC

Commission Decision 2006/754/EC

Commission Decision 2008/162/EC

Guidance notes for sampling food and feed to determine the presence of genetically modified material

The Smoke Flavourings (Scotland) Regulations 2005

Scope

These Regulations provide for the enforcement and execution of certain specified provisions of Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods.

Ingredients/Products

In particular these Regulations formally designate the Food Standards Agency as the national competent authority to receive applications for the authorisation of new primary smoke condensates and primary tar fractions for use as such in or on foods, or in the production of derived smoke flavourings for use in or on foods.

The regulations:

- 1. Prohibit the marketing of smoke flavourings not listed in the authorised list or use outside the criteria and conditions of the authorisation.
- 2. Prohibit the use of treated wood unless the treatment agent used does not give rise to toxic substances when combusted.
- 3. Prohibit use of water insoluble oily phase during manufacture of smoke flavourings.
- 4. Require users to adhere to conditions and restrictions on use of the flavourings specified in the authorisation.
- 5. Require manufacturers to inform Commission of any new evidence that casts doubt on the safety of the smoke flavouring for which authorisation was granted.
- 6. Require systems in place to identify suppliers and customers who received their product.

Smoke flavourings which fail to meet the criteria stated in points 1, 2, 3, 4 and 5 can be treated as failing the food safety requirement and as such may be seized and condemned by an order of the justice of the peace.

Smokeze

In the course of food standards intervention authorised officers may encounter flavourings e.g. smokeze which has the potential to develop colour in products such as cooked chicken. Current legislation does not permit the addition of colour to chicken. If such substances are primarily added to provide colour to food then officers may wish to consult the Colour in Food (Scotland) Regulations 1996 (as amended).

Public Analyst Observations

Traditional methods of fish smoking and ham smoking can give rise to high levels of poly aromatic hydrocarbons and as such officers who conduct standards inspections of such establishments may consider it appropriate to sample and submit for analysis products that have been put through the smoking process.

Associated Regulations

The Smoke Flavourings (Scotland) Regulations 2005 (SSI No 215)

Regulation (EC) No. 2065/2003

Further Information

The regulation helps to establish a list of approved primary products for smoke flavourings. During the first 18 months that the regulation is in force, business operators are encouraged to submit primary products for approval to the competent authority of a Member State. Applications for approval of primary smoke products must be available to the public, and food business operators must supply information to ensure the traceability of the product.

http://www.efsa.europa.eu/en/science/afc/afc_guidance/680.html

Specified Products from China (Restriction on first placing on the market) (Scotland) Regulations 2008

Scope:

The regulations implement Commission Decision 2008/289/EC on the importation into the EC of an unauthorised genetically modified organism BT63 in rice products originating, or consigned from China.

The regulations made by the Department of Health and Social Services and Public Safety (DHSSPS) under the European Communities Act 1972 are enforced by the Department of Agriculture and Rural Development (DARD) in relation to animal feed and Local Authorities in respect of food.

Ingredients/products

The rules relate to BT 63 as it is an unauthorised Genetically Modified Organism (GMO) found in rice products originating from China.

Regulation 3 implements Article 2 of the Commission Decision requiring that the first placing on the market of any rice is prohibited unless the consignment is accompanied by

- a. An original analytical report based on the construct specific method developed by D Made at al for determination of Bt 63 issued by an official or accredited laboratory and accompanying the consignment demonstrating that the product does not contain, consist of, or is not produced from GMO Rice Bt 63.
- b. In the case of an analytical report issued by a Chinese accredited laboratory, the analytical report must be endorsed by the relevant competent authority.
- c. In the case of a split consignment a copy of the analytical report must accompany each part of the split consignment.

In the absence of an analytical report the business operator responsible for first placing on the market of the product must have the product s tested to demonstrate that they do not contain GMO Rice Bt 63.

Regulation 4 requires operators who become aware of a positive test result for GMO Rice Bt 63 in a specified product under their control must inform the Agency of the results immediately.

Public Analysts Observations

Associated Regulations

<u>Specified Products from China (Restriction on first placing on the market) (Scotland)</u> Regulations 2008

<u>Commission Decision 2008/289/EC on the importation into the EC of an unauthorised genetically modified organism BT63 in rice products originating, or consigned from China</u>

Further Information

Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed

The Specified Sugar Products (Scotland) Regulations 2003

Scope

The Regulations implement the provisions of <u>EC Directive 2001/111</u> relating to certain sugars intended for human consumption. The Regulations lay down reserved descriptions for the sugar products they cover and provide additional labelling requirements for these products. The Regulations also implement Commission Directive 79/796/EEC on methods of analysis for testing certain sugars.

Ingredients/Products

The Regulations apply to specified sugar products intended for human consumption and ready for delivery to the ultimate consumer or to a catering establishment. A 'specified sugar product' means one of the sugar products covered by the reserved descriptions in Schedule 1 of the Regulations. Icing sugars, candy sugars and sugar in loaf form (as defined in Regulation 2) are not covered by the scope of the Regulations. (Schedule 1 is reproduced in Annex 1 of these notes).

Reserved descriptions

A product may not be described using one of the reserved descriptions unless it meets the relevant compositional criteria laid down in Schedule 1. The name under which a specified sugar product is sold must be (or include) a reserved description. The reserved descriptions may also be used in the name of a food in the following circumstances:

- (a) Where it is clear that the sugar product to which the reserved description relates is only an ingredient of the food (e.g. 'sugar mouse', 'barley sugar')
- (b) Where it is clear that the food is not, and does not contain, the sugar product to which the reserved description relates (e.g. 'sugar-free gum', 'sugar snap peas')
- (c) Where it is clear that the term is being used as a customary name for a food product and is not liable to mislead the consumer (e.g. 'icing sugar').

Under the general rules of the Food Labelling Regulations (FLR) relating to ingredient listing, where a specified sugar product is used as an ingredient in another food, an appropriate reserved description must be used to describe that product in the list of ingredients.

Methods of analysis

The compositional and quality criteria for the specified sugar products are determined using the methods of analysis specified in Schedule 2. The Schedule stipulates which method is to be used in respect of each of the compositional criteria.

Labelling Requirements

Labelling of Specified Sugar Products

Regulation 5 provides the labelling requirements for specified sugar products. There are also a number of additional labelling provisions set out in the notes to Schedule 1, some of which are optional.

As well as the specific labelling requirements of the Regulations, specified sugar products are subject to the general labelling rules of the FLR. In addition, Regulation 6 requires that any labelling information required by the Regulations must be provided according to the manner of marking provisions in the FLR.

Mandatory Labelling Provisions (Regulation 5 and Schedule 1, Notes 2 and 3) The Regulations provide the following mandatory labelling provisions for specified sugar products:

- (a) Reserved descriptions: Any specified sugar product must be an appropriate reserved description for that product.
- (b) Dry matter content: Sugar solution, invert sugar solution and invert sugar syrup must be labelled with the dry matter content of the product.
- (c) Invert sugar content: Sugar solution, invert sugar solution and invert sugar syrup must also be labelled with the invert sugar content of the product.
- (d) Crystallised invert sugar syrup: Where invert sugar syrup contains crystals in the solution, the term 'crystallised' must be added to the description of the product e.g. 'crystallised invert syrup'.
- (e) Glucose syrup: Where glucose syrup or dried glucose syrup contains more than 5% fructose, the reserved description used must reflect this. The reserved description must be either 'glucose-fructose syrup' or 'fructose-glucose syrup' (or 'dried glucose-fructose syrup' or 'dried fructose-glucose syrup' if appropriate), where the sugar component which is in the greater proportion is mentioned first.

Schedule 3 of the FLR provides generic names that may be used to describe categories of ingredients in the list of ingredients. The Schedule provides that the name 'glucose syrup' may be used to describe both glucose syrup and anhydrous glucose syrup where they appear in an ingredients list. This flexibility does not cover glucose syrup with more than 5% fructose; these products must be labelled as described above.

Additional optional labelling provisions (Schedule 1, Notes 1, 4, 5 and 6) The Regulations also provide a number of optional labelling provisions. These allow the reserved descriptions to be modified or supplemented with additional terms, where the product meets certain requirements, as follows:

- (a) Extra-white sugar: A product meeting the requirements for the reserved description 'extra-white sugar' may alternatively carry the reserved description 'sugar' or 'white sugar'.
- (b) Additional qualifying terms: Any specified sugar product may be labelled with commonly used qualifying terms in addition to the reserved description, providing this labelling is not misleading. e.g. 'granulated sugar', 'fructose: fruit sugar'.
- (c) White sugar solution: The description 'white' may be used in the labelling of 'sugar solution' where the product has a colour of not more than 25 ICUMSA

- units. (ICUMSA stands for International Commission for Uniform Methods of Sugar Analysis).
- (d) White invert sugar solution or syrup: The description 'white' may be used in the labelling of invert sugar solution or invert sugar syrup where the product has a colour of not more than 25 ICUMSA units and an ash content of not more than 0.1%.

Public Analyst Observations

There tends to be few issues identified in relation to composition of the range of sugar products.

Associated Regulations

The Specified Sugar Products (Scotland) Regulations 2003 (SSI No. 527)

The Food Additives (Scotland) Regulations 2009 (SSI No. 436)

EC Directive 2001/111 relating to certain sugars intended for human consumption

Further Information

FSA Guidance on specified sugar products

Sugar Traders Association

Annex 1 SPECIFIED SUGAR PRODUCTS AND THEIR RESERVED DESCRIPTIONS

1. Semi-white sugar	Purified and crystallised sucrose of sound and fair				
	marketable quality with the following characteristics:				
	(a) polarisation not less than 99.5°Z				
	(b) invert sugar content not more than 0.1% by weight				
	(c) loss on drying not more than 0.1% by weight				
2. Sugar or white	Purified and crystallised sucrose of sound and fair				
sugar	marketable quality with the following characteristics:				
	(a) polarisation not less than 99.7°Z				
	(b) invert sugar content not more than 0.04% by weight				
	(c) loss on drying not more than 0.06% by weight				
	(d) type of colour not more than nine points				
	determined in accordance with paragraph (2) of Schedule 2				
3. Extra-white sugar	The product having the characteristics referred to in				
	paragraph 2(a), (b) and (c) of this Schedule and in respect				
	of which the total number of points determined according to the				
	provisions of paragraphs 2 to 4 of Schedule 2 does not exceed eight,				
	and not more than:				
	– four for the colour type,				
	- six for the ash content,				
	- three for the colour in solution				
4. Sugar solution	The aqueous solution of sucrose with the following				
	characteristics:				
	(a) dry matter not less than 62% by weight				
	(b) invert sugar content (ratio of fructose to dextrose = 1.0 +/- 0.2) not				
	more than 3% by weight of dry matter				
	(c) conductivity ash not more than 0.1% by weight of dry matter,				

	determined in accordance with paragraph 3 of Schedule 2				
	(d) colour in solution not more than 45 ICUMSA units				
5. Invert sugar	The aqueous solution of sucrose partially inverted by hydrolysis, in				
solution	which the proportion of invert sugar does not predominate, with the				
	following characteristics:				
	(a) dry matter not less than 62% by weight				
	(b) invert sugar content (ratio of fructose to dextrose = 1.0 +/- 0.1)				
	more than 3% but not more than 50% by weight of dry matter				
	(c) conductivity ash not more than 0.4% by weight of dry matter,				
	determined in accordance with paragraph 3 of Schedule 2				
6. Invert sugar	The aqueous solution, whether or not crystallised, of sucrose that has				
syrup	been partly inverted via hydrolysis, in which the invert sugar content				
	(fructose/dextrose quotient = 1.0 +/- 0.1), must exceed 50% by weight				
	of dry matter, but which must otherwise meet the requirements laid				
	down in paragraph 5(a) and (c) of this Schedule.				
7. Glucose syrup	The purified and concentrated aqueous solution of nutritive				
	saccharides obtained from starch and/or inulin, with the following				
	characteristics:				
	(a) dry matter not less than 70% by weight				
	(b) dextrose equivalent not less than 20% by weight of dry matter and				
	expressed as D– glucose				
	(c) sulphated ash not more than 1% by weight of dry matter				
8. Dried glucose	Partially dried glucose syrup with at least 93% by weight of dry				
syrup	matter, but which must otherwise meet the requirements laid down in				
	paragraph 7(b) and (c) of this Schedule.				
9. Dextrose or	Purified and crystallised D–glucose containing one molecule of water				
dextrose	of crystallisation, with the following characteristics:				
monohydrate	(a) dextrose (D–glucose) not less than 99.5% by weight of dry matter				

	(b) dry matter not less than 90% by weight			
	(c) sulphated ash not more than 0.25% by weight of dry matter			
10. Dextrose or	Purified and crystallised D–glucose not containing water of			
dextrose	crystallisation, with at least 98% by weight of dry matter, but which			
anhydrous	must otherwise meet the requirements laid down in paragraph 9(a)			
	and (c) of this Schedule.			
11. Fructose	Purified crystallised D-fructose with the following characteristics:			
	fructose content 98% minimum			
	glucose content 0.5% maximum			
	loss on drying not more than 0.5% by weight			
	conductivity ash not more than 0.1% by weight determined			
	in accordance with paragraph (3) of Schedule 2			

The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations 2008

Scope

These regulations provide for the execution and enforcement, of certain provisions of Council Regulation (EC) No.1234/2007 establishing a common organisation of agriculture markets and on specific provisions for certain agricultural products.

The Council Regulation repeals a number of other EC instruments and re-enacts their provisions without amendment. These Regulations provide for the enforcement of provisions formerly contained in two of the repeated EC instruments and formerly enforced in two separate statutory rules.

The provisions of the Council Regulation include:

- (a) the requirement that milk and milk products marketed for human consumption must comply with certain specifications as to names and composition (Article 114(I) and Annex XII); and
- (b) the requirement that certain spreadable fats intended for human consumption must comply with specifications relating to their sales description, labelling and presentation, and use of terminology (Article 115 and Annex XV).

Ingredients/Products

The EC Regulation defines 'milk' as the normal mammary secretion obtained from one or more milkings without any additions or extractions. The term can be used to describe standardised milk.

Milk products means products derived exclusively from milk on the understanding that substances may be added for manufacture, but not used to replace in whole or in part any milk constituent.

The following terms are reserved exclusively for milk products:

- Whey
- Anhydrovs milkfat (AMF)
- Cream
- Cheese
- Butter
- Yogurt
- Buttermilk
- Kepher (a fermented milk drink)
- Butteroil
- Koumiss (a fermented milk drink)
- Caseins
- Viili/fil
- Fil

The term 'milk' and the designations used for 'milk products' may also be used in association with a word or words to designate composite products.

The origin of the milk must be stated of if it is not bovine.

Council Regulation 1234/2007

This Regulation protects consumers from the possibility of confusing butter, margarine and other spreadable fats (e.g. minarines etc) by differentiating them according to their percentage of fat content and their animal or vegetable origin.

Spreadable fats are products with a fat content of at least 10% but less than 90% by weight and which remain solid at a temperature of 20c (complete definition in Article II5). To avoid any possible confusion, the regulation limits use of the terms 'butter' and 'margarine' to products with a fat content of not less than 80%.

'Reduced fat' claims

The term can be used for Spreadable fats with a fat content of more than 41% but not more than 62%. This term may also be used to replace the term "Three Quarter Fat".

Under the terms of the Regulation, the fact that the product has a reduced fat content must be mentioned clearly in the product designation. The Regulation therefore permits the use of nutritional claims which underline that the product has a reduced fat content. (Such claims consist of information relating to labelling, presentation and advertising which inform consumers about the characteristics of a foodstuff or food ingredient).

'Low fat / Light' claims

The term can be used for Spreadable fats with a fat content of 41% or less. This term may also be used to replace the term "Half Fat".

Please note that the Regulation sets out specific criteria for the use of nutrition claims on spreadable fats. The Commission has not yet indicated when they are likely to amend these Regulations to bring the criteria for claims on Spreadable fats in line with Council Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Therefore, Food Business Operators should continue to comply with the criteria outlined in Council Regulation (EC) No 1234/2007.

Labelling Requirements

No label, commercial document, publicity material or any form of advertising or presentation may be used which claims, implies or suggests that a product is a dairy product if it falls outside the definition of milk and milk products as set out in the EC Regulation.

Sales and import descriptions

The various sales descriptions which are permitted, such as "minarine", "butter", "cream" or the terms "vegetable" or "traditional" are defined in Annex XV.

Spreadable fats which are imported from non-Community countries are subject to the same requirements as those manufactured in the European Union (EU).

The different compositional standards are set out in the schedule to these notes.

Public Analyst Observations

Typical issues concern the abuse of the term buttercream where the fat constituent must be butter and cream with artificial cream being substituted.

There are occasional problems with descriptions. The regulations focus on technical compositional and labelling terms.

Associated Regulations

The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations 2008

Food Labelling Regulations 1996 as amended

Council Regulation (EC) No. 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)

SCHEDULE Compositional standards set out in Council Regulation 1234/2007

Fat Group	Sales	Additional description
	Description	
A. Milk fats Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived exclusively from milk and/or certain milk products, for which the fat is the essential constituent of value. However, other substances necessary for their manufacture may be added, provided those substances are not used for the purpose of replacing, either in whole or in part, any milk constituents.	1. Butter	The product with a milk-fat content of not less than 80% but less than 90%, a maximum water content of 16% and a maximum dry non-fat milk-material content of 2%.
	2. Three-quarter- fat butter (*)	The product with a milk-fat content of not less than 60% but not more than 62%
	3. Half-fat butter (**)	The product with a milk-fat content of not less than 39% but not more than 41%.
	4. Dairy spread X %	The product with the following milk-fat contents • less than 39%, • more than 41% but less than 60%, • more than 62% but less than 80%.
B. Fats Products in the form of a solid, malleable emulsion, principally of the water-in-oil	1. Margarine	The product obtained from vegetable and/or animal fats with a fat content of not less than 80% but less than 90%.
type, derived from solid and/or liquid vegetable and/or animal fats suitable for human consumption, with a milk-fat content of not	2. Three-quarter- fat margarine (*)	The product obtained from vegetable and/or animal fats with a fat content of not less than 60% but not more than 62%.
more than 3% of the fat content.	3. Half-fat margarine (**)	The product obtained from vegetable and/or animal fats with a fat content of not less than 39% but not more than 41%.
	4. Fat spreads X %	The product obtained from vegetable and/or animal fats with the following fat contents: • less than 39%, • more than 41% but less than 60%, • more than 62% but less than 80%.

C. Fats composed of plant and/or animal products Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived from solid and/or liquid vegetable and/or animal fats suitable for human consumption, with a milk-fat content of between 10% and 80% of the fat content.	1. Blend	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 80% but less than 90%.
	2. Three-quarter- fat blend (*)	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 60% but less than 62%.
	3. Half-fat blend (**)	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 39% but less than 41%.
	4. Blended spread X %	The product obtained from a mixture of vegetable and/or animal fats with the following fat contents: • less than 39%, • more than 41% but less than 60%, • more than 62% but less than 80%.

The Tryptophan in Food (Scotland) Regulations 2005

Scope

These Regulations were initially put in place in 1990, following an outbreak of Eosinophilia-Myalgia Syndrome (EMS) in people taking dietary supplements containing tryptophan in the US and UK.

The purpose of the regulations is to generally prohibit the use of Tryptophan in food except under certain special conditions.

No person can add Tryptophan to food, or sell, offer or expose for sale food containing Tryptophan.

The prohibition does not extend to Tryptophan sold or offered for sale from a pharmacist or in the course of activities within a hospital to a person in respect of whom there is an appropriate medical certificate.

Ingredients/Products

Tryptophan is an amino acid, and is essential in human nutrition. For some time, Tryptophan has been available in health food stores as a dietary supplement, being used as a remedy for sleep disorders, and may also be used by some body-builders in body building supplements.

Other exceptions from the prohibitions included in the regulations are:

- Food to be used under medical supervision
- Food supplements, which can contain I-tryptophan at 220mg or less
- Laevoratory-tryptophan added to infant formula, follow-on formula, and processed cereal-based food or baby food
- Laevoratory-tryptophan and some derivatives added to foods for particular nutritional use if the above substances comply with specified purity criteria.

For the purposes of the provisions of the Food Safety Act and General Food Regulations, if a food analyst certifies food containing Tryptophan as failing the food safety requirement that food can be seized and destroyed under the order of a justice of the peace.

Public Analyst Observations

It is not anticipated that this type of product will be encountered in retail shops in the United Kingdom, however, where officers are aware of supplements etc sold in health and body building clubs checks could be made to ensure that this product is not being sold.

Associated Regulations

Tryptophan in Food (Scotland) Regulations 2005 SSI No 479

Further Information

Committee on Toxicity Report

The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007

Scope

There are a wide range of nutrients and other ingredients that might be used in food production (but not limited to) vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts.

These regulations implement the provisions of <u>EC Regulation No. 1925/2006</u> on the addition of vitamins and minerals and of certain other substances to food. It should be noted that these regulations do not apply to 'food supplements' as these are covered by <u>Directive 2002/46/EC.</u>

The scope of the EC Regulation 1925/2006 extends to:

- PARNUTS (Foods for particular nutritional Use)
- Novel foods and novel food ingredients
- Genetically modified food
- Food additives and flavourings
- Authorised oenological practices and processes e.g. wine making

Ingredients/Products

Article 3 requires that only vitamins and/or minerals listed in Annex 1 in the formulation in Annex 2 may be added to food.

Article 4 restricts the use of vitamins and minerals to:

- Unprocessed foodstuffs, including but not limited to fruit, vegetables, meat, poultry and fish
- Beverages containing more than 1.2% by volume of alcohol and provided that no nutrition or health claim is made

Article 5 sets out the requirements for vitamins and minerals to conform to purity criteria.

Article 6 requires that when added to foods, vitamins and minerals must result in significant amounts which are defined in the annex to Directive 90/496/EEC.

Labelling Requirements

Article 7 labelling, presentation and advertising of foods:

- Must not mention or imply that a balanced and varied diet cannot provide appropriate quantities
- Must not mislead or deceive the consumer as to the nutritional merit of a food
- The labelling in Article 4(1), Group 2 of <u>Directive 90/496/EEC</u> and of the total amount of vitamins and minerals present

Foods placed on the market or labelled prior to 1st July 2007 which do not comply with the regulations may be marketed until their expiry date but not later than 31st December 2009.

Public Analyst Observations

Officers who are considering sampling of this type of food need to be aware of the fact that vitamins because of their organic nature may deteriorate if exposed to air or sunlight therefore it will be preferable to sample unopened packets.

Associated Regulations

<u>The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations</u> 2007 SSI No 325

The Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations 2009 (SI No 3251)

EC Regulation No. 1925/2006 on the addition of vitamins and minerals and of certain other substances of food

Directive 2002/46/EC

Directive 90/496/EEC

Further Information