

For safe food and healthy eating

FOOD STANDARDS TRAINING MANUAL 2017

Scottish Food and Feed Law

In addition to using the Food Standards Training manual, further information on Scottish legislation can be obtained from Scottish Food and Feed Law. This information can be accessed from the Food Standards Scotland website:

http://www.foodstandards.gov.scot/scottish-food-and-feed-law-guide

Foreword

The composition, labelling 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. Food Standards 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 in Scotland in 2012, following on from the success of the manual in Northern Ireland. The manual was produced in partnership with local authority officers.

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 on-going 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.

Geoff Ogle Food Standards Scotland

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SECTION 1 - INTRODUCTION AND ENFORCEMENT

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 (Chapter 16) rests with Local Authorities. 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.

<u>The Framework Agreement on Official Feed and Food Controls</u> by Local Authorities sets out what Food Standards Scotland 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 safety and standards</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 a 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 4.10 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 HERB 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:-

- The nature and types of food industry in their area and the technology utilised in those premises the officer is authorised to inspect;
- 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, Food Standards Scotland and 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 information 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

New provisions on food information, with respect to seizure and detention of food are available when dealing with contraventions of food information law.

Food (Scotland) Act 2015 ("the 2015 Act") came into effect on 1 April 2015, introducing powers to authorised officers of a food authority with respect to food information law. The Act also introduced a new duty on food business operators to report non-compliance with food information law.

In summary, where it appears to an officer that food information law is being, or has been, contravened, the officer may:

- a) give notice that the food is not to be used for human consumption and is not to be removed (except to some place specified in the notice); or
- b) seize the food and remove it in order to have it dealt with by the sheriff.

It will be an offence for any person to knowingly contravene the requirements of a notice and the officer must determine whether or not food information law has been contravened as soon as is practicably possible (and in any event within 21 days). If the officer is satisfied that the law has been contravened the food should be seized and removed to be dealt with by the sheriff.

This aligns enforcement powers for contravention of food information law with the existing powers officers have with regard to contraventions of food hygiene law. However, for food information contraventions the sheriff is given wider discretion than is available for cases where food hygiene law has been contravened. For food information law cases the sheriff may still order that food is destroyed or disposed of (as in food hygiene cases), but may choose to order that the food be modified and returned to the person who was in charge of the food or to order that the food be redistributed as the sheriff may determine. Expenses in respect of destruction, modification, disposal or distribution would fall to the owner of the food to meet.

The following pages consist of the Officers' Guidance Notes and the 3 model notices.

Food Information Law Seizure and Detention Powers – Authorised Officer Guide



Authorised Officer Guide Food Information Law-Seizure and Detention Powers

Background

Section 33 in Part 2 of the 2015 Act details new provisions on food information amending the Food Safety Act 1990, with respect to seizure and detention of food in contravention of food information law. These new provisions were introduced as part of the recommendations of the Scudamore inquiry into the fraudulent substitution of horsemeat.

The purpose of the new provisions is to give powers to authorised officers to seize food in order to have it dealt with by a sheriff, where significant contraventions of food information law are found, and to allow food to be detained pending further examination where suspicions of non-compliance require to be verified, through analysis if necessary, prior to the authorised officer making the determination that food information law has been contravened.

Section 15A, defines the meaning of "food information" for the new provisions as having the same meaning as it has in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and specifies that food information law means any enactment relating to food information specified by Scottish Ministers by regulation.

Scope of the new powers

The detention and seizure powers should only be applied where serious breaches of food information law are found. It is anticipated they will be used for breaches of the European Food Information to Consumers Regulation No 1169/2011 (FIC) and related legislation which specifies the nature and substance of the food described in these regulations.

Examples of scenarios when the new powers could be applied include serious breaches of food information relating to substitution, authenticity, adulteration and misleading descriptions.

Application of Seizure and Detention Powers

As is the case with the existing seizure and detention powers under Section 9 of the Food Safety Act 1990, careful consideration should be given before initiating detention and seizure provisions, since there are explicit protocols specified in the Act, which must be adhered to.

There are no specific appeals against the application of these powers for the affected food businesses, such as exist for the service of improvement notices. This is because representations to the sheriff are explicitly provided for in the Act itself.

Once food is seized, the determination as to what ultimately happens to the food must be made by the sheriff. The authorised officer cannot release the seized food, even if assurances regarding rectifying non-compliances are given. Similarly, once detained the authorised officer must either fully withdraw the notice if no contraventions are confirmed or remove it to have it dealt with by the sheriff. Therefore the detention provisions cannot be used as a mechanism to obtain compliance by informal means and in the first instance traditional enforcement approaches to achieve compliance for minor breaches should be used.

The formal process is detailed below:

Where it appears to an officer that food information law is being, or has been, contravened, the officer may:

- a) give notice that the food is not to be used for human consumption and is not to be removed (except to some place specified in the notice) (Model notice 1);
- b) seize the food and remove it in order to have it dealt with by the sheriff (Model notification form 2); or
- c) Issue a withdrawal notice (Model notice 3)

Use of Detention Notices

The purpose of the detention notice is to allow authorised officers to carry out further necessary investigations, including examination of foods, where serious contraventions are suspected, but further investigation is required to confirm this. Examples include circumstances where meat or fish is suspected to have been adulterated or substituted for financial gain, but further examination is necessary to confirm this.

It is an offence for any person to knowingly contravene the requirements of a detention notice and the officer must determine whether or not food information law has been contravened as soon as is practicably possible (and in any event within 21 days). If the officer is satisfied that the law has been contravened the food should be seized and removed to be dealt with by the sheriff. If the officer decides, following further investigation, that no food information law contraventions exist, the food detention notice must be withdrawn and the food released to the market.

Seizure of foods

If the officer making the determination is satisfied that serious breaches of food information law have occurred, the officer must seize the food and remove it to have it dealt with by the sheriff. This determination must be made as soon as practicable. So, if initial investigations determine serious breaches exist, without the need for further investigation or examination, the officer should seize the food immediately without the use of detention notice procedures.

The sheriff may then order that food is destroyed or disposed of but may also choose to order that the food be modified and returned to the person who was in charge of the food, or to order that the food be redistributed as the sheriff may determine. Expenses in respect of destruction, modification, disposal or distribution would fall to the owner of the food to meet.

Compensation

In circumstances where a detention notice is withdrawn, or the sheriff refuses to make an order confirming food information law has been contravened, the food authority must compensate the owner of the food for any depreciation in its value resulting from the action taken by the authorised officer.

Food Information Law – Detention Notice – Model 1

FOOD INFORMATION LAW DETENTION OF FOOD NOTICE

Local Authority:	Reference Number:	
The Food Safety Act 1990 (as amen	ded)	
Section 15B – Apparent contravention of food i	nformation law	
_		
To: (The person in charge of the food)		
(The person in charge of the tood)		
At:		
(Address of person in charge of the food)		
And (only <u>if</u> the person in charge of the food is not the owner of the food, a	bove):	
То:		
(The owner of the food)		
At:		
(Address of the owner of the food)		
In my opinion the food does not comply with food information r	equirements because:	
Name of food business:		
Address of food business		
	·····	
The food and any related food information described below, or a described, is being detained for the purposes of analysis/inspect		
described, is being detained for the purposes of analysis/inspect		
Description:		
Quantity:		
Identification Marks:		
1. This food is not to be used for human consumption.		
 The food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food information described about the food and any related food and about the food and any related food any related	ove, or any specified part of it is	
not to be removed from the address below.		
Address of where this food described is to remain:		

You will be informed in writing as soon as is reasonably practicable and in any case within 21 days of the Authorised Officers determination. This notice will then either be withdrawn and the food and any related food information released, or the food and related food information will be seized to be dealt with by the sheriff, who may make such an order as the sheriff considers appropriate in respect of the food and any food information relating to it.

Signed:	(Authorised Officer)
Name in capitals:	Date:
Address:	
Tel: E-mail:	

Please read the notes below carefully. If you are not sure of your rights or the implications of this notice, you may want to seek independent legal advice.

<u>NOTES</u>

- 1. The Authorised Officer has, by means of this notice, required the detention of the food and relevant food information specified for the purposes of analysis/inspection.
- 2. The food and relevant food information must remain where it is. If it is moved it may only be moved within the place stated in Section 2 of this notice.
- 3. If an Authorised Officer is satisfied that the food and relevant food information need no longer be detained this notice will be withdrawn by means of a further notice in writing.
- 4. If, for some reason, you need to move the food or relevant food information after receiving this notice, you should contact the Authorised Officer at the address given.

WARNING

FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Food Information Law – Seizure Notification – Model 2

FOOD INFORMATION LAW NOTIFICATION OF SEIZURE OF FOOD

Local Authority:	Reference Number:
The Food Safety Act 1990 (as amend	ded)
Section 15B – Determination that Food Information Lav	v has been Contravened
То:	
(The person in charge of the food)	
At:	
(Address of person in charge of the food)	
And (only <u>if</u> the person in charge of the food is not the owner of the food, a	bove):
То:	
(The owner of the food)	
At:	
(Address of the owner of the food)	
In my opinion the food does not comply with food information r	equirements because:
Name of food business:	
Address of food business	
This notification applies to the following food and any related fo	od information which has been
seized by an authorised officer of this authority. Description:	
Quantity:	
Identification Marks:	
· · · · · · · · · · · · · · · · · · ·	

It is my intention to have the food dealt with by a sheriff at

on date.....

or

You will be notified as soon as possible of the location and date and time of the sheriff's deliberations.

You will be entitled to attend before the sheriff by whom the food falls to be dealt with and entitled to be heard and call witnesses.

If it appears to the sheriff that food information law has been contravened the sheriff may make such an order as they consider appropriate with respect to the food and any related food information.

In particular the order may require that:

- The food be destroyed or otherwise disposed of to prevent its use for human consumption;
- Any information relating to the food be modified, destroyed or disposed of;
- That any food which is fit for consumption along with related information be returned to the person in charge of it or distributed to some other person.

In the event that the sheriff refuses to make an order in respect of the food or related information the food authority will be liable to compensate the owner of the food for any depreciation in its value.

Signed:	(Authorised Officer)
Name in capitals:	Date:
Address:	
Tel: E-mail:	

Food Information Law – Withdrawal Notice – Model 3

Local Authority	Reference Number:
The Food Safety Act 1990 (as amend	ed)
Section 15B – Apparent contravention of food in	formation law
To: (The person in charge of the food)	
At:	
(Address of person in charge of the food)	
And (only <u>if</u> the person in charge of the food is not the owner of the food,	above):
То:	
(The owner of the food)	
At:	
(Address of the owner of the food)	
Name of food business: Address of food business	
I being an Authorised Officer am satisfied that the food and rele specified in	evant food information
the Detention Notice reference number	
served on you on	(date)
is compliant with food information law and need no longer be on Notice is hereby withdrawn.	
Signed:	(Authorised Officer)
Name in capitals:Da	te:
Address:	
Tel: E-mail:	

WITHDRAWAL OF FOOD INFORMATION LAW DETENTION NOTICE

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek independent legal advice.

<u>NOTES</u>

- 1. The Authorised Officer is now satisfied that the food and relevant food information specified in the Food Law Information Notice need no longer be detained.
- 2. The relevant notice is now withdrawn.

1.5 Sampling of Food and Ingredients

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 <u>sampling guidance</u> issued by Scottish Food Enforcement Liaison Committee and Food Standards Scotland.

1.6 Food Control Primary Legislation

Food Standards Scotland has published a comprehensive guide to Scottish Food and Feed law at: <u>http://www.foodstandards.gov.scot/scottish-food-and-feed-law-guide</u>

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 in the paragraphs below.

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 <u>Regulation (EC) 178/2002.</u>

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.

Part 2 - Main Provisions

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

General Enforcement Provisions
 See section 1.6.3 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 a 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 with 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 Committee of Advertising Practice (<u>www.cap.org.uk/</u>) is 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.

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 provides for appeals to the Sheriff.

Section 38 provides 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 requirements of the <u>Food</u> <u>Safety Act 1990</u> to that outlined in **Article 14** of Regulation (EC) 178/2002.

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 the 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.

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.

Traceability (Article 18)

Article 18 of Regulation (EC) 178/2002 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/Labelling/scheme

Product Recall (Article 19)

Under Article 19 of <u>Regulation (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 FSS 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:

Europa Website Food Standards Scotland Website

SECTION 2 – TRAINING NOTES ON LEGISLATION

Food Information

2.1 EU Food Information to Consumers Regulation

Food Information – Definition

Regulation (EU) No 1169/2011 of the provision of food information to consumers (FIC) sets out the requirements for the:

- labelling,
- advertising and
- presentation of foodstuffs.

It refers to food information rather than just food labelling and states that food information means:

"information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication".

Application Dates

The FIC entered into force on 13 December 2011 and most of the general labelling requirements applied from 13 December 2014. From 13 December 2016, nutrition information became necessary for most pre-packed food.

Transitional arrangements

- With regard to general labelling requirements (ingredients lists, highlighting of allergen information etc.), products are allowed to be sold through if they have been placed on the market before 13 December 2014 regardless of how long a time period this is. Some products such as frozen, dried and canned products have a long shelf life and may well remain on the shelves for several years.
- In the case of nutrition information, since 13 December 2014, any nutrition declarations (i.e. provided voluntarily or required due to the addition of vitamins and minerals or to support nutrition and health claims) should be given using the format set out in the FIC.
- Pre-packed food placed on the market before 13 December 2016 and which would otherwise require a nutrition declaration may continue to be sold until stocks are exhausted.

Scope of the FIC

The FIC applies to food business operators at **all stages** of the food chain where their activities concern the provision of food information to consumers. The rules do not apply to food sold by Charities which are not operating and registered as food businesses.

Mandatory Particulars

The principal provisions of the FIC are to require all foods intended for the final consumer, including foods delivered by mass caterers, and foods intended for supply to mass caterers, subject to certain exceptions, to be marked or labelled with the following information:

- The name of the food
- The list of ingredients
- Substances or products known to cause food allergy or intolerance
- The quantity of certain ingredients or categories of ingredients
- Net quantity
- The date of minimum durability or the 'use by' date
- Any special storage conditions and/or conditions of use
- The name or business name and address of the food business operator
- The country of origin or place of provenance in certain cases
- Instructions for use
- Alcohol % by volume if greater than 1.2% vol.
- Nutrition declaration

Additional Information

The mandatory information, set out below, is described in Article 9 of the FIC. This needs to be read in conjunction with the additional mandatory particulars referred to in Article 10 and Annex III. In addition, other specific requirements in the FIC such as minimum font size and how to present nutrition information also need to be considered.

- The name of the food (Article 9 (1) (a), Article 17 and Annex VI);
- A list of ingredients (Article 9 (1) (b c), Article 18 to 20 and Annex VII) including any
 ingredients or processing aid causing allergies or intolerances used in the manufacture
 or preparation of food and still present in the finished product (Article 9 (1) (c), Article 21
 and Annex II);
- The quantity of certain ingredients or categories of ingredients (Article 9 (1) (d) and Article 22);
- The net quantity of food Article 9 (1) (e), Article 23 and Annex IX);
- The date of minimum durability or the 'use by' date (Article 9 (1) (f), Article 24 and Annex X);
- Any special storage conditions or conditions of use (Article 9 (1) (g), and Article 25);
- The name or business name and address of the manufacturer or packer or of a seller established within the European Community (Article 9 (1) (h));

And in certain cases -

- Particulars of the place of origin or provenance of the food (Article 9 (1) (i) and Article 26);
- Instructions for use (Article 9 (1) (j) and Article 27);
- Regarding beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume (Article 9 (1) (k), Article 28 and Annex XII);
- A nutrition declaration (Article 9 (1) (I) and Articles 29 to 35).

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

Name of the Food – Article 17

Where there is a name laid down by law i.e. a prescribed name, this must be used. If this is not the case, 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.

Prescribed Name

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, EU Regulations on spreadable fats require names like 'butter' or 'margarine' to be used for particular product categories. Other examples include jam, honey and fish for which there are specific EU provisions.

Reserved Descriptions

In the case of some foods, there are compulsory product names that must be used for foods meeting certain compositional criteria, e.g. the reserved descriptions for foods such as coffee, chocolate, jam and sugar. These names constitute legal names for the purposes of Article 17 of FIC.

Customary Name

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, as the name of the food without it needing any further explanation. Some examples are '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. 'Yum Yum') 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. The business will need to consider whether or not supplementary information describing what the food is needs to be provided. A fancy name, with an accompanying description, may (in time) become acceptable as a customary name, possibly without the necessity of an accompanying description. Article 17(4) of FIC sets out that the name of a food shall not be replaced with a name protected as intellectual property, brand name or fancy name.

Descriptive Name

If there is no customary name, or it is not used, a descriptive name must be used. The descriptive name must not be misleading. 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 for example 'cheese, tomato with egg encased in short crust pastry'.

Additional Specific Requirements with regard to the Name of a Food

- Trademarks, Brand Names or Fancy Names cannot be substituted for the name of a food, but may be used in addition to it (Article 17(4)).
- Processes and treatments (Article 17(5) and Annex VI) Dried, Frozen, Pasteurised etc.

The name of the food must include or be accompanied by particulars as to the physical condition of the food or the specific treatment which it has undergone where the absence of such information might mislead (for example, powdered, refrozen, freeze-dried, guickfrozen, concentrated, smoked). 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'.

Where the food has been frozen and subsequently defrosted, this information needs to be given except in specific circumstances. This requirement shall not apply to the following: a) ingredients present in the final product:

- b) foods for which freezing is a technologically necessary step of the production process;
- c) foods for which the defrosting has no negative impact on the safety or quality of the food.

To determine if the omission of the information might mislead, the whole of the selling environment needs to be taken into account.

Use of substitute ingredients

If a substitute ingredient is used in a dish expected to be made from a specific ingredient, then the name of the substitute ingredient must be in close proximity to the name of the product e.g. parsley pesto sauce. There are further requirements concerning the font size (Annex VI (4)(b)).

Meat products, meat preparations and fishery products containing added proteins

Where *added* proteins and/or hydrolysed proteins such as albumin, collagen or casein are used in the production of any meat preparations, meat products or fishery products and are of a different animal species to the original food, then these proteins need to be included in the name of the food together with the name of the animal species from which they are derived. For example if a pork pie was made with added bovine collagen then it would be called a "Pork pie with added beef collagen".

Formed Meat

When meat products, meat preparations and fishery products have the appearance of a whole piece of meat or fish but are a combination of different pieces of meat (or fish) combined together, then the words 'formed meat' or 'formed fish' must accompany the name of the food.

Protected Food Names (Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) and Traditional Speciality Guaranteed (TSG))

Certain food names are protected against imitation under a separate piece of European law. These products must meet the requirements of the registered specification and be subject to verification inspections in order to use the protected name and carry the PDO, PGI or TSG designations and accompanying EU logo. The rules for these quality schemes are laid down in Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs.

The designations under the EU Protected Food Name (PFN) scheme are:-

- Protected Designation of Origin (PDO) these products must be produced, processed and prepared with features and characteristics due to the geographical area.
- Protected Geographical Indication (PGI) products **produced or processed or prepared** and have features or certain qualities attributable to a geographical area.
- Traditional Speciality Guaranteed (TSG) does not refer to product origin but highlights traditional character, either in the composition or means of production.

Examples of Scottish Protected designations include:

- 'Scotch beef' (PGI)
- 'Orkney Lamb' (PDO)
- 'Arbroath Smokie' (PGI)

EU database of PDO, PGI, and TSGs

The EU Database of Origin and Registration (DOOR) lists the progress of PFN applications received by the European Commission and provides a link to the relevant documents for registered products:

EU DOOR Database - http://ec.europa.eu/agriculture/quality/door/list.html

European Commission Website - http://ec.europa.eu/agriculture/quality/

Since 2009 legal requirements for use of the terms 'Protected Designation of Origin', 'Protected Geographical Indication', or 'Traditional Speciality Guaranteed' **and/or** the appropriate logo associated with the designation came into force. These are required to appear on the product label and accompany the **registered name**. On **4 January 2016**, use of the logo became compulsory for products marketed as registered PDO/PGI/TSGs. The logo must appear in the same field of vision as the registered name. The terms 'Protected Designation of Origin', 'Protected Geographical Indication', or 'Traditional Speciality Guaranteed' or the corresponding abbreviations 'PDO', 'PGI', or 'TSG' must be used in addition to the logo.

Further information on the scheme can be found on the Scottish Government website: http://www.gov.scot/Topics/Business-Industry/Food-Industry/national-strategy/rep/PFNs

Irradiated Foods (Annex VI (3))

Point 3 of Part A of Annex VI to FIC requires that foods treated with ionising radiation are labelled with the words 'irradiated' or 'treated with ionising radiation' as stated in Directive 1999/2/EC concerning foods and food ingredients treated with ionising radiation. Where an irradiated product is used as an ingredient in another product, the same words must accompany its designation in the list of ingredients.

For irradiated foods, or foods containing an irradiated ingredient, which are sold in bulk (for example non-pre-packed foods), the same words must appear together with the name of the product on a display or notice above or beside or on the container in which the products are placed.

The requirement to indicate that an ingredient has been irradiated applies even in the case of compound ingredients where the inclusion of the ingredient in the list of ingredients would otherwise not be required under the provisions of point 2 of Part E of Annex VII to FIC.

These provisions apply to the labelling of irradiated foods intended for either the ultimate consumer or catering establishments. The Food Irradiation (Scotland) Regulations 2009 (as amended) provide requirements on the documentation for irradiated foods which are not ready for the ultimate consumer or catering establishment as well as other restrictions on the sale of irradiated food.

Meat products, preparations containing added water (Annex VI Point 6)

In the case of meat products and meat preparations which have the appearance of a cut, joint, slice, portion or carcase of meat, the name of the food shall include an indication of the presence of added water if the added water makes up more than 5% of the weight of the finished product. The same rules shall apply in the case of fishery products and prepared fishery products which have the appearance of a cut, joint, slice, portion, fillet or of a whole fishery product.

Name and compositional requirements for minced meat

The FIC requires minced meat to conform with specific standards for fat content and collagen/meat protein ratio.

	Fat content	Collagen/meat protein ratio*
Lean minced meat	≤7%	≤ 12%
Minced pure beef	≤ 20%	≤ 15%
Minced meat containing pig meat	≤ 30%	≤ 18%
Minced meat of other species	≤ 25%	≤ 15%

Composition criteria checked on the basis of a daily average:

* The collagen/meat protein ratio is expressed as the percentage of collagen in meat protein. The collagen content means the hydroxyproline content multiplied by a factor of 8.

Only these descriptions may be used when the product complies with the compositional standard. Products which are so described must also have on the label a declaration of:

- a) 'percentage of fat content under...'
- b) 'collagen/meat protein ratio under...'

Under a flexibility in the FIC, products may be sold on the national market which does not meet compositional requirements provided the labelling clearly shows:

- a) a square ' \Box 'followed with a statement 'for the UK market only';
- b) details percentage of fat content and collagen/meat protein ratio.

Sausage Casings

If a sausage casing is not edible, this must be indicated.

Use of terms such as fresh, pure, natural etc.

The Food Standards Agency (FSA) has 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 such as:

- Fresh, Natural, Pure, Traditional, Original, Authentic, Home-made, Farmhouse

These terms should not be applied to foods that have been subject to some form of processing or treatment.

FSA Guidance Notes - <u>http://www.food.gov.uk/multimedia/criteriafoodlabelling.pdf</u>

2.2 List of Ingredients

Foods which do not require a list of ingredients

The majority of manufactured foods are required to have a list of ingredients, however, Article 19 of FIC lists a number of exemptions to this requirement:

- a) fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated;
- b) carbonated water, the description of which indicates that it has been carbonated;
- c) fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;
- d) cheese, butter, fermented milk (e.g. buttermilk) and cream, to which no ingredient has been added other than lactic products, food enzymes and micro-organism cultures essential to manufacture, or in the case of cheese other than fresh cheese and processed cheese the salt needed for its manufacture;
- e) foods consisting of a single ingredient, where:
 - i. the name of the food is identical to the ingredient name; or
 - ii. the name of the food enables the nature of the ingredient to be clearly identified.

Other foods may be exempt from having a list of ingredients because of the conditions in which they are sold e.g. in small packages (less than 10 cm²) or pre-packed for direct sale (Articles 16 and 44 respectively). However, in the case of packaging or containers the largest surface of which has an area of less than 10 cm² only the following particulars listed in Article 9(1) shall be mandatory on the package or on the label:

- Name of the food
- Allergenic ingredients
- Net quantity
- Minimum durability or 'use by' date

A list of ingredients shall be provided through other means or shall be made available at the request of the consumer.

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 FIC.

Heading of list of ingredients (Article 18 (1))

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.

Order of ingredients (Article 18)

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 e.g. (the mixing bowl stage).

The following are a number of exemptions (listed in Annex VII) to this requirement:-

Category of ingredient	Provision concerning indication by weight
1. Added water and volatile products	Shall be listed in order of their weight in the finished product. The amount of water added as an ingredient in a food shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount shall not be required to be taken into consideration if it does not exceed 5% by weight of the finished product. This derogation does not apply to meat, meat preparations, unprocessed fishery products and unprocessed bivalve molluscs
2. Ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture	May be listed in order of weight as recorded before their concentration or dehydration
3. Ingredients used in concentrated or dehydrated foods, which are intended to be reconstituted by the addition of water	May be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression, such as 'ingredients of the reconstituted product', or 'ingredients of the ready-to-use product'
4. Fruit, vegetables or mushrooms, none of which significantly predominates in terms of weight and which are used in proportions that are likely to vary, used in a mixture as ingredients of a food	May be grouped together in the list of ingredients under the designation 'fruit', 'vegetables' or 'mushrooms' followed by the phrase 'in varying proportions', immediately followed by a list of the fruit, vegetables or mushrooms present. In such cases, the mixture mushrooms present. In such cases, the mixture shall be included in the list of ingredients in accordance with Article 18(1), on the basis of the total weight of the fruit, vegetables or mushrooms present
5. Mixtures of spices or herbs, where none significantly predominates in proportion by weight	May be listed in different order provided that the list of ingredients is accompanied by an expression such as 'in variable proportion'
6. Ingredients constituting less than 2% of the finished product	May be listed in a different order after the other ingredients

Category of ingredient	Provision concerning indication by weight
7. Ingredients, which are similar or mutually substitutable, likely to be used in the manufacture or preparation of a food without altering its composition, its nature or its perceived value, and in so far as they constitute less than 2 % of the finished product	May be referred to in the list of ingredients by means of the statement 'contains and/or', where at least one of no more than two ingredients is present in the finished product. This provision shall not apply to food additives or to ingredients listed in Part C of this Annex, and to substances or products listed in Annex II causing allergies or intolerances
8. Refined oils of vegetable origin	May be grouped together in the list of ingredients under the designation 'vegetable oils' followed immediately by a list of indications of specific vegetable origin, and may be followed by the phrase 'in varying proportions'. If grouped together, vegetable oils shall be included in the list of ingredients in accordance with Article 18(1), on the basis of the total weight of the vegetable oils present. The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated oil.
9. Refined fats of vegetable origin	May be grouped together in the list of ingredients under the designation 'vegetable fats' followed immediately by a list of indications of specific vegetable origin, and may be followed by the phrase 'in varying proportions'. If grouped together, vegetable fats shall be included in the list of ingredients in accordance with Article 18(1), on the basis of the total weight of the vegetable fats present. The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated fat

Note – Reference to "vegetable origin" refers to the type of vegetable oil e.g. from Palm, Rapeseed, Sunflower or other sources.

Omission of constituents of food from the list of ingredients (Article 20)

Article 20 of FIC provides exemptions for ingredients that do not need to be named in a list of ingredients. These are:

- a) ingredients which have been temporarily separated during the manufacturing process;
- b) food additives and food enzymes where the carry over principle applies;
- c) carriers and substances which are not food additives;
- d) substances which are not food additives but are used in the same way;
- e) water:
 - (i) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form; or
 - (ii) in the case of a liquid medium which is not normally consumed.

In previous guidance to the Food Labelling Regulations it was noted that abbreviation is not acceptable in the labelling of food. This would be supported by Article 18(2) which 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. Abbreviations for ingredients are also 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. 'Wheatflour'. In addition, there are legal requirements to fortify UK produced flour with certain vitamins and minerals. Under FIC such flour is regarded as a compound food and the fortified substances must appear in brackets after the word 'wheatflour'. For example, 'wheatflour (calcium, iron, niacin and thiamin)'.

Designation of ingredients by food category name

Annex VII Part B defines 18 categories of food ingredient for which specific designations are identified.

Definition of category of food	Designation
1. Refined oils of animal origin	'Oil', together with either the adjective 'animal', or the indication of specific animal origin. The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated oil
2. Refined fats of animal origin	'Fat', together with either the adjective 'animal' or the indication of specific animal origin. The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated fat
3. Mixtures of flour obtained from two or more cereal species	'Flour', followed by a list of the cereals from which it has been obtained, in descending order by weight
4. Starches, and starches modified by physical means or by enzymes	'Starch'

Definition of category of food	Designation
5. All species of fish where the fish constitutes an ingredient of another food and provided that the name and presentation of such food does not refer to a specific species of fish	'Fish'
6. All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the name and presentation of such food does not refer to a specific type of cheese	'Cheese'
7. All spices not exceeding 2% by weight of the food	'Spice(s)' or 'mixed spices'
8. All herbs or parts of herbs not exceeding 2% by weight of the food	'Herb(s)' or 'mixed herbs'
9. All types of gum preparations used in the manufacture of gum base for chewing gum	'Gum base'
10. All types of crumbed baked cereal products	'Crumbs' or 'rusks' as appropriate
11. All types of sucrose	'Sugar'
12. Anhydrous dextrose or dextrose monohydrate	'Dextrose'
13. Glucose syrup and anhydrous glucose syrup	'Glucose syrup'
14. All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof	'Milk proteins'
15. Press, expeller or refined cocoa butter	'Cocoa butter'
16. All types of wine as covered by Annex XIb to Regulation (EC) No 1234/2007 ¹	'Wine'

Definition	of category	of food	Designation
17. Skeletal muscles ¹ of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not		fit for human ncluded or total fat and	' meat' and the name(s) ² of the animal species from which it comes
exceed the values indicated below and where the meat constitutes an ingredient of another food. Maximum fat and connective tissue contents for ingredients designated by		an ingredient e tissue	
the term '… mea Species	Fat content	Collagen/ meat protein ratio*	
Mammals (other than rabbits and porcines) & mixtures of species with mammals predominating	25%	25%	
Porcines	30%	25%	
Birds and rabbits	15%	10%	
 *The collagen/meat protein ratio is expressed as the percentage of collagen in meat protein. The collagen content means the hydroxyproline content multiplied by a factor of 8. If these maximum limits are exceeded, but all other criteria for the definition of 'meat' are satisfied, the ' meat' content must be adjusted downwards accordingly and the list of ingredients must mention, in addition to the term ' meat', the presence of fat and/or connective tissue. The products covered by the definition of 'mechanically separated meat' are excluded from this definition 		ge of collagen en content content exceeded, definition of meat' content ds accordingly ust mention, eat', the ective tissue. e definition of eat' are	'mechanically separated meat' and the
18. All types of products covered by the 'mechanically separated meat' and the definition of 'mechanically separated meat'		at' and the	name(s) of the animal species from which it comes

¹ The diaphragm and the masseters are part of the skeletal muscles, while the heart, tongue, the muscles of the head (other than the masseters), the muscles of the carpus, the tarsus and the tail are excluded ² For labelling in English, this designation may be replaced by the generic name of the ingredient for the animal species concerned

Flavouring (Annex VII part D)

Flavourings shall be designated either by the terms:

- 'flavouring(s)' or by a more specific name or description of the flavouring if the flavouring component contains flavourings as defined in points (b), (c), (d), (e), (f), (g) and (h) of Article 3(2) of Regulation (EC) No 1334/2008;
- 'smoke flavouring(s)', or 'smoke flavouring(s) produced from food(s) or food category or source(s)' (e.g. 'smoke flavouring produced from beech'), if the flavouring component contains flavourings as defined in point (f) of Article 3(2) of Regulation (EC) No 1334/2008 and imparts a smoky flavour to the food.

The term 'natural' for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No 1334/2008.

Quinine and/or caffeine used as a flavouring shall be mentioned by name in the list of ingredients immediately after the term 'flavouring(s)'.

Additives listing (Article 20 and Annex VII Part C)

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.

Additive categories

Acid	Foaming agent
Acidity regulator	Gelling agent
Anti-caking agent	Glazing agent
Anti-foaming agent	Humectant
Antioxidant	Modified starch ²
Bulking agent	Preservative
Colour	Propellant gas
Emulsifier	Raising agent
Emulsifying salts ¹	Sequestrant
Firming agent	Stabiliser
Flavour enhancer	Sweetener
Flour treatment agent	Thickener

(1) Only for processed cheeses and products based on processed cheeses.(2) The specific name or E number shall not be required to be indicated.

FIC requires that, where an additive is added or used in a food to serve the function of one of the categories of additives in Annex VII, it must be identified by the category name followed by the additives specific name or serial number (e.g. colour E124).

Although the category names listed in Annex VII Part C 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 Annex VII Part C must be identified by its specific name.

There is no longer a requirement to indicate additives for food sold non-pre-packed or prepacked for direct sale. This would include the six Southampton colours, which will no longer need to be declared on a notice or a ticket at point of sale.

• 'Specific Names' and 'Serial Numbers' for Additives

Details of these can be found in the annexes of:

- Regulation (EC) No 1333/2008 on food additives that re-enact the annexes of Directive 95/2, 94/35 and 94/36;
- Regulation (EC) No 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 EU legislation that are enacted in national legislation by the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI 2013 No. 266).

• Carry-over Additive (Article 20 (b)(i)) and Annex VII Part C)

'Carry over additives' are additives which are present in a food because they were contained in an ingredient of that food (e.g. the preservative in a sponge finger used to make a trifle). If they perform a significant technological function in the final food, they must be listed as ingredients of that food. If they do not perform a significant technological function in the final food, they do not have to be listed as ingredients of that food. In determining the role of technological function in a food, consideration must be given to the nature of the ingredient which contains the additive and the food in which that ingredient is used. For example, the preservative(s) which may have been used in a fruit puree will not necessarily be performing that function once the puree has been added to a pie which has then been baked, or in a yoghurt which has then been pasteurised.

This exemption does not apply to the allergenic ingredients or their derivatives listed in Annex II of FIC.

• Processing Aids (Article 20 (b) (ii))

A processing aid is any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that the residues do not present any health risk and do not have any technological effect on the finished product. They do not generally have to be listed as ingredients, except where the processing aid is an allergenic ingredient listed in Annex II or its derivative. However, if the processing aid leaves residues which perform a technological function in the food in which they have been used, they must be considered to be additives and are then subject to the same requirements that apply to other additives (as per Regulation EC 1333/2008).

Compound Ingredients (Annex VII Part E)

A compound ingredient is an ingredient of the food that is itself made up 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.

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

- a) the composition of the compound ingredient is defined and constitutes less than 2% of the finished product;
- b) the compound ingredients consists of mixtures of spices and/or herbs that constitute less than 2% of the finished product; or
- c) the compound ingredient is a food for which a list of ingredients is not required

2.3 Quantitative Indication of Certain Ingredients or Categories of Ingredients

Quantitative Indications (QI) - Article 22 and Annex VIII

Article 22 specifies the requirement to provide quantitative indications for certain ingredients or categories of ingredients. In general this applies where:

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

Scope of the requirement

The need for QIs principally applies to all food, including drink, with more than one ingredient.

- Foods not required to carry an ingredients list are not in principle exempt from providing a QI. However, such foods will not have to provide an ingredients list even if a QI is given;
- The requirements do not affect the labelling of non-pre-packed and pre-packed for direct sale foods³ (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 QI is not needed for constituents naturally present in foods which have not been added as ingredients. Examples are caffeine (in coffee), vitamins and minerals (in fruit juice);
- A QI is not needed for 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.

Specific situations where the QI requirements do not apply

These are:

(a) In respect of an ingredient or category of ingredients -

- The drained net weight which is indicated in accordance with point 5 of Annex IX, e.g. canned carrots in brine.
- The quantities of which are already required to be given on the labelling under other Union provisions (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.

³ See Regulation 7 of The Food Information (Scotland) Regulations 2014 (as amended) regarding products that are not pre-packed containing meat

- 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 (e.g. products, such as pickles and sauces, which are highly processed and in which it is only the spices and/or flavourings which are likely to distinguish one product from another).
- (b) Where specific Union provisions stipulate precisely the quantity of an ingredient or a 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) In the cases referred to in points 4 and 5 of Part A of Annex VII, foods which contain either a mixture of vegetables, fruit, mushrooms, 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 sweetener(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 to a nutritional declaration to the food in question i.e. those vitamins and minerals in point 1 of Part A of Annex XIII and present in significant amounts as defined in Part 2 of Part A of Annex XIII.

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.

Formula used to calculate the QI

• For foods that require further processing:

QI % =	Wt. of ingredient in mixing bowl	x 100
	Total Wt. of all ingredients in mixing bowl	

• For foods that have been thermally processed:

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) A declaration 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.

Position of the QI (Annex VIII (3)(b))

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. A more detailed account of the application of the QI rules is provided in the FSA guidance.

https://www.food.gov.uk/sites/default/files/multimedia/pdfs/quid.pdf

The guidance remains useful and includes details on:

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

European Commission guidance for implementing the principle of QUID

While this guidance was first published in 1998 and some of the legislation referred to has been repealed, the general principles remain valid.

2.4 Appropriate Durability Indication

Date marking provisions (Article 24 and Annex X)

The majority of pre-packed foods are required to have an indication of minimum durability. There are however exemptions which are set out in Annex X to FIC. These are:

- Fresh fruit or vegetables including potatoes that have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts.
- Wine, liqueur wine, sparkling wine, aromatised wine and any similar products obtained from fruit other than grapes and beverages falling into CN Code 2206 00 obtained from grapes or grapes musts.
- Any drink with an alcoholic strength by volume of 10% or more.
- Baker's or pastry cook's wares which given the nature of their content are normally consumed within 24 hours of preparation.
- Vinegar.
- Cooking salt.
- Solid sugar.
- Confectionary products consisting almost solely of flavoured and/or coloured sugars.
- Chewing gums and similar chewing products.

There are two types of durability indication for pre-packed foods:

- 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 and after a short period are likely to constitute an immediate danger to human health. The food should be consumed by the end of the date given.

The Defra/FSA guidance on the application of date labels to food, issued in September 2011, still applies and can be found at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69316/pb132 629-food-date-labelling-110915.pdf

Form used for the 'best before' date mark Article 24(2) and Annex X

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
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
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
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 year only

If need be, these particulars shall be followed by a description of the storage condition which must be observed if the product is to keep for the specified period.

Form used for the 'use by' date mark Article 24(2) and Annex X

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 must be observed e.g. 'Keep refrigerated – store at 5 degrees centigrade'.

Flexibility in application Article 24(2) and Annex X

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).

Foods that should carry a 'Use By' Date

In the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the 'use by' date.

Storage conditions given with the date mark (Article 25)

Storage conditions and conditions of use must be given, where appropriate, to ensure the proper storage and use of the food and that the consumer can use the food in the way intended. Pictograms and symbols (such as a snowflake to indicate frozen storage or star marking) may be used only in addition to, rather than in place of, mandatory information expressed in words and numbers.

Sale of food with expired shelf life

It is an offence to sell food that has exceeded its 'use by' date. After a 'use by' date a food shall be deemed to be unsafe in accordance with Article 14(2) and 5 of Regulation (EC) No 178/2002. There is no obligation on Enforcement Officers to prove that the food is unsafe in order to prosecute an offence under the General Food Regulations 2004 (as amended for Scotland).

Selling a food after its 'best before' date is not an offence. Whilst it may not be an offence under the food information 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 1990.

Date of First Freezing (Article 24 and Annex III and Annex X)

The date of freezing (or first freezing if frozen more than once) for frozen meat, frozen meat preparations and frozen unprocessed fisheries products is required under Article 24 and Annex X of FIC. This date shall be preceded by the words 'Frozen on'. The date must consist of the day, the month and the year in that order. The actual date, given as part of the date of first freezing requirement, may appear separately from the words 'Frozen On', provided these words are followed by a reference to the place where the date appears (*e.g. Frozen on: see side of pack*), which is a similar format to the durability date referred to paragraph 2.2.5.4.

2.5 Special Storage Conditions and/or Conditions of Use (Articles 9 (1)(g) and 25)

Meaning of 'Special Storage Conditions or Conditions of Use'

Special storage conditions or conditions of use should be given, where appropriate, to ensure the proper storage and use of the food. For example:

- 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'); 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 must accompany the date mark are intended to ensure that the consumer knows how to store the food if it is to last as long as the date indicates while it remains unopened.

Pictograms and symbols (such as snowflakes to indicate frozen storage or star marking) may be used only in addition to, rather than in place of, mandatory information expressed in words and numbers.

Conditions for use

Conditions 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 safe cooking and microwave instructions for a product that can only be microwaved.

2.6 Name and Address

Name and Address (Article 8(1) and Article 9 (1)(h))

Article 9 (1) requires the name and address of the food business operator under whose name the food is being marketed, or where the food is imported, the importer established with the EU.

The details provided for the address should be sufficient to enable the purchaser to contact the business. A contact telephone number, e-mail address, or other non-physical contact details would not be an acceptable replacement for the full postal address of the food business operator (FBO).

2.7 Origin

Origin Labelling - (Articles 9, 26 and Annex XI)

Mandatory origin requirements

Article 26 of FIC as read with Article 9, requires the mandatory display on food labels of the country of origin or place of provenance where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance

'Place of provenance' is defined within FIC as any place where a food is indicated to come from, and that is not the 'country of origin' as determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92.

For meat falling within the Combined Nomenclature ('CN') codes listed in Annex XI i.e. from pigs, sheep, goats and poultry the requirements are contained within Regulation (EU) No 1337/2013.

Requirements when giving origin information for multi-ingredient foods

Where the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient:

- (a) the country of origin or place of provenance of the primary ingredient in question shall also be given; or
- (b) the country of origin or place of provenance of the primary ingredient shall be indicated as being different to that of the food.

As at November 2016, EU discussions remain ongoing regarding an Implementing Act to govern this area.

Article 26 also tasked the European Commission to carry out reports to the European Parliament and the Council on the feasibility of extending mandatory origin requirements to a range of other foods. These are:

- types of meat other than beef, pork, lamb, goat and poultry;
- milk;
- milk used as an ingredient in dairy products;
- unprocessed foods;
- single ingredient products;
- ingredients that represent more than 50 % of a food;
- meat used as an ingredient in processed foods.

On 20 May 2015, the Commission produced reports on the foods mentioned at the first six bullet points above which considered: maintaining a voluntary approach; requiring mandatory information at Member State or 3rd Country level and; requiring mandatory information at EU/non-EU level.

Following discussion of the reports at EU level, the Commission concluded that they favoured maintaining the current voluntary approach. Concerns included the likelihood of higher costs to consumers and producers due to the additional traceability systems and labelling information necessary to support mandatory origin information.

In December 2013, the Commission published a report into the feasibility of extending mandatory country of origin labelling to meat used as an ingredient in processed foods. The report contained an impact assessment that highlighted the high cost to food sector businesses of any potential regulation. Following this report, the Commission has indicated that they favour a voluntary approach to country of origin information other than for specific foods where EU rules have already been introduced.

The Trade Descriptions Act 1968 and FIC provide similar definitions of 'origin.'

For the purposes of the Trade Descriptions 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 FIC. 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.

Avoiding Misleading Labelling in Relation to Origin Labelling

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 food business operator or importer established in EU under whose name the food is being marketed is a mandatory labelling requirement. This information should not be provided in a way that incorrectly implies origin.

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 given as set out in any applicable regulation, clearly worded and that only products to which the claim applies are presented or associated with those indications.

In catering establishments, care should be taken to ensure the wording of any voluntary origin information on menus etc. does not mislead the consumer and is clear and unambiguous.

Summary of Commission Implementing Regulation (EU) No 1337/2013

The Commission implementing rules were published in the Official Journal of the European Union on 13 December 2013 and lays down rules for the application of FIC as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry. The principal provisions may be summarised as follows:

Article 1: Scope: This establishes the range of species as outlined above.

Article 2: Definitions: Trimmings and batch are defined

Article 3: Traceability. This established the need to have a traceability system to facilitate accurate designations used for origin/provenance that can be traced back to source **Article 4:** Defines group of animals

Article 5: Labelling of meat:

- 1. Pre-packed meat intended for the final consumers must be labelled with the following information as appropriate for the species involved:
 - (a) the Member State or third country in which the rearing took place indicated as 'Reared in: (name of the Member State or third country)', in accordance with the following criteria:
 - i. for swine:
 - in the case the animal is slaughtered older than 6 months, the Member State or third country in which the last rearing period of at least 4 months took place;
 - in the case the animal is slaughtered younger than 6 months and with a live weight of at least 80 kilograms, the Member State or third country in which the rearing period after the animal has reached 30 kilograms took place;
 - in the case the animal is slaughtered younger than 6 months and with a live weight of less than 80 kilograms, the Member State or third country in which the whole rearing period took place.
 - ii. for sheep and goats:
 - the Member State or third country in which the last rearing period of at least 6 months took place or, in case the animal is slaughtered younger than 6 months, the Member State or third country in which the whole rearing period took place;
 - iii. for poultry:
 - the Member State or third country in which the last rearing period of at least one month took place or, in case the animal is slaughtered younger than one month, the Member State or third country in which the whole rearing period after the animal was placed for fattening took place.
 - (b) the Member State or third country in which the slaughter took place indicated as 'Slaughtered in: (name of the Member State or third country)'; and
 - (c) the batch code identifying the meat supplied to the consumer or mass caterer.

Where the rearing period referred to in point (a) is not attained in any of the Member States or third countries where the animal was reared, the indication referred to in point (a) shall be replaced by 'Reared in: several Member States of the EU' or, where the meat or the animals have been imported into the Union, by 'Reared in: several non-EU countries' or 'Reared in: several EU and non-EU countries'.

However, where the rearing period referred to in point (a) is not attained in any of the Member States or third countries where the animal was reared, the indication referred to in point (a) may be replaced by 'Reared in: (list of the Member States or third countries where the animal was reared)' if the food business operator proves to the satisfaction of the competent authority that the animal was reared in those Member States or third countries.

- 2. The indications referred to in points (a) and (b) of paragraph 1 may be replaced by the indication 'Origin: (name of Member State or third country)' if the food business operator proves to the satisfaction of the competent authority that the meat referred to in Article 1 has been obtained from animals born, reared and slaughtered in one single Member State or third country.
- 3. Where several pieces of meat, of the same or of different species, correspond to different labelling indications in accordance with paragraphs 1 and 2 and are presented in the same pack to the consumer or mass caterer, the label shall indicate:
 - a) the list of the relevant Member States or third countries in accordance with paragraphs 1 or 2, for each species;
 - b) the batch code identifying the meat supplied to the consumer or mass caterer.

Article 6: Derogation for meat from third countries

Article 7: Derogations for minced meat and trimmings

Article 8: of the Implementing Regulation 1337/2013 outlines the rules concerning additional voluntary information on the label: FBOs may supplement the indications referred to in Articles 5-7 with additional information concerning the provenance of the meat. For example 'Reared in: Scotland, UK'.

That information must not be contrary to the indications in Article 5-7 and must also comply with Chapter V of the FIC on voluntary information.

Article 9: The requirements of the implementing regulation applied from 1 April 2015.

<u>Commission Implementing Regulation (EU) No 1337/2013</u> regarding the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry is covered later in this Manual under the heading The Country of Origin of Certain Meats (Scotland) Regulations 2016.</u>

2.8 Omission of Certain Particulars (Article 16)

In the case of glass bottles intended for reuse and which are indelibly marked the following particulars of Article 9(1) shall be mandatory:

- Name of the food
- Allergenic ingredients
- Net quantity
- Minimum durability
- Nutrition declaration

In the case of packaging or containers the largest surface of which has an area of less than 10 cm², only the following particulars of Article 9(1) shall be mandatory on the package or on the label:

- Name of the food
- Allergenic ingredients
- Net quantity
- Minimum durability

An ingredients list shall be provided through other means or shall be made available at the request of the consumer.

Mandatory nutrition information is not required for the following foods listed in Annex V of FIC:

- 1. Unprocessed products that comprise a single ingredient or category of ingredients;
- 2. Processed products which the only processing they have been subjected to is maturing and that comprise a single ingredient or category of ingredients;
- 3. Waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings;
- 4. A herb, a spice or mixtures thereof;
- 5. Salt and salt substitutes;
- 6. Table top sweeteners;
- Products covered by Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts, whole or milled coffee beans and whole or milled decaffeinated coffee beans;
- 8. Herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea or tea extract, decaffeinated instant or soluble tea or tea extract, which do not contain other added ingredients than flavourings which do not modify the nutritional value of the tea;
- 9. Fermented vinegars and substitutes for vinegar, including those where the only added ingredients are flavourings;
- 10. Flavourings;
- 11. Food additives;
- 12. Processing aids;
- 13. Food enzymes;
- 14. Gelatine;
- 15. Jam setting compounds;
- 16. Yeast;
- 17. Chewing-gums;

- 18. Food in packaging or containers the largest surface of which has an area of less than 25 cm²;
- 19. Food, including handcrafted food, directly supplied by the manufacturer of small quantities of products to the final consumer or to local retail establishments directly supplying the final consumer.

(Guidance on the interpretation of 'small quantities' and 'local establishments' can be found at: <u>https://consult.foodstandards.gov.scot/regulatory-policy/nutrition-labelling</u>).

An ingredients list and a nutrition declaration shall not be mandatory for beverages containing more than 1.2% by volume of alcohol.

2.9 Allergen Labelling (Article 9(1) and Annex II and Article 21)

Allergen labelling rules applied from 13 December 2014

Allergen information is required on the labelling of pre-packed foods as set out in Article 9(1)(c) and Annex II. The former provisions of EC Directive 2000/13 (as amended) are carried forward in FIC and there is the extra requirement to emphasise allergens within the ingredients list. Currently there are 14 allergenic substances and associated derivatives listed in Annex II which need to be declared where used as an ingredient or processing aid. The Commission can add to this list as and when necessary.

Allergen information for foods sold loose

Under FIC, allergen information is mandatory where food is offered for sale to the final consumer or to mass caterers without pre-packaging, or where foods are packed on the sales premises at the customer's request, or "pre-packed for direct sale". Food Business Operators (FBOs) selling "loose" food, e.g. caterers, delicatessens, butchers, bakers, confectioners, stalls and vehicles selling loose unwrapped food, will all be required to provide allergen information. There is however flexibility about how this information is given under these circumstances i.e. it may be written on a ticket, notice, label, menu, or as verbal information given by staff working in the premises (as set out in regulation 5 of the Food Information (Scotland) Regulations 2014 (as amended)). Where allergen information can be obtained.

To provide the information verbally FBOs will need to consider setting up a system that helps them identify the various different food and compound ingredients that contain allergenic food ingredients. This will require identifying the allergens either on the food labels or commercial documents when the food is delivered to the establishment and advising the recipes which accurately reflect the ingredients used and highlight and identify the allergenic components. These recipes will need to be reviewed when changes to a recipe are made or ingredient suppliers changed.

In a catering setting the food business operator has the option of identifying each allergenic ingredient for specific dishes or may choose to insert a statement advising customers with a food allergy to seek further details of the possible allergenic components in the food of their choice.

In a bakery setting similarly the baker must capture specifications for all raw materials identifying allergenic ingredients and establish accurate recipes which highlight and identify the allergenic ingredients.

In relation to foods sold loose, individual labels could be provided naming the various allergenic ingredients or alternatively a general notice could be displayed in a conspicuous position in the shop advising customers with a food allergy to seek advice from the designated person to provide information on food allergens in food on display.

Allergen information for food offered for sale by distance selling

- With respect to pre-packed food: Allergen information must be available before the purchase is concluded, and at the moment of delivery.
- FBOs selling non-pre-packed food through distance selling (e.g. such as a takeaway food business which offers purchase through telephone or internet) will need to ensure that mandatory allergen information is available to the consumer:
 - before the purchase is concluded; and
 - o at the point of delivery.

The allergen information should be held in written form by the business and available in written form at some point between a consumer placing the order and taking delivery of it.

Relevant parts of the EU FIC are detailed as follows:-

Article 9

The list of mandatory particulars which have to be given on food labels include the labelling of allergens or their derivatives (Article 9(1) (c)), as listed in Annex II. If any processing aid or ingredient, derived from a substance or product listed in Annex II of the FIC, known to cause allergies or intolerances, is used in the manufacture or preparation of food, and is still present in the finished product, even in an altered state, it must be clearly declared on the labelling, and emphasised to ensure it stands out from the other ingredients within the ingredients list.

EU FIC Annex II – Substances or products causing allergies or intolerances:-

Annex II lists the ingredients or processing aids causing food allergies that are recognised across Europe. If there is a food product which contains or uses an ingredient or processing aid derived from any one of the 14 substances or products listed in Annex II, it will need to be declared, by the FBO regardless of the level of use.

The products specified in Annex II are:

- 1. **Cereals** containing gluten, namely: wheat (such as spelt and Khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:
 - a) wheat based glucose syrups including dextrose;
 - b) wheat based maltodextrins;
 - c) glucose syrups based on barley;
 - d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin.
- 2. Crustaceans and products thereof.
- 3. Eggs and products thereof.
- 4. Fish and products thereof, except:
 - a) fish gelatine used as carrier for vitamin or carotenoid preparations;
 - b) fish gelatine or Isinglass used as fining agent in beer and wine.
- 5. Peanuts and products thereof;

- 6. **Soybeans** and products thereof, except:
 - a) fully refined soybean oil and fat;
 - b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
 - c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
 - d) plant stanol ester produced from vegetable oil sterols from soybean sources.
- 7. Milk and products thereof (including lactose), except:
 - a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
 - b) lactitol.
- Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin.
- 9. Celery and products thereof.
- 10. Mustard and products thereof.
- 11. Sesame seeds and products thereof.
- 12. **Sulphur dioxide** and **sulphites** at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.
- 13. Lupin and products thereof.
- 14. **Molluscs** and products thereof.

All information about ingredients from the Annex II list (above) must be emphasised in a contrasting font to other ingredients to clearly differentiate them from other ingredients.

Article 13 (1) - (4)

All written mandatory allergenic information should be clear and legible and not, in any way hidden or obscured, and where appropriate, indelible.

Minimum font sizes on labels are stipulated for all labelling. Icons or symbols should not be used without words to ensure consumers can understand the information.

Article 19

Where the name of the product consists of a single ingredient e.g. mustard powder, peanuts; and the name clearly refers to the presence of an Annex II ingredient, further indication of the presence of the substance or product (in this case mustard, peanuts) is not required.

Article 21

Information about the Annex II ingredients will need to be emphasised within the ingredients list by means of contrasting font, size, style or background colour.

For example, "INGREDIENTS: Oatmeal, sunflower oil, prawn (crustaceans)".

The presence of allergens for each ingredient needs to be declared, even if there are several ingredients from the same allergenic food.

Example Label

INGREDIENTS: Water, Carrots, Onions, Red Lentils (4.5%) Potatoes, Cauliflower, Leeks, Peas, Cornflour, **Wheat**flour (with calcium, iron, niacin and thiamin), Salt, **Cream**, Yeast Extract, Concentrated Tomato Paste, Garlic, Sugar, **Celery** Seed, Vegetable Oil (sunflower), Herb and Spice, White Pepper, Parsley.

If the name of an ingredient partly includes the Annex II allergen in a single word, then the name of the ingredient corresponding to the Annex II food can be emphasised. For example, "wheatflour" or the entire name "wheatflour".

Where the ingredient comprises several words, only the Annex II food should be emphasised.

For example, "skimmed milk powder" "Egg powder".

There is certain flexibility as regard to the means of maintaining emphasis, so it can be done for example by typeset of a different **font**, <u>style</u>, or <u>colour</u> (see Articles 12 and 13 of FIC for more information).

For some ingredients it might be clear from the use of a common name that they are products that are made from an Annex II food (such as cheese, butter, yoghurt and cream) and these type of products may not need further qualification of their allergenic origin.

For small packaging where the largest surface area of the food packaging or container is less than 10 cm², and the ingredient list has been omitted (Article 16 – omission of certain particulars), the presence of Annex II ingredients in the food should still be stipulated e.g. by the word "contains..." followed by the name of the substance or product (e.g. Contains: celery, sulphites, fish).

Some foods are sold under a less common name due to appellation, trade name, foreign cuisine etc., which makes it difficult to tell whether they contain any of the Annex II products or substances (e.g. **tilapia (fish), ghee (milk), edamame (soya)**). In such cases, further qualification is required.

Some foods do not require an ingredients list (e.g. wine). However, they will need to declare the presence of any substances or products derived from the Annex II list. For example, wine could have a statement such as "**Contains: sulphites**" if sulphites are used to preserve the wine.

The use of allergen advisory statements such as "Contains nuts", to provide supplementary allergen information to that already provided in the ingredients lists is not permitted. Information about allergens as ingredients may only be presented in the required format (i.e. emphasised within the ingredients list). This is so that the information is presented in a common format across food products to avoid potential consumer confusion.

The use of a food allergy/ intolerance warning box which signposts the consumer to the ingredients list, and how the substances or products causing allergies or intolerances are emphasised in the list, is permitted.

For example:-

Allergy Advice For allergens, including cereals containing gluten, see ingredients in **bold**/underlined/red. Or For allergens, see ingredients in **bold**/underlined/red.

The voluntary declaration of gluten following the mandatory declaration of a cereal containing gluten is permitted, but it should not be emphasised e.g. **wheat** (gluten).

Article 36

Food businesses often use precautionary allergen statements to indicate the risk of the unintentional presence of an allergen in a food product, due to the allergen entering the product accidentally during production, through close contact or cross contamination.

The voluntary use of precautionary allergen statements is still permitted. Food businesses may choose to use different phrases to warn of allergen crosscontamination risks, e.g.

- May contain x
- Made on equipment that also processes x
- Made in a factory that also processes x.

The application of precautionary allergen labelling should only be applied after a thorough risk assessment and there is considered to be a real risk to the consumer. These different phrases describe how the risk arises, but are not indicative of the severity of risk. Therefore none of these warnings should be read as being more or less serious than another phrase.

Terms 'Gluten Free' and 'Very Low Gluten'

The EU requirements relating to 'Gluten Free' and 'Very Low Gluten' claims on food are detailed in Commission Implementing Regulation (EU) No 828/2014, for which the enforcement powers are provided by The Food Information (Scotland) Amendment Regulations 2016 which can be found at: http://www.legislation.gov.uk/ssi/2016/191/made/data.pdf

Claims that a food is 'gluten-free' or contains 'very low gluten' are specifically controlled whether the food is sold pre-packed or loose. Gluten-free foods can have no more than 20 ppm gluten. Foods containing ingredients that have been processed to reduce their gluten content or had the gluten containing ingredients substituted, can be labelled 'very low gluten' when they contain no more than 100 ppm gluten. The terms 'suitable for coeliacs' and 'suitable for people intolerant to gluten' can be used to supplement the 'gluten-free' and 'very low gluten' claims.

The phrase 'no gluten-containing ingredients' can no longer be applied to 'normal' foods. The Food Standards Agency (FSA) Allergen and Intolerance team interpret this to mean that the phrase cannot be used for a single pre-packed food or for a dish on a menu. They have decided that it could be used to cover a separate selection of products available for sale in a shop (or online) and for non-pre-packed foods it could be used when listing a group of products/dishes or a separate section in a menu e.g. a caterer could have a specific menu or page entitled 'No gluten containing ingredients menu'. This statement can only be used if the products cannot be guaranteed to be gluten-free.

References to further information on food allergens

The Food Standards Agency website section on food allergen labelling: http://www.food.gov.uk/science/allergy-intolerance

This gives access to the following resources for allergen information:

- FSA Technical Guidance and Q&A
- Online training
- EU FIC communication toolkit
- EU FIC presentation to local businesses
- Letter and poster for schools
- Leaflets for businesses and consumers
- Infographics and their artwork
- Allergy videos
- Allergen artwork
- Factsheet
- Posters and templates

<u>UK food industry guidance on allergen labelling</u> and the requirements in FIC as published by the British Retail Consortium (BRC) in partnership with the Food and Drink Federation

European Commission guidance on the EU FIC:

Allergen Labelling for Wine

Although wine is exempt from showing a list of ingredients, the statement 'Contains sulphur dioxide (or sulphites/sulfites)' must be shown, if the finished wine contains more than 10 mg per litre of SO_2 (which many table wines will have).

For the UK market, this should be in English following the general principle of intelligibility for the final consumer. Other languages may also be shown. Similarly, the presence of wine fining agents based on milk or eggs must be indicated on the label using the statement

'Contains' followed by:

- 'egg', 'egg protein', 'egg product', 'egg lysozyme' or 'egg albumin';
- 'milk', 'milk products', 'milk casein' or 'milk protein'.

Use of symbols:

In addition to the compulsory labelling, the optional use of pictograms is permitted.

References to further information on wine labelling

FSA guidance on Allergens Labelling for Wine

Regulation (EU) No 579/2012 (covers milk and eggs)

Wine regulations, including Commission Regulation (EC) No 607/2009

Languages permitted in each Member State

European Food Safety Authority

2.10 Manner of Marking and Labelling

Presentation of Mandatory Particulars

Mandatory food information must be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It must not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material. Voluntary food information must not be displayed to the detriment of the space available for mandatory food information.

When appearing on the package or on the label attached thereto, the mandatory particulars listed in Article 9(1) of the FIC must be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height is equal to or greater than 1.2 mm.



Legend

- 1 Ascender line
- 2 Cap line
- 3 Mean line
- 4 Baseline
- 5 Descender line
- 6 x-height
- 7 Font size

In the case of packaging or containers, the largest surface of which has an area of less than 80 cm², the x-height must be equal to or greater than 0.9 mm.

When preparing print specifications it will be important for the FBO to clearly indicate this requirement at the label design stage, along with all the other mandatory requirements.

Same Field of Vision

Under the FIC, the following particulars must appear in the same field of vision:

- the name of the product;
- the net quantity of food;
- the actual alcoholic strength by volume for beverages containing more than 1.2% by volume of alcohol.

Field of vision is defined in the FIC as meaning "all the surfaces of a package that can be read from a single viewing point".

2.11 Nutrition Labelling (Articles 29 - 34)

Mandatory nutrition labelling

From 13 December 2016, the requirement for nutrition information became mandatory for most pre-packaged foodstuffs. Previously, a nutrition declaration was only required when making a nutrition or health claim or adding vitamins and minerals to food. For food businesses that provide nutrition information on a voluntary basis, the declaration must comply with the requirements in the FIC.

There are a number of foodstuffs which are exempt from the mandatory requirement to provide nutrition information and these are listed in Annex V of FIC and include unprocessed products that comprise a single ingredient or category of ingredients, herbs, spices, salt, chewing gums and foods in packaging or containers the largest surface of which has an area of less than 25 cm². Also included in the exemption is food, including handcrafted food directly supplied by the manufacturer of small quantities of products to the final consumer or to local retail establishments directly supplying the final consumer. FSS advice on interpreting 'small quantities' and 'local' for purposes of this exemption is available at: https://consult.foodstandards.gov.scot/regulatory-policy/nutrition-labelling

To facilitate the comparison of products in different package sizes, the requirement that the mandatory nutrition declaration should refer to 100 g or 100 ml amounts has been retained.

Portion-based declarations are allowed in addition to this where food is pre-packed and individual portions or consumption units are identified.

The format of the nutrition table has changed in the FIC, in so far as the mandatory declaration is as follows:

- a) energy value; and
- b) the amounts of:
 - fat,
 - saturates,
 - carbohydrate,
 - sugars,
 - protein, and
 - salt.

An example of the nutrition panel showing both mandatory and permitted supplementary nutrients is given below:

Energy	kJ and kcal
<u>Fat</u>	g
of which:	
- <u>saturates</u>	g
- monoun <u>saturates</u>	g
- polyunsaturates	g
Carbohydrate	g
of which:	
- <u>sugars</u>	g
- polyols	g
- starch	g
Fibre	g
Protein	g
Salt	g
Vitamins and minerals	Units as per Annex XIII

Front of Pack Nutrition Labelling

All components of the mandatory nutrition declaration should be in the same field of vision on the foodstuff packaging. In addition, on a voluntary basis, listed elements of the nutrition information may be repeated in the principal field of vision, in order to help consumers to easily see the essential nutrition information when purchasing foods.

Where the labelling of a pre-packed food provides the mandatory nutrition declaration, the following information may be repeated:

(a) **Energy** value alone; or

(b) Energy value together with the amounts of fat, saturates, sugars, and salt

In the case of beverages containing more than 1.2% by volume of alcohol, the content of the declaration may be limited to the energy value only.

Additional forms of expression (AFE)

Nutrition information may be expressed in other ways, for example colour coding of nutrients. However, the use of AFE must meet certain tightly defined criteria, for example they must be based on sound and scientifically valid consumer research.

Criteria for acceptance

The energy value and the amount of nutrients may be given by other forms of expression – presented using graphical forms or symbols as well as words or numbers. However, the forms of expression must meet the following criteria:

• They are based on sound and scientifically valid consumer research and do not mislead the consumer.

- They are developed as a result of stakeholder consultation.
- They aim to facilitate consumer understanding of the contribution or importance of the food to the diet.
- They are supported by scientifically valid evidence of understanding of such forms of expression or presentation by the average consumer.
- In the case of other forms of expression, they are based on harmonised reference intakes or on generally accepted scientific advice.
- They are objective and non-discriminatory.
- They do not create obstacles to the free movement of goods.

Government recommendations and notification requirements

Member States may recommend to businesses the use of one or more additional forms of expression or presentation, but must inform the European Commission. Member States must monitor the use of AFE on their territory and may require businesses that label foods with additional forms of expression to notify the competent authority.

Recommended additional form of expression in the UK

The four UK governments have published guidance on creating a front of pack nutrition label. It supports the Health Ministers' recommendation on the use of colour coding as an additional form of expression.

A front of pack label developed in accordance with the guidance contains:

- Energy (kJ and kcal) per 100 g or 100 ml and in a specified portion
- Amounts of fat, saturates, sugars and salt in a specified portion
- Portion size information
- % Reference Intake information based on the amount of each nutrient and energy value in a portion
- Red, amber and green colour coding of the nutrients (not energy)



of an adult's reference intake Typical values (as sold) per 100g: Energy 966kJ / 230kcal

The descriptors "High", "Medium" and "Low" can also be used. Please click on the link below to view guidance:

Guide to creating a front of pack (FoP) nutrition label for pre-packed products sold through retail outlets

2.12 Nutrition Claims

Nutrition and health claims on foods are controlled in the EU by dedicated legislation, Regulation (EU) No. 1924/2006, which is separate from the rest of the general controls on food information. The Regulation defines 'claim', 'nutrition claim' and 'health claim'.

The Commission has established an EU register of nutrition and health claims made on foods, which is available online.

The register includes:

- the permitted nutrition claims and their conditions of use;
- the authorised health claims, split into their different types;
- the non-authorised health claims, split into their different types, with the reasons for their non-authorisation.

The register can be freely searched at: EU Register of nutrition and health claims made on foods

For further information on the Nutrition and Health Claims (Scotland) Regulations 2007 please go to Section 3.

2.13 Labelling Requirements for Alcoholic Drinks other than Spirit 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 Scotland.

The general food labelling rules concerning the presentation and labelling of foodstuffs apply to spirit drinks. However, specific labelling and presentation rules are provided for by Regulation (EC) No 110/2008 of the European Parliament and the Council of 15 January 2008 on the definition, description, presentation, labelling and protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89.

The labelling of Community-controlled wine is governed by European legislation. The following link gives some useful notes on rules pertaining to wine. <u>Wine Labelling Guidance</u>

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.

List of ingredients

Alcoholic drinks containing more than 1.2 % by volume of alcohol are exempt from requiring an ingredients list pending a report and possible future implementing acts from the European Commission.

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.

Special storage conditions or conditions of use

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

Name and Address (Article 8(1))

The food business operator responsible for food information is the operator under whose name or business name the food is marketed or, if that operator is not established in the EU, the importer into the EU market. The FBO responsible for the food information must ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions. A contact telephone number, e-mail address, or other non-physical contact details would not be an acceptable replacement for the FBO address.

Place of origin of the product

There is no obligation to provide origin information on alcoholic drinks other than spirit drinks. Origin would only be required when a claim has been made by the FBO. Clearly if a beer was brewed in one country but described as originating in another would be misleading to the consumer.

Instructions for use

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

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 Annex XII of FIC.

The following national measures on no/low alcohol terms from the Food Labelling Regulations 1996 (as amended) will be retained until 13 December 2018. Specified descriptions can be used to describe drinks of not more than 1.2% (abv).

- '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%.

As these are national measures there are no requirements for imported alcoholic drinks to be labelled with these terms or to comply with the standards specified.

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.

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'. Regulation (EC) No 110/2008 on the definition, description, presentation, labelling and the protection of geographic indications of spirit drinks (and repealing Council Regulation 1576/89) lays down definitions, minimum strengths and certain other labelling requirements for spirit drinks can be found at: Regulation (EC) No 110/2008

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.

2.14 Voluntary Information

Where food information referred to in Articles 9 and 10 of FIC is provided on a voluntary basis, such information must comply with the requirements laid down in Sections 2 and 3 of Chapter IV e.g.

Section 2

- Name of food (Article 17)
- List of ingredients (Article 18)
- Omission of list of ingredients (Article 19)
- Omission of constituents of food from the list of ingredients (Article 20)
- Labelling of certain substances or products causing allergies or intolerance (Article 21)
- Quantitative indication of ingredients (Article 22)
- Net quantity (Article 23)
- Minimum durability date, use by date and date of freezing (Article 24)
- Storage conditions or conditions of use (Article 25)
- Country of origin or place of provenance (Article 26)
- Instructions for use (Article 27)
- Alcoholic strength (Article 28)

Section 3

- Nutrition content (Article 30)
- Calculation (Article 31)
- Expression per 100 g or per 100 ml (Article 32)
- Expression on a per portion basis or per consumption unit (Article 33)
- Presentation (Article 34)
- Additional forms of expression (Article 35)

Food information provided on a voluntary basis must also meet the following requirements:

- a) it shall not mislead the consumer, as referred to in Article 7;
- b) it shall not be ambiguous or confusing for the consumer; and
- c) it shall, where appropriate, be based on the relevant scientific data.

The Commission must adopt implementing acts on the following voluntary food information:

- a) information on the possible and unintentional presence in food of substances or products causing allergies or intolerances;
- b) information related to suitability of a food for vegetarians or vegans; and
- c) the indication of reference intakes for specific population groups in addition to the reference intakes set out in Annex XIII.

Those implementing acts must be adopted in accordance with the examination procedure referred to in Article 48(2).

In order to ensure that consumers are appropriately informed, where voluntary food information is provided by food business operators on a divergent basis which might mislead or confuse the consumer, the Commission may, by means of delegated acts, in accordance with Article 51, provide for additional cases of provision of voluntary food information to the ones referred to in paragraph 3 of this Article.

Presentation (Article 37)

Voluntary food information must not be displayed to the detriment of the space available for mandatory food information.

2.15 National Provisions and Derogations

Milk and Milk Products Derogation

Member States can adopt measures to derogate from the mandatory labelling provisions set out in Articles 9(1) and 10(1). In the case of milk and milk products presented in glass bottles intended for re-use, this derogation is available to FBOs in Scotland.

2.16 Food Information (Scotland) Regulations 2014 (as amended) (SSI 2014 No. 312)

The 2014 Regulations provide for the enforcement of the EU Food Information to Consumers Regulation take up some of the permitted flexibilities and set penalties for non-compliance with the European and Scottish requirements.

The 2014 Regulations also maintain national provisions for certain types of food sold loose and provide for flexibility in the way allergen information can be provided for loose foods and in catering situations.

Flexibilities

- Regulation 3 takes up the derogation (flexibility) available in the FIC for milk and milk products in reusable glass bottles.
- Regulation 4 and Schedule 1 take up the derogation (flexibility) available in the FIC for minced meat which does not comply with the compositional standards.

National provisions on food sold non-pre-packed

- Regulation 5 gives businesses flexibility in how they provide allergen information to consumers for food supplied:
 - non-pre-packed (including catering)
 - o packed on the premises at the consumer's request
 - o pre-packed for direct sale
- Regulation 6 maintains the requirement from the Food Labelling Regulations 1996 for the name of the food to be given for food supplied:
 - o non-pre-packed (excluding catering)
 - o packed on the premises at the consumer's request
 - o pre-packed for direct sale

The name must appear on a label attached to the food or on a notice, ticket or label that is readily discernible by an intending purchaser where they choose that food. These requirements do not apply to food supplied by mass caterers either directly or via distance communication to consumers.

- Regulation 7 maintains the requirement from the Food Labelling Regulations 1996 for an indication of the meat content for products containing meat supplied:
 - non-pre-packed (excluding catering)
 - o packed on the premises at the consumer's request
 - o pre-packed for direct sale

The information must appear on a label attached to the food or on a notice, ticket or label that is readily discernible by an intending purchaser where they choose that food. These requirements do not apply to food supplied by mass caterers either directly or via distance communication to consumers.

Annex VII point 17 of Part B of the FIC gives details on how the indication of meat quantity for consumers must be determined. This includes a table of the total amount of fat and connective tissues to be considered where a downward adjustment of the meat content figure is necessary, e.g. the total fat and connective tissue content of the product exceeds the values in the table.

Enforcement

Local Authorities in Scotland have enforcement responsibility for food information legislation in Scotland. The offences are described in Regulation 10 with the penalty for non-compliance. These are:

- A person is guilty of an offence if the person fails to comply with:
 - (a) any specified FIC provision (in Schedule 3);
 - (b) regulation 5(3), (4) or (5);
 - (c) regulation 6(1) as read with 6(4);
 - (d) regulation 7(1) as read with 7(5); or
 - (e) regulation 8(1) or (3).
- Regulation 11 provides for a penalty of a maximum of Level 5 on summary conviction for anyone found guilty of an offence under Regulation 10. Notice provisions are not currently available to support the enforcement of food labelling and standards requirements in Scotland, but this is under consideration.

2.17 Links to resources/further information

Please be aware that Food Standards Agency Guidance remains valid until it is superseded by Food Standards Scotland versions in due course.

Regulation (EU) No 1169/2011 on the provision of food information to consumers

European Commission (FIC Regulation and Commission Q & A)

Food labelling e-learning course

Food Information (Scotland) Regulations 2014

FSA guidance on the Food Information Regulations for food business operators and enforcement officers

Nutrition

Nutrition Labelling Guidance

EC guidance document on tolerances for nutrition labelling purposes

Allergens

Food allergy on-line training

British Retail Consortium (Guidance on food allergens)

FSA Allergen Guidance and materials to assist local authorities and food businesses

'safefood' Video on Allergen Handling

2.18 Food Labelling Regulations 1996 (as amended)

Following the introduction of the EU Food Information to Consumers Regulation, most of the 1996 Regulations were revoked on 13 December 2014 by the Food Information (Scotland) Regulations 2014. Until 13 December 2018, only the parts of Schedule VIII to the 1996 Regulation relating to compositional standards for cream and traditional British cheeses remain in force along with the alcohol definitions mentioned previously.

2.19 Scottish Government Beef Labelling Regulations

The Beef Labelling Scheme

The Beef Labelling Scheme is a European Union (EU) wide system which is intended to provide consumers with clear, accurate information about the beef (including veal) that they are buying. The Scheme is administered in Scotland by the Scottish Government, contact details are supplied in this document.

Compulsory beef labelling applies to fresh and frozen beef and veal at all stages of production from slaughterhouse to retailer. The Beef Labelling (Enforcement) (Scotland) Regulations 2001 (SSI 2001/252) provide the means for enforcement of the system in Scotland.

The labelling of beef (and veal) at processor and retail level is governed by EU Beef and Veal Labelling (Scotland) Regulations 2010. In addition to ensuring traceability, this EUwide 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.

Businesses must supply specific compulsory information giving references and codes to ensure traceability of the beef back to its source. The Scheme has two aims:

- to provide customer information, and
- to ensure traceability

Businesses must provide information that states the countries of birth and rearing (EU or third country); and where the beef was slaughtered and cut. Provision of this information is mandatory, but all other labelling claims require approval, by Scottish Government, under the Beef Labelling Scheme.

The type(s) of beef which must comply with the rules includes whole or part carcasses, cuts and joints, e.g. fresh and frozen sirloin, rump steak, etc. and mince and uncooked beef burger patty with no added ingredients. It does not include uncooked beef that has been seasoned in depth or seasoned on the surface of the product, whether it is visible to the eye or clearly distinguishable by taste. Neither does it include beef and veal which have been incorporated into processed products.

Pre-wrapped beef must be labelled with the required information on its packaging. If packages are grouped together in boxes or cartons then the information can be shown on the box or carton, rather than individual packages.

If the package is split then the information must be transferred to the individual packages. For non-pre-wrapped meat sold to the customers, e.g. shoppers, caterers, etc., the information must be on the meat tray or be displayed within the shop, e.g. on a ticket close to the beef or on a sign visible to the customer. It must be obvious to customers what labelling information applies to which beef. The relevant European legislation is Commission Regulation No. 1760/2000 and Commission Regulation No. 1825/2000.

The Beef Labelling Scheme requires that written information must be given to customers at the point of sale. This includes information given on packaging material and on labels near the product. It also includes information given at the points of sale in advertisements, posters, announcements and leaflets associated with the product. Information given by word of mouth is not covered, although it is an offence under legislation to mislead the consumer.

Information covered by pictures or symbols may require approval too. A summary of the significant definitions is provided below.

Compulsory Information which must accompany beef and veal includes;

- Reference number/code this is a traceability reference number or reference code which ensures the link between the animal or group of animals from which it is derived. (For a retail outlet, any reference number or code enabling traceability can be used provided there is a link through your register and documentation to your supplier's reference number/code).
- Member state or third country whether the animal or group of animals were born – this this must be a single member state or single third country. A regional name, e.g. 'Aberdeenshire' or 'Scotland' is not enough. Meat from animals born in different countries cannot be together in the same batch.
- Member state or third country where the animal or group of animals were raised this must include all of the countries where the animal lived between birth and slaughter and each animal in a group must have lived in each of the countries listed. If the animal spent less than 30 days immediately after birth in the country of birth, then you do not have to list it.

Similarly if the animal spent less than 30 days immediately before slaughter in the country of slaughter then you do not have to list that country on the label as a country of rearing.

If beef was derived from animals that were born, raised and slaughtered in the same country, then separate details are not needed. It is enough to state 'Origin; name of member state or third country', e.g. 'British beef – origin: UK' and the label would have to show 'slaughtered in the UK (licence number), cut in UK (licence number(s)' together with the reference number/code.

• **Member state or third country of** slaughter – labelling must include the words 'slaughtered in (name of member state or third country)'. This must be a single member state or third country.

- **Approval number of the** slaughterhouse this is the approval number which has been granted to the establishment by the Food Standards Agency (UK plants) and which appears on the health mark stamp.
- **Approval number of the cutting** plant this is the approval number which has been granted to the establishment by Food Standards Scotland and which appears on the operator's identification mark. The labelling must also include the Member State or third country in which the plant is established.

Meat from animals aged 12 months or less

When labelling meat from animals aged 12 months or less at slaughter, additional indications must be made:

- Age on slaughter: up to 8 months (or V) and Veal; or
- Age on slaughter: from 8 to 12 months (or Z) and Beef

Labelling of Beef Mince

Mince must be labelled with the following indications:

- The reference number/code this traces back to the source animal, group of animals of batches of beef used for mincing.
- The member state or third country of slaughter beef minced in UK may be derived from animals slaughtered in more than one country but not more than two countries. Labelling must include the words 'slaughtered in (names of countries)'.
- The member state or third country of mincing mince must show the country where the beef was minced. The batch must be minced in only one country. Labelling must include the words 'minced in (name of country)'.

You should be aware that machines must be cleaned between mincing of batches where animals have been slaughtered in a different country or mix of two countries. If different from the country of mincing, all the countries where the animals lived must be indicated. The label must include the words 'Origin: name of member state or third country' or if non-EU then 'origin non-EC'. This information does not have to be shown if the country of mincing is the same as the country of origin.

Non-Compulsory Information Requiring Approval

Non-compulsory information labelling requires to be approved by an independent verifier before it can be used. The following are examples of information for which approval is needed:

- region or local origin where the animal was born and reared
- breed or crossbreed
- age or sex of the animal
- method of production e.g. organic, farm assured, grass assured, grass-fed etc.
- method of slaughter e.g. halal, kosher, etc.
- date of slaughter
- method or length of maturation.

If beef is labelled with this type of information it is required that it is common to all animals/ meat from which it was sourced. The terms must be clear to consumers.

If it cannot be guaranteed that all labelling is accurate and common to all meat or animals from which the beef is sourced, then applications may not be approved.

It is required to employ an independent verifier, accredited to European Standard EN45011, who will check traceability system to ensure labelling information is true. This verifier must be employed at the businesses expense. The verifier must be allowed access to the premises at all times to check records and systems of work. Verification must cover all outlets at which beef is sold.

Application for Approval

To apply for approval of labelling producers/businesses should apply for an application pack and return the completed application to:

The Beef Labelling Section Scottish Government Livestock Policy Branch B1 Spur Saughton House Broomhouse Drive Edinburgh, EH11 3XD

Telephone number: 0330-244-9290

A list of independent verifiers can also be obtained from this address.

Non-Compulsory Information Not Requiring Approval

Besides non-compulsory labelling not requiring approval, any information that can be easily checked at the point of sale also does not need approval. This includes:

- name of the product or cut
- the weight of the product
- the 'best before' or 'use-by' dates
- storage conditions or conditions of use
- instructions for use
- name and address of manufacturer, packer, seller etc.
- details of any atmospheric packaging
- health marks.

In-House Traceability

All operators in the supply chain must operate a system of recording which will link animals/ beef to reference numbers/codes of the beef sold. The information it should contain depends on the nature of the business. It should record the reception and despatch of each carcase, part-carcase, primal cut, etc.

Examples of what may be included are:

- intake date
- name of supplier
- delivery note details
- kill date
- weight
- UK ear tag/cattle passport number or reference code
- product (cut)
- tray number or colour
- date displayed
- reference numbers/codes
- compulsory labelling

Poultry Meat

The **Poultrymeat Marketing Standards** apply to fresh, chilled, frozen or quick frozen whole carcasses, parts and offal of the following species of poultry only (other areas of legislation may have a wider interpretation of 'poultry'):

- Domestic fowl (gallus domesticus) (e.g. meat (broiler) chickens, laying hens, etc.)
- Ducks
- Geese
- Turkeys
- and Guinea fowls.

The following products are not covered:

- Prepared or preserved poultry (e.g. cooked, processed, treated or value added products/recipe dishes);
- Poultry meat intended for export from the EC;
- Sale from farms with an annual production of under 10,000 birds, providing the farmer supplies fresh poultrymeat from the holding direct to the final consumer or to local retail establishments directly supplying to the final consumer; or
- New York Dressed poultry (i.e. delayed evisceration poultry, such as Traditional Farm Fresh turkeys).

NOTE: The above would, if pre-packed, still have to comply with Regulation (EU) No 1169/2011 on the provision of food information to consumers.

Marketing Standards

The **Poultrymeat Marketing Standards** were adopted to facilitate harmonised standards throughout the EU for the marketing of poultrymeat intended for human consumption. They relate in particular to the classification by quality, weight, packaging (including labelling), water content and storage.

In this guide, the term 'Poultrymeat Marketing Standards' refers to Council Regulation (EEC) No 1906/90 on certain marketing standards for poultrymeat and Commission Regulation (EEC) No 1538/91 introducing detailed rules for implementing (EEC) No 1906/90.

Special Marketing Term (SMT)

Poultrymeat marketing standards allow optional indications of certain alternative farming methods, often referred to as Special Marketing Terms (SMT's).

These specify the criteria which must be met before claims about certain types of farming can be made. The standards seek to protect the consumer by setting high uniform standards and providing informative labelling. They also protect the producer against unfair competition.

An example of a SMT would be '**Free Range**' on pre-packed poultry meat. In order to comply with this claim, the producer must comply with the criteria set out in the Poultry Meat Marketing Standards. The same would apply to terms such as 'Organic', 'Corn Fed' and 'Traditional Free Range'.

More detailed information and guidance is available at <u>www.defra.gov.uk</u>.

Note: A ticket or sign showing the name, e.g. Fresh Whole Chicken with weight would be sufficient when displayed for sale.

The Poultrymeat (Scotland) Regulations 2001 (SSI 318) introduce statutory controls on the marketing of poultry meat following changes agreed at EU level. The regulations revoke the Poultry Meat (Water Content) (Scotland) Regulations 1983 and the Poultry Meat (Water Content) (Scotland) (Amendment) Regulations. The regulations will apply to those involved in the production, slaughter, processing and sale.

Links to regulations:

The Beef and Veal Labelling (Scotland) Regulations 2010

SECTION 3 – LEGISLATION GUIDANCE – ALPHABETICAL ORDER

Legislation under A

The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (SSI No. 325)

Legislation under B

Bread and Flour Regulations 1998 (SI No. 141)

Legislation under C

Caseins and Caseinates (Scotland) Regulations 1986 (SI No. 836) 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 2013 (SSI No. 217) Country of Origin of Certain Meat (Scotland) Regulations 2016 (SSI No. 84)

Legislation under D

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

Legislation under E

Legislation under F

The Fish Labelling (Scotland) Regulations 2013 (SSI 2013 No. 256) (as amended)

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

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

Food Additives (Scotland) Amendment Regulations 2012 (SSI No. 119)

Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 226)

Food Enzymes (Scotland) Regulations 2009 (SSI No. 435) (as amended)

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)

Legislation under F (cont'd)

Food Irradiation (Scotland) Regulations 2009 (SSI No. 261)
Food (Lot Marking) Regulations 1996 (SI No. 1502)
Food Supplements (Scotland) Regulations 2003 (SI No. 273) (as amended)
Foods for Special Medical Purposes (Scotland) Regulations 2000 (SSI No. 130)
Foods for Specific Groups (Scotland) Regulations 2016
Fruit Juices and Fruit Nectars (Scotland) Regulations 2013 (SSI No. 305)

Legislation under G

The Genetically Modified Food (Scotland) Regulations 2004 (SSI No. 432) The Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 (SSI No. 438)

Legislation under H

The Honey (Scotland) Regulations 2015 (SSI No. 208)

Legislation under I

Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (SSI No. 549) Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008 (SSI No. 322)

Legislation under J

The 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

Legislation under M

The Materials and Articles in Contact with Food (Scotland) Regulations 2012 (S.S.I. No. 318)

Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (SI No 1263)

Legislation under N

Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (SI No. 483)

Novel Foods and Novel Food Ingredients Regulations 1997(SI No. 1335)

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

Legislation under O

Legislation under P

The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 (SSI. 2011 No. 282)

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)

The Products Containing Meat etc. (Scotland) Regulations 2014 (SSI 2014 No. 289) (as amended)

Legislation under Q

Quick Frozen Foodstuffs Amendment (Scotland) Regulations 2007 (SSI No. 110)

Legislation under R

Legislation under S

Specified Products from China (Restriction on First Placing on the Market (Scotland) Regulations 2008 (SSI No. 148)

Specified Products from China (Restriction on First Placing on the Market) (Scotland) Amendment Regulations 2012 (SSI No. 3)

Specified Sugar Products (Scotland) Regulations 2003 (SSI No. 527) Spirit Drinks Regulations 2008 (SSI 3206)

Spirit Drinks Regulations 2008 (SI No. 3206)

The Spreadable Fats, Milk and Milk Products (Scotland) Regulations 2008 (SSI No. 216) (as amended)

Legislation under T

Tryptophan in Food (Scotland) Regulations 2005 (SSI No. 479)

Legislation under U, V, W, X, Y and Z

The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (SSI No. 325)

Scope

There are a wide range of nutrients and other ingredients that might be used in food products (but not limited to) vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts.

There 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 31 December 2009.

Associated Regulations

The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 SSI No 325

The Addition of Vitamins, Minerals and Other Substances (Scotland) Amendment Regulations 2010 (SSI No 308)

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

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

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, bun loaves, chapattis, pitta bread, potato bread or bread specially prepared for sufferers of coeliac disease.
- 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 0.2%, 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 Food Additives (Scotland) Regulations 2009 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. For example 'White', 'Brown' or 'Sodabread'.

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.

Associated Regulations

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

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

Further Information

Bakers Federation web page

FSA Bread and Flour Guidance Notes

Caseins and Caseinates (Scotland) Regulations 1986 (SI No. 836)

Scope

These regulations implement <u>Commission Directive 83/417/EEC</u> relating to certain lactoproteins (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 microbiological 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 (not currently available on legislation.gov.uk) were amended 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.

Associated Regulations

Caseins and Caseinates (Amendment) (Scotland) Regulations 1990 (SI No. 1)

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

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 <u>must</u> be used in the <u>name of the food</u>.

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 Information (Scotland) Regulations 2014 made an amendment to these regulations to move the requirements previously set out in Schedule 8 Part 1 of the Food Labelling Regulations 1996 (as amended) to regulation 5 (d) of these regulations so 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 <u>Schedule 2 of the Regulations</u>.

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 Food Additives Regulations⁴. These provide restrictions on the specific sweeteners that may be used and Regulation (EU) No 1169/2011 requires additional labelling to indicate their presence.

⁴ EC Regulation 1333/2008

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

- a) <u>'Chocolate' including some added sugars with sweeteners</u> used to replace part of the sugar is a chocolate product and must comply with Coca and Chocolate Products Regulations.
- b) '<u>Chocolate' with no added sugars and no added sweeteners</u> 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 description 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) <u>'Chocolate' where there are no added sugars but with added sweeteners</u>. 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 Food Additives Regulations and additional labelling requirements in Regulation (EU) No 1169/2011. 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 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 820 g/80 g = 25%Is calculated on Cocoa solids 2020 g/98 g = 20%Vegetable fats 4 Hazelnut 18 Lecitin 1 Vanillin 1 Total 100 g

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.

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.

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

Further Information

The FSA guidance notes (Revised June 2009) 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

Column 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 - for other cocoa butter, not more than 0.5 per cent unsaponifiable matter (so determined).
2. (a)	Cocoa powder <i>or</i> 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 <i>or</i> Fat-reduced cocoa powder	Cocoa powder containing less than 20 per cent cocoa butter, calculated according to the weight of the dry matter
(c)	Powdered chocolate <i>or</i> Chocolate in powder	The product consisting of a mixture of cocoa powder and sugars, containing not less than 32 per cent cocoa powder.

(d)	Drinking chocolate <i>or</i> Sweetened cocoa <i>or</i> Sweetened cocoa powder	The product consisting of a mixture of cocoa powder and sugars, containing not less than 25 per cent cocoa powder.
	 (e) Fat-reduced drinking chocolate or Fat-reduced sweetened cocoa or Fat-reduced sweetened cocoa powder 	The product consisting of a mixture of cocoa powder specified at item 2(b) and sugars, containing not less than 25 per cent of such 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) (i)	If "Chocolate" is supplemented by "vermicelli" <i>or</i> "flakes"	The product presented in the form of granules or flakes containing not less than 32 per cent 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 Derivatives of "Gianduja"	The nut chocolate product obtained (1) from chocolate having a minimum total dry cocoa 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:
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 total fat (cocoa butter and milk fat).

(b) (i)	If "Milk chocolate" is supplemented by - "vermicelli" or "flakes"	The product presented in the form of granules or flakes containing not less than 20 per cent 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).
(ii)	"couverture"	The product containing a minimum total fat (cocoa butter and milk fat) content of 31 per cent.
(iii)	"Gianduja" <i>or</i> one of the derivatives of "Gianduja"	The nut milk chocolate product obtained (1) from milk chocolate having a minimum content of 10 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 (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) (i)	If "Milk" is replaced by - "cream"	The product containing a minimum milk fat content of 5.5 per cent.

(ii)	"skimmed milk"	The product containing a milk fat content not
(11)	Skinineu mik	
		greater than 1 per cent.
5.	Family milk chocolate or	The product obtained from cocoa products,
Milk c	hocolate	sugars and milk or milk products which
		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.
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7.	Filled chocolate or	The filled product, the outer part of which
Chocolate with filling or		consists of a product specified in column 2 of
Chocolate with centre		item 3, 4, 5 or 6 and constitutes not less than
		25 per cent of the total weight or 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.
9.	Chocolate familiar a la	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.
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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.
- 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 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 Regulation (EU) No 1169/2011. 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 from a declaration of the minimum coffee / chicory based dry matter content expressed as a percentage.
- In the case of coffee extracts in liquid from containing more than 25% coffee based dry matter and for chicory extracts in liquid from 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.

Associated Regulations

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

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

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

SCHEDULE

Annex 1 Table

Coffee Extracts and their Reserved Descriptions

Column 1		Column 2
Reserved descrip	tions	Designated Products
	<i>or</i> Soluble coffee ant coffee <i>or</i> Soluble	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.
extract or Instant	supplemented in each case by the word "paste" or the words "in paste form"	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.
extract or Instant	supplemented in each case by the word "liquid" or the words "in liquid form"	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 descr	iptions	Designated Products
 Chicory extract <i>or</i> Instant chicory <i>or</i> Soluble chicory 		Chicory extracts in powder, granular, flake, cube or other solid form, of which the chicory-based dry matter content is not less than 95%. NOTE: This product may contain no more than 1% of substances not derived from chicory.
2. Chicory extract <i>or</i> Instant chicory <i>or</i> Soluble chicory	supplemented in each case by the word "paste" or the words "in paste form"	Chicory extracts in paste form, of which the chicory-based dry matter content is not more than 85%, and not less than 70%. NOTE: This product may contain no more than 1% of substances not derived from chicory.

3. Chicory	supplemented in each	Chicory extracts in liquid form, of
extract or	case by the word	which the chicory-based dry
Instant chicory	"liquid" or the words "in	matter content is not more than
or	liquid form"	55%, and not less than 25%.
Soluble chicory		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. 311)

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>, Regulation (EU) No 1169/2011 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 SSI 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 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 Regulation (EU) No 1169/2011. 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 skimmed-milk 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 Regulation (EU) No 1169/2011, 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 SSI 2003

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

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)

The Condensed Milk and Dried Milk (Amendment) (Scotland) Regulations 2003 (SSI No. 492)

Food Safety Act 1990

Specified Sugar Products (Scotland) Regulations 2003

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

The Food Additives (Scotland) Regulations 2009

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

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

Food Standards Scotland 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	Partly dehydrated milk containing, by weight, not more than 1% fat, and not less than 20% total milk solids.
- Types of sweetened condensed milk	Partly dehydrated milk with an
(e) Sweetened condensed milk	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	Partly dehydrated milk with an
skimmed milk	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	Partly dehydrated milk with an
milk	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.

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

2. Totally 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

- 1. 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
 - 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.
- 2. 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).
- 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.
- 4. 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.
- 5. 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 party 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 2013 SSI No 217

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 contributions 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	-	Nitrite
Section 2	2 —	Mycotoxins

- Ochratoxin A
- Patulin
- Deoxynivalenol
- Zearalenone
- Fumonisins
- T-2 and HT-2 Toxin
- Citrinin

- Lead

- Ergot sclertoria and ergot alkaloids

Section 3 – Metals

- Cadmium
- Mercury
- Tin (inorganic)
- Arsenic (inorganic)
- Section 4 3-monochloropropane-1, 2-diol (3-MCPD)
- Section 5 Dioxins and PCB's
- Section 6 Polycyclic aromatic hydrocarbons Benzo(a)pyrene
- Section 7 Melamine and its structural analogues
- Section 8 Inherent plant toxins

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

Contaminants in Food (Scotland) Regulations 2013 (SSI 217) 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 aflatoxins, 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.

When the Contaminants in Food Regulations (Scotland) 2010 were drafted in 2010 a provision was inserted to allow for an 'ambulatory reference'. The effect of this is that any amendments made by the EU to the Annex to Commission Regulation 1881/2006 apply in Scotland when they are amended in the EU and no further Scotland/domestic legislation is required to bring them into effect.

Associated Regulations

Contaminants in Food (Scotland) Regulations 2013 (SSI 217)

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

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

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

Commission Regulation (EU) No. 835/2011 amending Regulation 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs

Commission Regulation (EU) No. 836/2011 amending Regulation 337/2007 laying down the methods of sampling and analysis for the official control of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs

Further Information

FSA Guidance on the Contaminants in Food (Scotland) Regulations

Country of Origin of Certain Meat (Scotland) Regulations 2016 (SSI No. 84)

Scope

These Regulations make provision to enforce implementing Regulation (EU) No 1337/2013 (the EU Regulation) laying down rules for the application of Regulation (EU) No 1169/2011 (FIC) as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry.

Ingredients/Products

The EU Regulation covers pre-packed fresh, chilled and frozen meat of swine, sheep, goat and poultry.

Please note: The EU Regulation does not currently cover non-pre-packed or 'loose' products. So if the meat is presented without packaging at the point of sale e.g. on a butchers counter display, origin labelling is not currently required.

Labelling requirements contained in EU Regulation

Article 5 of this regulation requires that all fresh, chilled and frozen pork, lamb, goat and poultry meat will have to be labelled with an indication of:

- i. the place of rearing;
- ii. the place of slaughter of the animal from which the meat is obtained; and
- iii. a batch code identifying the meat at retail.

FBO's must be able to demonstrate that they *can establish the link* between the meat and the animal at slaughter, evidenced by records showing their country of origin (Article 3).

Each business will be responsible for the maintenance of their records as set out in regulation 5 of the Country of Origin of Certain Meats (Scotland) Regulations 2016. There is a minimum 12 month retention period from the end of the calendar year to ensure compliance.

Mandatory labelling of a batch code identifying the meat at retail

Packs of meat must carry a batch code that clearly identifies the origin of the meat. This means that the code can be referenced with other information to enable food businesses to demonstrate the accuracy of the information on the label (Article 5(1)(c) of the EU Regulation).

A definition of batch code is provided in regulation 2(1) of the domestic Regulation as: "Any existing mark on a label or packaging, such as a date mark or lot number, which a food business operator can demonstrate, when cross referenced with other information, allows them to identify the origins of the meat".

A food business should be able to demonstrate that the batch code chosen is one that is valid for determining the accuracy of the mandatory origin claims.

Article 3: Traceability: Identification of animal

FBOs must have an identification and registration system in place which must be applied to ensure:

- i. At slaughter stage, a link between the meat and the animal or group from which it has been obtained Slaughterhouses responsibility;
- **ii.** Transmission of information relating to the country of origin labelling with the meat, to operations at subsequent stages of production and distribution FBO responsibility.

Article 4: Group of animals

The size of a group of animals discussed in Article 3 is to be defined by:

- the number of carcases cut together and constituting one batch for the cutting plant in the case of cutting carcasses;
- It is the number of carcases the meat of which constitutes one batch for the cutting or mincing plant concerned in case of further cutting or mincing.

"Batch" is defined in Article 2(b) as "meat, falling within the Combined Nomenclature codes listed in Annex XI to Regulation (EU) No 1169/2011, obtained from a single species, with or without bone, whether or not cut or minced, that has been cut, minced or packed under practically identical conditions."

The size of a batch cannot exceed the production of one day.

When constituting a batch, establishments in which meat is cut or minced must ensure that all carcasses in a batch correspond to animals whose meat requires identical labelling indications; (except where Article 7 is applied).

Article 5: Labelling of meat - compulsory requirements

Rearing Criteria

Swine

The criteria set out in Article 5(1)(a)(i) determine the place of rearing where:

- The animal is slaughtered older than 6 months, the Member State or Third Country in which the last rearing period of at least 4 months took place;
- The animal is slaughtered younger than 6 months and with a live weight of at least 80 kilograms, the Member State or third country in which the rearing period after the animal had reached 30 kilos took place;
- The animal is slaughtered younger than 6 months and with a live weight of less than 80 kilograms, the Member State or third country in which the whole rearing period took place.

Slaughter age/weight Indication on label

Member State or Third Country of Rearing	Slaughtered ≥ 6 months old	Reared In: Member state or third country in which last rearing period of at least 4 months took place.
Member State or Third Country of Rearing	Slaughtered < 6 months old and at least 80 kg liveweight	Reared In: Member state or third country in which rearing from 30 kg took place.
Member State or Third Country of Rearing	Slaughtered < 6 months old and < 80 kg liveweight	Reared In: Member state or third country in which the whole rearing period took place.
Member State or Third Country of Slaughter		Slaughtered in: Member State or third country where animal was slaughtered.
Origin Labelling (Voluntary Indication) Reserved for animals Born, Reared and Slaughtered in a single EU Member state or Third Country.		Origin: Member State or Third Country.
Batch Number		Assigned by FBO in accordance with requirements of Regulation (EU) No 1337/2013.

Sheep and goats

For sheep and goats, the following criteria are also outlined in Article 5(1)(a)(ii) determine place of rearing where:

• The Member State or third country in which the last rearing period of at least 6 months took place; or the animal is slaughtered younger than 6 months, the Member State or third country in which the whole rearing period took place.

Indication on label Slaughter age/weight **Member State or Third** Slaughtered \geq 6 months Reared In: Member state **Country of Rearing** old or third country in which last rearing period of at least 6 months took place. Member State or Third Slaughtered < 6 months Reared In: Member state **Country of Rearing** old or third country in which the whole rearing period took place. Member State or Third Slaughtered in: Member ---**Country of Slaughter** State or third country where animal was

Origin Labelling
(Voluntary Indication)
Reserved for animals
Born, Reared and
Slaughtered in a single EU
Member state or Third
Country.---Origin: Member State or
Third Country.Batch Number------Assigned by FBO in

Assigned by FBO in accordance with requirements of Regulation (EU) No 1337/2013.

slaughtered.

Poultry

For poultry the rearing criteria are set out in Article 5(1)(a)(iii) to determine place of rearing where:

• The member state or third country in which the last period of at least one month took place or, the animal is slaughtered younger than one month it would be the Member State or third country in which the entire rearing period after the animal was placed for fattening took place.

Slaughter age/weight Indication on label

Member State or Third Country of Rearing	Slaughtered ≥ 1 month old	Reared In: Member state or third country in which last rearing period of at least 1 month took place.
Member State or Third Country of Rearing	Slaughtered < 1 month old	Reared In: Member state or third country in which the whole rearing period took place.
Member State or Third Country of Slaughter		Slaughtered in: Member State or third country where animal was slaughtered.
Origin Labelling (Voluntary Indication) Reserved for animals Born, Reared and Slaughtered in a single EU Member state or Third Country.		Origin: Member State or Third Country.
Batch Number		Assigned by FBO in accordance with requirements of Regulation (EU) No

When the rearing criteria are not met

Article 5(1) explains that where the rearing period as explained is not attained in any of the Member States or third countries where the animal was reared then the indication must be replaced by:

1337/2013.

- \circ "Reared in: several Member States of the EU" or
- o "Reared in: several non-EU countries" or
- o "Reared in: several EU and non-EU countries"

In the situation where the FBO can prove to the enforcing authority of the Member States or third countries that the animal was reared in then these can be specified:

- o "Reared in UK and Ireland" or
- o "Reared in UK and Denmark" or
- o "Reared in Thailand and Ireland and UK"

These can be used instead of "Reared in several Member States of the EU".

Slaughter labelling as a compulsory requirement

Article 5(1)(b) requires the Member State or third country in which the slaughter took place to be indicated on the label as:

"Slaughtered in: (Member State name or third country)"

Origin labelling as a compulsory requirement

Article 5(2) allows the term "Origin: (Name of Member State or third country)" to replace the terms required by Article 5(1)(a) and (b) (reared and slaughtered) if the FBO proves to the satisfaction of the competent authority that the meat has been obtained from animals born, reared and slaughtered in one single Member State or third country.

Several pieces of meat labelling as a compulsory requirement

Article 5(3) requires that where several pieces of meat, (of the same or of different species), are presented in the same pack to the consumer or mass caterer which *correspond to different labelling indications* in respect of *"reared in"* and or *"slaughtered in"*, the label must indicate:

- The list of Member States or third countries in accordance with Article 5(1) or (2) for each species
- The batch code identifying the meat supplied to the consumer or mass caterer

Article 6: Derogation for meat from third countries

Article 6 of Regulation (EU) No 1337/2013 allows meat referred to in Article 1 imported for placing on the EU market from a non EU source to indicate on the label:

- "Reared in non-EU" and
- o "Slaughtered in (name of the third country where the animal was slaughtered)"

Article 7: Derogation for minced meat and trimmings

Article 7 provides a derogation from Articles 5 (1)(a) and (b), 5(2) and 6 for minced meat and trimmings whereby a range of alternative indications may be applied related to "EU" and "Non EU origin".

For example:

"Origin EU" may be used when the minced meat comes from animals born, reared and slaughtered in different EU Member States or "reared and slaughtered in: non- EU" where minced meat or trimmings are produced exclusively from meat imported into the Union.

Article 8: Additional Voluntary information

Under Article 8 there are provisions for **additional voluntary information** to be provided on the label. This voluntary information on the provenance of the meat is allowed as long as it does not contradict the mandatory statements and complies with Chapter V of Regulation (EU) No 1169/2011 scientific data (where appropriate).

e.g. Reared in: Scotland, UK

Associated Regulations

The Country of Origin of Certain Meats (Scotland) Regulations 2016

Commission Implementing Regulations (EU) No 1337/2013

Drinking Milk (Scotland) Regulations 2011 (SSI No. 84)

Scope

These Regulations made provisions for the enforcement of Article 114(2) of, and Annex XIII to, <u>Council Regulation (EC) No 1234/2007</u> 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

Associated Regulations

Council Regulation (EC) No. 2597/97

Drinking Milk (Scotland) Regulations 2011 SSI No. 84

The Fish Labelling (Scotland) Regulations 2013 (SSI No. 256) (as amended)

Scope

These regulations implement the provisions of Regulation (EU) No 1379/2013 on the common organisation of the markets in fishery and aquaculture products. They also enforce the traceability requirements of Council Regulation (EC) No. 1224/2009 establishing a community control system for ensuring compliance with the rules of the common fisheries policy and Article 67 of Commission Implementing Regulation (EU) No. 404/2011 laying down detailed rules for the implementation of Council regulation (EC) No. 1224/2009.

These Regulations require fish sold at retail to be labelled with all of the following information:

- Commercial name of the fish species. It requires Member States to establish a list of commercial designation of fish species which are names prescribed by law. A live upto-date list of accepted names can be found at the link below: <u>Commercial Designations of Fish</u>
- 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)
- The need to have the scientific name available to consumers on fish when sold prepacked or loose. In the case of loose fish, the scientific name may appear on a billboard or poster.
- The need to have information available to consumers about whether or not the fish has been previously frozen. There are exemptions from this requirement for fish which has been frozen at sea to preserve it until the vessel reaches port and also for fish defrosted prior to smoking, salting, cooking, pickling, drying or a combination of those processes.

New requirements to provide the consumer with additional information on fishery products at retail stage have been introduced throughout the EU and applied from 13 December 2014. The new requirements will provide information on fishery products to include:

- The equipment used to catch the fish
- The date of minimum durability

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 afore-mentioned 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 app;ly to sales of <u>small quantities</u> of fish⁵ sold directly to the final consumer by either fisherman (e.g. from the quayside) or aquaculture producers (e.g. from lakes, ponds, etc.).

⁵ (to the value of less than £17 (€20)

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, FSS 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 '<u>caught</u>' or '<u>caught in</u>' 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 '<u>caught</u>' or '<u>caught</u> 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</u> give 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, FSS *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 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 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-pre-packed e.g. at supermarket fish counters, fishmongers, etc.)

The manned of marking for food which is not pre-packed and sole 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, *FSS 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 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, Marine Scotland <u>marinescotland@scotland.gsi.gov.uk</u> 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.

Associated Regulations

The Fish Labelling (Scotland) Regulations 2013 (as amended)

The Fish Labelling (Scotland) Amendment Regulations 2015

<u>Regulation (EU) No 1379/2013</u> – repealed and replaced Regulation (EC) No 104/2000 from 1 January 2014 and introduced revised consumer information requirements from 13 December 2014.

Regulation (EU) No 1420/2013 – repealed Regulation (EC) No 2065/2001 with effect from 13 December 2014.

<u>Council Regulation (EC) No 1224/2009</u> of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy

<u>Commission Implementing Regulation (EU) No. 404/2011</u> of 8 April 2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the Common Fisheries Policy.

Further Information

FSA Quick Guide

CN Codes for fish

Seafish Guidance on traceability and labelling

UK commercial designations of fish

Flavourings in Food (Scotland) Regulations 2010 (SSI No. 439)

These Regulations have largely been revoked by the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 226) - only Regulations 1, 2 and 7 still have effect. These relate to consequential amendments to the Food Labelling Regulations 1999.

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

These Regulations have largely been revoked by the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 226) – only Regulations 1, 2, 18 and 19 still have effect. These relate to consequential amendments to the Condensed Milk and Dried Milk (Scotland) Regulations 2003 and the Jam and Similar Products (Scotland) Regulations 2004 (all at regulation 18) and a minor amendment to the Specified Sugar Products (Scotland) Regulations 2003 at Regulation 19.

Food Additives (Scotland) Amendment Regulations 2012 (SSI No. 119)

These Regulations have been partially revoked by the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 226). Regulations 1 and 2(1), (2) (3) and (5) still have effect and relate to consequential amendments to the Food Additives (Scotland) Regulations 2009.

Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 226)

Scope

These regulations provide for the continuing enforcement of the following EU Regulations -

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;
- Regulation (EC) No 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.
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes;
- 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.

These regulations also implement Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

The Regulations revoked all existing statutory rules on food additives, flavourings, food enzymes, smoke flavourings and extraction solvents and replaced them with a single consolidated statutory instrument.

The following instruments are partially revoked:

The Food Enzymes (Scotland) Regulations 2009 The Food Additives (Scotland) Regulations 2009 The Food Additives (Scotland) Amendment Regulations 2012 The Flavourings in Food (Scotland) Regulations 2010

Food Additives

The main impact of the food additives legislation was to:

- Carry forward the community lists of approved food additives (Annex II & III)
- Establish conditions for use of additives encompassing those also acting as enzymes, food flavourings and nutrients.
- Establish rules for labelling food additives sold as such
- Define the carry over principle
- Require labelling specific to the Southampton colours used in food (doesn't apply to food sold non-pre-packed or pre-packed for direct sale)
- Establish purity criteria for permitted food additives.

A food additive is defined as any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

By virtue of this definition there will be some things that can be excluded e.g.

- Normal food and food ingredients.
- Processing aids; There is no legally defined list of approved processing aids but they are regarded to be substances that:
 - 1. is not consumed as a food by itself;
 - 2. is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and
 - 3. may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risks and do not have any technological effect on the final product.
 - Substances added to foods as nutrients, however if they have a dual function then the primary purpose for which these are used will determine whether or not the legislation will apply.
 - Also excluded are substances added to foods as nutrients e.g. minerals, trace elements or vitamins, substances used for the protection of plants and plant products in conformity with European Union rules on plant health e.g. pesticides, herbicides and substances used for the treatment of water.
- The use of additives in wine must comply with Regulation 1333/2008 and with the provisions in the relevant EU legislation on oenological practices and processes.

Additives are allowed on the approved list when they meet the requirements set out in Regulation 1333/2008, i.e.

- do not present safety concerns,
- are technologically justified, and
- do not mislead the consumer.

Additives should also have advantages and benefits for the consumer such as preserving the nutritional quality of food, enhancing its keeping quality or stability, aiding the manufacture and processing of the product or in its transport or storage. Additional specific conditions are also laid down for colours and sweeteners. Conditions of use for food additives in foods, including restricted uses in specified foods and maximum limits, are set out in Annex II.

The maximum limits in the annexes are based on the food as sold unless otherwise specified. However, for dried and/or concentrated foods (including drinks), the maximum limits apply to the food as reconstituted following manufacturers' instructions, taking into account the minimum dilution factor. It is recognised that certain substances, for example phosphates and glutamates, are naturally present in certain foods. The quantitative limits apply to the amount of additive added. There is however, an exception in the case of sulphites, as the legislation requires that the specified quantitative limits include sulphites available from all sources and therefore take into account any natural occurrence of the substance.

Where no numerical limit is set for additive use, a level known as quantum satis (QS) is set requiring that it must not be used at a level higher than is necessary to achieve the intended purpose and must not be used in a way that misleads the consumer.

Carry Over Rule

"Carry-over" provisions apply to most foods permitted to contain food additives, but not to those specially prepared for infants and young children. These provisions permit the presence of a permitted food additive in a compound food, to the extent that the food additive is allowed by the provisions of Annex II of Regulation 1333/2008 in one of the ingredients of the compound food (Article 18.1 (a) refers).

The level of the additive in the final food should be no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice, thus preventing misuse of carry-over.

For example, if a non-heat treated meat product is used as an ingredient in a compound food (e.g. the cooked bacon in a bacon lettuce and tomato (BLT) sandwich), the presence of nitrate would be permitted in the BLT sandwich up to the limit permitted for the cooked bacon.

Reverse Carry over Principle

Permitted food additives may be present in foods (such as intermediary products) in which they would not otherwise be permitted, provided that those foods are to be used solely in the preparation of a compound food that will conform to the provisions of Annex II.

For example, annatto (not normally permitted to be used in seasonings) could be added to a seasoning that is intended solely for use in a snack food, provided the level of annatto does not result in the maximum level of annatto permitted for the snack food being exceeded. The annatto would not be permitted to be added to a seasoning that was intended to be used in a food that is not permitted to contain annatto, such as a minced meat preparation.

Labelling of additives sold as such and business to business sales

Where food additives not intended for sale to the final consumer are sold singly or mixed with each other and/or other food ingredients and/or with other substances added to them, their packaging or containers shall bear the following information:

- (a) the name and/or E-number laid down in this Regulation in respect of each food additive or a sales description which includes the name and/or E-number of each food additive;
- (b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;
- (c) if necessary, the special conditions of storage and/or use;
- (d) a mark identifying the batch or lot;
- (e) instructions for use, if the omission thereof would preclude appropriate use of the food additive;
- (f) the name or business name and address of the manufacturer, packager or seller;
- (g) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the quantum satis principle;
 - (h) the net quantity;
 - (i) the date of minimum durability or use-by-date;
 - (j) where relevant, information on a food additive or other substances referred to in this Article and listed in Annex II to EU Regulation 1169/2011 as regards the indication of allergens present in foodstuffs.

There are a number of additional labelling requirements for table top sweeteners requiring that the sweetener(s) present is indicated in the sales description (e.g. x based table sweetener). Table top sweeteners containing polyols must carry the warning "excessive consumption may induce laxative effects", and table top sweeteners containing aspartame or aspartame-acesulfame salt must be marked with the indication "contains a source of phenylalanine"

Food Colours

The category of colour in food is a subset of food additives. Only a permitted colour may be used in or on food. The function of such colour is to

- (a) restore the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;
- (b) making food more visually appealing;
- (c) giving colour to food otherwise colourless.

Lists of permitted food colours can be found in Annexes II and III of Regulation 1333/2008. Annexes II and III have been populated by way of separate Regulations (Commission Regulations (EU) No's 1129/2011 and 1130/2011) 'as amended'.

Conditions of use for food colours in foods, including restricted uses in specified foods and maximum limits, are set out in Annex II.

Health Marking of certain meat and meat products

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

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

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
- E160b Annatto, Bixin, Norbixin
- E173 Aluminium and
- E180 Litholrubine BK

Southampton colours

Foods containing Tartrazine (E 102), Ponceau 4 R (E 124), Sunset yellow (E 110), Carmoisine (E 122), Quinoline yellow (E 104) and Allura Red (E 129) are required to be labelled with the following additional information:

 'name or E number of the colour(s)': may have an adverse effect on activity and attention in children'.

There is no longer a requirement to indicate additives for food sold non-pre-packed or prepacked for direct sale. This would include the six Southampton colours, which will no longer need to be declared on a notice or a ticket at point of sale.

Food Colourings

EU guidance has been drawn up to distinguish between food colours, which are subject to EU food additives legislation and colouring food extracts, which are not. The guidance describes the criteria that determine the difference between selective and non-selective extraction for the classification of food extracts/concentrates as food colours or colouring foods and proposes a decision tree and checklist to facilitate this classification. The guidance is aimed at industry and enforcement authorities/regulators and is available on the European Commission's website at:

http://ec.europa.eu/food/safety

Specifications for additives and certain restrictions

EC Regulation (EU) No. 231/2012 lays down specifications for food additives listed in Annexes II and III of Regulation 1333/2008. It includes a number of technical changes and clarifications whilst specifications for additives, which are no longer permitted, have been removed (e.g. Red 2G).

EC Regulation (EU) No. 232/2012 amends Annex II to restrict the use and levels for three colours - E 124 Ponceau 4R, E 104 Quinoline Yellow and E 110 Sunset Yellow. The levels of these colours are now restricted in a number of food categories, including soft drinks, confectionery, sauces and seasonings and in some cases (for example Ponceau 4R in sauces and seasonings) are no longer permitted. The Regulation includes a use level of 20 mg/l for Sunset Yellow in soft drinks. EC Regulation 232/2012 is directly applicable in Member States' legislation and applied from 1 June 2013. Foods placed on the market that comply with the provisions of the previous legislation (EC Directive 94/36/EC) can continue to be marketed until stocks are exhausted.

Smoke Flavourings

Smoke used to flavour foods contains carcinogenic components that are harmful to health. Whilst smoke flavourings are produced from smoke, these are purified to reduce some harmful components such as polycyclic aromatic hydrocarbons (PAHs). Smoke flavourings can be used in the production of smoked food (e.g. smoked bacon, smoked salmon) and are also used to provide a smoky/BBQ flavour to snack foods and sauces. These Regulations formally designate Food Standards Scotland 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:

- Prohibit the marketing of smoke flavourings not listed in the authorised list or use outside the criteria and conditions of the authorisation. Commission Regulation (EU) No. 1321/2013 established the Union List of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings.
- 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 the 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.

There are no specific labelling provisions set out in Regulation (EC) No. 2065/2003. The labelling requirement in 1334/2008 (on sale of flavourings to consumers and Business to Business labelling) applies to smoke flavourings. Additionally the EU Food Information for Consumers Regulation (No. 1169/2011) states that if smoke flavouring impart a smoky taste to food then the ingredients list should have "smoke flavouring(s)", or "smoke flavouring(s) produced from "food(s) or food category or source(s)"".

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.

Transitional periods were specified in the Smoke Flavouring Regulation 2065/2003 (Article 20). This states that any foods (including compound flavourings) which contain primary products that are not on the Union list may stay on the market for 12 months after the date of application of the Union list (1 January 2015).

The 12 month transitional period allowed industry time to adapt to the proposed measures and potentially reduce their impact. In addition, foods which were lawfully placed on the market before the end of the transitional period may remain on the market until stocks are exhausted. As the Union list now applies, unapproved primary products cannot be sold in the EU.

Flavourings

Flavourings mean products not intended to be consumed as such which are added to food in order to impart or modify odour and or taste. They are made of or consist of the following categories:

- Flavouring substances;
- Flavouring preparations;
- Thermal process flavourings;
- Smoke flavourings;
- Flavour precursors or;
- Other flavourings.

The definition does not include fresh, dried or frozen spices and or herbs, mixtures of tea and mixtures of infusion as such as long as they have not been used as an ingredient. Substances which have exclusively a sweet, sour or salty taste are outside the scope of the Flavouring Regulation (EC) No. 1334/2008.

Legal Requirements

Article 4: Only flavourings or food ingredients with flavouring properties which do not pose a safety risk to the consumer and do not mislead the consumer may be used in food.

Article 5: A person must not place on the market flavourings or food ingredients with flavouring properties unless they comply with this regulation.

Article 6.1: Substances listed in Part A of Annex III shall not be added as such to food.

Article 6.2: The maximum levels of certain substances naturally present in flavourings and or food ingredients with flavouring properties in the compound foods listed in Part B of Annex III must not be exceeded.

Provision is made to allow for derogation for safrole, methyleugenol and estragole. "The maximum levels shall not apply where a compound food contains no added flavourings and the only food ingredients with flavouring properties which have been added are fresh, dried or frozen herbs and spices. After consultation with the Member States and the Authority, based on data made available by the Member States and on the newest scientific information, and taking into account the use of herbs and spices and natural flavouring preparations, the Commission, if appropriate, proposes amendments to this derogation."

For dried or concentrated food which needs to be re-constituted, the maximum level shall apply to the food as re-constituted according to the instructions on the label taking into consideration the minimum dilution factor.

Article 7: Source materials listed in Part A of Annex IV must not be used for the production of flavourings and or ingredients with flavouring properties.

Flavourings and or food ingredients with flavouring properties listed in Part B Annex IV may be used under the conditions specified.

Article 10: Only approved flavourings and source materials may be placed on the market and used in or on food under the conditions of use specified.

Labelling Requirements for flavourings

Article 14 (1): Flavourings not intended for sale to the final consumer may only be marketed with the labelling provided for in Articles 15 and 16, which must be easily visible, clearly legible and indelible.

The information provided for in Article 15 shall be in a language easily understandable to purchasers. The information set out in Article 15 relating to packaging and containers is as follows:

- (a) the sales description: either the word 'flavouring' or a more specific name or description of the flavouring;
- (b) the statement either 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;
- (c) if necessary, the special conditions for storage and/or use;
- (d) a mark identifying the batch or lot;
- (e) in descending order of weight, a list of:
 - i. the categories of flavourings present and
 - ii. the names of each of the other substances or materials in the product or where appropriate, their E-number;
- (f) the name or business name and address of the manufacturer, packager or seller;
- (g) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law;
- (h) the net quantity;
- (i) a date of minimum durability or use-by-date;
- (j) where relevant, information on a flavouring or other substances referred to in this Article and listed in Annex II to EU Regulation 1169/2011 as regards the indication of allergens present in foodstuffs

Article 16 relates to the use of the term "Natural" requiring that the term 'natural' for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances.

The term 'natural flavouring substance(s)' may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances.

The term 'natural' may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by weight by weight from the source material referred to.

Article 16: The description must read 'natural "food(s) or food category or source(s)" flavouring'.

The term 'natural "food(s) or food category or source(s)" flavouring with other natural flavourings' may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.

The term 'natural flavouring' may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

Article 17: Labelling of flavourings intended for the final consumer: Flavourings sold singly or mixed with each other and/or with other food ingredients and/or to which other substances are added and which are intended for sale to the final consumer may be marketed only if their packaging contains the statement either 'for food' or 'restricted use in food' or a more specific reference to their intended food use, which must be easily visible, clearly legible and indelible. Use of the term "Natural" must comply with the requirements of Article 16.

Other provisions

Article 19: This article imposes a requirement for a producer of flavouring to re-submit an application for a substance already approved if there is a modified production method or characteristics. There is also an obligation to inform the Commission when there is new scientific or technical evidence regarding the safety of an approved flavouring substance.

Food Enzymes

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 Union 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.
- A producer or user of a food enzyme shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food enzyme.

• For a food enzyme already approved under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the European Food Safety Authority (hereinafter referred to as the Authority), a producer or user shall, before marketing the food enzyme, submit to the Commission the necessary data to allow an evaluation of the food enzyme with regard to the modified production method or characteristics to be undertaken by the Authority.

The Union (positive) list is still being developed and will not be in place for several years. The deadline for applications to be in the first Union List was 10 March 2015.

Labelling requirements for Enzymes

- 1. Where food enzymes and their preparations not intended for sale to the final consumer are sold singly or mixed with each other and/or other food ingredients, their packaging or containers must bear the following information:
 - (a) the name laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme or in the absence of such a name, the accepted name;
 - (b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;
 - (c) if necessary, the special conditions of storage and/or use;
 - (d) a mark identifying the batch or lot;
 - (e) instructions for use, if the omission thereof would preclude appropriate use of the food enzyme;
 - (f) the name or business name and address of the manufacturer, packager or seller;
 - (g) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the *quantum satis* principle;
 - (h) the net quantity;
 - (i) the activity of the food enzyme(s);
 - (j) the date of minimum durability or use-by-date;
 - (k) where relevant, information on a food enzyme or other substances as referred to in Article 11 of EC Regulation 1332/2008 and listed in Annex II to EU Regulation 1169/2011.
- 2. Where food enzymes and/or food enzyme preparations are sold mixed with each other and/or with other food ingredients, their packaging or containers shall bear a list of all ingredients in descending order of their percentage by weight of the total.
- 3. The packaging or containers of food enzyme preparations must bear a list of all components in descending order of their percentage by weight of the total.

- 4. By way of derogation from paragraphs 1, 2 and 3, the information required in paragraph 1 points (e) to (g) and in paragraphs 2 and 3 may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question.
- 5. By way of derogation from paragraphs 1, 2 and 3, where food enzymes and food enzyme preparations are supplied in tankers all of the information may appear merely on the accompanying documents relating to the consignment which are to be supplied with the delivery.
- 6. In addition, without prejudice to EU Regulation 1169/2011, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs and Regulation (EC) No. 1829/2003, food enzymes and food enzyme preparations sold singly or mixed with each other and/or other food ingredients intended for sale to the final consumer may be marketed only if their packaging contains the following information:
 - (a) the name laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme or in the absence of such a name, the accepted name;
 - (b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use.
- 7. For the information provided for in paragraph 1 of Article 12 of EC Regulation 1332/2008, Article 8 of EC Regulation 1169/2011 shall apply accordingly.

Extraction Solvents

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 available in Annex I of Directive 2009/32. The Regulations also require that certain information be given with permitted extraction solvents on sale or imported into Scotland from outside the EC.

Annex I Part 2 of Directive 2009/32 defines foods in which only certain extraction solvents may be used and the certain purposes for which they can be used.

Annex I Part 3 of Directive 2009/32 gives maximum permissible residue levels for named extraction solvents when used to prepare flavourings.

Labelling information for extraction solvents

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.

Condemnation of Food

Where the Public Analyst certifies food as contravening these regulations that food may be treated for the purposes of Schedule 9 of the Food Safety 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.

Note: The use in jelly mini-cups of certain additives specified in Annex II of Regulation 1333/2008, and the sale of these jelly mini-cups, is prohibited. Jelly mini-cups are defined as:

Jelly confectionery of a firm consistence, contained in semi-rigid mini-cups or minicapsules, intended to be ingested in a single bite by exerting pressure on the mini-cup or mini-capsule to project the confectionery into the mouth.

In addition, the use of E425 konjac in all jelly confectionery, including jelly mini-cups, and the sale of such confectionery, is not permitted under Regulation 1333/2008

Should you have doubts as to whether a product complies with food additives legislation and requires to be tested further advice can be obtained from Stewart Herd in FSS's Regulatory Policy Branch - <u>stewart.herd@fss.scot</u>

Associated Regulations

The Food additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 SSI No 266

The Food Enzymes (Scotland) Regulations 2009

The Food Additives (Scotland) Regulations 2009

The Food Additives (Scotland) Amendment Regulations 2012

The Flavourings in Food (Scotland) Regulations 2010

Regulation EC 1333/2008 of the European Parliament and of the Council on Food Additives (as amended)

Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives

Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

Regulation (EC) No 2065/2003 on smoke flavourings used for use in or on foods

Regulation for positive list of smoke flavourings Commission Implementing Regulation 1321/2013

Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008

Regulation 1332/2008 on Food Enzymes

Commission Directive 2009/32 on extraction solvents used in the production of foodstuffs and food ingredients

Commission Regulation (EU) 2016/178 of 10 February 2016 amending Annex I to Regulation (EC) No 1334/2008 as regards removal from the Union list of certain flavouring substances

Further Information

Guidance on the labelling of certain food colours as set out in Regulation EC 1333/2008

Current EU approved additives and their E numbers

<u>Guidelines on approaches to the replacement of Tartrazine, Allura Red, Ponceau 4R,</u> <u>Quinoline Yellow, Sunset Yellow and Carmoisine in food and beverages</u>

Food additives legislation: guidance to Compliance

The Food Enzymes (Scotland) Regulations 2009 (SSI 2009 No. 435)

Scope

Regulations 3, 4, 5 and 6 have been revoked by the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 226). The remaining provisions concern consequential amendments to the Food Labelling Regulations 1996, the Caseins and Caseinates Regulations 1985, the Fruit Juices and Fruit Nectars (Scotland) Regulations 2003 and the Novel Food and Novel Food Ingredients Regulations 1997.

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** <u>Commission Directive 2001/15/EC</u> on substances that may be added for specific nutritional purposes in food for particular nutritional uses.

Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control repeals Commission Regulation (EC) No 953/2009 from the date of application of 4 separate delegated acts. (Please see entry on Foods for Specific Groups (Scotland) Regulations 2016)

In the meantime, Commission Regulation (EC) No 953/2009 continues to apply for the addition of substances to the following categories only:

- Foods for special medical purposes;
- Total diet replacement for weight control.

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 <u>Commission Directive 2006/141/EC</u>, <u>Directive 1999/21/EC</u> and <u>Commission Directive 2006/125/EC</u> (which are repealed from the date of application of delegated acts associated with Regulation (EU) 609/2013 – please see entry on Foods for Specific Groups (Scotland) Regulations 2016 for more detail).

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 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 fulfils 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.

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

Commission Directive 2001/15/EC

Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 SI No. 2182(as amended)

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

(a) The legislation essentially deals with food 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 total daily diet.

Composition

The relevant foods must meet certain compositional requirements and be described only as

Total diet replacement for weight control Labelling Requirements

The labelling requirements for the relevant food can be generally summarised as follows:

- Energy value in kj and Kcal
- Protein
- Carbohydrate
- Fat
- Average quantity of each mineral and vitamin specified in the directive
- Instructions for appropriate preparation and importance of following the instructions
- Where 20 g or more polyols will be provided as part of the daily diet when used according to instructions then there should be a statement of laxative effects
- A statement of the importance of maintaining an adequate daily fluid intake
- A statement that the product provides adequate amounts of all essential nutrients and a statement that the produce should not be used for more 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.

Associated Regulations

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

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 SI No. 408

The Foods for Specific Groups (Scotland) Regulations 2016

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended) <u>http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf</u>

Further Information

Commission Directive 96/8/EC

The Advertising Standards Authority have references to the above legislation in their <u>CAP</u> <u>Code</u>.

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	0kGy
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 1.5Y 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
 - o Batch number
 - o 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 FSS and Local Authorities have different roles and responsibilities in relation to enforcement of the regulations. In general it will be the FSS who licence irradiation facilities in the UK.

Labelling Requirements

Regulation (EU) No 1169/2011 requires that a food or food ingredient must bear the treatment description e.g. 1rradiated' or Treated with ionising radiation'.

Associated Regulations

Food Irradiation (Scotland) Regulations 2009 SSI No. 261

Directive 1999/2/EC Food ingredients treated with ionising radiation

Directive 1999/3/EC Establishment of Community list of irradiated foods and food ingredients

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.

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

Scope

These Regulations revoke and replace the Food (Lot Marking) Regulations 1992 and implement <u>Council Directive 89/396/EEC</u> as amended by <u>Council Directives 91/238/EEC</u> and <u>92/11/EEC</u>.

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 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 pre-packaging 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 real 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 prepacked, 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 Regulation (EU) No 1169/2011 requires 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 Regulation (EU) No 1169/2011.

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 retails 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 require 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 <u>92/11/EEC</u>.

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

Further Information

FSA Guidance on Lot marking

Food Supplements (Scotland) Regulations 2003 (SSI No. 278)

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 Article 17 of Regulation EU 1169/2011 Food Information to Consumers.
- 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 amount given must be per portion of the product as recommended on the label and be an average amount based on the manufacurers' 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 EU Food Information to Consumers Regulation No. 1169/2011) at all times to be labelled with name of food, minimum durability, Storage conditions and name or business name and address of the food business operator. 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 discernible 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 (Scotland) (Amendment) Regulations 2007 SSI No. 78 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 Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 SSI No. 438 which incorporates requirements set out in Regulation 1170/2009/EC.

Associated Regulations

Food Supplements (Scotland) Regulations 2003 SSI No. 278

Food Supplements (Scotland) Amendment Regulations 2007 SSI No 78

Food Supplements, Vitamins, minerals and other Substances (Scotland) Regulations 2009 SSI No 438

EC Directive 2002/46/EC relating to food supplements

<u>EC Directive 2001/83/EC</u> relating to medicinal products for human use <u>Commission</u> <u>Directive 2006/37/EC</u> amending 2002/46/EC <u>Commission Regulation (EC) No. 1170/2009</u>

<u>Commission Regulation (EC) No 1161/2011</u> amends the list of mineral permitted for use in food supplements, fortified food and Foods for Particular Nutritional Uses (Parnuts).

From 5 December 2011 the following substances will be permitted for use in food supplements (Directive 2002/46/EC):

- Ferrous Ammonium Phosphate
- Ferric Sodium EDTA
- Sodium Sulphate
- Potassium Sulphate

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

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

Foods for Special Medical Purposes (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 Food Standards Scotland is a statutory requirement under Foods for Special Medical Purposes (Scotland) Regulations 2000 (SSI 2000 No. 130).

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 nourishment.</u>

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 Regulation (EU) No 1169/2011, 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 100 g or 100 ml as appropriate
- Average quantity of each mineral substance and each vitamin mentioned in the annex expressed in numerical form per 10 g or 100 ml as appropriate
- Selectively the contents of components of protein, carbohydrate and fat and or/or other nutrients and their components, the declaration of which would be necessary for the appropriate intended use expressed in numerical form per 100 g or 100 ml 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.

Associated Regulations

Foods for Special Medical Purposes (Scotland) Regulations 2000 SSI No. 130

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 SSI No. 424

Further Information

Commission Directive 1999/21/EC on dietary foods for special medical purposes

The Foods for Specific Groups (Scotland) Regulations 2016 (SSI No 190)

Scope

These Regulations enforce the provisions of Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.

From 20 July 2016, Regulation (EU) 609/2013 repeals the framework Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (referred to as PARNUTS) and replaces it with a new regime for regulating the compositional, labelling and advertising requirements for food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

Ingredients/Products

There are now only 4 categories of food within this framework which are:

- Infant formula and follow-on formula
- Processed cereal-based food and baby food
- Food for special medical purposes
- Total diet replacement for weight control.

Other groups of foods normally considered as foods for particular nutritional uses and for which specific provisions have not been laid down, in particular:

- sports foods
- young child formulae
- meal replacement for weight control
- suitable for diabetic

will, from 20 July 2016, be classed as normal foods, regulated by general food labelling rules.

Delegated Acts

In line with the requirements of the FSG regulation, detailed compositional and labelling rules for relevant foods are to be set out separately. Two delegated regulations have been adopted with a further two expected in due course:

 Commission Delegated Regulation (EU) 2016/127 of 25 September 2015, as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. It shall apply from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2021.

- Commission Delegated Regulation (EU) 2016/128 of 25 September 2015, as regards the specific compositional and information requirements for foods for special medical purposes. It shall apply from 22 February 2019, except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.
- Commission draft Delegated Regulation (EU) .../... of XXX as regards the specific compositional and information requirements for processed cereal-based food and baby food. It shall apply from 3 years after entry into force. *(currently under discussion at EU level)*
- Commission draft Delegated regulation (EU) .../... of XXX as regards the specific compositional and information requirements for total diet replacement for weight control. It shall apply from 5 years after entry into force. (currently under discussion at EU level)

Transition Period

The transition period for the Delegated Regulations on the four categories of food is expected to be 3-5 years as detailed above. The transitional measures in Article 21 of the FSG regulation apply and allows affected foods (such as sports foods and young child formulae) which were placed on the market or labelled before 20 July 2016 to continue to be marketed after that date until stocks of such food are exhausted.

Legislation still in force

The offences and penalties relating to the Delegated Regulations will be put in place nearer to their dates of application (2019 at the earliest) by future amendments to the Scottish Regulations. In the meantime the following pieces of Scottish legislation remain in force:

- The Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (as amended)
- The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004
- The Foods for Special Medical Purposes (Scotland) Regulations 2000
- The Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (as amended). (This has been amended to now only cover total diet replacement)
- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009

Revoked legislation

Where rules are now unnecessary they have been revoked by the new Scottish Regulations, in particular the following piece of legislation has been revoked from 20 July 2016:

• The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 (as amended)

Foodstuffs Suitable for People Intolerant to Gluten

On 20 July 2016, Regulation (EU) 609/2013 on foods for specific groups repealed Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. From that date, the rules on gluten claims are contained in Commission implementing Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. The Foodstuffs Suitable for People Intolerant to Gluten have therefore been repealed by The Food Information (Scotland) Amendment regulations 2016 which also allows for the enforcement of the provisions of commission Implementing regulation (EU) No 828/2014.

Composition requirements

The framework regulation sets out general compositional requirements for the 4 categories of food. They are:

- The composition of food shall be such that it is appropriate for satisfying the nutritional requirements of, and is suitable for, the person for whom it is intended
- It shall not contain any substance in such quantity as to endanger human health for the persons for whom it is intended
- Substances added to the food shall be bio-available for use by the human body, have a nutritional or physiological effect and be suitable for the person for whom the food is intended.

The framework regulation does have an annex detailing substances which may be added to the categories of food it covers however this will not apply until the date of application of the delegated acts.

In the meantime the Food for Particular Nutritional uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009 still applies as do the compositional requirements of the other Scottish regulations which remain in force.

Labelling requirements

The framework regulation sets out general labelling requirements for the 4 categories of food. They are:

- The labelling, presentation and advertising of food shall provide information for the appropriate use of such food, and shall not mislead, or attribute to such food the property of preventing, treating or curing human disease, or imply such properties.
- This shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare.

There are additional requirements for infant formula and follow-on formula which are:

- The labelling, presentation and advertising of infant formula and follow-on formula shall be designed so as not to discourage breast-feeding.
- The labelling, presentation and advertising of infant formula, and the labelling of followon formula shall not include pictures of infants, or other pictures or text which may idealise the use of such formulae.
- Graphic representations for easy identification of infant formula and follow-on formula and for illustrating methods of preparation shall be permitted.

Associated regulations

The Foods for Specific Groups (Scotland) Regulations 2016

Further information

Regulation (EU) No 609/2013

The Fruit Juices and Fruit Nectars (Scotland) Regulations 2013 (SSI No. 305)

The Regulations implement the provisions of Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, as amended by Directive 2012/12/EU.

The regulations control the use of the names fruit juice, fruit juice from concentrate, concentrated fruit juice, water extracted fruit juice, dehydrated fruit juice and powdered fruit juice and fruit nectar and take account of developments in international standards dealing with quality and labelling. The amended text is needed to reflect new rules on authorised ingredients.

The rules set out what additional ingredients and substances may be added to regulated products and what treatments the products may undergo in their manufacture.

The following particulars must be indicated when trading in regulated products:

- Indication of the kinds of fruits or the number of kinds of fruits used;
- Indication of whether extra pulp or cells have been added to a fruit juice;
- A requirement for a fruit juice made from a mixture of fruit juice and fruit juice from concentrate(s) to indicate that it is partially made from concentrate(s);
- A requirement to indicate any added lemon juice, lime juice or acidifying agents in a concentrated fruit juice that is not intended for delivery to the final consumer;
- Indication of the fruit content for a fruit nectar.

Regulation 3 deals with definitions of the different terms such as fruit puree, authorised treatment etc. used in the regulation.

The rules also make provision for the manner in which the particulars are marked and labelled.

Regulated products

The following table identifies the types of regulated product showing how they should be described.

Product name	Specification (x = name of fruit
Fruit juice	"x" juice
Fruit juice from concentrate	"x" juice from concentrate
Concentrated fruit juice	Concentrated "x" juice
Water extracted fruit juice	Water extracted "x" juice
Dehydrated/powdered fruit juice	Dehydrated "x" juice or powdered "x" juice
Fruit nectar	"x" nectar

Kinds of fruit for regulated products

A person must not trade in a regulated product unless the product indicates the kind of fruit from which it has been made:

- a) A single fruit "x" = named fruit
- b) 2 kinds of fruit "x" = list of fruit names e.g. apple and blackberry
- c) 3 or more kinds of fruit "x" = one of the following options:
 - a list of the names of fruits e.g. apple, pear and blackcurrant;
 - the words "several fruits"; or
 - the number of kinds of fruits.

These need to be in descending order by volume.

Labelling Requirements

Indication of added extra pulp or cells

If a fruit juice product contains extra pulp/cells the label must indicate this.

Labelling of Fruit juice partially made from concentrate

Must be labelled "partially from concentrate" or "partially from concentrates"

· Labelling of concentrated fruit juice not intended for final consumer

Must indicate presence and quantity on its packaging, on a label attached to its packaging or on a trade document:

- added lemon juice
- added lime juice, and
- acidifying agents permitted by Regulation (EC) No 1333/2008

Labelling of a fruit nectar

- Label must indicate minimum content of fruit juice, fruit puree or mixture of fruit juice and fruit puree by "fruit content x"% minimum" in the same field of vision as the product name.
- A fruit nectar obtained wholly from one or more concentrated products must be labelled "from concentrate" or "from concentrates". The words must appear close to the product name clearly visible and stand out well from the background against which appears.
- A fruit nectar obtained partly from one or more concentrated products must bear the words "partially from concentrate" or "partially from concentrates". The words must appear close to the product name clearly visible and stand out well from the background against which appears.
 - Claims that sugars not added to a fruit nectar means that it does not contain added monosaccharides or disaccharides or any other sweetening properties including sweeteners as defined in Regulation (EC) No 1333/2008.
 - Where sugars are naturally present in a nectar the words "containing naturally occurring sugars" must also appear on the label.

Enforcement

Any person who contravenes or fails to comply with a provision listed in regulation 17 commits an offence. Any person who commits an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

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

- Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption
- Council Directive 2012/12/EU amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption

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.

Product Specifications

Fruit Juice

Fruit juice is the fermentable but unfermented product obtained from the edible part of fruit which is sound, ripe and fresh or preserved by chilling or freezing of one or more kinds mixed together having the characteristic colour, flavour and taste typical of the juice of the fruit from which it comes.

The fruit juice may contain any of the following - (but see also Schedule 11) an authorised additional ingredient/substance; restored flavour, pulp and cells (or any one or more of them) obtained by suitable physical means from the same species of fruit. In the case of grape juice, restored salts of tartaric acids; and in the case of tomato juice, salt, spices and aromatic herbs.

In the case of citrus fruits, except for lime, the fruit juice must come from the endocarp. In the case of lime juice, the fruit juices must come from the endocarp or the whole fruit. Where a juice is processed from a fruit with pips, seeds and peel, parts or components of pips, seeds and peel must not be incorporated in the juice. Subject to good manufacturing practice, Fruit juice may be mixed with fruit purée in the production of the fruit juice.

No treatment, except for an authorised treatment, may be used in the manufacture of a fruit juice. The Brix level of the product must be the Brix level of the juice as extracted from the fruit and must not be modified, except by blending with the juice of the same species of fruit.

Fruit Juice from Concentrate

Fruit juice from concentrate is the product obtained by reconstituting concentrated fruit juice with potable water.

In a case where a fruit juice from concentrate is manufactured from a fruit specified in column 2 of Schedule 13, the soluble solids content of the finished product must have a Brix level of at least the level specified in the corresponding entry in column 3 of that Schedule, as read together with the Notes to that Schedule.

In a case where a fruit juice from concentrate is manufactured from a fruit that is not specified in column 2 of Schedule 13, the soluble solids content of the finished product must have a Brix level of the juice as extracted from the fruit used to make the concentrate.

The product must be prepared by suitable processes that maintain the essential physical, chemical, organoleptical and nutritional characteristics of an average type of juice of the fruit from which it comes.

In the production of the product, concentrated fruit juice, or both fruit juice and concentrated fruit juice, may be mixed with –

- fruit purée;
- concentrated fruit purée; or
- both fruit purée and concentrated fruit purée.

The product may contain any of the following -

- an authorised additional ingredient/substance;
- restored flavour, pulp and cells (or any one or more of them) obtained by suitable physical means from the same species of fruit; and
- in the case of tomato juice from concentrate, salt, spices and aromatic herbs.

No treatment, except for an authorised treatment, may be used in the manufacture of a product and any reference to a Brix level in this section is a reference to the Brix level of a juice exclusive of the soluble solids of any added optional ingredients and additives.

Concentrated Fruit Juice

Concentrated fruit juice is the product obtained from fruit juice of one or more fruit species by the physical removal of a specific proportion of its water content.

Where the product is intended for direct consumption, the proportion of water content removed must be at least 50%.

As well as the ingredients mentioned in paragraph 1, the product may contain any of the following –

- an authorised additional ingredient/substance and ;
- restored flavour, pulp and cells (or any one or more of them) obtained by suitable physical means from the same species of fruit.

No treatment, except for an authorised treatment, may be used in the manufacture of a product.

Water extracted fruit juice

Water extracted fruit juice is the product obtained by diffusion with water of -

- pulpy whole fruit whose juice cannot be extracted by any physical means; or
- dehydrated whole fruit.

The product may contain either, or both, of an authorised additional ingredient or substance.

No treatment, except for an authorised treatment, may be used in the manufacture of a product.

Dehydrated or Powdered Fruit Juice

Dehydrated fruit juice or powdered fruit juice is the product obtained from fruit juice of one or more fruit species by the physical removal of virtually all of its water content.

The product may contain either, or both, of an authorised additional ingredient or substance.

No treatment, except for an authorised treatment, may be used in the manufacture of a product.

Fruit Nectar

Fruit nectar is the fermentable but unfermented product that is obtained by adding water to a juice listed below either with or without sugar or honey.

The juices are -

- fruit juice;
- fruit juice from concentrate;
- · concentrated fruit juice;
- water extracted fruit juice;
- dehydrated fruit juice;
- powdered fruit juice;
- fruit purée;
- concentrated fruit purée; and
- any mixture of the products mentioned above.

The amount of sugars or honey, or sugars and honey, added to the product must not exceed 20% of the total weight of the finished product.

The product must contain the minimum content of fruit juice, fruit purée, or a mixture of such juice and purée, specified in Part 2 of Schedule 7.

Where the product is manufactured without added sugar or with reduced energy value, sugars may be replaced wholly or partially by sweeteners in accordance with the requirements of Regulation (EC) No 1333/2008.

The product may contain any of the following:

- an authorised additional ingredient/substance;
- restored flavour, pulp and cells (or any one or more of them) obtained by suitable physical means from the same species of fruit; and
- sweeteners (which may be added in addition to any sugar or honey added.

No treatment, except for an authorised treatment, may be used in the manufacture of a product.

Part 2 of Schedule 7 sets out the different minimum % juice, puree and juice and puree content by volume for finished nectar products.

Authorised additional ingredients

These are defined in Schedule 8 as any vitamin or mineral authorised in accordance with 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. Any food additive authorised in accordance with Regulation (EC) No 1333/2008 and any one or more of the following juices (expressed as anhydrous citric acid) added for the purpose of regulating acidic taste if the total amount of such added juice does not exceed 3 grams per litre of the product:

- a) lemon juice;
- b) lime juice;
- c) concentrated lemon juice;
- d) concentrated lime juice.

Authorised additional substances

These are defined in Schedule 9 as the following:

- Enzyme preparations meeting the requirements of Regulation (EC) No 1332/2008
 - a) pectinases, for the breakdown of pectin;
 - b) proteinases, for the breakdown of proteins; and
 - c) amylases, for the breakdown of starch.
- Edible gelatine.
- Tannins.
- Silica sol.
- Charcoal.
- Nitrogen.
- Bentonite as an adsorbent clay.
- Chemically inert filtration aids and precipitation agents, including perlite, washed diatomite, cellulose, insoluble polyamide, polyvinylpolypyrrolidone, and polystyrene, which comply with Regulation (EC) No 1935/2004.

• Chemically inert adsorption aids which comply with Regulation (EC) No 1935/2004 and which are used to reduce the limonoid and naringin content of citrus juice without significantly affecting the limonoid glucosides, acid, sugars (including oligosaccharides) or mineral content of such juice.

Authorised Treatments

These are defined in Schedule 10 as:

- Mechanical extraction processes.
- The usual physical processes, including in-line water extraction (diffusion) of the edible part of the fruit used in the manufacture of a concentrated fruit juice (except in-line water extraction (diffusion) in relation to grapes used in the manufacture of a concentrated fruit juice), if the fruit juice obtained in this way complies with
 - a) in the case of fruit juice, the requirements in Schedule 2; and
 - b) in the case of fruit juice from concentrate, the requirements in Schedule 3.
- In the production of grape juice where sulphitation of the grapes with sulphur dioxide has been used, desulphitation by physical means if the total quantity of sulphur dioxide in the finished product does not exceed 10 mg per litre of the juice.

Associated Regulations

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

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 <u>Regulation (EC) No 1829/2003</u> 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.

Labelling

The labelling requirements shall apply to foods which are to be delivered as such to the final consumer or mass caterers which:

- a) Contain or consist of GMOs; or
- b) Are produced from or contain ingredients produced from GMOs.

This section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9% of the food ingredients, considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

Foods within scope shall be subject to the following specific labelling requirements:

 a) Where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified (name of the ingredient)" shall appear in the list of ingredients in parentheses immediately following the ingredient concerned;

- b) 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;
- c) Where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified (name of organism)" shall appear clearly on the labelling;
- d) The indications referred to in a) and b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling.
- e) 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 10cm², 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.

In addition to the labelling requirements above, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

- a) Where a food is different from its conventional counterpart as regards the following characteristics or properties:
 - i. Composition;
 - ii. Nutritional value or nutritional effects;
 - iii. Intended use of the food;
 - iv. Implications for the health of certain sections of the population;
- b) Where a food may give rise to ethical or religious concerns.

Seizure and detention

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.

Associated Regulations

Regulation (EC) No 1830/2003

Further Information

European Food Safety Authority EFSA Register of GM Food and Feed

<u>GM Food Debate</u>

Guidance note for sampling food and feed to determine the presence of genetically modified material.

GM material in animal feed

The Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004

Scope

These regulations provide for the enforcement and execution of certain specified provisions (related to food and feed) of <u>Regulation (EC) 1830/2003</u> of the European Parliament and the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

These regulations apply, at all stages of placing on the market, to:

- a) Products consisting of, or containing, GMOs;
- b) Food produced from GMOs;
- c) Feed produced from GMOs.

These regulations do not apply to medicinal products for human and veterinary use.

Traceability and labelling requirements for products consisting of or containing GMOs

At the first stage of placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

- a) That it contains or consists of GMOs;
- b) The unique identifier(s) assigned to those GMOs

At all subsequent stages of the placing on the market of products referred to above, operators shall ensure that the information regarding GMOs is passed on in writing to the operators receiving the products.

Operators shall have in place systems and standardised procedures to allow the holding of information specified above and the identification, for a period of 5 years from each transaction, of the operator by whom and the operator to whom the products have been made available.

For products consisting of or containing GMOs, operators shall ensure that:

- a) For pre-packaged products, the words "this product contains genetically modified organisms" or "this product contains genetically modified (name of organism)" appear on the label;
- b) For non-pre-packaged products offered to the final consumer the words "this product contains genetically modified organisms" or "this product contains genetically modified (name of organism)" shall appear on, or in connection with, the display of the product.

This shall not apply to adventitious or technically unavoidable traces of GMOs that are no higher than the thresholds established in Articles 12, 24 or 47 of Regulation (EC) No 1829/2003.

Traceability requirements for products for food and feed produced from GMOs

When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

- a) An indication of each of the food ingredients which is produced from GMOs;
- b) An indication of each of the feed materials or additives which is produced from GMOs;
- c) In the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

Again, traceability information should be held for 5 years.

This again does not apply to adventitious or technically unavoidable traces of GMOs.

Associated Regulations

Regulation (EC) No 1829/2003

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.

GM material in animal feed

The Honey (Scotland) Regulations 2015 (SSI No. 208)

Scope

The Honey (Scotland) Regulations 2015 regulate the labelling and use of the name "honey" and different types of honey in trade. They revoke and replace the Honey (Scotland) Regulations 2003 (as amended) and implement Council Directive 2001/110/EC as amended by Directive 2014/63/EU in Scotland.

Ingredients/Products

The Regulations apply to honey and different types of honey as defined in Regulation 3.

Honey and different types of Honey - Regulation 3

'Honey'

Honey means the natural sweet substance produced by *Apis mellifera* bees from the nectar of plants or from the secretions of living parts of plants or excretions of plant sucking insects on the living parts of plants which the bees collect, transform by combining with specific substances of their own deposit, dehydrate, store and leave in honeycombs to ripen and mature.

'Baker's honey'

Baker's honey is defined as honey that is 'suitable for industrial uses or as an ingredient in other foodstuffs which are then processed'.

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 later in this guidance note.

'Blossom honey' & 'Nectar honey'

Honey that is obtained from the nectar of plants.

'Chunk honey' & 'Cut comb in honey'

Honey that contains one or more pieces of comb honey.

'Comb honey'

Honey that is stored by bees in the cells of freshly built broodless combs or thin comb fountain sheets made solely of beeswax and sold in sealed whole combs or sections of such combs.

'Drained honey'

Honey obtained by draining de-capped broodless combs.

'Extracted honey'

Honey obtained by centrifuging de-capped broodless combs.

'Filtered honey'

Honey obtained by removing foreign inorganic or organic matters in such a way as to result in the significant removal of pollen.

'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.

'Pressed Honey'

Honey obtained by pressing broodless combs with or without the application of moderate heat not exceeding 45°C.

Compositional requirements

Regulation 15 and the Schedule prescribe compositional criteria with which Honey and different types of Honey" must comply when *placed on the market*. Please see the following requirements:

- The honey consists of essentially different sugars, predominantly fructose and glucose as well as other substances such as organic acids, enzymes and solid particulars derived from honey collection.
- The colour varies from nearly colourless to dark brown.
- The consistency can be fluid, viscous or partly or entirely crystallised.
- The flavour and aroma are derived from the plant origin.
- No food ingredient has been added.
- No addition to the honey except for other honey.
- It must be free as far as possible from organic or inorganic matters foreign to its composition.

Apart from *bakers honey* it must not have:

- Foreign tastes or odours.
- Started to ferment.
- An artificially changed acidity.
- Been heated in a way that has destroyed/significantly inactivated natural enzymes.

With the exception of *filtered honey* no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic/ organic matter.

The table in **Schedule 1** contains additional compositional criteria for honey and different types of honey:

Criteria	Americat
Criteria	Amount
 Sugar Content (1) Fructose and glucose content (sum of both) 	
 a) blossom honey; b) honeydew honey, blend of honeydew honey with blossom honey. 	not less than 60 g/100 g not less than 45 g/100 g
 (2) Sucrose content a) in general - except for (b) and (c); b) false acacia (<i>Robinia</i> pseudoacacia), alfalfa (<i>Medicago</i> sativa), Menzies Banksia (<i>Banksia</i> menziesii), French honeysuckle 	not more than 5 g/100 g not more than 10 g/100 g
 (Hedysarum), red gum (Eucalyptus camaldulensis), leatherwood (Eucryphia lucida, Eucryphia milliganii), Citrus spp.; c) lavender (Lavandula spp.), borage (Borago officinalis). 	not more than 15 g/100 g
 2. <u>Moisture content</u> a) all honey except for those specified in paragraphs (b), (c) or (d): 	not more than 20%
(d); b) honey from heather (<i>Calluna</i>);	not more than 23%
 c) baker's honey except for baker's honey from heather (<i>Calluna</i>); d) baker's honey from heather (<i>Calluna</i>). 	not more than 23%
	not more than 25%
 3. <u>Water-insoluble content</u> a) all honey except pressed honey; b) pressed honey. 	not more than 0.1 g/100 g not more than 0.5 g/100 g
 4. <u>Electrical conductivity</u> a) all honey except for bell heather (<i>Erica</i>), chestnut, eucalyptus, honeydew, lime (<i>Tilia</i> spp.), ling heather (<i>Calluna vulgaris</i>), manuka or jelly bush 	
(<i>Leptospermum</i>), strawberry tree (<i>Arbutusunedo</i>) and tea tree (<i>Melaleuca</i> spp.);	not more than 0.8mS/cm
 b) blends of honeys to which paragraph (a) applies; 	not more than 0.8mS/cm
c) honeydew honey;	not less than 0.8mS/cm

 d) blends of honeydew honey exception blends with bell heather (<i>Erica</i>), eucalyptus, lime(<i>Tilia</i> spp.), ling heather (<i>Calluna vulgaris</i>), 	ot
manuka or jelly bush (<i>Leptospermum</i>), strawberry tree (<i>Arbutus uned</i> o) and tea tree	not less than 0.8mS/cm
 (<i>Melaleuca</i> spp.); e) chestnut honey; f) blends of chestnut honey except blends with bell heather (<i>Erica</i>), eucalyptus, lime (<i>Tilia</i> spp.), ling heather (<i>Calluna vulgaris</i>), manuka or jelly bush 	not less than 0.8mS/cm
(<i>Leptospermum</i>), strawberry tree (<i>Arbutus unedo</i>) and tea tree (<i>Melaleuca</i> spp.).	not less than 0.8mS/cm
 5. <u>Free acid</u> a) all honey except for baker's 	not more than 50 milli-equivalents acid
honey;	per 1000 g
b) baker's honey.	not more than 80 milli-equivalents acid per 1000 g
 <u>Diastase activity and HMF content</u> - determined after processing and blending 	
(a) diastase activity (Schade scale) –	
 all honey except baker's honey and honey to which sub- paragraph (ii) applies; 	not less than 8
ii. honey with a low natural enzyme content (e.g. citrus honey) and a HMF content of not more than 15 mg/kg.	n
(b) HMF -	
 all honey except baker's honey and honey to which sub- paragraph (ii) applies; 	not more than 40 mg/kg
ii. honey of a declared origin from a region with a tropical climate and blends of these honeys.	

Labelling Requirements

A person must use the name for the type of honey but must not use that name if it as defined in the regulations does not meet the compositional requirements (see regulations 5(3), 6(2), 7(2), 8(2), 9(2), 10(2), 11(2), 12(2), 13(2), and 14(2)).

As well as the specific labelling provisions of the Regulations, honey products are also subject to the general labelling rules of the EU Food Information to Consumers Regulation (EU) No 1169/2011. In particular, this includes the requirement to give a 'best before' date and any special storage instructions on the label of honey products.

Additional Labelling requirements (Regulation 16)

Commission Directive 2014/63/EU amended Directive 2001/110/EC to state that all honey sold in the EU must include a country of origin declaration.

An exception is provided for honey sold in blends which may be from more than one country and where it would be unwieldy and meaningless to have to list various countries. The regulations therefore provide for an alternative phraseology which highlight whether the blend is from EU countries and which may be more meaningful to consumers. The Regulations prescribe that one of three statements may be used, as appropriate:

- "blend of EU honeys";
- *"blend of non-EU honeys";* or
- "blend of EU and non-EU honeys".

A manufacturer's address on the label is not sufficient as a declaration of country of origin. It is the view of Food Standards Scotland that 'country' could represent the UK (i.e. the Member State) or the individual country such as Scotland, Northern Ireland etc. No precise form of words is laid down in the Directive, therefore statements such as "produce of Scotland", "Scottish honey", or "made from honey harvested in Scotland" would be acceptable.

Apart from baker's honey and filtered honey the product name of a relevant honey may be supplemented by information relating to its:

- *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.
- **Regional, territorial or topographical origin:** provided that the honey comes entirely from the indicated source.
- **Specific quality criteria:** this provision relates to additional descriptions that emphasise the quality of the product.

Directive 2014/63/EU which amended Directive 2001/110/EC recognises that pollen, being a natural constituent particular to honey, *should not* be considered an ingredient of honey.

Labelling provisions specific to baker's honey and filtered honey (regulations 6 and 12)

- a) Baker's honey and filtered honey may not be labelled with additional information relating to floral or vegetable origin; its regional, territorial or topographical origin; or its specific quality criteria.
- b) 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'.
- c) Baker's honey is sold as food in its own right, it must be labelled with the words 'intended for cooking only' close to the product name.
- d) 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. Where 'honey' is not used in the name of the food the list of ingredients must identify the honey ingredient as 'bakers honey' if it is the ingredient used.

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.

Associated Regulations

Directive 2001/110/EC relating to honey

Directive 2014/63/EU which amends EC Directive 2011/110 in relation to honey

The Honey (Scotland) Regulations 2015

Further Information

Honey Association

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

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	Follow on Formula
Must be named 'infant formula' except when manufactured entirely from cows' milk protein, in which case it must be named 'infant milk'.	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 from birth when not breast fed	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 100 ml of product as ready to use: i.e. Energy kj or kcal Proteins Lipids	Nutrition data per 100 ml 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 100 mls of the product ready for use • Choline • Inositol • Carnitine	Carbohydrates Average quantity of each mineral and vitamin as per Annex II of the Commission Directive 2006/141/EC and where applicable per 100 mls of the product ready for use • Choline • Inositol • Carnitine
Average quantity of nutrients mentioned in Annex III per 100 mls 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	 Average quantity of nutrients mentioned in Annex III per 100 mls of the product ready for use: Vitamins Mineral substances Amino acids and other nitrogen compounds 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 advice of a medical person 	

Must not contain:	
Must not contain:	
1. Picture of an infant	
2. Picture or text that idealises	
Only nutrition claims listed in Annex	Nutrition claims on follow-on formula are
IV of Directive 2006/141/EC can only	controlled by the <u>Nutrition and Health Claims</u>
be made if the conditions warranting	Regulation 1924/2006
the claim are fulfilled.	
The permitted nutrition claims are:	
1. Lactose only	
2. Lactose free	
3. 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	Health claims on follow-on formula are controlled
listed in Annex IV of Directive	by the Nutrition and Health Claims Regulation
2006/141/EC can be made if the	<u>1924/2006</u>
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	
	Information on vitamins and minerals included
	in Annex VII, expressed as a % of the reference
	values given in Annex VII, per 100 ml of the
	product ready for use.
	ollow on formula must be designed to provide
	priate use of the product and must not discourage
	such as 'humanised', 'materialised', '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 formula	Dilow 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 2008 (SSI No. 322)

These regulations amend the infant formula and follow-on formula (Scotland) Regulations 2007 in relation to the marketing and presentation of infant formula and follow-on formula, make revisions in relation to the export of infant formula and follow-on formula to third countries, and create certain transitional arrangements that apply in relation to the enforcement of the labelling requirements and the requirements that apply in relation to the shape, appearance and packaging of infant formula and follow-on formula.

These regulations also provide transitional arrangements with regard to the Foods for Special Medical Purposes (Scotland) Regulations 2000.

Associated Regulations

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

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 SSI No. 424

Food Standards Agency Guidance on Infant Formula and Follow on Formula 2007

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 Article 17 of Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC). 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.
- 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 words 'Preserve' and 'Conserve' are not mentioned in the regulations and the jam regulations do not control the use of the terms preserve and conserve. However, this was more an oversight on the part of the UK as the terms were previously synonymous with jam and extra jam in the old jam regulations. The trade association representing the jams industry are aware but were keen to see the synonymous use retained so their Industry Code recommends that the term preserve should not be used unless the product is jam and conserve unless extra jam. In the FSA guidance we do not highlight this discrepancy as we support the industry approach. However clearly legally the regulations do not require it. It is also worth noting that the Codex standard for such products does recognise the terms preserve and conserve and that they are synonymous with jam/extra jam respectively. i.e. The terms, "preserve" or "conserve" are sometimes used to represent products covered by this Standard. The use of the terms "preserve" and "conserve" are thereby required to comply with the requirements for jam and/or extra jam as set out in this Standard.

In summary, the regulations do not specifically control the use of the terms preserve and conserve but there is a certain consumer expectation that these names are synonymous with products meeting the requirements of a jam or extra jam. In addition under Codex rules such term are synonymous and FSA would therefore encourage appropriate usage of the terms.

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, blackcurrants, blueberries 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 FIC provides 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 Article 17 of FIC.
- Sulphur dioxide content where a specified product has a residual sulphur dioxide content of more than 10 mg per kg, this must be declared as 'sulphur dioxide' and emphasised in the product's 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 100 g'. The proportion of sugar declared represents the total soluble solids content determined by refractometer at 20°C (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 Article 30 of FIC, 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/100 g.

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/100 g.

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 100 g'. 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 5(2)(b) may not be the same as the fruit content calculated to ensure that the 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.

Annex III of FIC requires that a specified product containing a permitted sweetener must be labelled with the following information:

- (i) The words '<u>with sweetener(s)</u>'. 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 aspartame (a</u> <u>source of phenylalanine)'</u>.
- (iii) Where the specified product contains more than 10% added polyols, the words <u>'excessive consumption may produce laxative effects'</u>.

Pre-packed for direct sale

Products which fall within this category will be subject to certain exemptions by virtue of Article 44 of FIC. 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 100 g' and 'Y grams of sugar per 100 g' on the label.

Associated Regulations

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

The Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (SSI No. 266)

<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 2002 (SSI No. 523)

Scope

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, or 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 Regulatory Agency</u> (<u>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 rood 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.

Associated Regulations

Kava Kava in Food (Scotland) Regulations 2002 (SSI No. 523) Kava Kava in Food (Scotland) (Amendment) Regulations 2004 (SSI No 244)

Further Information Kava Kava

The Materials and Articles in Contact with Food (Scotland) Regulations 2012 S.S.I. No. 318

Scope

The Regulations consolidate into one Scottish Statutory Instrument nearly all existing legislation on materials and articles intended to come into contact with food, with the exception of the Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 and provide for the enforcement of the provisions of Commission Regulation (EU) No. 10/2011 of 14 January 2011, on plastic materials and articles intended to come into contact with food.

The Regulations also revoke the following five sets of Regulations:

- The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009
- The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2008
- The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011
- The Materials and Articles in Contact with Food (Scotland) Regulations 2010; and
- The Ceramic Articles in Contact with Food (Scotland) Regulations 2006, which implement the provisions of Council Directive 84/500/EEC, as amended by Commission Directive 2005/31/EC.

Ingredients/Products

The regulations contain provisions for materials and articles that fall under the following general classifications:

- General requirements for all materials and articles in contact with food Requirements on active and intelligent materials and articles
- Ceramic articles
- Regenerated cellulose film Plastic materials and articles
- Requirements on certain epoxy derivatives
- Vinyl chloride

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

General requirements for all Materials and Articles in contact with food

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.

It is an offence for a person to place on the market or use in the course of a business in connection with the storage, preparation, packaging, sale or service of food any material or article that does not meet the general safety requirements set out in Article 3(1) of EC Regulation 1935/2004.

It is also an offence for a business operator to use an authorised substance or material or article outside any conditions or restrictions specified in the authorisation.

There is also a general requirement on manufacturers to ensure traceability at all stages. There are specific labelling provisions for all materials and articles in contact with food set out in Article 15 of EC Regulation 1935/2004.

- Materials and articles should be labelled with the words "for food contact" or a specific indication as to their use. A symbol as given in Annex II of 1935/2004 may be used. Also special instructions are to be observed for safe use e.g. "not suitable for microwaving" etc.
- The name or trade name and address or registered office of the manufacturer, processor or seller responsible for placing the item on the market.
- Adequate labelling to identify traceability.
- In the case of active and intelligent materials and articles, information on the permitted use or uses e.g. name and quantities of substances released by the active component to enable a food business operator to ensure that the food will comply with other relevant Community legislation such as the rules on levels of permitted additives etc.
- Labelling information must be conspicuous, clearly legible and indelible Labelling information must be in a language understood by purchasers.
- At retail level labelling information must be displayed on the actual material or article or on their packaging or labels affixed to the materials and articles or to their packaging or on a notice in immediate vicinity.
- At the marketing stages other than retail the required labelling information must be displayed on accompanying documents or labels or packaging or on the materials and articles.

The regulations also require that the business operators must comply with Article 4 of Regulation EC 2023/2006 (Conformity with good manufacturing practice).

Business operators must ensure that the manufacturing operations are in accordance with:

- General rules on Good Manufacturing practice (GMP). These are detailed in -Article 5 Conformity with Quality Assurance System Article 6 Quality control systems, and Article 7 Documentation.
- 2. Detailed rules are set out in the Annex to Regulation EC 2023/2006.

Requirements on active and intelligent materials and articles

Active materials and articles means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

Intelligent materials and articles means materials and articles which monitor the condition of packaged food or the environment surrounding the food.

A person must not place on the market an active or intelligent food contact material that

- Alters the composition of food to the extent that it would contravene food law e.g. additives rules or bring about unacceptable changes to the composition or organoleptic characteristics of the food that would mask spoilage.
- Give misleading information about the condition of food
- Has not been labelled that it is not edible
- Has not been labelled to identify that it is an active/intelligent material or article.

Ceramic Articles

The specific requirements for Ceramic materials are contained in EC Directive 84/500.

Regulation 9 of S.S.I. 318/2012 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 10 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 Article 2(4) as read with Article 2(3) and (5) which refers to 3 categories of ceramic ware.

Annexes I and II of Directive 84/500 sets out how an article is to be tested.

Regulation 10 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 Annex III.

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, Council Directive 84/500 and 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 Annex I of Council Directive 84/500 have been met and the tests in Annex II of Council Directive 84/500 have been carried out.

Regulation 4 will apply to ceramic articles where it would be an offence to_place on the market or use in the course of a business in connection with the storage, preparation, packaging, sale or service of food any material or article that does not meet the general safety requirements set out in Article 3(1) of EC Regulation 1935/2004.

Regenerated Cellulose Film

Commission Directive 2007/42/EEC sets out the conditions regarding use of regenerated cellulose film.

"Regenerated cellulose film" means a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton, with or without the addition of suitable substances, either in the mass or on one or both surfaces, but does not include synthetic casings of regenerated cellulose. There are different forms of the material e.g.

- URCF means uncoated regenerated cellulose film;
- CRCF means coated regenerated cellulose film with coating derived from cellulose; and
- PRCF means coated regenerated cellulose film with coating consisting of plastics.

URCF and CRCF may be manufactured using only the authorised substances or groups of substances listed in Annex II and subject to the restrictions set out.

PRCF may be manufactured, prior to coating, using only approved substances or groups of substances listed in the first part of Annex II and subject to the restrictions set out. The coating to be applied to PRCF may be manufactured using only approved substances or groups of substances listed in Annex I to Regulation 10/2011 and subject to the restrictions.

Materials and articles made of PRCF must comply with Article 12 (overall migration limit) as read with Articles 17 (expression of migration test results) and Article 18 (rules for assessing compliance with migration limits) of Regulation 10/2011.

Printed surfaces of regenerated cellulose film must not come into contact with foodstuffs. Any material or article made of regenerated cellulose film that is not by its nature clearly intended to come into contact with food must, at a marketing stage other than the retail stage, be accompanied by a written declaration attesting that it complies with the legislation applicable to it.

Where special conditions of use are indicated, the material or article made of regenerated cellulose film must be labelled accordingly.

A person must not place on the market any regenerated cellulose film which does not meet these requirements.

Plastic Materials and Articles

Commission Regulation 10/2011 sets out the requirements for plastic materials and articles in contact with food.

Article 2 identifies what is regarded as a plastic material e.g.

- (a) materials and articles and parts thereof consisting exclusively of plastics;
- (b) plastic multi-layer materials and articles held together by adhesives or by other means;
- (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
- (d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
 - (e) plastic layers in multi-material multi-layer materials and articles.

The term "Plastic " means a polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles; and a "Polymer" is any macromolecular substance obtained by:

 (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or (b) chemical modification of natural or synthetic macromolecules; or (c) microbial fermentation;

Regulation 14 (Schedule 1) creates the following offences in relation to placing on the market plastic materials and articles

Article 4(e), as read with Articles 17 and 18	Prohibition on placing on the market plastic materials or articles if they do not meet specified compositional and declaration requirements
Article 5(1) and Annex I, as read with Article 6	Requirement, subject to certain derogations, to use only authorised substances in the manufacture of plastic layers in plastic materials and articles
Article 8, first sentence	General quality and purity standards that must be observed for substances used in the manufacture of plastic layers in plastic materials and articles

Article 9 as read with Annex I	Particular restrictions and specifications for substances used in the manufacture of plastic layers in plastic materials and articles
Article 10 as read with Annex II	General restrictions on plastic materials and articles
Article 11(1) and (2) and Annex I, as read with Article 11(3)	Specific limits on the degree to which constituents of plastic materials and articles are permitted to migrate into foods
Article 12	Overall limits on the permitted level of migration of the constituents of plastic materials and articles into food simulants
Article 13(1),(3),(4) and (5) and Annex I as read with Article 13(2)	Particular restrictions and specifications for the composition of each plastic layer in plastic multi- layer materials and articles
Article 14(1) and (5) and Annex 1, as read with Article 14(2),(3) and (4)	Particular restrictions and specifications for the composition of each plastic layer in multi-material
	multi-layer materials and articles
Article 15 and Annex IV	Requirements that written declaration of compliance for plastic materials and articles, for products from the intermediate stages of their manufacture and for substances intended for the manufacture of those materials or articles should be available at the marketing stages other than the retail stage

In addition it is also an offence to fail to comply with Article 8 which requires that substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

Regulation 14 also requires that appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation (Regulation EU 10/2011) must be made available by the business operator to the national competent authorities on request.

That documentation must contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

As per Regulation 4 it is an offence for a person to place on the market or use in the course of a business in connection with the storage, preparation, packaging, sale or service of food any material or article that does not meet the general safety requirements set out in Article 3(1) of EC Regulation 1935/2004.

Epoxy Derivatives (BADGE, BFDGE and NOGE)

Provisions relating to certain epoxy derivatives are contained in Commission Regulation 1895/2005. e.g. ("BADGE" i.e. Bisphenol-A DiGlycidyl Ether), bis(hydroxyphenyl)methane bis(2,3- epoxypropyl) ethers ("BFDGE" i.e. Bisphenol-F DiGlycidyl Ether) and novolac glycidyl ethers "NOGE")

Regulation 16 requires that a person must not place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food, any material or article in contravention of Article 3 which prohibits the use or presence of BFDGE in food contact materials or Article 4 which prohibits the use or presence of NOGE or

any material or article that fails to comply with the restrictions contained in Article 2 (BADGE) as read with Annex I dealing with specific migration limit for BADGE and certain of its derivatives.

A person must not place on the market any material or article which fails to comply with the requirements of Article 5 concerning written declarations. At the marketing stages other than the retail stages, materials and articles containing BADGE and its derivatives shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

Vinyl Chloride

Provisions controlling vinyl chloride are set out in Commission Regulation 10/2011.

In addition Regulation 18 requires that materials and articles, other than those materials and articles controlled by Regulation 10/2011, which are manufactured with vinyl chloride polymers or copolymers must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram of the material or article; and must be manufactured in such a way that they do not transfer to foods with which they are in contact any quantity of vinyl chloride exceeding 0.01 milligrams of vinyl chloride per kilogram of food.

A person must not place on the market; or use in the course of a business in connection with the storage, preparation, packaging, selling or service of food, any material or article that does not comply with these requirements.

Associated Regulations

The Materials and Articles in Contact with Food (Scotland) Regulations 2012

<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/EEC</u> regarding a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs <u>General Product Safety Regulations 2005</u>

Further Information

EU Guidance to the Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food

Commission Regulation EC No. 1935/2004

Commission Regulation EC 1895/2005

Commission Regulation EC No. 2023/2006

Commission Directive 2007/42/EC

Commission Directive 2002/72/EC

Commission Regulation EC 450/2009

Council Directive 82/711/EEC

Commission Directive 93/8/EC

Commission Directive 85/527/EEC

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

Commission Directive 2011/8/EC

Council Directive 78/142

Commission Regulation (EU) No. 10/2011

Commission Regulation (EU) No. 1183/2012

Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (SI No 1263)

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 Regulations 1995 (SI No. 3187) (now repealed)⁶. 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.

Associated Regulations

Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (SI No 1263)

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

⁶ Although the amendment remains with the Mineral Hydrocarbons in Food Regulations 1966

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (SSI No. 483)

Scope

The regulations control the exploitation and marketing of natural mineral waters, spring water and bottled drinking water. These Regulations implement and enforce the following European instruments:

Council Directive 98/83/EC in relation to spring water and bottled drinking water relating to the quality of water intended for human consumption.

Council Directive 2003/40 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone enriched air for the treatment of natural mineral waters and spring waters.

Council Directive 2009/54 on the exploitation and marketing of natural mineral waters.

Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters.

Council Directive 2013/51/EURATOM laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

In Wales and Northern Ireland, consolidated regulations on natural mineral water, spring water and bottled drinking water, including the transposition of Council Directive 2013/51/EURATOM on radioactivity monitoring, came into force on 28 November 2015. Defra, who has responsibility for bottled water regulations in England, has consulted on proposed consolidated regulations (including the transposition of Council Directive 2013/51/EURATOM) but has not yet brought them into force. In Scotland, FSS brought into force the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015 on 28 November 2015 which transposed the requirements of Directive 2013/51/EURATOM only. Consequently, there are currently some differences in bottled water legislation throughout the UK. These include:

Disinfection treatments for spring waters:

The UK advice on spring water and the use of UV disinfection treatments dates back to when there was separate legislation for Natural Mineral Water and Spring Water. Following a re-reading of the current EU Directive on Natural Mineral Water, Spring Water and Bottled Drinking Water and discussion with the Commission, the FSA has advised the Governments in Wales and Northern Ireland that UV disinfection of spring water should be expressly prohibited in their respective domestic legislation. Defra for England and FSS for Scotland, although encouraging producers to move away from using UV, have not yet finalised their position on this.

For spring water and bottled drinking water: Removal of a national provision which calls for the re-calcification of up to at least 60 mg/l for any bottled water or spring water which had been softened or desalinated

There is no longer a scientific basis for this provision and as a result, it is not considered necessary to maintain this national measure at cost to industry which has no associated identified health benefits for consumers. This requirement no longer exists in Northern Ireland and Wales following their consolidation. It is anticipated England and Scotland will follow suit, at the earliest opportunity.

For spring water and bottled drinking water: Radioactivity monitoring

In Wales, Northern Ireland and Scotland, monitoring of Radon as well as Tritium and Indicative Dose, required by Council Directive 2013/51/EURATOM is enforced by national regulations. In all three countries, exemptions from monitoring for food authorities are available if evidence supports this. England has yet to finalise their position on this. FSS is currently working on draft guidance for food authorities and food business operators on the requirements for radioactivity monitoring which we will consult on in due course.

Sampling procedures which apply to local authorities as part of their official control obligations

This concerns the application of the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013. These Regulations specify the procedures to be followed when a sample has been procured under Article 29 of the Food Safety Act 1990 for chemical or microbiological analyses, and prescribes the form of certificate to be used by analysts and examiners in making their reports. The 2013 Regulations exclude the 2007 Regulations in relation to the procedures for taking samples of bottled drinking water. In Wales and Northern Ireland the 2013 Regulations have now been applied to their consolidated Regulations removing the need to carry forward more precriptive provisions from the 2007 Regulations. Scotland and England intend to follow suit but have yet to finalise their position on this.

Ingredients/Products

The regulations cover the exploitation and marketing of three distinct types of bottled product:

- 1. **Natural Mineral Water:** as defined in regulation 2(1) and recognised in accordance with regulation 4(1).
- 2. Spring Water: in accordance with regulation 10 and schedule 4.
- 3. **Bottled Drinking Water:** water which is bottled in accordance with regulation 13 and schedule 2.

Exemptions

Exemptions apply to:

- products that have a licence or authorization for medicinal use or veterinary use
- water not intended for human consumption
- packed ice used for cooling food
- natural mineral water used at source for curative purposes in thermal and hydro-mineral establishments; and
- natural mineral water exported to a country other than an EEA State

Recognition of Natural Mineral Water (Regulation 4)

Natural mineral water extracted from the ground may be sold:

- In **Scotland**, when the Food Authority has granted recognition in accordance with Schedule 3 Part 1.
- In another part of the **United Kingdom** when the responsible authority recognises it pursuant to Directive 2009/54
- In a Non EEA state when FSS grants recognition in accordance with Part 2 of Schedule 3 or an equivalent responsible authority of another part of the United Kingdom or non EEA State.
- In **an EEA state other than the UK**, if it has been officially recognized by a responsible authority of the EEA State pursuant to EC Directive 2009/54.

Natural Mineral Waters and Spring Water

Schedule 3 Part 1: Recognition of a Natural Mineral Water in Scotland and Schedule 3 Part 2: Natural Mineral Water extracted from the ground in a country other than an EEA state requires the Food Authority (Part 1) or the FSS (Part 2) to publish an announcement of such recognition and the grounds on which it has been granted in the Edinburgh Gazette (Part 1) or the London, Edinburgh and Belfast Gazette (Part 2).

Information to be supplied to the Food Authority for the purpose of recognition as set out in Schedule 3 Part 3 include:-

- geological and hydrogeological surveys,
- physical, chemical and physico-chemical surveys
- microbiological analyses
- clinical and pharmacological analyses

Declining to grant or withdrawing recognition (Regulation 4)

The Food Authority of FSS can withdraw recognition on the grounds that the minimum requirements are not being met. Where a Food Authority or FSS declines to grant or withdraws recognition, the person who exploits (or wishes to exploit) the spring from which that water emerges or, if different, the landowner on which the spring is situated may apply to FSS for a review of that decision.

The Food Authority can also facilitate the change in a named source by placing an advertisement in the Edinburgh Gazette and informing FSS.

A Food Authority must immediately inform FSS if it grants, restores or withdraws recognition or it is notified of any change to the trade description or name of the spring from which the natural mineral water is extracted.

FSS must confirm the decision or direct the Food Authority to grant or restore or itself to restore, as appropriate, recognition of the water in question.

If a Food Authority is directed by FSS to grant or restore recognition then they must comply immediately.

Application to withdraw recognition (Regulation 4)

A person who exploits recognized natural mineral water from a spring may apply to have that recognition withdrawn

Exploitation of natural mineral water springs (Regulation 5)

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.

Treatments and additions for natural mineral water (Regulation 6)

There are four treatments that are allowed for natural mineral water

- Filtration or decanting
- Physical elimination of free carbon dioxide
- Fluoride removal (authorized activated alumina treatment)
- Ozone-enriched air oxidation

Details of these treatments and under what circumstances they are allowed to be carried out are contained in the Regulations.

You may introduce carbon dioxide to produce effervescent natural mineral water.

No other treatments are permitted if you want to sell the water as Natural Mineral Water.

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.

Bottling of natural mineral water (Regulation 7)

Regulation 7 and Schedules 4, 6 and 7 set out the requirements for bottling natural mineral waters. Schedule 4 includes a requirement that natural mineral water can only be transported from the spring to the bottling plant in containers authorized for distribution to the ultimate consumer unless it was transported in containers not for distribution to the ultimate consumer (e.g. tankers) on or before 17 July 1980.

Schedule 6 sets out maximum limits for certain constituents of natural mineral water which must not be exceeded at time of bottling.

Labelling, 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.

Labelling requirements include:

- a trade description must not include the name of the locality unless it refers to a natural mineral water spring exploited at the place indicated and is not misleading
- a trade description must not have a different name of the spring or place of exploitation unless the name of the spring or place of exploitation is also labelled using letters x 1.5 height and width of the largest letters used for the trade description
- must not contain any indication, picture etc. use of which suggests a characteristic which the water does not posses

Permitted indications on the label of natural mineral water (Regulation 8 (1) (f) and (g))

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 as possessing the property attributed by the indication in accordance with the physic-chemical analysis and pharmacological, physio-chemical analysis and clinical examination as appropriate.

Bottled water from a natural mineral water source can only be marked with the following sales descriptions which are defined in the Regulation 8 (1) (h):-

- natural mineral water
- naturally carbonated natural mineral water
- natural mineral water fortified with gas from the spring
- carbonated natural mineral water

Further mandatory labelling requirements for natural mineral waters (Regulation 8(2))

- Statement of the analytical composition indicating the characteristic constituents;
- Name of the spring and the place of its exploitation.

And where applicable:

- Indication of partial/total elimination of free carbon dioxide see 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)).

Mandatory requirements for advertising natural mineral water (Regulation 8)

In accordance with the source name labelling requirements, the same requirements apply to written advertisements; equal prominence must be given to either the place of exploitation or the name of the spring as given to the trade description.

Sale of natural mineral water (Regulation 9

Requirements for the sale of natural mineral water including the microbiological criteria that natural mineral water is required to meet when placed on sale are set out in Regulation 9 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.

SPRING WATER

Bottling of spring water and exploitation of spring water springs (Regulation 10)

Spring water must meet stringent analytical requirements but is not required to have essential characteristics of constant chemical composition or have formal recognition as required in the case of a natural mineral water. It must be extracted from a spring, bottled at source, intended for human consumption in its natural state and comply with the requirements of Schedule 2 and Schedule 4.

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 on or before 13 December 1996. The right to tanker is linked to the spring, not the bottler.

Treatments and additions for spring water (Regulation 10 and Schedule 1 and 1A) see also Guidance Notes on the 2007 Regulations:

<u>Guidance on the Natural Mineral Water, Spring Water and Bottled Drinking Water</u> (Scotland) (No. 2) Regulations (as amended)

There are six treatments that are allowed in Scotland for the production of spring water:

- filtration or decanting
- activated alumina treatment to remove fluoride
- ozone-enriched air oxidation

Articles 9 and 4 of Directive 2009/54 on the exploitation and marketing of natural mineral waters permit:

- the introduction or re-introduction of carbon dioxide to make sparkling spring water or use spring water in the manufacture of soft drinks.
- the physical elimination of free carbon dioxide

In addition, for the meantime,

 disinfection treatments such as UV treatment - although FSS is encouraging food business operators to move away from using this treatment.

Activated alumina treatment and ozone-enriched air treatments for spring waters must be authorized.

Labelling of spring water (Regulation 11)

Spring water can only be marked and labelled if, when bottled at source, it is intended for consumption in its natural state 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 to the nature of the water and the place of exploitation of the spring.

Labelling of spring water treatment (Regulation 11 (3) (c))

Where the water has undergone authorised ozone-enriched air oxidation, specific labelling text is provided in the Regulations.

Advertising of water as spring water (Regulation 11 (2) & 4)

It is an offence to advertise a bottle of water as "spring water" minus the name of the spring or place of exploitation if it is a requirement to have both.

In accordance with the source name labelling requirements, the same requirements apply to written advertisements; in any other advertisement, at least equal prominence must be given to either the place of exploitation or the name of the spring as is given to the trade description.

Sale of spring water Trade description for spring water (Regulation 12)

Sets out restrictions on the sale of water as "spring water." Water from one and the same spring must not be sold under more than one trade description.

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 (Regulations 14 and 15)

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.

Removal of hardness from a spring or bottled water (Regulation 10 & 13 and Schedule 2))

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.

In England and Scotland, for the meantime, there is still a legal requirement for a minimum calcium content in any water which has been softened or desalinated. This national requirement no longer exists in Northern Ireland and Wales.

MONITORING AND SAMPLING REQUIREMENTS

EU requirements for monitoring of radioactivity in water (Regulation 16 (2) (e) to (h) (Schedules 12 and 13)

Council Directive 2013/51/Euratom which was transposed in Scotland by The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015, came into force on 28 November 2015 and lays down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (the "Directive").

The Directive sets out parametric values, and frequencies and performance characteristics for analytical methods for monitoring radioactive substances in water intended for human consumption. This includes water as defined in the scope of the Drinking Water Directive 98/83/EC for drinking, cooking, food preparation or other domestic purposes supplied from a distribution network, tanker or in bottles or containers. It also includes all water used in any food production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption. Natural mineral waters are exempt from the requirements of the Directive.

Guidance for Food Authorities and Food business operators on radioactivity monitoring is being developed and will be consulted on shortly.

Monitoring and sampling (natural mineral water) (Regulation 16(1) (c))

Periodic checks must be carried out to ensure that the composition, temperature and other essential characteristics of the water remain stable within the limits of natural fluctuation, are unaffected by variations in the rate of flow, that viable colony count at source is reasonably constant and satisfies Schedule 3 Part 1 and also the requirements of Schedule 4 are met.

Monitoring of water bottled and labelled as "spring water" and bottled drinking water (Regulation 16 (2))

Regular monitoring of the quality of the water must be carried out to ensure it:

- satisfies the requirements of Directive 98/83
- contains a concentration or value for any parameter in excess of its prescribed concentration or value
- contains a concentration or value for a property, element, substance or organism set out in Schedule 9 in excess of the concentration or value specified as measured by the unit of measurement so specified.

Regular monitoring is also required in the case where, in accordance with the point above, a Food Authority determines that the water concerned contains a concentration or value for *Clostridium perfringens* (including spores) in excess of the concentration or value specified in relation to it in Schedule 9, there is any potential danger to human health arising from the presence in the water of pathogenic micro-organisms.

Regular monitoring is also required to ensure that where disinfection treatment is being used for spring and bottled drinking water it is effective.

Food Authorities must carry out monitoring in accordance with Schedules 9 and 10 as appropriate, in accordance with the relevant minimum frequencies set out in Schedule 11.

Additional monitoring must be carried out in relation to any property, element, substance or organism which is neither a parameter nor a property, element, substance or organism set out in Schedule 9 if the Food Authority has reason to suspect that it may be present in the water concerned in an amount or number which constitutes a potential danger to human health.

Food Authorities must carry out additional monitoring in accordance with Parts I and 2 of Schedule 12 to check whether the water complies with the relevant parametric values specified in the table in Part 3. Sampling and analysis to be in accordance with Schedule 13 to check compliance with the parametric value for Indicative Dose specified in the table in Part 3 of Schedule 12. For this sampling and analysis, take samples at the point at which the water is put into the bottle and if necessary take the remedial measures specified in Part I of Schedule 12.

Treatments monitoring (Regulation 16 (1)(b) and 16 (1) (d))

For natural mineral waters and spring waters, each Food Authority must carry out periodic checks on any fluoride removal treatment and ozone-enriched air treatment which it has authorised to ensure that the relevant requirements are satisfied.

Sampling (Regulation 16 (3))

The Food Authority must ensure that each sample is representative of the quality of the water concerned consumed throughout the year in which the sample is taken.

General labelling requirements for all types of bottled water

In addition to the specific labelling requirements in the 2007 Regulations, labels for natural mineral water, spring water and bottled drinking water must also comply with the EU Food Information to Consumers Regulation No 1169/2011.

Associated Regulations

Directive 1996/29/EURATOM on basic safety standards for the protection of the health of workers and general public against the dangers from ionizing radiation

Directive 2009/54 on the exploitation and marketing of natural mineral waters

Directive 2013/51/EURATOM on radioactivity monitoring requirements for spring water and bottled drinking water

<u>Commission Directive 2003/40 establishes the list, concentration limits and labelling</u> requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters

<u>Council Directive 98/83 concerning the quality of water intended for human consumption</u> so far as it applies to spring water and bottled drinking water

Commission Regulation (EU) No. 115/2010 laying down the conditions of use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No 2) Regulations 2007 (SSI 2007 No. 483)

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2009 (SSI 2009 No. 273)

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2010 (SSI 2010 No. 89)

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment (No 2) Regulations 2010 (SSI No 127)

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2011 (SSI No 94)

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015 (SSI No 363)

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

Further Information

<u>Guidance on the Natural Mineral Water, Spring Water and Bottled Drinking Water</u> (Scotland) (No. 2) Regulations (as amended)

Zam Zam water

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 <u>Regulation (EC) No. 258/97</u> 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 15 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).

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. However the PARNUTS legislation is currently being reviewed.

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 Sugar' 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. In consequence where a food is high in more than two nutrients e.g. fat and sugar only 'Reduced' claims can be made.

Nutrient Profile:

The Regulation puts in place provisions that may restrict the use of claims on certain foods or categories of foods based on their nutritional composition (nutrient profile). Nutrient profiles should have been adopted by 19 January 2009 but this deadline has not been met and it is not known when profiles will be in place. Food business operators will have two years to comply with these controls once the profiles are adopted in Europe.

It will depend on the extent to which a product complies with the profile, what claims can be made.

- **Meets the profile** Nutrition and health claims can be made, if they comply with the other requirements of the Regulation on nutrition and health claims.
- Fails on one nutrient No health claim can be made. Nutrition claims can only be made if the statement 'high (name of nutrient that fails the profile) content' is also made. This must be done in close proximity to, and with the same prominence as the nutrition claim. For example, a food high in sugar might carry the claim 'low fat' only if the statement 'high sugar content' is made. Article 4 specifies that this would have to be in the same field of vision as the claim and in the same size of typeface.
- Fails on more than one nutrient No nutrition or health claim can be made, except for certain reduced claims. Article 4(2) exempts foods making 'reduced' claims from having to respect the nutrient profile, but only where the reduced claim relates to a nutrient that fails the profile. For example if a product fails the profile due to its fat and sugar content, it cannot make a nutrition or health claim except 'reduced fat' or 'reduced sugar'.

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 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.

The EU Register of claims can be found at: <u>http://ec.europa.eu/nuhclaims/</u>

Health claims cannot be made where any nutrient does not meet the criteria set by the nutrient profile.

Only authorised claims can be added to the community register. There are three ways a claim could go on the Community Register:

- Member States had until 31 January 2008 to submit claims based on scientific evidence to the European Commission. EFSA then decided if the claim is permissible.
- Claims based on new science with supporting dossiers can be sent to the Department of Health in England 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 the Department of Health in England 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 applied from 1 July 2007 but there are transition measures allowing industry time to comply. For products on the market or labelled before 1 July 2007 the regulation generally applies from the food expiry date on the product bearing the claim or 31 July 2009. A detailed breakdown of transitional arrangements is given in Section 7 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.

The Nutrition and Health Claims (Scotland) (Amendment) Regulations 2010 (SSI No. 307)

These Regulations amend the definition of 'the Regulation' contained in regulation 2 of the Nutrition and Health Claims (Scotland) Regulations 2007 ('the 2007 Regulations'). The effect of the amendment is that the reference in the 2007 Regulations to the Regulation now includes any subsequent amendments to its Annex, which consists of the list of authorized nutrition claims and conditions relating to their use.

Associated Regulations

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

The Nutrition and Health Claims (Scotland) (Amendment) Regulations 2010 (SSI No. 307)

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

Food Safety Act 1990

EC Regulation 1924/2006 on nutrition and health claims made on food

Further Information

Guidance on nutrition and health claims on foods

SCHEDULE 1

Summary table

Nutrition Claim	Condition
Low Energy	Product not to contain > 40kcal (170 kJ/100 g (solid) or 20Kcal
	(80kJ/100 ml (liquid)
	Table top sweeteners not > 4kcal (17kJ) per portion with
	equivalent sweetening properties of 6 g sucrose
Energy Reduced	Reduction must be at least 30%. There must be an indication
	of the characteristics which make the food 'reduced'
Energy Free	Product contains not > 4 kcal 17kJ/100 ml
	Table top sweeteners 0.4Kcal (1.7 kJ) per portion with
	equivalent sweetening properties of 6 g sucrose.
Low Fat	Not > 3 g fat/100 g (solids) 1.5 g fat/100 ml (liquid) (1.8 g
	fat/100 ml for semi skimmed milk)
Fat Free	Not > 0.5 g/100 g or 100 ml
	The term 'X% fat free' is prohibited.
Low Saturated	The sum of saturated fatty acids and trans fatty acids must
Fat	not be > 1.5 g/100 or 0.75 g/100 ml
	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/100 g or 100 ml
Low Sugars	Not > 5 g sugar/100 g (solid) or 2.5 g/100 ml (liquid)
Sugars Free	Not > 0.5 g sugar/100 g or 100 ml
With No Added	Product must not contain added mono or disaccharides or any
Sugars	other food for sweetening. If natural sugars are present the
	claim must state 'CONTAINS NATURALLY OCCURRING
	SUGARS'
Low Sodium/Salt	Not > 0.12 g sodium or equivalent/100 g or 100 ml. For water
	other than Natural Mineral Water not > 2 mg/100 ml
Very Low	Not > 0.04 g sodium or equivalent/ 100 g or 100 ml. Cannot
Sodium/Salt	be used on waters or Natural Mineral Waters.
Sodium Free or Salt Free	Not > 0.005 g sodium or equivalent per 100 g

Source of Fibre	Food to contain at least 3 g fibre/100 g or 1.5 g fibre / 100kcal
High Fibre	Food to contain at least 6 g fibre/100 g or 3 g 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 named	Significant amount as defined in EC Directive 90/496 or as
vitamin and or	per Article 6 EC Regulation 1925/2006
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 named	Reduced by 30% compared with similar foods. Micronutrients
nutrient	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
Source of	Must contain at least 0.3 g alpha-linolenic acid per 100 g and
omega-3 fatty	per 100 kcal or at least 40 mg of the sum of eicosapentaenoic
acids	acid and docosahexaenoic acid per 100 g and per 100kcal
High Omega-3	Must contain at least 0.6 g alpha-linolenic acid per 100 g
Fatty Acids	and per 100kcal or at least 80 mg of the sum of
	eicosapentaenoic acid and docosahexaenoic acid per 100 g

High	Can be made when at least 45% of the fatty acids present
Monounsaturate	derive from monounsaturated fat and with the condition that t
d Fat	the monounsaturated fat provides more than 20% of the
	energy of the product.
High	Can be made when at least 45% of the fatty acids present
Polyunsaturated	derive from polyunsaturated fat under the condition that the
Fat	polyunsaturated fat provides more than 20% energy of the
	product.
High	Can be made where are least 70% of the fatty acids in the
Unsaturated Fat	product derive from unsaturated fat under the condition that
	unsaturated fat provides more than 20% of energy of the
	product.

The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 (SSI. 2011 No. 282)

Scope

These Regulations were made under the Food Safety Act 1990, to implement the provisions of Commission Regulation (EU) No. 284/2011 ("the EU Kitchenware Regulation") that lays down specific conditions and detailed procedures for the import of polyamide ("Nylon") and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Administrative Region, China (together referred to hereafter as "China").

The Regulation was introduced by the EU because of concern about the presence in polyamide kitchenware of detectable levels of primary aromatic amines (PAAs) some of which are carcinogenic and due to the incidence and levels found of formaldehyde migrating from Chinese melamine kitchenware at levels greater than the Specific Migration Limit of 15 mg/kg.

Ingredients/Products

The products covered typically include Nylon Kitchenware such as kitchen spoons, spatulas, fish slices and similar catering implements and Melamineware like bowls and mugs. Within the context of the regulations "plastic kitchenware" means plastic materials as described in paragraphs 1 and 2 of Article 1 of Directive 2002/72/EC and falling within CN code ex 39241000. It should be noted that the requirements for plastic materials and articles intended for food contact given in Regulation (EU) 10/2011, which superseded Directive 2002/72/EC, are now applicable under Article 21 of the Regulation as of 1 May 2011.

Regulations

These prohibit the placing on the market of polyamide and melamine plastic kitchenware from China that does not comply with the regulations conditions or has not undergone import checks and certification (Regulation 3).

It is an offence under Regulation 4 to breach any prohibition.

The regulations are enforced by Food Authorities, as set out in Regulation 5 and the Food Authorities must execute and enforce the Regulation and inform FSS where products analysed under the Regulations do not comply (Regulation 6).

Regulation 7 provides for expenses incurred by Food Authorities in carrying out their official controls to be recovered from the importer in accordance with certain provisions of Regulation (EU) No. 882/2004 on the official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Regulation 8 specifies the measures to be taken by Food Authorities where a consignment is not accompanied by the required documentation or is otherwise non-compliant.

An importer can appeal the decision of an authorised officer of a Food Authority, as set out in Regulation 9.

Regulation 10 provides for FSS, if satisfied that the continued operation of a first point of introduction designated under Article 5 presents a serious risk to public health, to suspend that designation.

Associated Regulations

The Plastic Kitchenware (Conditions on Imports from China) Regulations (Scotland) 2011 (SSI. 2011 No. 282)

Commission Regulation EU No. 284/2011

Commission Regulation (EC) No. 882/2004

EC Directive 2002/72/EC

EC Regulation 10/2011

Commission Guidance: EU guidelines for the import of polyamide and melamine kitchenware

Commission Guidance: Technical guidelines concerning polyamide and melamine kitchenware

The Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990 (SI No. 1139)

Scope

This regulation implements the provision 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, milk, 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 difference 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%.

Associated Regulations

Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990 (SI No. 1139)

EC Directive 2136/89 on provisions relating to marketing of preserved sardines.

Commission Regulation (EC) No 1181/2003 of 2 July 2003 amending Council Regulation

(EEC) No 2136/89 laying down common marketing standards for preserved sardines)

Further Information

The Preserved Sardines (Marketing Standards) (Scotland) Regulations 1990 (SI No. 1139)

The Preserved Tuna and Bonito (Marketing Standards) Regulations 1994 (SI No. 2127)

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 90,
ex 1604 20 70	ex 1604 20 50, 1604 19 30
 Prepared from the species genus 	ex 1604 20 70, ex 1604 19 99
thunnus	and 1604 20 90
Albacore or longfin	Prepared from the species genus
Yellow fin	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%.

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.

Processed Cereal – Based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004 (SSI No. 8)

Scope

These Regulations implement <u>EC Directive 96/5/EC</u>, as amended by EC Directive 1998/36/EC, <u>1999/39/EC</u> and <u>2003/13/EC</u>.

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 0.35 mg.

Part II of Schedule 5 specifies foods and the maximum limit per 100 kcal 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 125 mg per 100 kcal.

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 0.003 mg/kg. All other pesticide residues of any individual pesticide not specified must not exceed 0.01 mg/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 than 6 months;
- the available energy value expressed in kJ and kcal, and the protein, carbohydrate and fat content per 100 g or 100 ml of the food sold. Where appropriate, per serving information may be given;
- the average quantity per 100 g or 100 ml 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 100 g or 100 ml 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 100 g or 100 ml cannot be expressed as a percentage of the reference value unless 15% or more of the reference value is present in 100 g or 100 ml.

Associated Regulations

Processed Cereal- Based foods and Baby Foods for Infants and Children (Scotland) Regulations 2004 SSI No 8

The Food for Particular Nutritional Uses (Scotland) (Miscellaneous Amendments) Regulations 2007 SSI No. 424

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

Further Information

EC Directive 96/5/EC EC Directive 98/36/EC EC Directive 1999/39/EC EC Directive 2003/13/EC

The Products Containing Meat etc. (Scotland) Regulations 2014 (as amended)

Scope

These regulations revoke and replace the Meat Products (Scotland) Regulations 2004.

The Meat Products Regulations apply to food which is ready for delivery to the final consumer or to a mass caterer. 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 your children.

These regulations retain existing national provisions on the reserved descriptions for meat products which are both produced and sold in Scotland.

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.).

The 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	15	10
All other red meats	25	25
and mixtures		

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.

Mechanically recovered meat (MRM) has the same meaning as in Commission Directive 2001/101/EC. It should be noted that there is also a definition of 'Mechanically separated meat' (MSM) in Regulation (EC) No. 853/2004.

The definitions are in effect the same and are not separate. When Directive 2001/101 was drafted, MSM was still written as 'MRM' in the hygiene Regulation EC 853/2004 but then this regulation was revised and the tem was changed to 'MSM' in the latter but clearly it was not then consequentially changed in the Directive. There is only one community definition of MRM (now known as MSM) which is in Regulation EC 853/2004 (National legislation will be amended in due course to reflect this change).

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 chipolata, frankfurters, link, salami 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 the schedule. 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 Regulation (EU) No 1169/2011 and is based on the EU meat definition. Therefore, the 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 Food Information (Scotland) Regulations 2014 (as amended) requires meat products sold loose or pre-packed for direct sale (e.g. by butchers, delicatessens, etc.) to be marked with the QUID declaration of the meat ingredient(s). QUID declarations are required only for those ingredients that fall within the EU definition of 'meat'. There is no requirement to mark or label the meat content of meat products sold loose or pre-packed 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.

Associated Regulations

- Meat Products (Scotland) Regulations 2004 SSI No. 6
- Food Labelling Amendment (Scotland) Regulations 2002 SSI No. 524
- Meat Products (Scotland) Amendment Regulations 2008 SSI No. 97
- Commission Directive 2001/101/EC
- The Food Additives (Scotland) Regulations 2009 (SSI No 436)
- The Food Additives (Scotland) Amendment Regulations 2012 (SSI No. 119)

Further Information

- Labelling and Composition of Meat Products (September 2003) FSA Guidance Notes
- 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
- Labelling of 'Added Ingredients' in Meat Product covered by MPR Regulation 5

Annex 1

SCHEDULE 2

Regulation 4(1) and (2)

RESERVED DESCRIPTIONS

Column 1	Column 2			Column 3
Name of Food	Meat or Cured Meat Content Requirements			Additional
				Requirements
	The food shall conta	in not less thar	n the	
	indicated percentage	e of meat, wher	e the	
	meat ingredient con	sists of the follo	owing:	
	Meat or, as the	Meat or, as	Meat or,	
	case may be, cured	the case may	as the	
	meat from pigs only	be, cured	case may	
		meat from	be, cured	
		birds only,	meat from	
		rabbits only,	other	
		or a	species or	
		combination	other	
		of birds and	mixtures of	
		rabbits only	meat	
1. Burger -	67%	55%	62%	1. Where the
whether or not				name "hamburger"
forming part of				is used, the meat
another word,				used in the
but excluding				preparation of the
any name				food must be beef,
falling within				pork or a mixture
items 2 or 3 of				of both.
this schedule.				

	2. Where eithe	ər
	of the names	
	"burger" or	
	economy burg	jer"
	is qualified by t	
	name of a type	
	cured meat, the	
	food must cont	
	a percentage o	of
	meat of the typ	
	from which the	
	named type of	
	cured meat is	
	prepared at lea	ast
	equal to the	
	minimum requi	red
	meat content for	or
	that food.	
	3. Where any c	of
	the names	
	"burger",	
	"economy burg	jer"
	or "hamburger'	' is
	qualified by the)
	name of a type	of
	meat, the food	
	must contain a	
	percentage of t	that
	named meat at	t
	least equal to t	he
	minimum requi	red
	meat content fo	

				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.
2. Economy Burger -	50%	41%	47%	
whether or not "burger"				
forms part of another word.				
3. Hamburger - whether or	67%	Not	62%	
not forming part of another		applicable		
word.				
L				I

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				
5. Corned X, there being	120%	120%	120%	1. The food
inserted in place of "X" the				shall consist
name "meat" or the name of				wholly of meat
a type of meat, unless				that has been
qualified by words which				corned.
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
Luncheon X, there being				requirement
inserted in place of "X" the				
name of a type of meat or				
cured meat				
	1	1	1	1

Meat pudding"Melton Mowbray pie" is used, the meat used in the preparation of the food must be meat from pigs only.The name 'pie" or "pudding" qualified by the name of a type of meat or cured meat unless qualified also by the name of a food other than meat or cured meatImage: Second	7. Meat pie				1. Where the name
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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 the				No additional
name "sausage" when				requirement
qualified by the words				
"liver" or "tongue" or both),				
link, chipolata or sausage				
meat.				
Where the name is qualified	42%	Not	Not	
by the name "pork" but not		applicable	applicable	
by the name of any other				
type of meat				
In all other cases	32%	26%	30%	

Quick Frozen Foodstuffs Amendment (Scotland) Regulations 2007 (SSI No. 106)

Scope

The regulations amend the <u>The Quick-frozen Foodstuffs Regulations 1990</u> and came into force on 16 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 -18°C or colder. This temperature has to be maintained, except for brief periods during transport (including local distribution) where it may reach not warmer than -15°C, and when in retail display cabinets where it may reach not warmer than -12°C

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 1 January 2006.

Existing instruments (installed before 1 January 2006) complying with previous legislation may continue to be used until 31 December 2009. All instruments must comply with the European Standards from 1 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 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)

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

European Commission legislation: <u>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

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

Specified Products from China (Restriction on first placing on the market) (Scotland) Regulations 2008 (SSI 2008 No. 148) (as amended)

Scope:

The regulations implement Commission Decision 2008/289/EC as amended by Commission Implementing Decision 2013/287/EU on the importation into the EC of an unauthorised genetically modified organism BT63 in rice products originating, or consigned from China.

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 products 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.

Further Information

Specified Products from China (Restriction on first placing on the market) (Scotland) Regulations 2008 (SSI No. 148)

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

Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed

The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Amendment Regulations 2012 (SSI 2012 No. 3)

These Regulations amend the aforementioned Specified Products from China (Restriction on First Placing on the Market) (Scotland) Regulations 2008 and implement Commission Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC.

The requirements of Decision 2011/884/EU are summarised as follows:

- i. Food and feed business operators must give adequate prior notice of the arrival of consignments falling within the Combined Nomenclature (CN) customs codes listed at annex I ('relevant consignments').
- ii. Relevant consignments must be accompanied by either:
 - An analytical report confirming the absence of GM rice material, based on the analytical methods stipulated in Annex II and a health certificate signed and verified by an authorised representative of the Chinese import/export authority; or
 - A statement indicating that the products in the consignment do not contain or consist of rice and have not been produced from rice.
- iii. Consignments that are not accompanied by the required documentation must be redispatched to the country of origin or destroyed.
- iv. All consignments accompanied by analytical reports and health certificates must be sampled and analysed in accordance with the methods stipulated in Annex II to ensure the absence of unauthorised GM rice material.
- v. Quarterly reports of the results of analytical tests carried out and the number of consignments rejected due to the absence of the necessary documentation must be submitted to the European Commission to allow it to monitor the effectiveness of the emergency Decision
- vi. All costs arising from the controls undertaken must be borne by food and feed business operators.

Associated Regulations

Specified Products from China (Restriction on First Placing on the Market) (Scotland) Amendment Regulations 2012-03-02

Commission Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC.

The Specified Sugar Products (Scotland) Regulations 2003 (SSI No. 527)

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 products 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 <u>Schedule 2</u>. 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 that 0.1%.

Associated Regulations

The Specified Sugar Products (Scotland) Regulations 2003 (SSI No. 527)

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

The Food Additives (Scotland) Amendment Regulations 2012 (SSI No. 119)

<u>EC Directive 2001/111</u> relating to certain sugars intended for human consumption

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (as amended)

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 sugar Purified and crystallised sucrose of sound and fair 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 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 the sugar
 (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 Sugar or White sugar Purified and crystallised sucrose of sound and fair 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 Extra-white The product having the characteristics referred to in paragraph 2(a),
 (b) invert sugar content not more than 0.1% by weight (c) loss on drying not more than 0.1% by weight Sugar or Purified and crystallised sucrose of sound and fair 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 Extra-white The product having the characteristics referred to in paragraph 2(a),
 (c) loss on drying not more than 0.1% by weight 2. Sugar or white sugar Purified and crystallised sucrose of sound and fair 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 The product having the characteristics referred to in paragraph 2(a),
 2. Sugar or white sugar Purified and crystallised sucrose of sound and fair 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 The product having the characteristics referred to in paragraph 2(a),
white sugarwith 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 23. Extra-whiteThe product having the characteristics referred to in paragraph 2(a),
 (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 The product having the characteristics referred to in paragraph 2(a),
 (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 The product having the characteristics referred to in paragraph 2(a),
 (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 The product having the characteristics referred to in paragraph 2(a),
 (d) type of colour not more than nine points determined in accordance with paragraph (2) of Schedule 2 3. Extra–white The product having the characteristics referred to in paragraph 2(a),
determined in accordance with paragraph (2) of Schedule 2 3. Extra–white The product having the characteristics referred to in paragraph 2(a),
3. Extra—white The product having the characteristics referred to in paragraph 2(a),
sugar (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 The aqueous solution of sucrose with the following characteristics:
solution (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	The purified and concentrated aqueous solution of nutritive			
syrup	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 matter,			
syrup	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 dextrose anhydrous	Purified and crystallised D–glucose not containing water of crystallisation, with at least 98% by weight of dry matter, but which 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

Spirit Drinks Regulations 2008 (SI No. 3206)

Scope

These Regulations make provision for the enforcement of Regulation (EC) No 110/2008 on the definition, description, presentation, labelling and protection of geographical indications of spirit and drinks, and give enforcement authorities new powers, including the power to give enforcement notices. The Regulations revoke the Spirit and Drinks (Scotland) Regulations 1990 SI 1990/1196.

Associated Regulations

Spirit Drinks Regulations 2008 (SI No. 3206)

The Spreadable Fats, Milk and Milk Products (Scotland) Regulations 2008 (SSI No. 216) (as amended)

Scope

These regulations provide for the execution and enforcement of certain provisions of Council Regulation (EU) No 1308/2013 establishing a common organisation of agriculture markets.

The Council Regulation repeals a number of other EC instruments including Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007.

The provisions of the Council Regulation include:

- (a) definitions, designations and sales descriptions for milk and milk products marketed for human consumption. Article 78 (1.) (c) and Part III of Annex VII
- (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 78 (1.) (f) and Part VII of Annex VII

Ingredients/Products

The EU 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
- Anhydrous milk fat (AMF)
- Cream
- Cheese
- Butter
- Yogurt
- Buttermilk
- Kephir (a fermented milk drink)
- Butteroil
- Koumiss (a fermented milk drink)
- Caseins
- Viili/fil
- Fil
- Smetana (Higher fat soured cream)
- Rjaženka, (Baked milk)
- Rūgušpiens (Cultured or curdled milk)

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 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 20°C (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 89%.

'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.

Associated Regulations

The Spreadable Fats, Milk and Milk Products (Scotland) Regulations 2008

The Food Information (Scotland) Regulations 2014 (SSI No. 312) (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 the Appendix to Annex XV to Council Regulation 1234/2007

Fat Group	Sales Description	Additional 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.	 Butter Three-quarter fat butter (*) Half-fat butter (**) Dairy spread X % 	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%. The product with a milk-fat content of not less than 60% but not more than 62% The product with a milk-fat content of not less than 39% but not more than 41%. 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 type, derived from solid and/or liquid vegetable and/or animal fats suitable for human consumption, with a milk-fat content of not more than 3% of the fat content.	 Margarine Three-quarter- fat margarine (*) Half-fat margarine (**) Fat spreads X % 	The product obtained from vegetable and/or animal fats with a fat content of not less than 80% but less than 90%. The product obtained from vegetable and/or animal fats with a fat content of not less than 60% but not more than 62%. The product obtained from vegetable and/or animal fats with a fat content of not less than 39% but not more than 41%. 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	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%.
emulsion, principally of the water-in-oil type, derived from solid and/or liquid vegetable and/or animal fats suitable for	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%.
human consumption, with a milk-fat content of between 10% and 80% of the fat content.	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 (SSI No. 479)

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 220 mg 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.

Associated Regulations

Tryptophan in Food (Scotland) Regulations 2005 SSI No 479

Further Information Committee on Toxicity Report