A reference to Food Composition and Labelling Legislation

Food Standards Training Manual

Developed in association with Environmental Health Services of District Councils in Northern Ireland

Foreword

This manual has been prepared in partnership with district councils in Northern Ireland.

District councils have a duty to enforce legislation relating to food standards, composition and labelling. Each council must ensure that all such legislation is enforced effectively, using means that are most appropriate to the food business operations.

In order to effectively enforce food standards legislation authorised officers must be familiar with the huge raft of legislation relating to food standards currently on the statute books. It is hoped that this manual will go some way to assisting officers to become more familiar with food standards legislation and associated guidance.

The aim of this manual is to provide a reference document for the wide range of food standards legislation in force in NI 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 or to provide interpretation but that it will give authorised officers an insight to some of the practical applications of its enforcement and identify other sources of useful information.

It should be noted that the guidance contained within the manual serves only as a general guide. Officers should also always consult the appropriate orders and regulations, many of which can be accessed from the legislation.gov.uk website. Where possible links to the appropriate web pages of legislation.gov.uk have been included in this manual.

The examples contained within this manual are provided for illustration only and should not be taken as an authoritative statement or interpretation of the law, as only the Courts have this power. Officers should always consult with their council's solicitors before considering the instigation of legal proceedings.

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 at least once every year.

In general, unless otherwise stated any references to legislation in the manual apply only to Northern Ireland legislation.

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Section 1
Introduction and Enforcement

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1.1 Section 1 - Introduction and Enforcement

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

- Food Safety (NI) Order 1991 and
- The Food Safety (NI) Order 1991 (Consequential Modifications) Order (NI) 1991
- Food Safety (1991 Order) (Commencement) Order (NI) 1991
- Food Safety (Enforcement) Order (NI) 1997
- Food Standards Act 1999 (Transitional and Consequential Provisions and Savings Regulations (NI) 2000
- The Food Safety (Act of Accession concerning the Czech Republic and other States) (Consequential Amendments) Regulations (NI) 2004

Responsibility for enforcement of the majority of the food standards, composition and labelling regulations under the Food Safety (NI) Order 1991 rests with district councils (Article 26). In Northern Ireland district councils appoint authorised officers specifically in writing (Article 2(2)), to enforce the legislation on their behalf. Separate authorisation is required for legislation made under the European Communities Act 1972.

The Food Safety (NI) Order 1991 is also supplemented with the Food Law Code of Practice (Northern Ireland) and Food Law Code of Practice Guidance.

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

- Authorisations
- Powers of entry
- Inspection, detention and seizure of food
- Application of laws to Crown premises etc

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

1.2 Food Standards Inspection Overview

In NI an authorised officer carrying out a food standards inspection and interventions as outlined in the Food Law Code of Practice (NI) looks at quality, composition, labelling, presentation, advertising of food and the materials and articles in contact with food.

The food standards inspection is a process of assessment and evaluation of systems used by a food business to demonstrate that the food being produced is of the correct composition and is fairly described and labelled. The food offered for sale should not mislead the consumer. 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 compositional requirements
- Manage systems in place to ensure that the standards can be met
- Comply with compositional, labelling, advertising, menus, claims and recipes
- Be able to demonstrate traceability
- Comply with specifications
- Adhere to industry codes and guidelines

Officers should be familiar with the requirements for a food standards intervention as set out in the Food Law Code of Practice.

Many officers use a standard inspection proforma or aide memoir to guide them through the inspection assessment process.

On completion of the inspection an officer is required to conduct a risk assessment which categorises the premises into one of three categories:-

A. **High:** Requiring intervention at least once per year
B. **Medium:** Requiring intervention at least once every 2 years
C. **Low:** Requiring an alternative enforcement strategy or intervention every 5 years

- The risk assessment is based on a score allocated under the following general headings:-

- Potential risk to consumers and other businesses
- Extent to which the activities of a business may affect a hazard
- Ease of compliance
- Consumers at risk
- Level of current compliance
- Confidence in management/control systems.

Before competent authorities authorise officers to deliver official controls (hygiene and standards), the lead food officer must ensure that the officer:

- holds the baseline qualification listed at section 4.4 of the Code OR one of the equivalent qualifications listed in section 4.5 of the Code;
- meets the relevant competencies listed at section 4.7 onwards in the Code;
- demonstrates they have maintained their Continuing Professional Development (CPD) in accordance with section 4.10.1 of the Code.

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

- Codes of practice and guidance
- Relevant food standards law
- District council enforcement policy
- Industry codes of practice
- Food Standards Agency guidance
- Guidance issued by Northern Ireland Food Liaison Group (NIFLG).

1.3 Principles of Enforcement

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

All officers should have an awareness of:

- Code for Crown prosecutors
- Enforcement concordat
- Relevant codes of practice under the Regulatory Reform Act 2001
- Regulatory and Investigatory Powers Act
- Police and Criminal Evidence
- District council 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 the statutory contraventions and remedial actions needed to secure compliance. The correspondence should also indicate the time scale suggested to achieve compliance.

In food standards inspections, the aspects of detention and seizure of food may not be as common as could be encountered in food hygiene inspections.

1.4 Detention and Seizure of Food

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

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

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

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

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

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

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

- The owner of the food has suggested this option.
- The owner will bear the cost of disposal
- The disposal will be supervised.

More detailed guidance on voluntary surrender is contained in the Food Law Code of Practice.

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. Section 8 of the Food Law Code of Practice gives a detailed account of sampling and analysis procedures. Officers should also be aware of sampling guidance issued by the Northern Ireland Food Liaison Group. (Details can be downloaded from Western Group of Councils webpage).

1.6 Food Control Primary Legislation

1.6.1 The Food Safety (NI) Order 1991

The Food Safety Order sets out the framework for most food standards regulation.

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

1.6.1.1 Part 1 - Introduction

Article 2 outlines definitions for commonly used terms such as food, food business, food premises, food sources etc. The article was amended by the Food Safety (NI) Order 1991 (Amendment) Regulations (NI) 2004 to bring the definition of food in line with the definition in Regulation (EC) 178/2002

Article 2(4) extends the meaning of sale to include food supplied in the course of a business.

Article 3 deals with food offered as prizes.

Article 4 sets out provisions regarding presumptions relating to food and ingredients, for instance, that food commonly used for human consumption found on certain food premises is presumed to be intended for sale.

1.6.1.2 Part 2 - Main Provisions

Article 5 defines the food safety requirement. This article was amended by the General Food Regulation (NI) 2004 to bring the definition in line with Regulation (EC) 178/2002

Article 6 describes the offence of rendering food injurious to health.

Article 7 setting out the offence of selling or processing for sale food that does not comply with the food safety requirement was removed from the Food Safety (NI) Order 1991 by the General Food Regulation (NI) 2004.

- General Enforcement Provisions
See section 1.6.2.1 regarding Food Safety Requirements.

Article 8 gives authorised officers power to inspect any food intended for human consumption and to detain and seize any food suspected of not complying with the food safety requirement. The article also allows a Justice of the Peace to condemn food failing the food safety requirement.

Article 9 allows for improvement notices where food hygiene or food processing regulations have been contravened. It is unlikely that such notices would be used in a food standards inspection.

Article 10 allows for prohibition orders to be issued by the court where there is a risk of injury to health and the proprietor of a food business has been convicted of an offence under food hygiene or food processing regulations.

Article 11 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 Order and can be used in relation to offences linked to food standards where there is a risk of injury to health.

Article 12 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 such food causing such injury to health.

Article 13 relates to the sale of food that is not of the nature, substance or quality expected by the consumer. Each term can be used independently of the others in legal proceedings. There is considerable case law on the terms but the following serves as a useful reference

In practice:

“Nature” covers a product sold as one thing, but which is in fact another, e.g. haddock sold as cod;

"Substance" covers situations where the food contains foreign bodies (e.g. and insect) or damaging residues or where there is a statutory or other standard for a food and the substance falls below it, for example milk powder with below the minimum milk protein level. The necessary substance for particular products is set through compositional standards in commodity regulations for which separate guidance exists;

"Quality" covers commercial quality, having regard to any statutory standards of composition in the food, so an example of food which would not be of the quality demanded would be a stale cake. If formal action is taken, it should, as a result of existing case law, specify whether it is because the food is "not of the nature", "not of the substance" or "not of the quality" demanded, and not all three simultaneously.

http://www.food.gov.uk/multimedia/pdfs/nifoodbusinessguide.pdf

Article 14 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.

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

G.W.Padley (Poultry) Ltd V Elkington
Wolkind and Northcott V Pura Foods Ltd or
Burleigh V Van den Bergh and Jurgens Ltd.

The 'CAP Code': 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 Article 16 of Regulation (EC) 178/2002 and is implemented by the General Food Regulation (NI) 2004.

- Defences

Article 19 enables the enforcement authority to bypass the immediate offender and prosecute the real offender.

Article 20 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. The prosecuting authority is not under obligation to prove that the defence was not fulfilled. The burden of proof is discharged on the balance of probability.

See Lincolnshire County Council V Safeway stores Plc.

1.6.1.3 Part 3 - Administration and enforcement

Article 26 of the Order sets out the scope of enforcement of the Order by different bodies i.e. District Councils and DAERA.

- Sampling of Food

Articles 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

Article 33 sets out who may enter premises to enforce the order and outlines what they can do while on the premises. Unauthorised disclosure of information obtained when using these powers is an offence.

Article 34 deals with obstruction of officers

Article 35 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.

- Offences

Article 36 for most offences a Crown Court may impose a prison sentence of up to 2 years and/or unlimited fines. Magistrate's Courts generally may impose a fine, up to level 5 and a prison sentence of up to 6 months. In relation to the most serious offences Magistrates Courts can impose a maximum fine of £20,000.

Articles 37 and 38 provide for appeals against decisions of an enforcement authority to serve an improvement notice, and to refuse certificates under Articles 10 and 11.

Article 49 deals with the application of the Order to Crown premises. This Article 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 (NI) 2004

These regulations implement the provisions of Regulation EC No. 178/2002 in respect of the general principles and requirements of food law.

The regulations amend the interpretation of the Food Safety Requirement of the Food Safety (NI) Order 1991 to that outlined in Article 14 of Regulation (EC) No. 178/2002.

1.6.2.1 Food Safety Requirement (Article 14)

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be
   (a) Injurious to health
   (b) Unfit for human consumption.

3. In determining whether any food is unsafe regard shall be had:
   (a) To the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

   (b) To the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health regard shall be had:
   (a) Not only to the probable immediate and/or short term and/or long term effects of that food on the health of a person consuming it, but also on subsequent generations

   (b) To the probable cumulative toxic effects

   (c) To the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption; regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch lot or consignment is also unsafe, unless following, a detailed assessment there is no evidence that the rest of the batch lot or consignment is unsafe.

7. Food that complies with specific community provisions governing food safety shall be deemed to be safe in so far as the aspects covered by the specific community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that despite such conformity the food is unsafe.

9. Where there is no specific community provision, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

The Food Safety Order is also amended by the omission of Article 7 in relation to selling of food not complying with the food safety requirement.

1.6.2.2 Presentation (Article 16)

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

1.6.2.3 Traceability (Article 18)

Article 18 of EC 178/2002 relates to traceability. The food business operator must have systems and procedures in place to 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.

Regulation (EU) No. 931/2011 applies to food defined as 'unprocessed and processed products' in Article 2(1) of Regulation (EC) No. 852/2004. It does not apply to food which contains products of plant origin together with processed products of animal origin.

This Regulation places an obligation on food business operators to ensure that the following information concerning consignments of **food of animal origin** is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:

(a) an accurate description of the food;

(b) the volume or quantity of the food;

(c) the name and the address of the food business operator from which the food has been dispatched;

(d) the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched;

(e) the name and address of the food business operator to whom the food is dispatched;

(f) the name and address of the consignee (owner), if different from the food business operator to whom the food is dispatched;

(g) a reference identifying the lot, batch or consignment, as appropriate; and

(h) the date of dispatch.

The information (a to h) must be updated on a daily basis and as a minimum be kept at least until it can be reasonably assumed that the food has been consumed.

1.6.2.4 Product Recall (Article 19)

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

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

Further guidance can be obtained from the following sites:

Europa Website

Food Standards Agency Website

Section 2
Training Notes on Food Labelling Legislation

2

2.1 Food Information Regulations (Northern Ireland) 2014 (SR No. 223) (as amended)

2.1.1 Introduction

Following an EU-wide review of both general food and nutrition labelling legislation, the European Parliament approved the text for a new Food Information for Consumers Regulation (EU FIC) on 6 July 2011 and this was adopted by the Council of the European Union on 29 September 2011.

The Food Information for Consumers Regulation (EU FIC) No. 1169/2011 brings EU rules on general and nutrition labelling together into a single regulation to simplify and consolidate existing labelling legislation and applies in all Member States, replacing current UK law after a three-year transitional period. Most requirements applied from 13 December 2014 with nutrition labelling becoming mandatory in December 2016. The Food Information Regulations (Northern Ireland) 2014 (as amended) provide administrative arrangements for enforcement of EU No. 1169/2011 in Northern Ireland.

The original objectives and the core components of the current EU labelling legislation are preserved and maintained in this Regulation, along with some new requirements in order to ensure easier compliance and greater clarity for stakeholders. The legislation also takes account of new developments in the field of food information. This section highlights some of the main elements of the Regulation. It should be noted however, that some of those elements require implementing rules or guidance to be published by the Commission.

2.1.2 Food Information – Definition

The EU FIC sets out the requirements for the

- labelling,
- advertising and
- presentation of foodstuffs.

It refers to food information rather than food labelling. It 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".

2.1.3 Application Dates

The EU FIC entered into force on 13 December 2011 but there was a phased introduction to its provisions.

Transitional arrangements for the Food Information for Consumers Regulations

FIC came into force	13 December 2011
Foods voluntarily using new nutrition declaration can be sold	13 December 2011
General labelling rules apply	13 December 2014
Current legislation (including 2000/13 and 90/496) repealed:	13 December 2014
Foods on the market or labelled prior to 13 December 2014 can be sold until	Food stocks are exhausted
Foods bearing a nutrition declaration on a voluntary basis must comply with the requirements of the FIC from:	13 December 2014
Nutrition labelling required for most prepacked foods	13 December 2016
Foods on the market or labelled prior to 13 December 2016, without a nutrition declaration can be sold until	Food stocks are exhausted

2.1.4 Scope of the Regulations

The regulation 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 are not intended to apply to food sold by Charities which are not operating and registered as food businesses.

2.1.5 Mandatory Particulars

The principal provisions of the Regulations 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 name of the food
- The list of ingredients
- Food allergens
- 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
- Instructions for use
- Alcohol % if greater than 1.2% vol.
- Nutrition declaration

2.2 General Labelling Requirements

2.2.1 Mandatory Requirements – Article 9

The mandatory information, set out below, is described in Article 9 of EU 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 EU FIC, such as, minimum font size and how to present nutrition information also needs to be considered -

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

And in certain cases -

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

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

2.2.2 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 not, a customary name may be used. If there is no customary name, or it is not used, a descriptive name must be used. The name should be sufficiently precise to inform a purchaser of the true nature of the food and to enable the food to be distinguished from products with which it could be confused. The name of a food may consist of a name, a description, or both.

2.2.2.1 Prescribed Name

A name may be prescribed by either European Community law or, in the absence of such law, by law in Northern Ireland. 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, EC 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.

2.2.2.2 Reserved Descriptions

In the case of some foods, there are compulsory product names that must be used for foods meeting certain composition 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 the EU FIC.

2.2.2.3 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. 'fifteens') 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 (see paragraph 2.2.2.4) 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 the EU 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.

2.2.2.4 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'.

2.2.2.5 Treatments and Physical Conditions of Food (Annex VI)

Further requirements on how the name of the food should be described are set out in Annex VI. There are requirements to give the particulars of any physical process the food has undergone where the absence of such information might mislead. 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.

2.2.2.6 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)).

2.2.2.7 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".

2.2.2.8 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.

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

It is important to be aware that certain food names are protected within the European Community. 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 scheme are: -

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

Examples of Northern Ireland PGI designations include:

- Lough Neagh Eels
- Comber Early Potatoes
- Armagh Bramley Apples

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

European Commission Website

Use of the logo became compulsory from **4 January 2016**, this means that use of the logo is now a compulsory requirement for products marketed as registered PDO/PGI/TSGs using a protected food name. 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' may be used in addition to the logo.

Further information on the scheme can be found on the Department of Agriculture, Environment and Rural Affairs website and the Europa website:

https://www.daera-ni.gov.uk/articles/european-union-protected-food-names-schemes

http://ec.europa.eu/agriculture/quality/

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

- Trademarks, Brand Names or Fancy Names (Article 17(4))
- Trademarks, brand names or any fancy names cannot be substituted for the name of a food, but may be used in addition to it.
- Processes and treatments (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 (for example, powdered, refrozen, freeze-dried, quick-frozen, 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'.

Irradiated Foods (Annex VI (3))
Point 3 of Part A of Annex VI to the EU 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-prepacked 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 the EU FIC

These provisions apply to the labelling of irradiated foods intended for either the ultimate consumer or catering establishments. The Food Irradiation Regulations (Northern Ireland) 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, filet or of a whole fishery product.

Name and compositional requirements for minced meat
The EU FIC requires minced meat to conform to specific standards for fat content and collagen/meat protein.

Composition criteria checked on the basis of a daily average:

	Fat content	Collagen/meat protein ratio[1]
Lean minced meat	≤ 7 %	≤ 12 %
Minced pure beef	≤ 20 %	≤ 15 %
Minced meat containing pig meat	≤ 30 %	≤ 18 %
Minced meat of other species	≤ 25 %	≤ 15 %

(1) 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…'

Products may be sold on the national markets which do not meet compositional requirements provided the labelling clearly shows:

(a) a square 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
The 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
  Such terms should not be applied to foods that have been subject to some form of processing or treatment.

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

2.2.3 List of Ingredients

2.2.3.1 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 EU 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 10cm^2) or pre-packed for direct sale (Article 16). However, in the case of packaging or containers the largest surface of which has an area of less than 10cm^2 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 EU FIC.

2.2.3.2 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.

2.2.3.3 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 i.e. 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 that list of ingredients is accompanied by an expression such as 'in variable proportion'

Category of ingredient	Provision concerning indication by weight
6. Ingredients constituting less than 2% of the finished product	May be listed in a different order after the other ingredients
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, Rape/Sunflower or other sources.	

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

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

(a) an ingredient which has been temporarily separated during the manufacturing process;

(b) food additives and food enzymes;

(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 in the Food Labelling Regulations it was noted that abbreviating 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 unacceptable e.g. **'bic soda'**. The correct name would be **'bicarbonate of soda'**. The use of the term **'flour'** or **'plain flour'** also needs to be expanded bearing in mind the need to draw attention to allergens e.g. **'Wheat flour'**. In addition, since flour in the UK is fortified, under EU FIC it would be regarded as a compound food and would need to have the fortified substances appear in brackets after the word "wheat flour". For example, 'wheat flour (calcium, iron, niacin and thiamine)'.

2.2.3.5 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 origin.	'Oil', together with either the adjective 'animal', or the indication of specific animal The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated oil

Definition of category of food	Designation
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'
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'

<table>
<tr><th>Definition of category of food</th><th>Designation</th></tr>
<tr><td>12. Anhydrous dextrose or dextrose monohydrate</td><td>'Dextrose'</td></tr>
<tr><td>13. Glucose syrup and anhydrous glucose syrup</td><td>'Glucose syrup'</td></tr>
<tr><td>14. All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof</td><td>'Milk proteins'</td></tr>
<tr><td>15. Press, expeller or refined cocoa butter</td><td>'Cocoa butter'</td></tr>
<tr><td>16. All types of wine as covered by Annex XIb to Regulation (EC) No 1234/2007[1]</td><td>'Wine'</td></tr>
<tr><td>17. Skeletal muscles[2] 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 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 the term '… meat'

<table>
<tr><th>Species</th><th>Fat content</th><th>Collagen/meat protein ratio[1]</th></tr>
<tr><td>- Mammals (other than rabbits and porcines) & mixtures of species with mammals pre-dominating,</td><td>25%</td><td>25%</td></tr>
<tr><td>- Porcines</td><td>30%</td><td>25%</td></tr>
<tr><td>- Birds and rabbits</td><td>15%</td><td>10%</td></tr>
</table>
(1) 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.</td><td>'… meat' and the name(s)[3] of the animal species from which it comes</td></tr>
</table>

Definition of category of food	Designation
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	
18. All types of products covered by the definition of 'mechanically separated meat'	'mechanically separated meat' and the name(s) of the animal species from which it comes

(1) 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) (OJ L 299, 16.11.2007, p.1). Please note this regulation has since been revised and replaced by Regulation (EU) No.1308/2013.

(2) 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.

(3) For labelling in English, this designation may be replaced by the generic name of the ingredient for the animal species concerned.

2.2.3.6 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 9(2) of Regulation (EC) No 1994/2008 and imports 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)'.

2.2.3.7 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.

EU 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-prepacked 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 1333/2008 on food additives that re-enacts the annexes of Directive 95/2, 94/35 and 94/36
- Regulation EC 1332/2008 on food enzymes

- **Specific Name used for an Additive**

Where the specific name of an additive is to be given in the ingredients list, the name used should be one which is set out in the annexes to the aforementioned directives that are enacted in national legislation by the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013.

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

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

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

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

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

- **Serial Number used for an Additive**

Where the serial number of the additive is to be given in the ingredients list the number used should be one which appears in the column headed 'E" No' in Annex II to EC Regulation 1333/2008.

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

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

- Vitamins, minerals or other nutrients used solely for the purpose of fortifying or enriching food, or for restoring the constituents of food;
- Any substance present in a food as a result of its addition to animal, bird or fish feedingstuff and

- Any substance present in food as a result of its use in a process or treatment carried out in crop or animal husbandry, or storage (including any pesticide, fumigant, sprout suppressant or veterinary medicine).

- **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 yoghurt which has then been pasteurised.

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

- **Processing Aids (Article 20 (b ii)**

A processing aid is any substances 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 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. (Regulation EC 1333/2008)

2.2.3.8 Compound Ingredients (Annex VII Part E)

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

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

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

(a) the composition of the compound ingredient is defined and constitutes less than 2% of the finished product;

(b) the compound ingredients consist 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

2.2.4 Quantitative Indication of Certain Ingredients or Categories of Ingredients (QUID)

2.2.4.1 Quantitative Ingredient Declarations Article 22 and Annex VIII

Article 22 specifies the requirement to quantify 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.

2.2.4.2 Scope of the Quid Requirement

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

The requirements do not apply to products not otherwise covered by EU FIC.

- Foods not required to carry an ingredients list are not in principle exempt from QUID declarations. Such foods will not have to provide an ingredients list even if a QUID declaration is given,

- The requirements do not affect the labelling of non pre-packed and pre-packed for direct sale foods (including those sold at catering establishments), food sold in small packages or certain indelibly marked glass bottles, or the information provided on the front of vending machines,

- A QUID declaration will not apply to constituents naturally present in foods which have not been added as ingredients. Examples are caffeine (in coffee), vitamins and minerals (in fruit juice),

- A QUID declaration will not apply to foods which, although mentioned in the name of a food, have not been used in its manufacture or preparation, examples are 'cream cracker' - a customary name used to describe a dry biscuit which never contains cream, or 'chicken flavour crisps' - where the chicken flavour comes from one or more ingredients which are not chicken.

2.2.4.3 Products to which the Quid requirements do not apply

There are exemptions to this requirement. These are:

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

- the drained net weight which is indicated in accordance with point 5 of Annex IX, e.g. tinned 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

- 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 sweeteners(s)' if that indication is required to accompany the name of the food; or

- Any added vitamin or mineral if that substance is the subject 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.

2.2.4.4 Formula used to calculate QUID

- For foods that require further processing

$$\text{QUID \%} = \frac{\text{Wt. Ingredients at mixing bowl}}{\text{Total Wt. Of all ingredients at mixing bowl}} \times 100$$

- For foods that have been thermally processed

$$\text{QUID \%} = \frac{\text{Wt. Ingredients at mixing bowl}}{\text{Total Wt. After product processing}} \times 100$$

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.

2.2.4.5 Position of QUID declaration (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 QUID rules is provided in the Agency guidance.

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

The guidance includes details on

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

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.

2.2.5 Appropriate Durability Indication

2.2.5.1 Date marking provisions (Article 24 and Annex X))

The majority of prepacked foods are required to have an indication of minimum durability. There are however exemptions which are set out in Annex X to the EU 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 220600 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 prepacked 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 after a short period to constitute an immediate danger to human health. The food should be consumed by the end of the date given.

Food on sale after the "use by "date is 'deemed' to be unsafe under Article 14(2) to (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 (Northern Ireland) 2004 (SR 2004 No. 505 (as amended)).

The Defra/ FSA guidance on date marking guidance issued in September 2011 still applies. This can be found here http://www.defra.gov.uk/publications/files/pb132629-food-date-labelling-110915.pdf

2.2.5.2 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
for foods expected to keep for 3 months or less:	the words best before may be followed by the date in terms of the day and month
for foods expected to keep for more than 3 months but no longer than 18 months:	the date mark may be given in the form best before end and the date in terms of the month and year
for foods expected to keep for more than 18 months:	the date mark may be shown as best before end followed by the date in terms of the 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.

2.2.5.3 Form used for the 'use by' date mark Article 24(2) and Annex 10

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'.

2.2.5.4 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).

2.2.5.5 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. After the 'use by' date a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002.

2.2.5.6 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.

2.2.5.7 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 (Northern Ireland) 2004 (as amended).

Selling a food after its "best before date" is not an offence. Whilst it may not be an offence under the food labelling regulations, the enforcement officer may wish to point out to a retailer that the food may not possess the required quality outside the shelf life and could result in a complaint being received of food failing to comply with Article 13 of the Food Safety (NI) Order 1991.

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

The date of first freezing for meat preparations and unprocessed fisheries products is required under Article 24 and Annex X to the EU 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.*

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

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

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.

2.2.6.2 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 the safe cooking e.g. microwave instructions for a product that can only be microwaved.

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

Article 9 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 or the producer outside 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 addresses, or other non-physical contact details would not be an acceptable replacement for the FBO address.

2.2.7 Origin

2.2.7.1 Origin Labelling - (Article 9, 26 and Annex XI)

Mandatory origin requirements

Article 26 of EU 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 EU 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 of EU FIC i.e. from pigs, sheep, goats and poultry the requirements are contained within Regulation (EU) No 1337/2013. This is covered in more detail in Section 3 of the Manual under the guide "Country of Origin of Certain Meats Regulations (NI) 2015".

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 March 2017, EU discussions remain ongoing regarding an Implementing Act to govern this area.

Article 26 of EU FIC 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.

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.

2.2.7.2 Avoiding Misleading Labelling in Relation to Origin Labelling

In absence of Commission guidance, information on how to avoid misleading descriptions can be found in FSA Country of Origin Labelling Guidance. The following notes taken from the guidance will be of interest.

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

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

- Use of country or place names in the name of the food or in its trade name, brand name or fancy name;

- Written or illustrative material including maps, flags, emblems (such as a shamrock), choice of colour (such as the colours of a country's national flag), references to persons associated with a particular place (like 'John Bull', 'Uncle Sam') and famous landmarks (such as the Eiffel Tower, Ben Nevis).

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

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

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

Subject to enabling legislation if the place of origin of the food is not the same as the place of origin of its primary ingredients, it will be necessary to provide information on the origin of those ingredients.

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.

- Avoiding Misleading Information in Catering Establishments

In catering establishments, care should be taken to ensure the wording of any origin information on menus etc. is clear and unambiguous.

2.2.8 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 $10cm^2$ 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:

- Unprocessed products that comprise a single ingredient or category of ingredients;
- Processed products which the only processing they have been subjected to is maturing and that comprise a single ingredient or category of ingredients;
- Waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings;
- A herb, a spice or mixtures thereof;
- Salt and salt substitutes;
- 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 (1), whole or milled coffee beans and whole or milled decaffeinated coffee beans;
- 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;
- Fermented vinegars and substitutes for vinegar, including those where the only added ingredients are flavourings;

- Flavourings;
- Food additives;
- Processing aids;
- Food enzymes;
- Gelatine;
- Jam setting compounds;
- Yeast;
- Chewing-gums;
- Food in packaging or containers the largest surface of which has an area of less than 25cm^2 ;
- 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' can be found at: https://www.food.gov.uk/sites/default/files/qa-nutrition-labelling_0.pdf)

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

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

Allergen information is required to be provided on the labelling of prepacked 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 EU 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 these Regulations, 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. Where allergen information is not provided upfront and written, it must be signposted where this information could be obtained. To provide the information verbally food business operators will need to consider setting up a system to help 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 ensuring recipes accurately reflect the ingredients used highlighting and identifying the allergenic components. These recipes will need to be reviewed when changes 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 food allergies to seek further details of other allergenic components in the food of their choice.

Similarly in a bakery setting 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 provided before the purchase is concluded and at the moment of delivery.

- FBOs selling non-prepacked 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
    - at the point of delivery.

The allergen information should be held in written form by the business and be 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 **(Art. 9(1) (c))**, as listed in **Annex II**. If any ingredient processing aid or ingredient, derived from a substance or product listed in **Annex II** of the Regulations, 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 from other ingredients within the ingredients list.

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

Annex II of EU regulation 1169/2011

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;
8. ***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 10mg/kg or 10mg/litre in terms of the total SO^2 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 noticeable and not, in any way hidden or obsured 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 (allergen) ingredient, further indication of the presence of the substance or product (in this case mustard, peanuts or eggs) is not required.

Article 21
Information about the Annex II (allergen) ingredients will need to be emphasised within the ingredients list by means of contrasting font, size, style or background colour. For example, "INGREDIENTS: **Oat**meal, 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.

Old label

INGREDIENTS: Water, Carrots, Onions, Red Lentils (4.5%) Potatoes, Cauliflower, Leeks, Peas, Cornflour, Wheatflour, Salt, Cream, Yeast Extract, Concentrated Tomato Paste, Garlic, Sugar, Celery Seed, Vegetable Oil, Herb and Spice, White Pepper, Parsley.

New Label

INGREDIENTS: Water, Carrots, Onions, Red Lentils (4.5%) Potatoes, Cauliflower, Leeks, Peas, Cornflour, **Wheat**flour, 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, "**wheat**flour" 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**, style, or colour (see Article 12 and 13 of 1169/2011 for more information).

If all the ingredients are in the Annex II list, they need to all be listed and emphasised against other mandatory information, such as the word "Ingredients" where it introduces the ingredients list.

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 origins.

For small packaging where the largest surface area of the food packaging or container is less than 10cm^2, and the ingredient list has been omitted (Article 16 – omission of certain particulars), the presence of Annex II ingredients (allergens) in the food should still be stipulated, e.g. by the word "contains…" followed by the name of 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 will be 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, a wine product 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 mandatory 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 substance or product causing allergies or intolerances are emphasised within it, 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 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 cross contact or contamination.

The voluntary use of precautionary allergen statements will still be permitted.

Food businesses may choose to use different phrases to warn of allergen cross-contamination 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 Food Information (Amendment) Regulations (NI) 2016 (SR No. 249) make provisions for the requirements of Commission Implementing Regulation (EU) No 828/2014, on the provision of information on the absence or reduced presence of gluten in food labelling requirements.

828/2014 sets out the conditions under which foods may be labelled "gluten free" or "very low gluten".

The new rules apply to prepacked and non-pre-packed food such as those served in restaurants and defines how gluten-intolerant consumers should be informed of the difference between foods that are naturally free from gluten and products that are specifically formulated for them.

Statements on the absence or reduced presence of gluten in food that are allowed to be made and conditions thereof-.

General Requirements

Gluten free – The statement 'gluten free' may only be made where the food is sold to the final consumers containing no more than 20mg/kg of gluten.

Very low gluten- The statement 'very low gluten' may only be used where the food, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specifically processed to reduce the gluten content, and contains no more than 100mg/kg of gluten in the food as sold to the final consumer.
"No Gluten Containing Ingredients" and other factual statements in addition to those mentioned in Regulation (EU) No. 828/ 2014 cannot be used in any food labelling.
Permitted additional statements:
"Suitable for people intolerant to gluten" or "suitable for coeliacs".

"Specifically formulated for people intolerant to gluten" or "specifically formulated for coeliacs".

There are additional requirements for food containing oats.

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

Please click here to view 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

FSA in NI Allergen and Calorie Calculator - Menucal
https://www.menucalni.co.uk/Account/LogOn?ReturnUrl=%2f

UK food industry guidance on allergen labelling and the requirements in the EU FIC as published by the British Retail Consortium (BRC) in partnership with the Food and Drink Federation (FDF):
http://www.brc.org.uk/brc_policy_content.asp?icat=46&isubcat=658&spolicy=food&ssubpolicy=labelling

European Commission guidance on the EU FIC:
http://ec.europa.eu/dgs/health_foodsafety/dgs_consultations/food/docs/consult_20150104_allergy-intolerance_guidance.pdf

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 milligrams per litre of SO2 (which most table wines will have).

This must be shown on any label of a wine-sector product. 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'

Alternative Ingredients List

Use of symbols - optional

In addition to the compulsory labelling, the amending Regulation also provides for the optional use of pictograms.

References to further information on wine labelling

FSA guidance on Allergens Labelling for Wine Wine
http://www.food.gov.uk/business-industry/winestandards/wine-labelling

Regulation 579/2012 (covers milk and eggs)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:171:0004:0007:EN:PDF

Food labelling Directives
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_en.htm

Wine regulations, including Commission Regulation 607/2009
http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R0607&from=EN

Languages permitted in each Member State
http://ec.europa.eu/agriculture/markets/wine/labelling_allergens.pdf

European Food Safety Authority
http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_NDA.htm

2.2.10 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 Regulation 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 1.2mm.

Legend
1 Ascender line
2 Cap line
3 Mean line
4 Baseline
5 Descender line
6 x-height

In the case of packaging or containers, the largest surface of which has an area of less than 80cm^2, the x-height of the font size must be equal to or greater than 0.9mm.

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 new Regulation, 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

The requirement to include date of minimum durability in the same field of vision which is a requirement under the current rules has been removed. Field of vision is defined in the Regulation as meaning "all the surfaces of a package that can be read from a single viewing point".

2.2.11 Nutrition Labelling (Articles 29 - 34)

Mandatory nutrition labelling

Since 13th December 2016 it has become mandatory for nutrition information to be provided on most prepacked foodstuffs. The declaration must comply with EU 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 to the Regulation and include unprocessed products that comprise a single ingredient or category of ingredients, herbs, spices, salt, chewing gums, foods in packaging or containers the largest surface of which has an area of less than 25cm^2. 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.

FSA advice on interpreting 'small quantities' and 'local' for purposes of this exemption is available at: https://www.food.gov.uk/sites/default/files/qa-nutrition-labelling_0.pdf

To facilitate the comparison of products in different package sizes, the requirement that the mandatory nutrition declaration should refer to 100g or 100ml 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 new Regulation, in so far as the mandatory declaration will now be as follows:

(a) Energy value; and
(b) The amounts of fat, saturates, carbohydrate, sugars, protein and salt

An example of the nutrition panel is given below

Energy	**kJ/Kcal**
Fat	g
of which	
- saturates	g
mono-unsaturates	g
polyunsaturates	g
carbohydrate	g
of which	
- Sugars	g
- polyols	g
- starch	g
fibre	g
protein	g
salt	g
vitamins and minerals	In and % of RI units specified in 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 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.

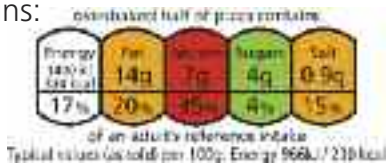
Government recommendations and notification requirements

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:



- Information on the energy value in kilojoules (KJ) and kilocalories (kcal) per 100g/ml and in a specified portion of the product
- Information on the amounts in grams of fat, saturated fat ("saturates"), (total) sugars and salt in grams, in specified portion of the product.
- Portion size information expressed in a way that is easily recognisable by, and meaningful to the consumer. For example, ¼ of a pie or 1 burger.
- % RI information based on the amount of each nutrient and energy value in a portion of the food.
- Colour coding of the nutrient content of the food.

Companies may additionally include the descriptors "High", "Medium" or "Low" (HML) together with the colours red, amber or green respectively to reinforce their meaning.

The FoP label design must not mislead or confuse the consumer.

Please click on the link below to view guidance:
https://www.food.gov.uk/sites/default/files/multimedia/pdfs/pdf-ni/fop-guidance.pdf

2.2.12 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:
http://ec.europa.eu/nuhclaims/?event=search.

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

2.2.13 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 Northern Ireland. 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.

http://www.food.gov.uk/business-industry/winestandards/wine-labelling/

2.2.13.1 The name of the food

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

2.2.13.2 List of ingredients

Alcoholic drinks are exempt from requiring an ingredients list pending a report and possible future implementing acts from the European Commission.

2.2.13.3 Appropriate indication of minimum durability (date mark)

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

2.2.13.4 Special storage conditions or conditions of use

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

2.2.13.5 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 addresses, or other non-physical contact details would not be an acceptable replacement for the FBO address.

2.2.13.6 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 this would be misleading to the consumer.

2.2.13.7 Instructions for use

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

2.2.13.8 Indication of alcoholic strength by volume

All pre-packed drinks with an alcoholic strength of more than 1.2% (abv) must be labelled with an indication of alcoholic strength by volume. This must be shown as a figure (to not more than one decimal place) preceded by the word 'alcohol' or by the abbreviation 'alc' and followed by the symbol '% vol'. Specified positive and negative tolerances are permitted in respect of the indication of alcoholic strength. These are listed in Annex XII of the EU FIC. The following national measures on no/low alcohol terms 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 spirit 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'. The EC Regulation 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.

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

When a composite name including the word 'wine' is used for a drink which has been made from fruit or similar substances other than grapes, the name of the fruit or substance used must be shown immediately before the word 'wine' in the composite name. If a mixture of fruits and/or other substances has been used, only those which give the wine its character must be shown.

2.2.14 Labelling of Genetically Modified Foods (GM)

For products consisting of or containing Genetically Modified Organisms (GMOs), operators shall ensure that:

(a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a 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(s)]' shall appear on, or in connection with, the display of the product.

Food must carry a label which refers to the presence of GMOs. However, these labelling requirements do not apply to food which contains, consists of, or is produced from GMOs in a proportion no higher than 0.9 % of the food ingredients considered individually and if this presence is adventitious or technically unavoidable.

Labelling provides information for consumers and allows them to make an informed choice. In the case of pre-packaged products consisting of, or containing, GMOs, the list of ingredients must indicate "genetically modified" or "produced from genetically modified [name of the organism]". In the case of products without packaging these words must still be clearly displayed in close proximity to the product (such as a note on the supermarket shelf).

REGULATION (EC) No 1830/2003
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF

2.2.15 Voluntary Information

Where food information referred to in Articles 9 and 10 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 100g or per 100ml (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.

2.2.16 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 will be available to FBOs in Northern Ireland.

National provisions on food sold non-pre-packed

Regulation 5 of FIR gives businesses flexibility in how they provide allergen information to consumers for food supplied:

- non-pre-packed (including catering)
- packed on the premises at the consumer's request
- pre-packed for direct sale

Regulation 6 of FIR maintains the requirement from the Food Labelling Regulations (NI) 1996 for the name of the food to be given for food supplied:

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

- non-pre-packed (excluding catering)
- packed on the premises at the consumer's request
- 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.

2.2.17 Improvement Notices - Food Information Regulations (NI) 2014

2.2.17.1 When Improvement Notices may be issued

Officers may issue an improvement notice where there has been a failure by a FBO to comply with any of the provisions of the EU FIC listed in Schedule 5 to the FIR 2014 Statutory Rule (SR).

For further training notes on the use of improvement notices in relation to food standards please see the annex to this section.

If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with such a provision, the officer may, by an Improvement Notice served on that person:

(a) State the officer's grounds for believing that the person is failing to comply with the FIR (with specific reference to their food business and what in practice they are doing or failing to do);

(b) Specify what provision (or provisions) of the EU FIC has (have) been breached;

(c) Specify what measures are needed to be taken by, the person in order to secure compliance with the EU FIC; and

(d) The date by which the person must put the measures in place

(e) The detail of the right of appeal will also be included in the notice

The notice may require the food business operator to remove products from sale until the contravention of the EU FIC has been addressed. This may involve the removal of the non-compliant food from the market on either a temporary basis (for example, where re-labelling will address the non–compliance) or permanently (for example, where a reformulation of the product is required).

'Over labelling' or 'over stickering' of the product label with a corrected version may be required or removal of an incorrect label and replacement with a correct label should be considered where possible.

If a business has a registered partnership with a Primary Authority, then the authorised officer will first be expected to discuss any issue with the Primary Authority before seeking any enforcement action. Similarly Home Authority arrangements should be taken into account.

2.2.17.2 Failure to comply

A person commits an offence if they do not comply with an improvement notice served on them under FIR 2014.

Failure to comply with the requirements of subparagraph of Article 21(1), Article 44(1)(a) may result in a criminal prosecution being brought against a FBO.

2.2.17.3 Appeals to Magistrates Court

Any person served with an improvement notice may appeal against that notice to the Magistrates Court.

For further training notes on the use of improvement notices in relation to food standards please see annex to this section.

2.18 The Food Information (Amendment) Regulations (Northern Ireland) 2016 (SR No. 249)

2.2.18 Links to resources/further information

Regulation EU No.1169/2011 on the provision of food information to consumers:
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

European Commission (FIC Regulation and Commission Q & A):
http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm

Food labelling e-learning course
http://labellingtraining.food.gov.uk/

Food Information Regulations (Northern Ireland) 2014
http://www.legislation.gov.uk/nisr/2014/223/made/data.pdf

FSA guidance on the Food Information Regulations for food business operators and enforcement officers
http://www.food.gov.uk/sites/default/files/fir-guidance2014.pdf

Nutrition

https://www.food.gov.uk/enforcement/regulation/fir/labelling

Nutrition Labelling Guidance:
https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling

Guide to creating a front of pack (FoP) nutrition label for prepacked products sold through retail outlets
https://www.food.gov.uk/sites/default/files/multimedia/pdfs/pdf-ni/fop-guidance.pdf

EC guidance document on tolerances for nutrition labelling purposes
http://ec.europa.eu/food/safety/docs/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_en.pdf

Allergens

Food allergy on-line training
http://allergytraining.food.gov.uk/english/default.aspx

British Retail Consortium (Guidance on food allergens):
http://www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf

FSA Allergen Guidance and materials to assist local authorities and food businesses
http://www.food.gov.uk/business-industry/allergy-guide/allergen-resources

safefood Video on Allergen Handling
http://www.safefood.eu/Professional/Food-Science/Resources/Managing-Allergens-in-Catering-See-how-it-s-done.aspx

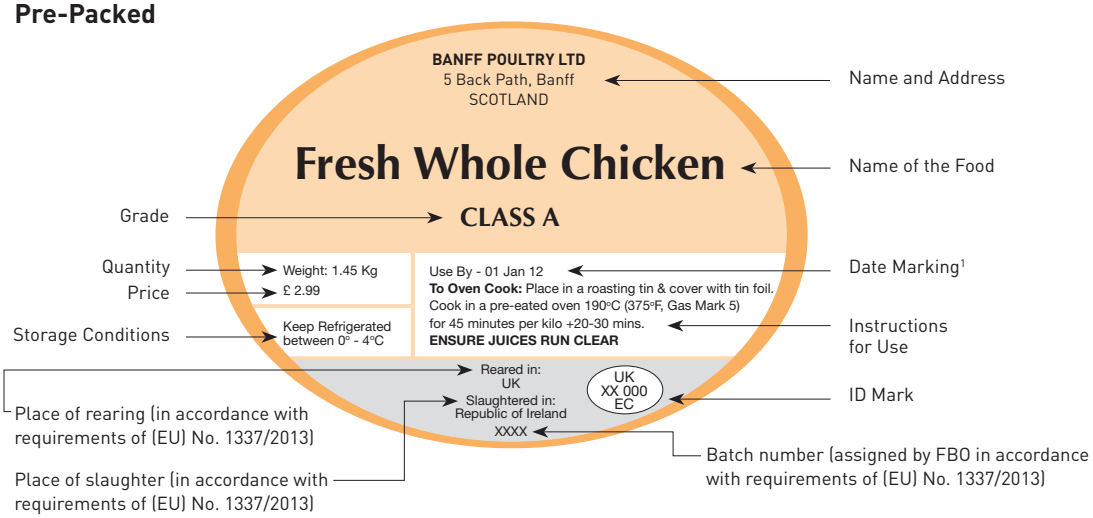
2.2.19 Example Labels

Examples of labels provided for the benefit of an enforcement officer in this training manual are in line with EU FIR. However, please note that the examples have not been designed with font size, colour or contrast in mind as these will vary across the food labelling spectrum. All mandatory information will be subject to minimum x-height for the font i.e. 1.2mm where the largest labelling surface is equal to or greater than 80cm^2 0.9mm where the largest labelling surface is less than 80cm^2

We would encourage officers when looking at the labels to also read the guidance and appropriate regulations.

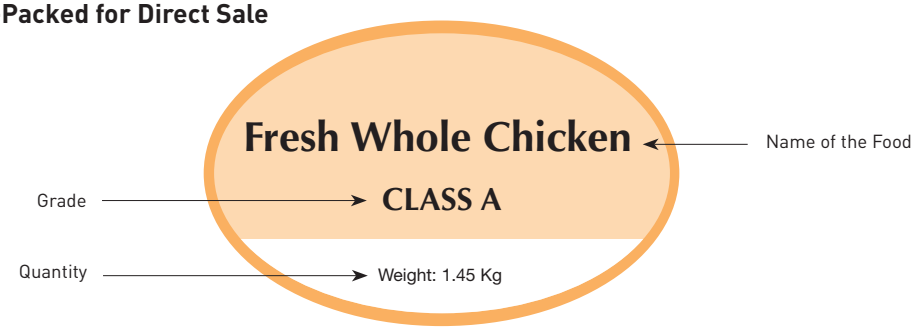
Please note these example labels should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power.

Fresh Whole Chicken - Pre-Packed



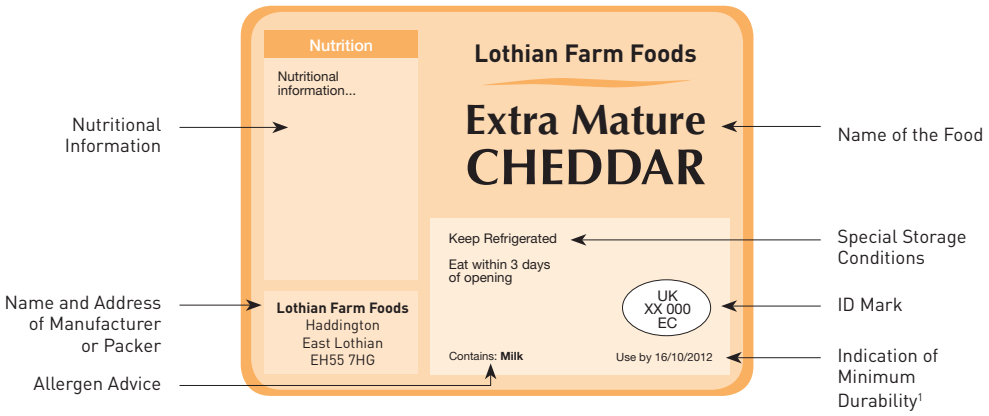
[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Fresh Whole Chicken - Pre-Packed for Direct Sale



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

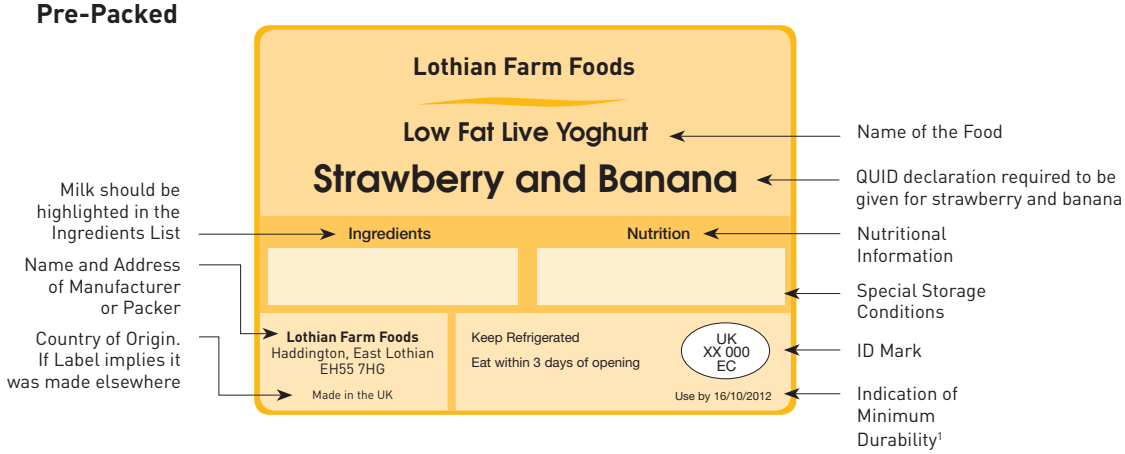
Cheese - Pre-Packed



[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

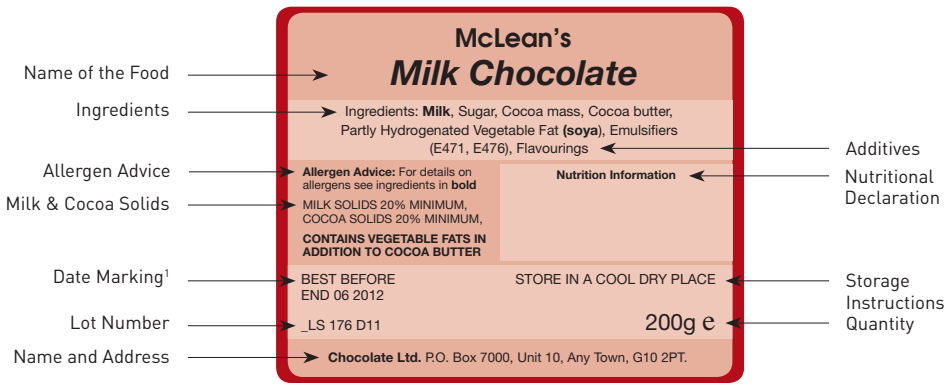
Cheese - Pre-Packed for Direct Sale

Yoghurt - Pre-Packed



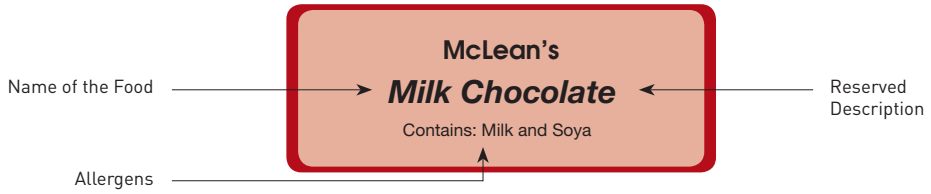
[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Chocolate - Pre-Packed

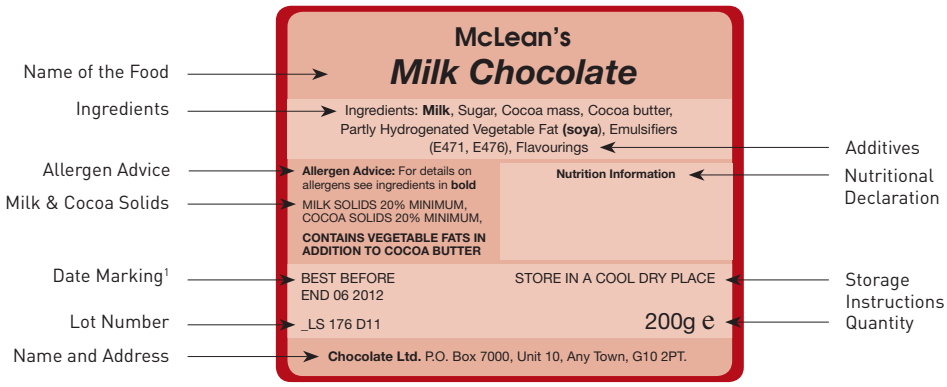


[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Chocolate - Pre-Packed for Direct Sale

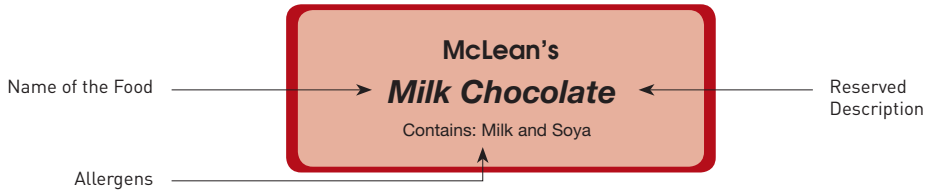


Chocolate - Pre-Packed

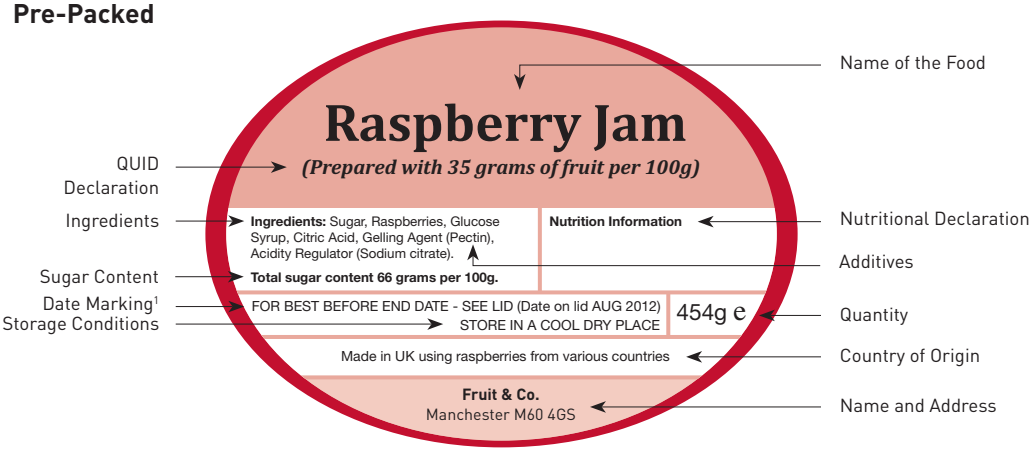


[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Chocolate - Pre-Packed for Direct Sale

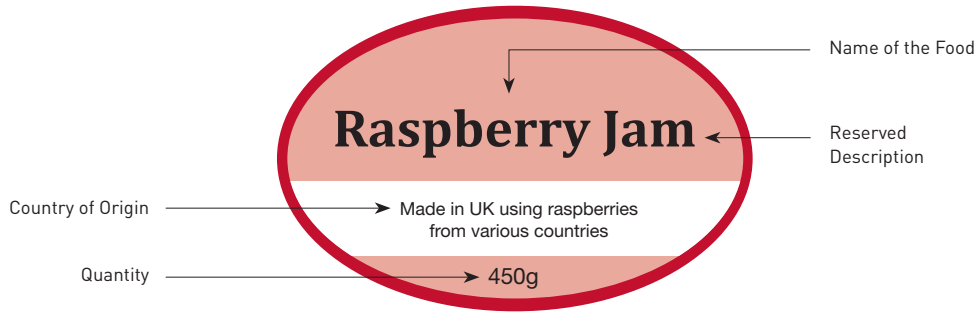


Raspberry Jam -
Pre-Packed



[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Raspberry Jam -
Pre-Packed for Direct Sale

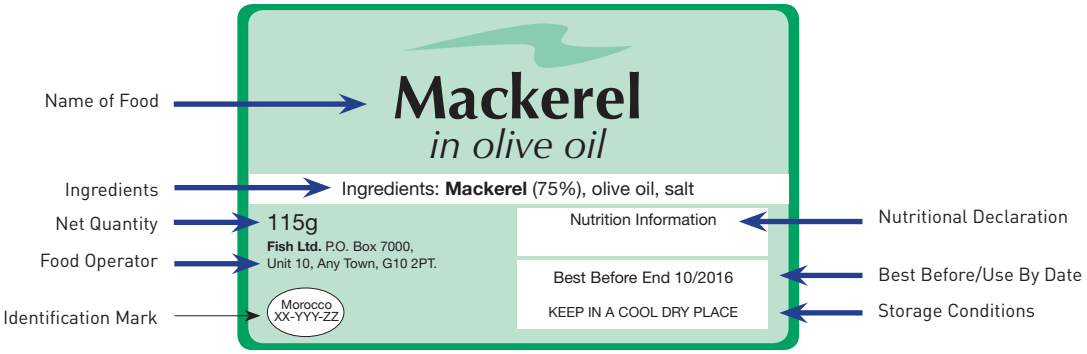


Honey - Pre-Packed

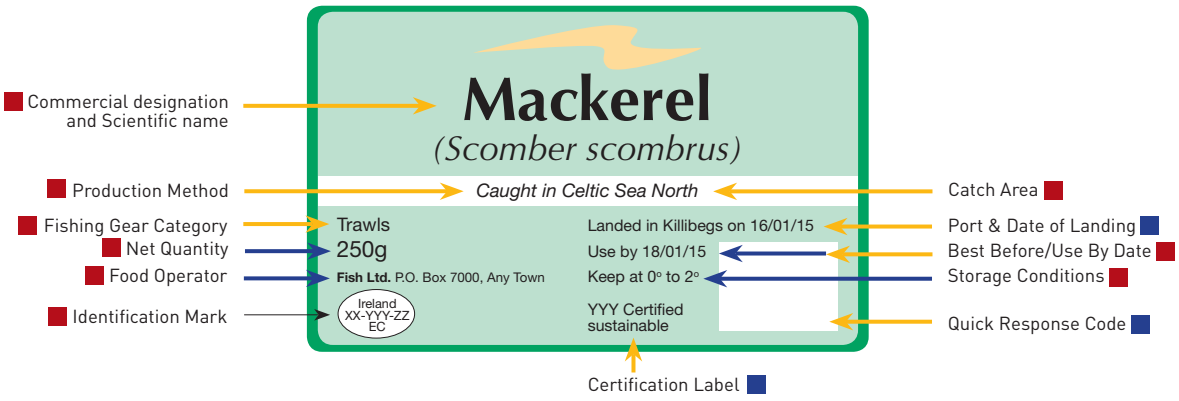
[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Honey - Pre-Packed for Direct Sale

A Processed Fish Product (Canned)

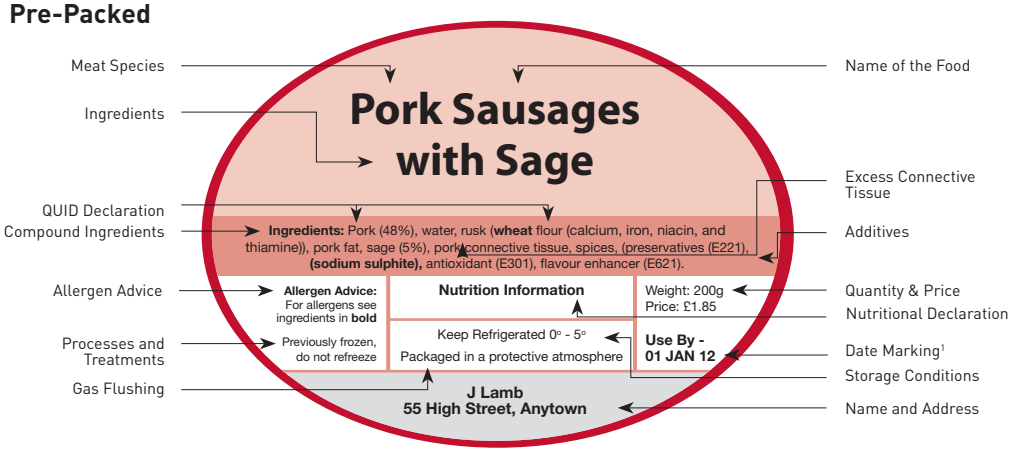


An Unprocessed and Prepacked Fresh Fish Product



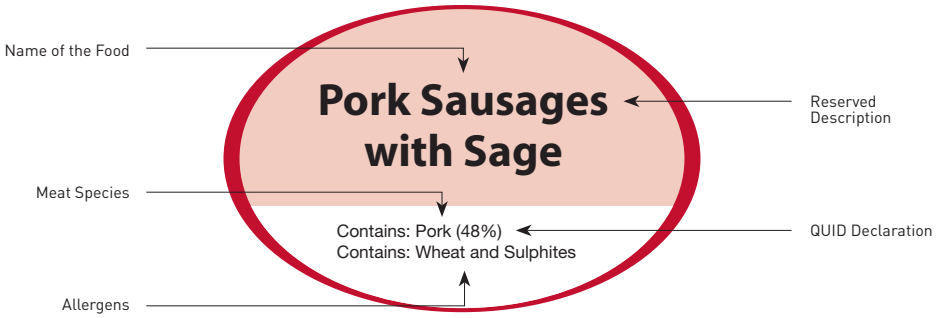
Mandatory **Voluntary** **CMO Regulation** **FIC Regulation**

Pork Sausages with Sage - Pre-Packed

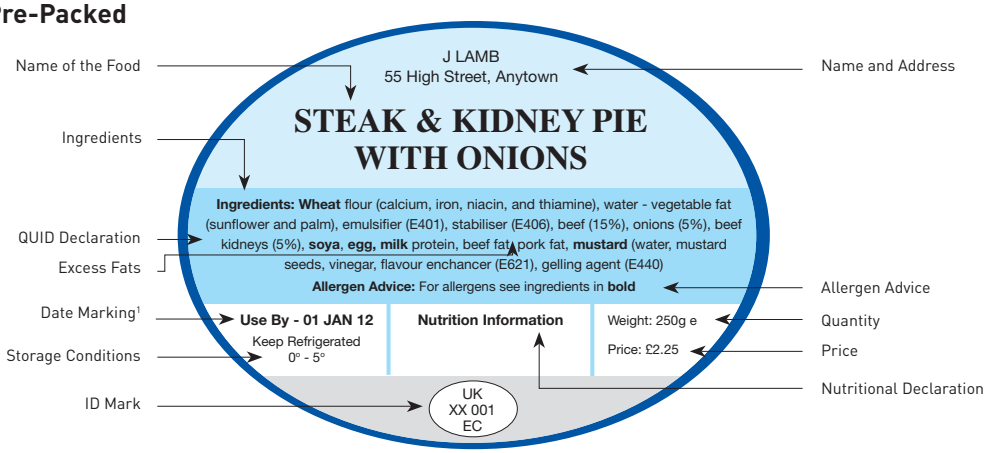


[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Pork Sausages with Sage - Pre-Packed for Direct Sale

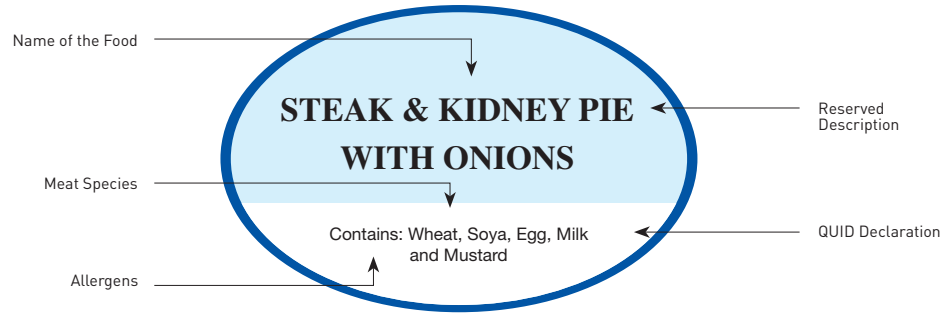


Meat Pie -
Pre-Packed



[1] The indication of minimum durability does not have to appear on the same field of vision as the name and weight but may be given elsewhere if the FBO chooses to do so.

Meat Pie -
Pre-Packed for Direct Sale Display Label



General Note:
Some of the examples of pre-packed for direct sale show where the FBO chooses to declare using a written notice of the allergens present. Equally an FBO could opt to provide this information on allergens orally were arrangements have been made for a member of staff to provide relevant details.

Annex
Training notes on the use of improvement notices in relation to food standards

What is an applied Improvement Notice?
In this guidance the term "applied Improvement Notice" means an improvement notice under Article 9(1) of the Food Safety (NI) Order 1991 (the "FSO 1991") which is applied to and modified by specific food regulations. In practice they will be named "Improvement Notices" and the form of the notice will cite the Regulations applying Article 9(1) of the FSO 1991. See the example of an Improvement Notice under Article 9(1) of the FSO 1991 as applied by Regulation 12 of the Food Information Regulations (NI) 2014.

Under what legislation will applied Improvement Notices be available for use?
The availability of applied Improvement Notices apply in respect of:

- Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013
- Food Information Regulations (NI) 2014
- Fish Labelling Regulations (NI) 2013
- Fruit Juices and Nectars Regulations (NI) 2013
- Products Containing Meat etc. Regulations (NI) 2014
- Caseins and Caseinates Regulations (NI) 2016 (SR No. 415)
- Food Safety (Information and Compositional Requirements) Regulations (NI) 2016 (SR No. 251)

What will applied Improvement Notices be issued for?
The notices will be used to deal with contraventions of regulations that specifically relate to food composition and labelling contraventions.

What are the general requirements for the information contained in an applied Improvement Notice?
If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with a provision of the regulations to which Article 9(1) of the FSO 1991 is applied and modified by those regulations the authorised officer may serve an improvement notice on that person. For example, the provisions of the Food information Regulations (NI) 2014 in respect of which an applied Improvement Notice may be served are specified in Regulation 12 of those Regulations whilst in the Fish Labelling Regulations (NI) 2013 they are specified in Regulation 4. The provisions differ in the various composition and labelling regulations to which applied improvement notices apply. For this reason care should be taken in drafting applied improvement notices under the different regulations.

The applied improvement notice should

(a) state the officer's grounds for believing that the person is failing to comply with the relevant provision;

(b) specify the matters which constitute the person's failure so to comply;

(c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and

(d) require the person to take those measures, or measures that are a least equivalent to them, within such period as may be specified in the notice.

Under what circumstances would an applied Improvement Notice be issued?
Applied Improvement Notices may be appropriate in any of the following circumstances or a combination thereof:

- formal action is proportionate to the risk to public health or a need to ensure that the consumer interest is protected;
- there is a record of non-compliance with breaches of legislation dealing with Regulations that specifically refer to availability of those notices in the Food Safety (NI) Order 1991;
- the authorised officer has reason to believe that an informal approach will not be successful.

Service of applied Improvement Notices
Applied Improvement Notices served under regulations applying Article 9(1) of the FSO 1991 may only be signed by officers who have been authorised to do so by the district council. To maintain a consistent approach, district councils should arrange that these notices are signed only by qualified officers with experience in food law enforcement, who are properly trained and competent.

These will be one of the following:
- Environmental Health Officers enforcing food standards regulations;
- holders of the Higher Certificate in Food Premises Inspection who are authorised to carry out food standards inspections; or
- holders of the Ordinary Certificate in Food Premises Inspection in relation to the premises they are authorised to inspect

The officer who signs the notice must have witnessed the contravention and be satisfied that it constitutes a breach of the relevant legislation.

Are there any time limitations regarding compliance with applied Improvement Notices?
Yes. Under the Food Information Regulations the usual 14 days minimum has been removed. Under most of the other food composition and labelling regulations which apply Article 9(1) of the FSO 1991 (Improvement Notices) the 14 day minimum stands. An appeal may be lodged against the time limit, so it must be realistic, justifiable, and have regard to the extent and complexity of the measures required. The time limit should normally be discussed and agreed with the operator/proprietor or with a person acting on the operator/proprietor's behalf who is in a position to agree a time limit, before a notice is issued. The officer may, however, set a time limit without such agreement if agreement cannot be reached or a responsible person cannot be contacted.

The following factors should be taken into consideration in setting a time limit:
- The risk to public health or a need to ensure that the consumer interest is protected
- The nature of the problem
- The availability of solutions.

Can a time limit in an applied Improvement Notice be extended?
Although applied Improvement Notices are to be complied with by the stipulated time limit, district councils should give due regard to any genuine difficulties that may occur in achieving compliance by that deadline.

There is no specific provision in the regulations to extend the time limit for compliance with a notice, but it may be unreasonable not to allow an extension if the food business operator/ food business proprietor has a genuine reason for needing more time.

The operator / proprietor should be advised when the notice is served that any request for an extension of time should be made in writing before the notice expires.

If the officer considers that the request is reasonable, they should make a note of the reasons for their decision on the relevant establishment file. The existing notice should then be withdrawn and a new notice issued reflecting the new time limit by which compliance must be achieved.

However, the officer should never issue such a notice automatically. When deliberating on a request for an extension of the time limit, the officer should always consider whether the facts at that time justify such an extension, taking into account:

- The risk to public health or consumer interest associated with the fault if an extension was granted
- The reason for the request
- The remedy involved
- The past record of co-operation of the operator / proprietor and
- Any temporary action which the operator / proprietor proposes to take to remedy the defect.

Is it possible to carry out works of equivalent effect?
Notices should make it clear that Article 9(1) of the Food Safety (NI) Order 1991, as applied, allows a food business operator / food business proprietor to carry out measures of at least equivalent effect to those specified in an improvement notice and recommend that alternative measures are discussed with the officer who served the notice before starting work to avoid unnecessary expenditure or inappropriate work.

The district council should respond in writing to any request from a proprietor to vary the work, and any agreed alternative measures should be confirmed in writing.

Disputes should be considered by the District Councils lead officer for food safety, or by the head of service or another senior manager.

District councils should ensure that they have procedures to consider such matters, so that it is clear to the proprietor that there is a proper review.

How do I verify compliance with an applied Improvement Notice?
The officer who served the applied Improvement Notice should liaise with the food business and monitor the work being undertaken and encourage the food business operator / food business proprietor to notify the officer when the work has been completed. Another authorised officer should monitor the work if the officer who served the notice is unable to do so.

The work should be checked as soon as practicable after notification has been received that it has been completed and the officer should confirm in writing that the works have been satisfactorily completed.

Are there appeals provisions in the legislation regarding the service of an applied Improvement Notice?
It should be clear to the recipient of an applied Improvement Notice that there is a right of appeal against the notice.

The notice should therefore include details of the right of appeal and the recipient provided with the name and address of the relevant local Magistrates Court.

The food business operator / food business proprietor should also be asked to notify the officer if an appeal is lodged. Appeals are under Article 37 of the FSO 1991 as applied and modified by the regulations applying the notice.

Discussions with other district councils
Although a food business operator / food business proprietor has a right of appeal against an applied Improvement Notice, the district council should be prepared to discuss a notice and its requirements informally with the operator / proprietor if they wish to do so.

The district council should similarly be prepared to discuss the requirements of any letter or other enforcement action.

If an operator / proprietor indicates that the requirements of an applied Improvement Notice are inconsistent with the interpretation or practice of other district councils the district council should have regard to the views of the "Primary Authority" and/or "Home Authority" for the business as defined by LBRO Local Government Group (LGG).

District councils should have internal arrangements to consider such requests for further discussion and consider how they make these arrangements known to operators / proprietors.

Any disputes that arise should be referred to the lead officer for food safety, or an appropriate senior manager nominated by the lead food officer.

What should the general enforcement approach be?
The primary objective of enforcement action should always be to achieve compliance in the most effective way possible.
The practice of giving advice, and communicating by letter about enforcement issues, are well-established approaches to enforcement that are understood by food businesses. Such procedures are therefore encouraged whenever they are likely to secure compliance with the requirements of food law within a time that is reasonable in the circumstances.

Service of notices
The Food Safety (NI) Order 1991 requires an applied Improvement Notice to be served on the proprietor of a food business.

Applied Improvement Notices should normally be served either by delivery to the food business operator/ food business proprietor in person, or at their usual or last known residence by a postal or courier service that included proof of posting or despatch and, ideally, proof of delivery.

It is not always possible to identify the food business operator and Section 24 of The Interpretation Act (NI) 1954 therefore allows an applied Improvement Notice to be addressed to the "Owner" or "occupier" and left at the premises if the proprietor cannot be identified.

The officer serving an applied Improvement Notice should ensure, wherever possible, that the person who is responsible for taking action also receives a copy, especially where the local manager is not the food business proprietor.

Drafting Notices
It should be clear from the applied Improvement Notice exactly what the recipient is required to do, and why. The notice should therefore be clearly drafted and easily understood.

As failure to comply with the requirements of an Improvement Notice within the specified period is an offence under Article 9(2) of the FSO 1991 as applied, an officer who has decided to serve a notice should consider whether a single notice with a single time limit is appropriate. Failure to comply with one or more items of such a notice would be a failure to comply with the whole notice and constitute a single offence.

Serving multiple notices, each with a different time limit, may be more appropriate where multiple contraventions are concerned. Separate notices with separate time limits may also be easier to handle if there is an appeal. An appeal against a single notice concerning multiple contraventions would result in the suspension of the whole notice until the appeal had been dealt with.

The officer should normally discuss the detail of any work requiring change in product composition or labelling with the food business operator, or with a person acting on the operator's behalf who is in a position to authorise the work, before a notice is issued. However, the issue of a notice should not be unduly delayed if agreement cannot be reached or a responsible person cannot be contacted.

Appendix I

Example template of an improvement notice under the Food Safety (NI) Order 1991 as applied by regulation 12(1) of, and Part 1 of Schedule 4 to, the Food Information Regulations (Northern Ireland) 2014

The Food Safety (Northern Ireland) Order 1991 Article 9 Improvement Notice

Authority: ……
(Name & Address of the issuing Council):

Reference Number: ……..

Article 9(1) of the Food Safety (Northern Ireland) Order 1991 as applied and modified by regulation 12(1) of, and Part 1 of Schedule 4 to, the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No. 223)

1. To: ……
……
……
……
……
(Name and address of the business on which the notice is being served)

2. I have reasonable grounds for believing that you are failing to comply with [Authorised officer to insert relevant provision of Regulation (EU) No. 1169/2011 (as specified by Schedule 5 of the Food Information Regulations (Northern Ireland) 2014) or the Food Information Regulations (Northern Ireland) 2014] because:……
……
……
……
……
……
……
[Authorised officer to insert grounds for believing that the Food Information Regulation (Northern Ireland) 2014 are being breached.]

*[**DN** -A description of the breach in plain English is necessary. Identify the product specifically the label the durability date/lot code and what exactly was wrong with the label. You may wish to attach copy of the label as supporting evidence.]*
in connection with where the contravention took place……..

……..

……..

……..

……..

……..

……..

(Name & Address of Food Business if different to that in 1 above)
The matters which constitute your failure to comply are:

……..

……..

……..

……..

……..

……..

…….. [Authorised officer to insert why there is a failure to comply]

3. In order to comply with the provision specified above, you must take the following measure(s) (or measures that will achieve the same effect)

……..

……..

……..

……..

……..

……..

4. You are required to take these measures by…….. (date)

5. It is an offence not to comply with this notice.

Signed: …… Authorised Officer)

Name in capitals:……

Date: ……

Address: ……

……

……

……

……

……

……

Tel: ……

Fax: ……

E-mail: ……

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 legal advice.

Model Form – Food Information Regulations (Northern Ireland) 2014 Improvement Notice (reverse)

NOTES

1. In the opinion of the authorised officer you are not complying with the provision of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council or the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No. 223) specified in paragraph 2 of the notice. The measures needed to put matters right are described in paragraph 3 of the notice and those measures (or measures with equivalent effect) must be completed by the date set.

2. You are responsible for ensuring that the measures are carried out within the period specified.

3. You have a right to take measures that will achieve the same effect as the measures described in the notice. If you think that there is another equally effective way of complying with the law, you should first discuss it with the officer who issued this notice or another officer.

YOUR RIGHT OF APPEAL

4. If you disagree with all or part of this notice, you can appeal against the notice to a court of summary jurisdiction in accordance with Article 37(1) of the Food Safety (Northern Ireland) Order 1991, as applied and modified by regulation 12(3) of, and Schedule 4, Part 3 to, the Food Information Regulations (Northern Ireland) 2014.

5. You have one month from the date on which notice of the decision was served on you or the time specified in the improvement notice whichever ends the earlier to a court of summary jurisdiction.

6. If you decide to appeal, then the period from when you have lodged your appeal until the appeal has been decided will not count in the computation of the time period specified in the notice for carrying out the specified measures.

7. The court may cancel or affirm the notice and if it affirms it may modify it.

8. If the improvement notice is affirmed or modified the District Council may enforce the notice as affirmed or modified by the court

9. You should notify the officer serving the notice if an appeal is lodged.

WARNING

FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Offenders are liable to be fined to a maximum amount of £5,000.

Appendix II

Complied examples of an Improvement Notice under the Food Safety (NI) Order 1991 as applied by regulation 12(1) of, and Part1 of Schedule 4 to, the Food Information Regulations (Northern Ireland) 2014.

Sample Improvement

Notice 1 Facts
A bakery manufacturing and labelling pre-packed salad bowls which are supplied to a supermarket for sale to the final consumer. Walnuts which were intentionally included in the salad bowl were omitted from the list of ingredients on the product. This is contrary to Article 9(1)(c) and 21(1) of Regulation (EU) 1169/2011 in that walnuts should have been listed as an ingredient and emphasised as an allergenic ingredient listed in Annex II of that Regulation.

Note: each notice must be specifically tailored to the factual situation for example if "walnuts" had been included in the list of ingredients and not emphasised there would not have been a breach of Article 21(1)(a) however there would still have been a breach of Article 21(1)(b).

With certain foods e.g. wine where there is no requirement for an ingredients list there would still be a breach of Article 9(1)(c) if allergen information was not included by virtue of Article 21(1) *"In the absence of a list of ingredients, the indication of the particulars referred to in point (c) of Article 9(1) shall comprise the word 'contains' followed by the name of the substance or product as listed in Annex II."* so this would apply for example to wine containing sulphites. In this instance an improvement notice could be served.

The Food Safety (Northern Ireland) Order 1991 Article 9
Improvement Notice

Authority: Tee Council, Main Street, Tee, CT1 5GS
(Name & Address of issuing Council)

Reference Number: IN15/2017

This Improvement Notice is issued under Article 9(1) of the Food Safety (Northern Ireland) Order 1991 as applied and modified by regulation 12(1) of, and Part 1 of Schedule 4 to, the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No. 223)

1. To: Tasty Treats, 4 Park Avenue, Tee, CT3 6HS
   (Name & Address of the business on which the notice is being served)

2. I have reasonable grounds for believing that you are failing to provide adequate food allergen information to consumers because you placed on the market salad bowls (with a best before of XX) that contained walnuts and did not include this information in the list of ingredients on or about 12/12/2016 (DATE/dates of breach) at T Supermarket, High Street, Tee, CT2 6HS (location of breach).

   This is contrary to Article 9(1)(c) and Article 21(1) of Regulation (EU) 1169/2011.

3. The matters which constitute your failure to comply are:
   The ingredient list did not declare the presence of walnuts. Walnuts are listed in Annex II paragraph 8 of Regulation EU 1169/2011 as a product causing allergies or intolerances which must be indicated in the list of ingredients with clear reference to the name of that product.

4. In order to comply with the provisions specified above, you must take the following measure(s) (or measures that will achieve the same effect)

a. amend the list of ingredients to include the allergen walnuts; **and**
b. emphasise the name of this ingredient in the list of ingredients by using a typeset that clearly distinguishes it from the rest of the list of ingredients for example by listing in bold, contrasting colours or underlining; **or**
c. remove walnuts as an ingredient in the product.

5. You are required to take these measures by. (date)

6. It is an offence under Article 9(2) of the Food Safety (NI) Order 1991 not to comply with this notice within the stated period.

Signed: F. Smith (Authorised Officer)

Name in capitals: FRANCIS SMITH
Date: (insert)
Address: Main Street, Tee, CT1 5GS

Tel: 028 9067 9725
Fax: 028 9067 9725
Email: fran.smith@teecouncil.gov.uk
(Details of the authorised officer serving the improvement notice)

Sample Improvement Notice 2

Facts

A restaurant serving a waldorf salad containing an allergen (namely walnuts) failed to provide any written or oral information that the salad contained walnuts. This should have been provided in writing or orally to comply with Article 44(1)(a) of Regulation (EU) 1169/2011. The FBO also failed to indicate to customers that details could be obtained by asking a member of staff. If provided orally this must also comply with Regulation 5 of the Food Information Regulations (NI) 2014.

Note: if the circumstances were that an indication was provided in accordance with Regulation 5 of the Food Information Regulations (NI) 2014 but on request staff could not provide that information then there is still a breach of Article 44(1)(a).

The Food Safety (Northern Ireland) Order 1991 Article 9
Improvement Notice

Authority: Tee Council, Main Street, Tee, CT1 5GS
(Name & Address of issuing Council)

Reference Number: IN38/2017

Article 9(1) of the Food Safety (Northern Ireland) Order 1991 as applied and modified by regulation 12(1) of, and Part 1 of Schedule 4 to, The Food Information Regulations (Northern Ireland) 2014 (SR 2014 No. 223)

1. To: The Court Yard Bar & Grill, Mossley Pass, Tee, CT37 5PA
   (Name & Address of the business on which the notice is being served)

2. I have reasonable grounds for believing that you are failing to make available food allergen information to consumers because you offered for sale a non-prepacked food, namely a salad bowl containing walnuts, with no provision of allergen information on (DATE) at The Court Yard Bar & Grill, Mossley Pass, Tee, CT37 5PA.

This is contrary to Article 9(1)(c) and Article 44(1)(a) Regulation (EU) No. 1169/2011 on the provision of food information to consumers.

3. The matters which constitute your failure to comply are:
   Offering for sale a non-prepacked salad (waldorf salad) , without making available information to consumers about the ingredients in that product which may cause allergy or intolerance, (namely walnuts).Walnuts are listed in Annex II paragraph 8 of Regulation EU 1169/2011 as a product causing allergies or intolerances.

4. In order to comply with the provisions specified above, you must take the following measure(s) (or measures that will achieve the same effect)

Your food business must make available to consumers information about ingredients in products as required by Article 9 (1)(c) and specified in Annex II of Regulation (EU) 1169/2011 (labelling of certain substances or products causing allergies or intolerances), by any means, including orally.

If you choose to supply the information orally you must (in accordance with regulation 5 of the Food Information Regulations (NI) 2014) indicate that details can be obtained by asking a member of staff.

The indication mentioned in the paragraph above must be given –

(a) on a label attached to the food, or
(b) on a notice, menu, ticket or label that is readily discernible by an intending purchaser at the place where the intending purchaser chooses that food.

5. You are required to take these measures by the 16th November 2016 (date)

6. It is an offence under Article 9(2) of the Food Safety (NI) Order 1991 not to comply with this notice within the stated period.

Signed: *Jane Doe* (Authorised Officer)

Name in capitals: Jane Doe
Date: (insert)
Address: Main Street, Tee, CT1 5GS

Tel: 028 9067 9725
Fax: 028 9067 9725
Email: jane.doe@teecouncil.gov.uk
(Details of the authorised officer serving the improvement notice)

Section 3
Legislation Guidance Alphabetical Order

3

Section 3 Alphabetical Guidance

Legislation under A

Legislation under B

Bread and Flour Regulations (NI) 1998 (SR No. 24) (as amended)

Legislation under C

Caseins and Caseinates Regulations (NI) 2016 (SR No. 415)

Cocoa and Chocolate Products Regulations (NI) 2003 (SR No. 313) (as amended)

Coffee Extracts and Chicory Extracts Regulations (NI) 2001 (SR No. 45) (as amended)

Condensed Milk and Dried Milk Regulations (NI) 2003 (SR No. 300) (as amended)

Contaminants in Food Regulations (NI) 2013 (SR No. 229) (as amended)

Country of Origin of Certain Meats Regulations (NI) 2015 (SR No. 321)

Legislation under D

Drinking Milk Regulations (NI) 2008 (SR No. 237)

Legislation under E

Legislation under F

Fish Labelling Regulations (NI) 2013 (SR No. 219) (as amended)

Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013 (SR No. 220) (as amended)

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (NI) 2009 (SR No. 398)

Food intended for Use in Energy Restricted Diets for Weight Reduction Regulations (NI) 1997 (SR No. 450) (as amended)

Food Irradiation Regulations (NI) 2009 (SR No. 258) (as amended)

Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (SR no. 251)

Food Supplements Regulations (NI) 2003 (SR No. 273) (as amended)

Fruit Juices and Fruit Nectars Regulations (NI) 2013 (SR No. 253) (as amended)

Legislation under G

Genetically Modified Food Regulations (NI) 2004 (SR No. 385)

Legislation under H

Honey Regulations (NI) 2015 (SR No. 261)

Legislation under I

Infant Formula and Follow-on Formula Regulations (NI) 2007 (SR No. 506) (as amended)

Legislation under J

Jam and Similar Products Regulations (NI) 2003 (SR No. 519)

Legislation under K

Kava Kava in Food Regulations (NI) 2005 (SR No. 288)

Legislation under L

Food (Lot Marking) Regulations (NI) 1996 (SR No. 384) (as amended)

Legislation under M

Materials and Articles in Contact with Food Regulations (NI) 2012 (SR No. 384)

Medical Foods Regulations (NI) 2000 (SR No. 187) (as amended)

Legislation under N

Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (NI) 2015 (SR No. 365)

Novel Foods and Novel Food Ingredients Regulations (NI) 2004 (SR No. 33)

Nutrition and Health Claims Regulations (NI) 2007 (SR No. 349)

Legislation under O

Legislation under P

Plastic Kitchenware (Conditions on Imports from China) Regulations (Northern Ireland) 2011 (SR. 2011 No. 236)

Preserved Sardines (Marketing Standards) Regulations (NI) 1990 (SR No. 194)

Preserved Tuna and Bonito (Marketing Standards) Regulations (NI) 1994 (SR No. 425)

Processed Cereal Based Baby Foods and Baby Foods for Infants and Young Children Regulations (NI) 2003 (SR No. 530) (as amended)

Products Containing Meat etc. Regulations (NI) 2014 (SR No. 285)

Legislation under Q

Quick Frozen Foodstuffs (No2) Regulations (NI) 2007 (SR No. 110) (as amended)

Legislation under R

Legislation under S

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

Specified Sugar Products Regulations (NI) 2003 (SR No. 301) (as amended)

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

Legislation under T

Tryptophan in Food Regulations (NI) 2005 (SR No. 440) (as amended)

Legislation under U

Legislation under V

Addition of Vitamins, Minerals and Other Substances Regulations (NI) 2007 (SR No. 301)

Legislation under W

Legislation under XYZ

Section A
Legislation Under A

Section B
Legislation Under B

B

Bread and Flour Regulations (NI) 1998 (SR No. 24)

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 a dough made from flour and water, with or without other ingredients, which has been fermented by yeast or otherwise leavened and subsequently baked or partly baked. It excludes buns, bunloaves, chapattis, pitta bread, potato bread or bread specially prepared for coeliac sufferers.

2. Flour: The product which is derived from, or separated during, the milling or grinding of cleaned cereal whether or not the cereal has been malted or subjected to any other process, and includes meal, but does not include other cereal products, such as separated cereal bran, separated cereal germ, semolina or grits.

3. Flour bleaching agent: Any food additive primarily used to remove colour from flour.

4. Flour treatment agent: Any food additive other than an enzyme preparation which is added to flour or dough to improve its baking quality.

Fortification of Wheat Flour

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

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

There is no provision in the EU Food Information for Consumers Regulation (No. 1169/2011) for a corresponding exemption for the essential ingredients added to flour. From 13 December 2014, UK produced wheat flour is considered a compound ingredient and the presence of the statutory nutrients require to be declared. Businesses may wish to consider using a phrase such as ‘wheat flour with added calcium, iron, niacin and thiamine’ in the ingredients list.

Added Ingredients

The Food Additives Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013 control the addition of additives to bread and flour.

Labelling Requirements

The food must be labelled with its name.
Bread may be described as

(a) 'Wholemeal' **only** if:-
All the flour used as an ingredient in the preparation of the bread is wholemeal; or

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

If none of the aforementioned names apply, the name of the bread may be one that is customary in the area where it is sold, or a name which is sufficiently precise to describe the food. (Food Information Regulations (NI) 2014). For example 'White', 'Brown' or 'Soda bread'.

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

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

Public Analyst Observation

Sampling provisions are contained in the Regulations.

Flour mills need to be checked in relation to descriptions of flour products (wholemeal and brown). Under 1169/2011 UK produced fortified flour is now considered a compound ingredient and the compound ingredient name must be given followed by the statutory nutrients. For example - Wheat Flour (Wheat Flour, Calcium Carbonate, Iron, Niacin, Thiamin)

Associated Regulations

Bread and Flour Regulations (NI) 1998 SR No. 24

Food Information Regulations (NI) 2014 SR No. 223

Further Information

Bakers Federation web page

FSA Bread and Flour Guidance Notes

NIFLG Bakers Guidance Document (available from Western Group of Councils webpage)

Section C
Legislation Under C

C

Caseins and Caseinates Regulations (NI) 2016 (SR No. 415)

Scope

These regulations implement Commission Directive 2015/2203 relating to certain lacto proteins (casein and caseinate) intended for human consumption and repeal Council Directive 83/417/EEC.

These regulations

- Prescribe definitions and standards for certain casein products (regulation 2 and Schedules 1 to 3)
- Prohibit the use of any casein or caseinate in the preparation of food if it does not comply with the particular standards (regulation 4 and Schedule 4)
- Subject to specified exceptions, prohibit the labelling or advertisement of food with the names of casein products unless the food is or contains a casein product (regulation 5)
- Impose additional requirements as to the labelling of casein products (regulation 6)

Ingredients/Products

This regulation applies to caseins and caseinates which are intended for human consumption and mixtures thereof.

The following definitions apply:

"casein product" means edible acid casein, edible caseinate or edible rennet casein;

"edible acid casein" means a milk product obtained by separating, washing and drying the acid-precipitated coagulum of skimmed milk and/or of other products obtained from milk and complying with the standards set out in Schedule 1;

"edible caseinate" means a milk product obtained by action of edible casein or edible casein curd coagulum with neutralizing agents, followed by drying and complying with the standards set out in Schedule 2;

"edible rennet casein" means a milk product obtained by separating, washing and drying the coagulum of skimmed milk and/or of other products obtained from milk; the coagulum is obtained through the reaction of rennet or other coagulating enzymes and complying with the standards set out in Schedule 3;

Labelling Requirements

- Without prejudice to the provisions of EU Regulation 1169/2011 on food information for consumers, a person must not sell any casein product unless it is marked or labelled with-
- the name of that casein product as defined in regulation 2 and in the case of edible caseinate with an indication of the cation or cations listed in Schedule 2, paragraph 4 (food additives);
  in the case of casein products sold as mixtures.
- the words "mixture of" followed by the names of the casein products which make up the mixture, in descending order of weight
- an indication of the cation or cations listed in Schedule 2 paragraph 4 (food additives) in the case of edible caseinates
- In the case of mixtures containing edible caseinates, the protein content
- the net quantity of the casein product, expressed in kilograms or grams
- the name or business name and address of the food business operator under whose name or business name the product is marketed or, if that food business operator is not established in the European Union, the importer into the European Union market;
- in the case of a casein product imported from third countries the name of the country of origin; and
- the lot identification of the casein product or the date of production.

The above particulars must be easily visible, clearly legible, indelible and given in English, either exclusively or in addition to any other language.

The protein content, net quantity, name and address of FBO and country of origin may be given in a document accompanying the product.

Without prejudice to the provisions of EU Regulation 1169/2011 , where any casein product exceeds the minimum milk protein content set out for that product in-

(a) entry 2 of the table in paragraph 1 of Schedule 1 in relation to edible acid caseins

(b) entry 2 of the table in paragraph 1 of Schedule 2 in relation to edible caseinates; or

(c) entry 2 of the table in paragraph 1 of Schedule 3 in relation to edible rennet casein
a person may mark that fact on the package, label or container of that product.

Enforcement

The method of enforcement will be via improvement notice served under Article 9 of the Food Safety (NI) Order 1991 as applied by these regulations. An improvement notice can also be served under Article 9 for breach of regulation 4, 5 or 6 of these regulations.

Improvement Notices would be used as a part of the hierarchy of enforcement when informal measures are no longer appropriate and the labelling contravention or issue should be elevated to formal action. If the conditions set by an improvement notice are not met then the noncompliance with those conditions will constitute a criminal offence. Improvement Notices can be appealed to a Court of Summary Jurisdiction.

Public Analyst Observation

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

Associated Regulations

Caseins and Caseinates Regulations (NI) 2016

Commission Directive (EU) 2015/2203 relating to caseins and caseinates intended for human consumption

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

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

Further Information

Health Issues: Milk allergy and intolerance

Cocoa and Chocolate Products Regulations (NI) 2003 (SR No. 313)

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 prepacked chocolate chip cookie (normal QUID rules apply to designated products).

Ingredients/Products

The products covered by the regulations include

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

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

Schedule 1 is provided in the annex to this document.

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

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

2003 SR No 313 Ver 2

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 Regulations (NI) 2014 made an amendment to these regulations to move the requirements previously set out in Schedule 8 Part 1 of the Food Labelling Regulations (NI) 1996 to Regulation 5(b) to (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 Schedule 2 of the Regulations.

Chocolate Products

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

Use of Sweeteners

Artificial sweeteners may be used in accordance with the rules in the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013. These provide restrictions on the specific sweeteners that may be used and Regulation (EU) No.1169/2011 requires additional labelling to indicate their presence.

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

a) 'Chocolate' including some added sugars with sweeteners used to replace part of the sugar is a chocolate product and must comply with Cocoa and Chocolate Products Regulations.

b) 'Chocolate' with no added sugars and no added sweeteners is not a chocolate product and does not have to comply with the Cocoa and Chocolate Products Regulations labelling requirements. The term 'chocolate' or any of the reserved descriptions in their labelling may be used provided that the term is used with sufficient context to indicate clearly that the food is not and does not contain chocolate. The name of the food and the use of the word 'chocolate' on the labelling must therefore be put into appropriate context.

c) 'Chocolate' where there are no added sugars but with added sweeteners. This is not a chocolate product and is not required to carry Cocoa and Chocolate Products Regulations labelling requirements. The product has to comply with the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013 and additional labelling requirements in the Food Information Regulations (NI) 2014, as amended. FSA guidance recommends that the use of the word 'chocolate' on the labelling of such products must be put into context so as not to confuse the consumer e.g. 'no added sugar chocolate with sweetener(s)'.

Labelling Requirements

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

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

Milk Solids Declaration

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

Cocoa Solids Declaration

Designated products (except cocoa butter, white chocolate, filled chocolate, chocolates and pralines) must be labelled with a declaration of the cocoa solids content as 'cocoa solids x % minimum'. For those products containing additional ingredients such as nuts or honeycomb

it should be clear that the declared percentage relates to the weight of the chocolate part and not the whole product.

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

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 8	20g/80g = 25%	Is calculated on
Cocoa solids 20		20g/98g = 20%
Vegetable fats 4		
Hazelnut 18		
Lecithin 1		
Vanillin 1		

Total 100g

Assortments

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

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

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

Seasonal Selection Packs

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

Minimum Durability

All chocolate food products sold prepacked are subject to the indication of minimum durability requirements of EU Regulation No.1169/2011.

Public Analyst Observation

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

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

EHO's should be aware of chocolate flavour coatings being described as chocolate.

The Chocolate Directive (Directive 2000/36/EC) allows the addition of up to 5% of vegetable fats other than cocoa butter in chocolate products. When these fats are added to chocolate, European legislation requires that consumers be informed by appropriate labelling of the product. The threshold of 5% is also an essential requirement for these products to move freely within the internal market.

Reliable analytical methods were successfully developed to detect and quantify so-called cocoa-butter equivalents (CBEs) in milk chocolate.

Cocoa beans naturally accumulate cadmium, and maximum limits for the cadmium content of cocoa and chocolate products are set in
COMMISSION REGULATION (EU) No 488/2014 (they are applicable from 01/01/2019)

Associated Regulations

Cocoa and Chocolate Products Regulations (NI) 2003 SR No. 313

Food Information Regulations (NI) 2014 SR No. 223

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

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

2003 SR No 313 Ver 2

SCHEDULE

Annex 1

Schedule 1 Regulations 2, 3 and 6

Cocoa and Chocolate Products and their Reserved Descriptions

Column 1 *Reserved descriptions*	*Column 2* *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 *or* Cocoa	The product obtained by converting into powder cocoa beans which have been cleaned, shelled and roasted, and which contains not less than 20 per cent cocoa butter, calculated according to the weight of the dry matter, and not more than 9 per cent water.
(b) Fat-reduced cocoa *or* 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 *or* 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 *or* Sweetened cocoa *or* 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) *If* "Chocolate" *is supplemented by*	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.
(i) "vermicelli" or "*flakes*"	
(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" or 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: - milk or dry milk solids obtained by evaporation or both, in such proportion that the finished product does not contain more than 5 per cent dry milk solids; - almonds, hazelnuts and other nut varieties, either whole or broken, in such quantities that, together with the ground hazelnuts, they do not exceed 60 per cent of the total weight of the product.

4. (a) Milk chocolate	The product obtained from cocoa products, sugars and milk or milk products which, subject to item 4(b), contains: - not less than 25 per cent total dry cocoa solids - not less than 14 per cent dry milk solids obtained by partly or wholly dehydrating whole milk, semi-skimmed or skimmed milk, cream, or from partly or wholly dehydrated cream, butter or milk fat - not less than 2.5 per cent dry non-fat cocoa solids - not less than 3.5 per cent milk fat - not less than 25 per cent total fat (cocoa butter and milk fat).
(b) *If* "Milk chocolate" is *supplemented by* -	
(i) "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" *or* 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) *If* "Milk" *is replaced by* - (i) "cream" (ii) "skimmed milk"	The product containing a minimum milk fat content of 5.5 per cent. The product containing a milk fat content not greater than 1 per cent.
5. Family milk chocolate *or* Milk chocolate	The product obtained from cocoa products, 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.
7. Filled chocolate *or* Chocolate with … filling or Chocolate with … centre	The filled product, the outer part of which consists of a product specified in column 2 of item 3, 4, 5 or 6 and constitutes not less than 25 per cent of the total weight of the product, but does not include any filled product, the inside of which consists of bakery products, pastry, biscuit or edible ice.
8. Chocolate a la taza	The product obtained from cocoa products, sugars, and flour or starch from wheat, rice or maize, which contains not less than 35 per cent total dry cocoa solids, including not less than 18 per cent cocoa butter and not less than 14 per cent dry non-fat cocoa solids, and not more than 8 per cent flour or starch.

9. Chocolate familiar a la taza	The product obtained from cocoa products, 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; (b) a single chocolate or a combination or a mixture of chocolate within the meaning of any of the definitions specified in column 2 of items 3, 4, 5 and 6 and any other edible substance, provided that the chocolate constitutes not less than 25 per cent of the total weight of the product.

Notes

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

Provided that this paragraph does not authorise the addition -

(a) of animal fats and their preparations not deriving solely from milk; or

(b) of flours, granular and powdered starch other than in accordance with the definitions specified in column 2 of items 8 and 9; or

(c) of other edible substances in a quantity exceeding 40 per cent of the total weight of the finished product.

(2) Only those flavourings which do not mimic the taste of chocolate or of milk fat may be added to the designated products specified in column 2 of items 2, 3, 4, 5, 6, 8 and 9.

2. (1) The minimum contents of the designated chocolate products specified in column 2 of items 3, 4, 5, 6, 8 and 9 shall be calculated after deduction of the weight of other edible substances provided for in Note 1.

(2) In the case of the designated chocolate products specified in column 2 of items 7 and 10, the minimum contents shall be calculated after deducting the weight of other edible substances provided for in Note 1, as well as the weight of the filling.

(3) The chocolate contents of the designated chocolate products specified in column 2 of items 7 and 10 shall be calculated in relation to the total weight of the finished product, including its filling.

3. In this Schedule, 'sugars' includes sugars covered by Council Directive 2001/111/EC (21) and other sugars.

Coffee Extracts and Chicory Extracts Regulations (NI) 2001 (SR No. 45)

Scope

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

Ingredients/Products

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

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

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

a) The food is the designated product to which the reserved description relates

b) The description is used in such a context as to indicate explicitly or by clear implication that the substance to which it relates is only an ingredient of that food

c) The description is used in such a context as to indicate explicitly or by clear implication that such food is not and does not contain a designated product.

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

Labelling Requirements

There are specific labelling requirements for the designated products in addition to the general requirements of the EU Food Information to Consumers Regulation 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 Regulations (NI) 1976 or if no reserved description the name of the product as if it were itself being sold as a food
- In the case of coffee/ chicory extracts in paste or liquid form a declaration of the minimum coffee/ chicory based dry matter content expressed as a percentage
- In the case of coffee extracts in liquid form containing more than 25% coffee based dry matter and for chicory extracts in liquid form containing more than 45% chicory based dry matter the word 'concentrated' may be added to the reserved description
- The information required by these regulations must be in a conspicuous place so as to be clearly visible, clearly legible and indelible and easy to understand.

Public Analyst Observation

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

Associated Regulations

Coffee Extracts and Chicory Extracts Regulations (NI) 2001. SR No 45

Food Information Regulations (NI) 2014

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

SCHEDULE

Annex 1

Table

Coffee Extracts and their Reserved Descriptions

Column 1 *Reserved descriptions*	*Column 2* *Designated products*
1. Coffee extract *or* Soluble coffee extract *or* Instant coffee *or* Soluble coffee	Coffee extracts in powder, granular, flake, cube or other solid form, of which the coffee-based dry matter content is not less than 95%, containing no substances other than those derived from the extraction of coffee.
2. Coffee extract *or* Soluble coffee extract *or* Instant coffee *or* Soluble coffee *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.

3. Coffee extract *or* Soluble coffee extract *or* Instant coffee *or* Soluble coffee *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 *Reserved descriptions*	*Column 2* *Designated products*
1. Chicory extract *or* Instant chicory *or* 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 not more than 1% of substances not derived from chicory.
2. Chicory extract *or* Instant chicory *or* 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 not more than 1% of substances not derived from chicory.
3. Chicory extract *or* Instant chicory *or* Soluble chicory *supplemented in each case by the word 'liquid' or the words 'in liquid form'*	Chicory extracts in liquid form, of which the chicory-based dry matter content is not more than 55%, and *not less than 25%.* **NOTE** This product may contain added sugar products, whether or not roasted, in a proportion not exceeding 35%.

Condensed Milk and Dried Milk Regulations (NI) 2003 (SR No. 300)

Scope

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

In addition all products covered by the Regulations must also comply with the general provisions of The Food Safety (NI) Order 1991, EU Food Information to Consumers Regulation 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 SR 2003 No. 300.

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.

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ADDED VITAMINS ARTICLE 3 OF 2001/114/EC
Regulation 2 and Notes to Schedule 1 of SR 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 (NI) Order 1991, as amended.

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

Condensed milk and dried milk products within the scope of these Regulations are subject to the general rules set by the EU Food Information to Consumers Regulation 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

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 SR 2003

Additives that are listed as permitted currently by the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013 for use in the designated products may continue be used for the foreseeable future.

Public Analyst Observation

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

Associated Regulations

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

The Condensed Milk and Dried Milk Regulations (Northern Ireland) 2003 (SR No.300)

Food Safety (NI) Order 1991

Food Information Regulations (NI) 2014

Specified Sugar Products Regulations (NI) 2003

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

Food Hygiene Regulations (NI) 2006

Further Information

Guidance on condensed milk and dried milk

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

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

Currently, the Agency is responsible for implementing **Directive 2001/114/EC** through domestic legislation; The Condensed Milk and Dried Milk Regulations (NI) 2003 (SR No. 300)

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 (CODEX)
- **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 1

Partly or wholly Dehydrated Preserved Milk Products and their Reserved Descriptions

Column 1 *Reserved descriptions*	*Column 2*
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	

(e) Sweetened condensed milk	Partly dehydrated milk with an admixture of sucrose* (semi-white sugar, white sugar or extra white sugar) and containing, by weight, not less than 8% fat and not less than 28% total milk solids.
(f) Sweetened condensed,	Partly dehydrated milk with an admixture of sucrose* (semi-white sugar, white sugar or extra white sugar) and containing, by weight, not less than 1% and less than 8% fat, and not less than 24% total milk solids. partly skimmed milk
(g) Sweetened condensed skimmed milk	Partly dehydrated milk with an admixture of sucrose* (semi-white sugar, white sugar or extra white sugar) and containing, by weight, not more than 1% fat and not less than 24% total milk solids.

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

2. Totally dehydrated milk *Reserved descriptions*	*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

(ii) Vitamins and minerals in accordance with the requirements Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods

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(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).

3. 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 partly dehydrated milk containing, by weight, at least 9% fat and 31% total milk solids.

2. The term 'evaporated semi-skimmed milk' may be used instead of the term 'condensed partly skimmed milk' in the case of partly dehydrated milk containing, by weight, between 4% and 4.5% fat and not less than 24% total milk solids.

3. The term 'semi-skimmed milk powder' or 'dried semi-skimmed milk' may be used instead of the term 'dried partly skimmed milk' or 'partly skimmed-milk powder' in the case of totally dehydrated milk with a fat content of between 14% and 16%.

Contaminants in Food Regulations (NI) 2013 SR No. 229

Scope

These Regulations make provision for the continuing implementation of Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats and of Commission Directive 80/891/EEC relating to the Community method of analysis for determining the erucic acid content in oils and fats intended to be used as such for human consumption and foodstuffs containing added oils or fats.

These Regulations also make provision for the continuing implementation of European Commission Regulation 1881/2006 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

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

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

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

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

Section 1 – Nitrate

Section 2 – Mycotoxins
- Aflatoxins
- Ochratoxin A
- Patulin
- Deoxynivalenol
- Zearalenone
- Fumonisins
- T-2 and HT-2 Toxin

Section 3 – Metals
- Lead
- Cadmium
- Mercury
- Tin (inorganic)

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

Section 5 – Dioxins and PCB's

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

In addition, the Contaminants in Food Regulations also provides for the enforcement of Commission Regulation EC No. 124/2009 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

Commission Regulation 165/2010 amending Regulation (EC) 1881/2006 raises the levels for aflatoxin in certain specified foods and aligns EU limits for aflatoxins with those agreed at the Codex Committee on contaminants in food in 2008.

The Contaminants in Food Regulations (NI) 2013 create the following offences:

- Placing on the market a product in which the level of erucic acid exceeds 5%, calculated on the total level of fatty acids in the fat component
- Placing on the market certain foods that contain contaminants at levels exceeding those specified in the EC Regulation 1881/2006 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.

These regulations revoked the Mineral Hydrocarbons in Food Regulations (NI) 1966 in their entirety. The Mineral Hydrocarbons in Food Regulations (Northern Ireland) 1966 (SR No 200) (purely national Regulations) are based on science which is now out of date. In addition the scope of the Regulations is too broad. By generally banning the sale or import of any food containing mineral hydrocarbons, the legislation has the unintended effect of banning the presence of residues of mineral hydrocarbons, which could be tolerated by EU contaminants legislation.

Public Analyst Observations

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

Associated Regulations

Contaminants in Food Regulations (NI) 2013

Contaminants in Food (Amendment) Regulations (NI) 2013

Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats

Commission Directive 80/891/EEC of 25 July 1980 relating to the Community method of analysis for determining the erucic acid content in oils and fats

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

Commission Regulation (EC) No 1126/2007 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards Fusarium toxins in maize and maize products

Commission Regulation (EC) No. 165/2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins

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. 105/2010 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A

COMMISSION REGULATION (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

COMMISSION REGULATION (EC) No 1882/2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs

COMMISSION REGULATION (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs

COMMISSION REGULATION (EU) No 420/2011 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

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

Commission Regulation (EU) No 1258/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for nitrates in foodstuffs

Commission Regulation (EU) No 1259/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs

Commission Regulation (EU) No 594/2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs

Commission Regulation (EU) No 1058/2012 amending Regulation (EC) No 1881/2006 as regards maximum levels for aflatoxins in dried figs

Commission Regulation (EU) No 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs and repealing Regulation (EC) No. 1883/2006

Commission Regulation (EU) No 610/2012 amending Regulation (EC) No 124/2009 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

Further Information

FSA Guidance on the Contaminants in Food Regulations (Northern Ireland) 2009

The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015 (SR No. 321)

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 prepacked fresh, chilled and frozen meat of swine, sheep, goat and poultry.

Please note: The EU Regulation does not currently cover non-prepacked or 'loose' product. 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) 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 Regulations (NI) 2015. There is a minimum of a 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)).

A definition of batch code is provided in Regulation 2(1) of the Country of Origin of Certain Meats (NI) 2015 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

FBO's 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.
	Slaughtered < 6 months old and at least 80kg liveweight	Reared In: member state or third country in which rearing from 30kgs took place.
	Slaughtered < 6months old and < 80kg 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 (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.

	Slaughter age/weight	Indication on label
Member State/s or Third Country of Rearing	Slaughtered ≥ 6 months old	Reared In: member state or third country in which last rearing period of at least 6 months took place.
	Slaughtered < 6 months old	Reared In: member state or third country in which whole rearing 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 (EU) No. 1337/2013.

Poultry

For poultry the 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/s 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.
	Slaughtered < 1 month old	Reared In: member state or third country in which whole rearing 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 (EU) No. 1337/2013.

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;

- "Reared in: several member states of the EU" or
- "Reared in: several non-EU countries" or
- "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:

- "Reared in UK and Ireland" or
- "Reared in UK and Denmark" or
- "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 1337/2013 allows meat referred to in Article 1imported for placing on the EU market from a non EU source to indicate on the label:

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

Article 7: Derogation for minced meat and trimmings

Article 7 of **1337/2013** 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 of 1337/2013 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.

Examples of additional voluntary information:
"Northern Irish"
"British"
"Scottish"

Enforcement

The method of enforcement for the EU Regulation will be via improvement notice served under Article 9 of the Food Safety (NI) Order 1991 as applied by these Regulations. An improvement notice can also be served under Article 9 for breach of regulation 5 of these regulations (record keeping).

Improvement Notices would be used as a part of the hierarchy of enforcement when informal measures are no longer appropriate and the labelling contravention or issue should be elevated to formal action. If the conditions set by an improvement notice are not met then the non-compliance with those conditions will constitute a criminal offence. Improvement Notices can be appealed to a Court of Summary Jurisdiction.

Public Analyst Observations

There are analytical tests available that will give an indication of the country of origin however these tests should be used as a tool to assist in investigative work through audit and document checks.

Associated Regulations

The Country of Origin of Certain Meats Regulations (NI) 2015
http://www.legislation.gov.uk/nisr/2015/321/made

Commission Implementing Regulations (EU) No. 1337/2013
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:335:0019:0022:EN:PDF

DAFM Guidance on origin Labelling Requirements for Fresh, Chilled or Frozen Meat from pigs, poultry, sheep and goats

http://www.agriculture.gov.ie/agrifoodindustry/foodlabelling/meatlabelling/labellingofswinesheepgoatsandpoultry/originlabellingrequirementsforfreshchilledorfrozenmeatfrompigspoultrysheepandgoats/

Food Safety (NI) Order 1991
http://www.legislation.gov.uk/nisi/1991/762/contents/made

Section D
Legislation Under D

D

Drinking Milk Regulations (NI) 2008 (SR No. 237)

Scope

These Regulations made provisions for the enforcement of Article 114(2) of, and Annex XIII to, Council Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products. Council Regulation (EC) No. 361/2008 amended Annex XIII of Council Regulation (EC) No. 1234/2007.

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 not 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

Heat treated milk not complying with the fat content requirements must be considered drinking milk provided that the fat content is clearly indicated, with one decimal and easily readable on the packaging in the form of "...% fat". Such milk must not be described as whole milk, semi skimmed milk or skimmed milk.

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

2008 SR No. 237 Ver 1

Public Analyst Observation

Dairies do sometimes have difficulty regulating the fat content of semi-skimmed milk.

Officers may encounter products described as "X% fat milk" e.g. 1% fat milk.
Such a product can not be described as semi skimmed or skimmed milk.

Associated Regulations

Council Regulation (EC) No. 2597/97

Drinking Milk Regulations (Northern Ireland) 2008 SR No. 237

Council Regulation (EC) No. 361/2008

Section E
Legislation Under E

Section F
Legislation Under F

Fish Labelling Regulations (NI) 2013 (SR No. 219)

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 (but scientific (Latin) name can be displayed on a billboard or poster instead of labelling it on the product itself). It requires Member States to establish a list of commercial designations of fish species which are names prescribed by law. A live up-to-date list of accepted names can be found at the link below:

  https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236702/pb14027-uk-commercial-designation-fish-list.pdf

- 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.

Requirements to provide the consumer with additional information on fishery products at retail stage were introduced throughout the EU and applied from 13 December 2014. These 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 aforementioned presentations) which is sold loose from fish counters or pre-packed for direct sale to the final consumer.

It should be noted that the regulations do not apply to

- fish that has been further processed, preserved treated or cooked e.g. tinned tuna;
- fish to which other ingredients have been added e.g. fish fingers; fish with colouring;
- crabsticks, fish sticks or similar;
- recipe dishes/fish ready meals e.g. fish pies;
- smoked fish with additional ingredients e.g. smoked salmon fillet treated with honey, salmon sandwiches;
- cooked molluscs e.g. cockle meat out of shell or winkle meat with or without shell.

Traceability requirements

Traceability information on the commercial designation including scientific name of the fish species, production method and catch area must be available at each stage of marketing of the species (i.e. at all stages of production / first landing, distribution, etc., where the ownership of the produce changes hands).It is generally understood that commercial documentation rather than labelling of the product per se is the usual means of providing traceability information.

Exemptions

The Regulations do not apply to sales of small quantities of fish (to the value of less than €20) sold directly to the final consumer by either fisherman (e.g. from the quayside) or aquaculture producers (e.g. from lakes, ponds, etc.).

Labelling Requirements

Labelling of Production method

The production method (which specifies the manner in which the fish was harvested) should to be given in one of the following ways:

(a) For products caught at sea or in freshwater - the terms ‘caught’ or ‘caught in freshwater’ should be used.

(b) For products of aquaculture - the terms ‘farmed’ or ‘cultivated’ should be used to indicate that the fishery and aquaculture products have been farmed. In order to ensure that accurate and meaningful information is provided to the consumer, the Agency recommends that the method of production be given prominently with the commercial designation (e.g. ‘farmed Scottish trout’).

Circumstances where the production method need not be indicated

For fish caught at sea, the terms 'caught' or 'caught in' do not have to be used if it is obvious from the commercial designation or the catch area that species have been caught at sea e.g. Sea bass, Pacific sand dab, However, if there is any doubt about the production method, then omitting the terms 'caught' or 'caught in' is not permitted. It is worth noting that much of the Seabass on sale in the UK is farmed in the Mediterranean.

Labelling of catch area

The catch area must be indicated as follows:

(a) ***For products caught at sea***, the origin must be 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 must 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 must 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 all countries be indicated on the labelling to give consumers accurate and meaningful information on the true place(s) of origin of the fish. So in the above example, the Agency ***recommends*** the product is labelled as 'Farmed Icelandic fish reared in France and Denmark'.

Meaning of 'final development' for farmed products?

The term 'final development' should be taken to mean the stage when the fish is finally 'harvested' from the water where it reaches its final size.

Rules for farmed products coming from more than one Member State or third country

The Fish Labelling Regulations (at Regulation 3(5)) 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 same species with different production methods and/or obtained from different catch/production areas

(1) For mixtures of fish of the same species coming from a variety of production methods, 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 same species coming from different catch areas or fish-farming countries, the origin that is most representative of the batch in terms of quantity must be stated. Processors must decide whether the basis of the labelling is representative and not misleading to the consumer. Hence a batch of 'farmed salmon steaks' may originate predominantly in Scotland but also Norway or Chile and could be described as 'farmed salmon steaks originating from Scotland, Norway and Chile'.

Labelling of products sold loose (non-prepacked e.g. at supermarket fish counters, fishmongers, etc.)

The manner of marking for food which is not pre-packed and sold loose should be consistent with general labelling requirements (Regulation 36 of Food Labelling Regulations). That is the name of the food on a label attached to the food or a ticket or notice should be 'readily discernible by the purchaser at the place where he chooses that food'.

In terms of best practice, the ***Agency recommends*** that where farmed fish/shellfish is offered for sale, an indication of this production method be indicated on the ticket/label next to the product. This will provide consumers with accurate and meaningful information about the production method and help consumer choice as to whether they wish to purchase a farmed fish product or not.

With regard to the catch area, it is possible for an in-store notice, wall chart/poster, etc., near the fish counter which is 'readily discernible' by the purchaser at point of sale to carry this information. For example, 'all our Icelandic fish is caught in the North-East Atlantic'.

Labelling of products sold in catering establishments

Fish/shellfish sold in catering establishments such as restaurants are outside the scope of the EC fish labelling rules. Provided the product is ready to eat without the need for further preparation, it is regarded as a catering sale and, therefore, does not need to be labelled according to the EC fish labelling rules.

Nevertheless, where a product is specifically named in the catering establishment and there is a name for it prescribed by law, such as a commercial designation laid down in the Regulations, then it must be used to describe the product.

Controls in place for checking traceability

Traceability checks will normally be carried at the point of sale by Environmental Health Officers when checking the required information. In addition, DAERA Sea Fisheries Inspectorate may also check traceability information in carrying out their responsibility for fish marketing for products at landing, wholesale chain and transit up to the point of retail sale.

Enforcement

The criminal sanctions for breaching the Regulations have been replaced in all cases with improvement notices except for record keeping and production of records which remain criminal offences. Improvement notices under Article 9 of the Food Safety Order (Northern Ireland) 1991 are modified and applied in these Regulations. Breach of an improvement notice is an offence under the applied Article 9.

Public Analyst Observations

Authenticity Issues.

Origin - farmed/wild sea bass, salmon, and sea bream can be analysed.

Associated Regulations

The Fish Labelling Regulations (NI) 2013 (SR No. 219)

The Fish Labelling (Amendment) Regulations (NI) 2014 (SR No. 287)

Regulation (EU) No 1379/2013 – 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.

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

Commission Implementing Regulation (EU) No. 404/2011 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

CN Codes for fish

Fish species list

A pocket guide to the EU's new fish and aquaculture consumer labels

2010 SR No. 54 Ver 1

Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013 (SR No. 220)

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 rule.

The main changes in bringing these areas together into one SR is the introduction of improvement notices for non-safety related sanction such as labelling requirements.

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-prepacked or prepacked 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.

e.g. 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.

e.g. 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 of EU Regulation 1169/2011 as regards the indication of 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-prepacked 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.

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 the Food Standards Agency as the national competent authority to receive applications for the authorisation of new primary smoke condensates and primary tar fractions for use as such in or on foods, or in the production of derived smoke flavourings for use in or on foods.

The regulations:

1. Prohibit the marketing of smoke flavourings not listed in the authorised list or use outside the criteria and conditions of the authorisation. 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) apply to smoke flavourings. Additionally the EU Food Information for Consumers Regulation (No. 1169/2011) state 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 (this will be 1st January 2015).

The 12 month transitional period will allow industry time to adapt to the proposed measures and potentially reduce their impact. In addition, foods which are lawfully placed on the market before the end of transitional period may remain on the market until stocks are exhausted. Once the Union list 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 are 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 III a to Directive 2000/13/EC as regards the indication of the ingredients present in foodstuffs (e.g. Allergen content).

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 w/w 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. It is anticipated that the application period to be in the first Union list is 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 and listed in Annex II of 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 (1) 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 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 this Article 12 of EC Regulation 1332/2008. Article 8 of EU 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 Northern Ireland from outside the EC.

Annex I Part 2 of Directive 2009/32 of the Regulations 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 Article 8 of the Food Safety (NI) Order 1991 (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.

Enforcement

The criminal sanctions for breaching the Regulations have been replaced in all cases with improvement notices except for record keeping and production of records which remain criminal offences. Improvement notices under Article 9 of the Food Safety Order (Northern Ireland) 1991 are modified and applied in these Regulations. Breach of an improvement notice is an offence under the applied Article 9.

Public Analyst Observations

Additives

Sweeteners: In general limits are being complied with but labelling issues can arise where food business operators fail to indicate it in the name of the food when being used as an ingredient. Officers who are inspecting premises that utilise sweeteners should take this into account when undertaking inspections. Officers need to consider use of sweeteners in foods which also contain sugars e.g. soft drinks.

2. Miscellaneous Additives: Issues can include
   a. Carry-over of sorbic acid preservative in bakery products not declared. Sorbic is used as a preservative in (for example) margarine, so whilst it may be deliberately added directly to bakery goods, it's presence at a low level might be due to "carry over" in a compound ingredient such as margarine. If the presence of this additive is due solely to "carry over" then the level in the final product may be too low for the preservative to have a significant technological effect.
   b. 100% steak burgers containing sulphur dioxide. Regulations require burger meat to contain a minimum of 4% of vegetable or cereal before the addition of sulphur dioxide preservative is permitted.
   c. Revised (lower) limits for nitrate/nitrite preservative in cured meat and meat products were introduced prior to these Regulations coming into force. Higher maximum limits are still applicable if certain defined "traditional" curing processes have been used. For this reason it is important for sampling officers to record and transmit to the lab details of the process used whenever possible (i.e. sampling in factory, this would likely be impossible when sampling from retail premises).

3. Colours: Note that Annex V to 1333/2008 introduces the additional labelling provisions which will become applicable to foods containing the colours identified in the "Southampton" study and which are listed in that Annex. There can be labelling issues for trade sales and trade documents. Officers may wish to pay particular attention to delivery ingredients held in the dry goods stores of food premises such as bakeries, butchers and other food processing factories.

Enzymes

Officers would need to pay particular attention to ensure that enzymes are used in practice strictly for the purpose for which they have been approved.

Flavourings

Flavourings used in bakeries should be monitored and samples taken as necessary. Flavourings are often complex mixtures. Natural flavourings can be much more expensive than their "nature" identical equivalents, and some may be differentiated by analysis (easier if the flavouring is submitted rather than the compound food containing it). Please enquire before sampling.

Extraction Solvents

Extraction solvents tend not to present many issues regarding food composition. The solvents can be used to take caffeine out of decaffeinated coffee. Today it is more likely that high pressure carbon dioxide would be used to remove caffeine and in consequence there tends to be no residue issues.

Associated Regulations

Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013 SR No. 220

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

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 Union 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 or intended 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 and Directive 2000/13/EC

Regulation EC No 1332/2008 on Food Enzymes

Commission Directive 2009/32/EC 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

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

Current EU approved additives and their E numbers

Lists of authorised food additives

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

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2009 SR No. 398

Scope

These regulations implement Commission Regulation (EC) No. 953/2009, which **consolidate** and **repeal** Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in food for particular nutritional uses.

A number of nutritional substances such as vitamins, minerals, amino acids and others may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the persons for whom they are intended are fulfilled and also conform to requirements of EC Directive 2009/39/EC.

New substances have been evaluated by EFSA and as such the list has been updated. In addition specifications are introduced for some vitamins and minerals for their identification.

Foods for specific groups are foods which, owing to their special composition or process of manufacture, are clearly distinguishable from foods intended for normal consumption, and are sold in such a way as to indicate their suitability for their claimed nutritional purpose.

A particular nutritional use means the fulfillment of the particular nutritional requirements of certain categories of persons

a) whose digestive processes or metabolism are disturbed or
b) whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs or
c) of infants or children in good health.

The regulations do not apply to infant formula, follow on formula, processed cereal based foods and baby foods for infants and young children as nutritional aspects for these foods are covered by Commission Directive 2006/141/EC, Directive 1999/21/EC and Commission Directive 2006/125/EC.

Ingredients/Products

The range of foods for particular nutritional uses is very wide and diversified. The widest possible choice of substances that can be safely used in the manufacture of foods for particular nutritional uses should be available for the categories of nutritional substance listed.

Offences: Regulation 3

It is an offence for a person to fail to comply with the specified provisions which are detailed in the Schedule to the regulation.

Specified provisions

1. Article 2(1) Eligible substances: Only the substances listed in the Annex to the Commission Regulation (EC) No. 953/2009 complying with the relevant specifications as necessary may be added for specific nutritional purposes for Parnuts as covered by Directive 2009/39.
2. Article 3(1) General Requirements: The use of substances added for specific nutritional purposes must result in safe food that 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 in NI) 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.

Note: At time of printing PARNUTS legislation is currently being reviewed and will thereafter become known as "foods for specific groups".

Public Analyst Observations

There are no major issues identified with these regulations. Officers may want to check that the label correctly reflects the nutritional criteria. Special precautions may be required if samples are taken and submitted for checks on vitamin(s) content; please seek advice before sampling.

Associated Regulations

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2009 SR No. 398.

2009 SR No. 398 Ver 1

Further Information

Guidance notes on the Notification of Marketing of Foods for Particular Uses, Medical Foods and Infant Formula http://multimedia.food.gov.uk/multimedia/pdfs/parnuts

Commission Directive 2006/141/EC

Directive 1999/21/EC

Commission Directive 2006/125/EC

EC Directive 2009/39/EC

Commission Directive 2001/15/EC

Commission Regulation (EC) No. 1161/2011 amending the list of minerals 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 Parnuts (Regulation EC No. 953/2009):

- Ferrous Ammonium Phosphate
- Ferric Sodium EDTA
- Chromium Picolinate

Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations (NI) 1997 SR No. 450

Scope

These Regulations implement Commission Directive 96/8/EC dealing with composition and labelling requirements on food intended for use in energy-restricted diets for weight reduction.

Ingredients/Products

The legislation essentially deals with foods for use in energy-restricted diets for weight reduction being food which complies with the requirements of schedule 1 and which, when used as instructed by the manufacturer, replace the whole 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 set out in the following table

A Total diet replacement foods	B Meal Replacement foods
Energy value in kJ and Kcal Protein Carbohydrate Fat	Energy value in kJ and Kcal Protein Carbohydrate Fat
Average quantity of each mineral and vitamin specified in the directive	The average quantity as a percentage of the values in Annex XIII of EU FIC 1169/2011
Instructions for appropriate preparation and importance of following the instructions	Instructions for appropriate preparation and importance of following the instructions
Where 20g or more polyols will be provided as part of the daily diet when used	Where 20g or more polyols will be provided as part of the daily diet when used

A Total diet replacement foods	B Meal Replacement foods
A statement of the importance of maintaining an adequate daily fluid intake	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	A statement that the product is useful as part of an energy restricted diet and that other foods should be a necessary part of the diet.

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.

Amendments to Regulations

Food Safety (Information and Compositional Requirements) Regulations (NI) 2016 (SR No. 251)

These regulations update the primary regulations by updating the definition of relevant food, defining the name under which food can be sold and amending Schedule 1 of the primary regulations. They allow only for total diet replacement foods and not for products presented as replacements for one or more meals to be presented as food intended for use us in energy restricted diets for weight control.

Public Analyst observations and comments

There tend to be few analytical problems, however, checks should be made for compliance with labelling requirements.

Associated Regulations

Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations (NI) 1997 SR No. 450

The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (NI) 2007 SR. No. 408

Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (SR No. 251)

Further Information

Commission Directive 96/8/EC

The Advertising Standards Authority has references to the above legislation in its CAP Code.

1997 SR No. 450 Ver 1

2009 SR No. 258 Ver 1

The Food Irradiation Regulations (NI) 2009 SR No. 258

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.

Food Type	Further qualification	Level deemed to be over irradiated *
Fruit	Includes fungi, tomatoes and rhubarb	2kGy
Vegetables	Excludes fruit, cereals, bulbs and tubers, and dried aromatic herbs, spices and vegetable seasoning but includes pulses	1kGy
Cereals		1kGy
Bulbs and tubers	Means potatoes, yams, onions shallots and garlic	0.2 kGy
Dried aromatic herbs, spices and vegetable seasoning		10kGy
Fish and shellfish	Includes eels, crustacean and molluscs	3kGy
Poultry	Includes domestic ducks, guinea fowl, geese, pigeons, quails and turkeys	7kGy

*(Food is deemed to be over irradiated when the "overall average dosage" calculated for a batch of food exceeds that given in the table; or when the maximum dose of ionising radiation absorbed by any food in a batch of which it forms a part is when so measured a dose of kGy higher than the lower of 3X and 1.5 Y where "X" is the minimum dose absorbed by any of the food in the batch in kGy and "Y" is the overall average dosage in kGy given in the table.).

Regarding the table, an average dose is calculated for the whole batch of food (called the "overall average dose") and this overall average dose must not exceed the values given. However, there are also constraints on the minimum and maximum doses received by any part of that batch, namely that the maximum dose received by any part of the batch must not be
- more than 3 times the minimum dose received by any other part of the batch or
- more than 1.5 times the dose values given.

For information, the first of the bullet points above is actually a constraint on the minimum dose to ensure no part of the food is under irradiated but it is stated the other way for consistency.

Prohibition on Treatment without a licence (Regulation 4)
The regulation prohibits any person from subjecting food to treatment by ionising radiation unless the person
- Holds a licence to do so
- Food is in a wholesome state and
- Treatment is in accordance with licence conditions

Restrictions on Importation (Regulation 5)
The regulations restrict the import of irradiated foods unless
- It falls within a permitted category
- It was irradiated in one of the approved facilities
- It was properly irradiated

If the food comes from another Member State of the EU it must be accompanied with the following details
- Name and address of irradiation facility and Official Reference Number
- For each batch
  - Nature and quantities
  - Batch number
  - Name and address of consignors and consignees
  - Date irradiated
  - Overall average dose applied

If the food comes from a 3rd Country it must be accompanied with the following
- Name and address of irradiation facility
- Nature and quantities
- Batch number
- Name and address of consignors and consignees
- Date irradiated
- Overall average dose applied

- Microbiological information relating to the batch
- Type of food packaging used during irradiation
- Temperature of food before irradiation (where appropriate)
- Maximum, minimum and overall dose of ionising radiation
- Type of ionising radiation
- Data used for control of the irradiation

For foods other than dried aromatic herbs, spices and vegetable seasoning, they must be irradiated by

- A person approved under a reference by which the approval can be identified by the competent authority in the country in which it was irradiated.
- The approval requires the method of measurement specified in Schedule 1.
- Legislation in the originating 3rd Country is of equivalent standard as the EU.
- Complies with conditions applied to the food.

The requirement applies to food which has (as well as has not) become an ingredient of another food.

Storage and Transportation restrictions (Regulation 6)

Only persons holding a licence may store or transport irradiated food, however, storage and transport is permitted for irradiated food that has been imported and is accompanied with the necessary documentation. The provision applies to food which has (as well as has not) become an ingredient of another food.

Restrictions on Sale (Regulation 7)

Irradiated food can not be sold in Northern Ireland 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

2009 SR No. 258 Ver 1

Enforcement (Regulation 9)
The FSA and district councils have different roles and responsibilities in relation to enforcement of the regulations. In general it will be the FSA who licence irradiation facilities in the UK.

Labelling Requirements
Regulation (EU) No. 1169/2011 requires that a food or food ingredient must bear the treatment description e.g. "Irradiated" or "Treated with ionising radiation".

Public Analyst Observations
Officers may consider checking sources of herbs and spices including supplements in premises that specialise in health products.

It is possible that imported sources of shellfish such as fresh/frozen prawn may have been irradiated. As part of routine monitoring of the microbiology of such materials it may be possible to correlate unusually good microbiological results with potentially irradiated foods that warrant further investigation.

There is a range of different techniques (PSL, TL, ESR) which may be used to determine if food has been irradiated.

Associated Regulations
Food Irradiation Regulations (NI) 2009 S.R. No. 258

Food Irradiation (Amendment) Regulations (NI) 2010 S.R. No. 322

Food Irradiation Provisions Regulations (NI) 2000 S.R. No. 303 – Regulation 13-20

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 Safety (Information and Compositional Requirements) Regulations (NI) 2016 (SR No. 251)

Scope

These Regulations enforce the provision of 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.

From 20th July 2016 (EU) 609/2013 repeals Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

Ingredients/Products

There are now only four 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 previously considered as foods for particular nutritional uses and for which specific provisions have not been laid down, in particular:

- Sports foods
- Young children formula
- Meal replacement for weight gain
- Suitable for diabetic

On the 20th July 2016, they were classed as normal foods, regulated by the general food labelling rules.

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 follow-on formula shall not include pictures of infants, or other pictures or text which may idealise the use of such formula.

- Graphic representations for easy identification of infant formula and follow-on formula and for illustrating methods of preparation shall be permitted.

Delegated Regulations

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 form 5 years after entry into force. (currently under discussion at EU level)

Transitional Period

The foods for specific groups Regulation applies to all Member States from 20 July 2016. The transition period for complete compliance with the new compositional and labelling requirements 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 formula) 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.

Enforcement

It is the duty of each district council within its district to enforce these Regulations. District councils are enabled by Articles 9(1) and (2) of the Order (improvement notices), with the modification (in the case of Article 9(1)) specified in Part 1 of Schedule 2, for the purposes of an improvement notice to be served on a person requiring that person to comply with a specified EU requirement and making the failure to comply with an improvement notice an offence.

A person who fails to comply with Article 9(2) of the EU Regulation (substances in dangerous quantities) as read with Articles 1(1) and 4(1) is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Revocation

The following Regulations are revoked-

(a) the Notification of Marketing of Food for Particular Nutritional Uses Regulations (Northern Ireland) 2007(1);

(b) Regulations 26 and 27 of the Infant Formula and Follow on Formula Regulations (Northern Ireland) 2007(2); and,

(c) The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (Northern Ireland) 2010(3).

Public Analyst Observations

Associated Regulations

The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016

Regulation (EU) No 609/2013

The Food Information Regulations 2014 (SR No. 1855)

Further Information

Regulation (EU) No 609/2013

Food Supplements Regulations (NI) 2003 (SR No. 273)

Scope

The Regulations implement the provisions of EC Directive 2002/46/EC 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 Directive 2001/83/EC.

The control of medicinal products is the responsibility of the Medicine and Healthcare Products Regulatory Agency (Department of Health in Northern Ireland).

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 sold in dose form 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 the EU Food Information to Consumers Regulation No. 1169/2011.
- 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 manufacturers' analysis.

The Regulations state that details on labels of food supplement must not mention, express, or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

The specific labelling requirements must be on the packaging, or on a label attached to the packaging, or on a label which is clearly visible through the packaging. Where the sale is otherwise than to the ultimate consumer, the specific details may be on commercial documents where it can be guaranteed that such documents either accompany the food supplement or were sent before or at the same time as the delivery.

The outermost packaging requires (as per the 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 pre-packed 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 (Amendment) Regulations (NI) 2007 SR No. 116 which add another form of the vitamin folate and another form of the mineral iron to the positive list in Annex II to Directive 2002/46. The regulations were further amended by the Food Supplements and the Addition of Vitamins, Minerals and Other Substances (amendment) Regulations (Northern Ireland) 2009 SR No. 407 which incorporates requirements set out in Regulation 1170/2009/EC.

Note:
Whilst there is no notification procedure for food supplements in Northern Ireland, officers should be aware that there is such a procedure in the Republic of Ireland and as such if they become aware that an FBO plans to distribute supplements in the Republic of Ireland then they should inform the Food Safety Authority of Ireland (FSAI) Link: http://www.fsai.ie/search-results.html?searchString=supplements

Public Analyst Observations

There are numerous products on sale which do not comply with EU labelling requirements for food supplements. Additionally, there are frequently issues with the use of unauthorised health claims. Imported products may contain ingredients which are regarded as unauthorised novel foods in the EU. Products have also been found on sale which contain dangerous and illegal ingredients such as DNP.

Traditional Chinese Medicine Shops - At present there is an exemption for herbal remedies and if dispensing to individuals after consultation. (Herbal medicines / herbs other than those used purely for culinary purposes are regulated under the Traditional Herbal Medicines Directive, which is administered by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK).

In relation to herbal remedies there may be issues of heavy metals or pesticides contamination.

There is no registration process for food supplements in the UK therefore there is no method to verify what is actually on the market. It is not possible to confirm if any brand is from an approved source.

Health Food Shops - EHOs should check vitamin and mineral level on products through submission of samples for analysis.

Associated Regulations

Food Supplements Regulations (Northern Ireland) 2003 SR No. 273

Food Supplements (Amendment) Regulations (NI) 2007 SR No 116

Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (NI) 2009 SR No 407

EC Directive 2002/46/EC relating to food supplements

EC Directive 2001/83/EC relating to medicinal products for human use

Commission Directive 2006/37/EC amending 2002/46/EC

Commission Regulation (EC) No. 1170/2009

Commission Regulation (EC) No. 1161/2011 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

Further Information

Food Supplements: guidance and FAQs

Guidance Notes on Food Supplements Regulations (NI) 2003

Medicines and Healthcare Products Regulatory Agency (MHRA)

Report of Expert Group on Vitamins and Minerals Safe Upper Level Report 2003

Classification of Supplements as Food or Medicinal Products

Fruit Juices and Fruit Nectars Regulations (NI) 2013 (SR No. 253)

Scope

The Regulations implement the provisions of Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, as last 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 concentrates 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 and
- 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.

Ingredients/Products

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

1. 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 come e.g.

(a) A single fruit – "x" = named fruit
(b) 2 kinds of fruit – "x" = list of fruit e.g. apple and blackberry
(c) 3 or more kinds of fruit – "x" = list of fruit in the product name

There are 3 options available

- A list of the names of fruits e.g. apple, pear or blackcurrant
- the words "several fruits" or
- the number of kinds of fruits

These need to be in descending order by volume

2. Specification of fruit Column 2 Schedule 13

Fruit Juice	Use the Common or botanical name
Fruit Puree	
Fruit Nectar	

3. Other specification of fruit

Fruit Juice	Use the Common or botanical name
Fruit Puree	
Fruit Nectar	

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 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 does not contain added monosaccharides or disaccharides or any other sweetening properties including sweeteners as defined in Regulation 1333/2008.

- Where sugars are naturally present in a nectar the words "containing naturally occurring sugars" must also appear on the label.

Enforcement

Existing frontline criminal sanctions for breaching the regulations are replaced with improvement notices applied under Article 9 of the Food Safety (NI) Order 1991 which provide for a criminal offence for a failure to comply with such notices. Breach of an improvement notice is an offence under the applied Article 9 of the Order.

Public Analyst Observations

Typical issues in relation to composition and labelling include:

- Added water in "not from concentrate" juices
- Addition of sugars and / or fruit acids to juices.
- Sales of pasteurised or high pressure treated juice being described as fresh.

Adulteration issues

- Product described as x juice but not in fact a fruit juice
- Concentrate not correctly hydrated
- Range of fruit not declared
- Percentage of fruit not as declared
- Fruit juice attributed to a geographic region which is incorrect
- Excess preservative in certain juice
- Excess added sugar to fruit juice above specified limits.

Associated Regulations

The Fruit Juices and Fruit Nectars Regulations (NI) 2013 (SR No. 253)

Council Directive 2001/112/EC on fruit juices and similar products

Council Directive 2012/12/EU amending Council Directive 2001/112/EC relating to fruit juices and certain similar products

Further Information

The British Soft Drinks Association provides guidance to their members on a range of fruit juice issues.

The British Fruit Juice Importers Association provides advice and guidance on juice.

British Soft Drinks Association

FSA Guidance on Fruit Juices and Nectars Regulations 2003

Product Specifications

1. 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.

2. 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 -
(a) fruit purée;
(b) concentrated fruit purée; or
(c) both fruit purée and concentrated fruit purée.

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

3. 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 -

(a) an authorised additional ingredient/substance
(b) 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.

4. Water extracted fruit juice

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

(a) pulpy whole fruit whose juice cannot be extracted by any physical means; or
(b) dehydrated whole fruit.

The product may contain either, or both, of an authorised additional ingredient/substance. No treatment, except for an authorised treatment, may be used in the manufacture of a product.

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

6. 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 1333/2008.

The product may contain any of the following
(a) an authorised additional ingredient/substance;
(b) restored flavour, pulp and cells (or any one or more of them) obtained by suitable physical means from the same species of fruit; and
(c) 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 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 1935/2004.

- Chemically inert adsorption aids which comply with Regulation 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.

Section G
Legislation Under G

Genetically Modified Food Regulations (NI) 2004 (SR No. 385)

Scope

These Regulations provide for the enforcement and execution of certain specified provisions (relating to food) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified (GM) food and feed.

In particular these Regulations formally designate the Food Standards Agency as the national competent authority to receive applications for the authorisation of new genetically modified organisms for food use, food containing or consisting of genetically modified organisms, or food produced from or containing ingredients produced from genetically modified organisms (GMO).

The regulations:

1. Prohibit the placing on the market of a GM food unless it has received an appropriate authorisation.
2. Require that products without authorisation be withdrawn from the market.
3. Require an authorisation holder to comply with conditions or restrictions imposed on an authorisation and post marketing requirements.
4. Authorisation holders must inform the Commission if scientific information raises doubts on the safety of the product.
5. Stipulates certain labelling requirements.

Under these regulations, authorised officers have power to detain food which fails to comply with this EC Regulation. The officer may also seize the food and apply for an order from a justice of the peace for it to be condemned and destroyed or disposed of to prevent its use in food or animal feed.

In the case of incorrectly labelled food, the justice of the peace may at their discretion order that the food be properly labelled and released to the operator.

Public Analyst Observations

Anyone selling soya, maize or rice can encounter issues surrounding cross contamination. Officers should consider sampling such products if encountered in manufacturing premises.

Associated Regulations

Regulation (EC) No. 1829/2003

The Genetically Modified Food Regulations (NI) 2004 SR No. 385

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.

GMO Compass

Section HI
Legislation Under HI

HI

The Honey Regulations (Northern Ireland) 2015 (SR No. 383)

Scope

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

Ingredients/Products

The Regulations apply to honey and different types of honey defined in Regulation 2.

Honey and different types of Honey - Regulation 2

"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 further on 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°Celcius.

Compositional requirements
Regulation 16 and Schedule 1 prescribe compositional criteria with which Honey and different types of Honey" must comply when *placed on the market*. Please see below 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	Amount
1. Sugar Content	
1(1) Fructose and glucose content (sum of both) - blossom honey - honeydew honey, blends of honeydew honey with blossom honey	 not less than 60g/100g not less than 45g/100g
1.2 Sucrose content - in general - false acacia (Robinia pseudoacacia), alfalfa (Medicago sativa), Menzies Banksia (Banksia menziesii), French honeysuckle (Hedysarum), red gum (Eucalyptus camaldulensis), leatherwood (Eucryphia lucida, Eucryphia milliganii), Citrus spp. - lavender (Lavandula spp.), borage (Borago officinalis)	 not more than 5g/100g not more than 10g/100g not more than 15g/100g
2. Moisture content - all honey except for honey specified in paragraph (b), (c) or (d) - honey from heather (Calluna) and baker'honey except for baker's honey from heather (Calluna)	 not more than 20% not more than 25%
3. Water-insoluble content - all honey except pressed honey - pressed honey	 not more than 0.1g/100g not more than 0.5g/100g

4. Electrical conductivity - honey not listed below and blends of these honeys - honeydew and chestnut honey and blends of these except with those listed below	 not more than 0.8mS/cm *not less than 0.8mS/cm
- exceptions: strawberry tree *(Arbutus unedo)*, bell heather *(Erica)*, eucalyptus, lime *(Tilia spp.)*, ling heather *(Calluna vulgaris)*, manuka or jelly bush *(Leptospermum)*, tea tree *(Melaleuca spp.)*	not more than 0.8mS/cm *not less than 0.8mS/cm
5. Free acid - all honey except for baker's honey	 not more than 50 milli-equivalents acid per 1000 grammes
- baker's honey	not more than 80 milli-equivalents acid per 1000 grammes
6. Diastase activity and HMF content determined after processing and blending	
(a) Diastase activity (Schade scale) - all honey except baker's honey and honey specified in sub paragraph (ii)	Not less than 8
- all honey with low natural enzyme content (e.g. Citrus honeys) and an HMF content of not more than 15mg/kg	Not less than 3
(b) HMF - all honey except baker's honey and honey specified in sub paragraph (ii)	
- honeys of declared origin from regions with tropical climate and blends of these honeys	Not more than 40mg/kg (subject to the provisions of (a), second indent Not more than 80mg/kg

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 6(3), 7(2), 8(2), 9(2), 10(2), 11(2), 12(2), 13(2), 14(2) and 15(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 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 17)

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. It replaces the "EC" reference to "EU" ones.

An exception to this 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:

Old Regulations (2003)	New Regulations (2015)
"blend of EC honeys"	***"blend of EU honeys"***
"blend of non-EC honeys"	***"blend of non-EU honeys"***
"blend of EC and non-EC honeys"	**"blend of EU and non-EU honeys"**

It is not enough simply to provide a manufacturer's address on the label as this is not sufficient as a declaration of country of origin. It is the Agency's view that country could represent the UK or the individual country NI, England, Scotland, Wales. A precise form of words is not laid down therefore statements such as "produce of Northern Ireland", "Northern Ireland honey", or "made from honey harvested in Northern Ireland" would be acceptable.

With the exception of 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 14 and 15)

(i) 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.

(ii) Where baker's honey or filtered honey is sold in bulk containers or packs, the full product name must appear on both the container and on any accompanying trade documents. In effect, this means that baker's honey and filtered honey sold in this way may not simply be labelled as 'honey'.

(iii) 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.

(iv) In the case of a food product containing baker's honey as an ingredient, the 'name of the food' may include a reference to simply 'honey' rather than 'baker's honey', the full reserved description. Hence a product may be called 'honey cake' rather than 'baker's honey cake', but 'baker's honey' must appear on the list of ingredients. Where 'honey' is not used in the name of the food the list of ingredients must identify the honey ingredient as 'baker's 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.

Enforcement

The method of enforcement will be via improvement notice served under Article 9 of the Food Safety (NI) Order 1991 as applied by these regulations. An improvement notice can also be served under Article 9 for breach of any of regulations 6-17.

Improvement Notices would be used as a part of the hierarchy of enforcement when informal measures are no longer appropriate and the labelling contravention or issue should be elevated to formal action. If the conditions set by an improvement notice are not met then the non-compliance with those conditions will constitute a criminal offence. Improvement Notices can be appealed to a Court of Summary Jurisdiction.

Public Analyst Observations

Adulterations of honey arise from addition of sucrose or cane sugar, beet sugar or high fructose corn syrup.

The mis-description of both the geographical and floral origin of honey is commonplace. For example more "New Zealand Manuka" honey is imported into the UK alone annually than is produced in that country.

Country of origin can be determined based on a range of analytical techniques, include NMR and pollen profile.

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Honey should also be analysed for antibiotic residues - antimicrobials may be used illegally to control diseases in hives.

Officers should also be aware of the differences between retail and baker's honey and the potential for adulteration. Analytical tests can distinguish between them.

Associated Regulations

EC Directive 2001/110 relating to honey

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

Honey Regulations (Northern Ireland) 2015

Further Information

Honey Association

Infant Formula and Follow-on Formula Regulations (NI) 2007 (SR No. 506)

Scope

These Regulations implement Commission Directive 2006/141/EC 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 Council Directive 92/52/EEC 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. Commission Directive 2013/46/EU additionally allows formulae manufactured from goats' milk proteins on the market provided that the final product complies with the compositional criteria laid down in 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
Carbohydrates	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 100ml of product as ready to use: i.e. Energy kj or kcal Proteins Lipids Carbohydrates	Nutrition data per 100ml of product as ready to use: i.e. Energy kj or kcal Proteins Lipids Carbohydrates
Average quantity of each mineral and vitamin as per Annex I of the Commission Directive 2006/141/EC and where applicable per 100mls of the product ready for use • Choline • Inositol • Carnitine	Average quantity of each mineral and vitamin as per Annex II of the Commission Directive 2006/141/EC and where applicable per 100mls of the product ready for use • Choline • Inositol • Carnitine
Average quantity of nutrients mentioned in Annex III per 100mls of the product ready for use: 1. Vitamins 2. Mineral substances 3. Amino acids and other nitrogen compounds 4. Other nutritional substances	Average quantity of nutrients mentioned in Annex III per 100mls of the product ready for use: 1. Vitamins 2. Mineral substances 3. Amino acids and other nitrogen compounds 4. Other nutritional substances
Preparation, storage and disposal instructions and a warning against health hazards from inappropriate preparation and storage	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: 1. Picture of an infant 2. Picture or text that idealises the use of the product	

<table>
<tr>
<td>Only nutrition claims listed in Annex IV of Directive 2006/141/EC can only be made if the conditions warranting the claim are fulfilled.
The permitted nutrition claims are:
1. Lactose only
2. Lactose free
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</td>
<td>Nutrition claims on follow-on formula are controlled by the Nutrition and Health Claims Regulation 1924/2006</td>
</tr>
<tr>
<td>Health Claims: only the health claims listed in Annex IV of Directive 2006/141/EC can be made if the conditions warranting the claim are fulfilled, the permitted claim is:

Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties</td>
<td>Health claims on follow-on formula are controlled by the Nutrition and Health Claims Regulation 1924/2006</td>
</tr>
<tr>
<td></td>
<td>Information on vitamins and minerals included in Annex VII, expressed as a % of the reference values given in Annex VII, per 100ml of the product ready for use.</td>
</tr>
<tr>
<td colspan="2">The labelling of infant formula and follow on formula must be designed to provide necessary information about the appropriate use of the product and must not discourage against breast feeding or contain terms such as “humanised”, “maternalised”, “adapted” or any similar term.</td>
</tr>
<tr>
<td colspan="2">Infant formula and follow on formula must be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow on formula.</td>
</tr>
</table>

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

The Food Safety (Information and Compositional Requirements) Regulation (NI) 2016 (SR No. 251)

These regulations update the primary regulations by taking account to regulation 28 (offences and enforcement) of the Infant Formula and Follow-on Formula (Northern Ireland) Regulations 2007 for "24, 25, 26 or 27", substitute "24 or 25".

Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 1997 SR. 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) Regulations (Northern Ireland) 2000 SR No. 235

These regulations update the primary regulations by taking account of amendments made by Commission Directive 1999/50/EC amending Directive 91/321/EC. The amendments extend the prohibition on sale or export to 3rd countries of food containing individual pesticide residues above a level of 0.01 mg/kg measured when ready for use or when re constituted.

Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2003 SR No. 529

These regulations amend the primary regulations by taking account of the Commission Directive 2003/14/EC amending Directive 91/321/EC. The amendment requires the insertion of new Schedule 7a "Pesticides whose residues must not be present in infant formula or follow on formula at a level exceeding 0.003mg/kg. Schedule 7b "Specific maximum residue levels of certain pesticides in infant formula or follow on formula" is also inserted.

The Infant Formula and Follow on Formula Regulations (NI) 2014 (SR No.11)

These regulations amend the primary regulations by allowing formula manufactured from goats' milk proteins on the market provided that the final product complies with the compositional criteria laid down in Directive 2006/141/EC.

Public Analyst Observations

Generally there tend to be few problems concerning product composition.

Associated Regulations

Infant Formula and Follow-on Formula Regulations (NI) 2007 (SR No. 506)

Infant Formula and Follow-on Formula (Amendment) Regulations (NI) 2008 (SR No. 405)

Infant Formula and Follow-on Formula Regulations (NI) 2014 (SR No.11)

The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (NI) 2007 SR No. 408

The Food Safety (Information and Compositional Requirements) Regulations (NI) 2016 (SR No. 251)

Guidance on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)

Guidance notes on the Notification of Marketing of Foods for Particular Uses, Medical Foods and Infant Formula
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/306583/PARNUTS_NOTIFICATION_GUIDANCE_2014.pdf

Section JK
Legislation Under JK

JK

Jam and Similar Products Regulations (NI) 2003 (SR No. 519)

Scope

The Regulations implement the provisions of EC Directive 2001/113 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 EU Food Information to Consumers Regulation No.1169/2011. 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

2003 SR No.519 Ver 2

Reserved descriptions - Fruit curds and mincemeat

These products are not controlled by Directive 2001/113 and because they are a different kind of product to jam, jelly and marmalade and some of the general provisions of the Regulations affect them in a slightly different way, as described below:

(i) *Permitted ingredients and treatments:* The restrictions on the ingredients and treatments that may be used in the preparation of specified products do not apply to fruit curds and mincemeat.

(ii) *Soluble solids content:* The minimum required soluble solids content for fruit curds and mincemeat is 65% (this compares with 60% for the rest of the specified products).

(iii) *Labelling:* Fruit curds and mincemeat are exempt from some of the labelling provisions such as the requirement to label their fruit and sugar content, but are still subject to general labelling provisions.

The compositional requirements for fruit curds and mincemeat do not apply to foods imported from other EU Member States. However, if a product made elsewhere in the EEA and sold here is substantially similar to mincemeat so that it could be confused with mincemeat by a consumer, it should make clear (by its labelling) that it is something other than mincemeat as understood in the UK.

Reserved Descriptions - 'conserve' and 'preserve'

The 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, EU FIC 1169/2011 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 EU FIC 1169/2011.
- *Sulphur dioxide content* - where a specified product has a residual sulphur dioxide content of more than 10mg per kg, this must be declared as 'sulphur dioxide' in the products list of ingredients. The general rules relating to the ordering of the ingredients list will still apply, i.e. its position in the list must be determined according to the weight of the residue in the final product.

All specified products other than fruit curds and mincemeat:

- *The total sugar content* - this declaration must be given in the form 'total sugar content: Yg per 100g'. The proportion of sugar declared represents the total soluble solids content determined by refractometer at 20 centigrade (accurate to +/- 3 refractometric degrees).

  In the case of a nutritional claim such as 'reduced sugar' and the product is labelled with nutritional information in accordance with Article 30, of EU FIC 1169/2011 the total sugar content declaration required by the Jams Regulations need not be provided. Products which provide nutritional information on a voluntary basis will still be required to contain a sugar content declaration as required by the Jam Regulations in the form of total sugar content: Xg/100g.

  It should be noted that in products where the nutritional information is provided on a voluntary basis, the numerical sugar value given in the table of nutritional information might appear different from the value given under the Jam Regulations i.e. Xg/100g. As a result two different values may appear on the product label and enforcement officers should note this possible anomaly.

Jam, Extra jam, Jelly, Extra jelly, Marmalade, Jelly marmalade:

- *The type of fruit used in the preparation of the food* - where the product contains two or more types of fruit, the fruit in question must be declared in descending order of weight used in the preparation. Where three or more types of fruit have been used, the words 'mixed fruit' (or a similar wording) may be used or alternatively the number of types of fruit used.
- *The proportion of fruit used in the preparation of the product* - this declaration must be given in the form 'prepared with Xg of fruit per 100g'. It is important to note that this proportion relates to the amount of fruit from which the fruit ingredients are derived. For example - in the case of a product made using fruit pulp, the declaration should relate to the weight of whole fruit used to make the fruit pulp not the weight of the fruit pulp itself.

NB - in the case of jam made from stone fruits, the fruit content calculated for the purposes of the labelling declaration required under regulation 52(b) may not be the same as the fruit content calculated to ensure that product meets the compositional requirements of Schedule 1. This is because the former relates to the amount of whole fruit used (including the stones), while the latter relate to the minimum amount of edible fruit (i.e. puree or pulp), which will no longer contain any peel or stones.

The declarations of both the fruit and sugar contents must appear in the same field of vision as the name of the product in clearly visible characters. The name of the product may also appear elsewhere on the labelling, and it is not necessary for the total fruit and total sugar content declarations to accompany the name of the product where it is in the largest type.

Specified products containing permitted sweeteners

EC Regulation No. 1333/2008 allows 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 EU Regulation 1169/2011 requires that a specified product containing a permitted sweetener must be labelled with the following information:

(i) The words 'with sweetener(s)'. This declaration must accompany the name of the food. e.g. "strawberry jam, with sweeteners".

(ii) The words 'with sugar(s) and sweetener(s). This declaration must accompany the name of the food if the food contains both an added sugar or sugars and a sweetener or sweeteners.

(iii) Where the specified product contains aspartame, the words 'contains aspartame (a source of phenylalanine)'.

(iv) Where the specified product contains more than 10% added polyols, the words 'excessive consumption may produce laxative effects'.

Pre-packed for direct sale

Products which fall within this category will be subject to certain exemptions by virtue of Article 44 of EU 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 are exempt from the requirement to include the declaration 'X grams of fruit per 100g' and 'Y grams of sugar per 100g' on the label.

Public Analyst Observations

From an analytical view point most jam samples from the major manufacturers tend to have correct fruit contents.

Officers might consider sampling a small manufacturer requesting analysis for sugar content. Inadequate sugar levels will have an impact on the keeping quality of the end product. Small manufacturers have difficulty regulating the sugar content.

Manufacturers check sugar content at room temperature using a refracometer. Please note that with a small manufacturer who pre-packs for direct sale, there is no requirement to declare sugar/ fruit content.

With fruit picked at the roadside officers might consider submitting samples for analysis for contaminants of platinum (used in catalytic converters in car exhausts) and lead.

Associated Regulations

The Jam and Similar Products Regulations (NI) 2003 (SR No. 519)

EC Directive 2001/113 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 Regulations (NI) 2005 (SR No. 288)

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, of the EC Treaty), and is being or is to be exported to an EEA state other than the United Kingdom (regulation 3(2)).

Ingredients/Products

Kava-kava is a plant, or an extract from such a plant, belonging to the species Piper methysticum.

The majority of products that Kava-kava was used in are classed as herbal medicines and are regulated in the UK by the Medicines and Health Care products Regulatory Agency (MHRA). However, there were some food products containing kava kava, for example herbal tea bags, 'smoothie' drinks, cereal bars and vodka products. In addition, internet sites offered Kava-kava root and root powder for sale.

Evidence has mounted that in rare cases the use of products containing Kava-kava (mostly in the form of herbal medicines) has been associated with severe liver damage. The occurrence of liver damage is unpredictable and the mechanism is unclear.

To date, the Agency is aware of 110 cases of severe liver damage (hepatoxicity), possibly associated with the use of Kava-kava containing products. Eleven patients have suffered irreversible liver failure and received a liver transplant. Overall, nine patients have now died, including two who had received liver transplants.

Public Analyst Observations

Since this product has been banned there has been nothing found on sale in retail outlets.

Associated Regulations

Kava Kava in Food Regulations (NI) 2005 (SR No 288)

Further Information

Kava Kava

Section L
Legislation Under L

Food (Lot Marking) Regulations (NI) 1996 (SR No. 384)

Scope

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

The Regulations require that food which has been produced, prepared or packaged as part of a lot is so marked or labelled as to enable the lot to be identified.

The following are useful definitions contained in the Regulations:

- **Lot:** a batch of sales units of food produced, manufactured or packaged under similar conditions.
- **Lot marking indication:** an indication which allows identification of the lot to which a sales unit of food belongs.

Ingredients/Products

The regulations apply to the sale of all foodstuffs intended for sale for human consumption, including wines and spirits Subject to the exemptions specified below, the sale of food forming part of a lot is not permitted unless it is accompanied by a lot mark.

Size of lot

The producer, manufacturer, packer or first seller within the EC must determine the size of lot most appropriate to the operational pattern. It will be necessary to consider the production, practicality and implications of a lot mark based on a large run to avoid having to recall more food than is necessary.

Labelling Requirements

The lot marking indication must appear in such a way as to be easily visible, clearly legible and indelible however, it does not have to be understood by the consumer provided that the indication can be clearly identified. If the lot identification is not clearly distinguishable from other information it should be prefixed by the letter 'L'. Code edging, another form of lot identification is permitted provided a reader key would not be necessary to identify the mark clearly. It is possible that another mark appearing on the package could serve a secondary purpose as a lot mark, in which case this would need to be made clearly distinguishable by prefixing it with the letter 'L'.

In the case of pre-packed food, the lot mark is required to appear on the 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 seal would impede a product recall. It would not be acceptable for a lot mark to appear on a cork or any other part of the packaging which was enclosed and thus not easily visible.

Exemptions

The following foods do not require a lot mark:

- Agricultural products which, on leaving the agricultural premises of production, are either sold or delivered to temporary storage, preparation or packaging stations or to producers' organisations; or collected for immediate use in an operational preparation or processing system. The term 'agricultural product' applies only to primary agricultural products (i.e. products of the soil, stock farming or fisheries which have not undergone initial processing). Examples could be harvested vegetables delivered to grading or packing stations, fresh fruit provided for canning operations.
- Individual items of food which at point of sale to the ultimate consumer are not pre-packed, such as loose sweets, fruit and vegetables.
- Foods sold to the ultimate consumer which are pre-packed for direct sale (for example bread baked on the premises for direct sale) or which are pre-packed at the request of the purchaser.
- Individual goods not intended to be sold separately, such as single tea bags or chocolates.
- Foods which are in a package or container, of which the largest side has a surface area of less than 10 square centimetres.
- Individual portions intended as an accompaniment to another food provided at a catering establishment for immediate consumption, such as sachets of salt, sauce or sugar. Also excluded are tea bags, coffee etc. provided as part of another service, for example drink making facilities in hotel rooms.
- Individual portions of ice cream and other edible ices.

Use of a date mark as a lot mark

A date mark ('best before', 'best before end' or 'use by') which appears on a product may be used as a lot mark whether or not EU Food Information to Consumers Regulation No. 1169/2011 (EU FIC) require the product to carry a date mark. For the date mark to qualify as a lot mark, it must be given in accordance with the requirements of EU FIC.

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).

1996 SR No. 384 Ver 1

Bulk packaging

The lot mark of a sales unit contained in bulk packaging, for example retail packs enclosed in a wholesale pack, should appear on the outer container in addition to those retail packs. A lot mark for items exempt by virtue of the provisions and identified by an asterisk '*' only should be indicated on any outer container, for example it should appear on the outer catering pack which contains catering sachets. Goods that are not pre-packed that are supplied in bulk containers are required to carry a lot mark, but this may appear on the container in which the sales units are contained or on a commercial document accompanying the container.

Where a pre-package is enclosed in an outer container, such as bottles within a presentation box or tins inside a cardboard sleeve, consideration should be given as to whether the mark should also appear on the outer container. This arrangement would assist product recall as the entire stock of outer cartons would not have to be opened in order to identify the lot mark on the enclosed pre-package. This approach would seem particularly practical in circumstances when only a small number of items of the total stock need to be withdrawn. In some circumstances it may be possible to narrow the batch down in the event of recall if there was a 'broader' indication on the outer package - such as a seasonal package or date mark.

Associated Regulations

Food (Lot Marking) Regulations (Northern Ireland) 1996 (SR No. 384)

Council Directive 89/396/EEC as amended by Council Directives 91/238/EEC and 92/11/EEC.

Further Information

FSA Guidance on Lot Marking

1996 SR No. 384 Ver 1

Section M
Legislation Under M

Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 S.R. No. 384

Scope

The Regulations consolidate into one Statutory Rule 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) Regulations (Northern Ireland) 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 four sets of Regulations:

- The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2009
- The Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Regulations) 2011
- The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2010; and
- The Ceramic Articles in Contact with Food Regulations (Northern Ireland) 2006, which implement the provisions of Council Directive 84/500/EEC, as amended by Commission Directive 2005/31/EC.

There will be new Regulations by 2018 on recycled materials and articles in contact with food to allow for enforcement of Commission Regulations (EC) No 282/2008

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 to be observed for safe use e.g. "not suitable for microwaving" etc.
- The name or trade name and address or registered office of 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:

1. 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 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 SR 2012 No. 384 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 of SR 2012 No. 384 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 and Council Directive 84/500/EEC, Regulation (EC) 1935/2004
- The declaration must be renewed if the article undergoes substantial change which alters the lead and cadmium migration

The Regulation also requires the manufacturer or importer of ceramic articles into the Community to keep documentation showing that the requirements of Annex I of 84/500/EEC have been met and the tests in Annex II of 84/500/EEC 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 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 Article 11(1) & (2) & Annex I, as read with Article 11(3)	General restrictions on plastic materials and articles 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) Article 14(1) & (5) & Annex 1, as read with Article 14(2),(3) and (4)	Particular restrictions and specifications for the composition of each plastic layer in plastic multi-layer materials and articles 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 Regulation10/2011, 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.

Public Analyst Observations

Materials and Articles

Recently officers have encountered unexpected types of material in contact with food in the form of food baskets intended to contain chips to which vinegar would be added. In one case a basket was lined with a zinc/tin plate which had reacted with the acid, releasing potentially harmful substances.

In another incident, officers encountered salt and pepper containers with metal lids being used to dispense vinegar in foods served in catering premises. The metal lids were found to be corroded as a result of reaction with the vinegar. In routine inspections officers should try and establish the nature and type of food coming into contact with a range of available contact materials.

Officers should not assume that:

1. materials used in contact with food were originally intended for such a purpose, and

2. even if they were intended for contact with certain foods, they may not be suitable for the purpose to which they have been put.

If samples of plastic material are submitted for migration testing, they must be un-used. Seek advice from the Public Analyst regarding the number of articles required for testing.

Active materials and articles in contact with food

Ceramic articles

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

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

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

Regenerated cellulose film
Enforcement checks should include verification that the material was intended for food contact use (paperwork audit). We currently have no specific migration methods available.

Plastic Materials and Articles
The enforcement officers need to take into consideration the following matters if they consider that a plastic contact material warrants testing:

- The sample should be taken from unused materials
- The analyst needs to know the type of material to be tested e.g. an area of a sheet of film or polystyrene trays
- Sample size is significant. If bottle caps are to be tested a considerable number will be required to facilitate the test
- The officer should establish what type of food the plastic material will be in contact with e.g. oils, fats, water or acid type foods including details of the shelf life of the food and storage conditions
- The material should also be suitable for the purpose

In the course of routine food standards inspections officers need to consider the nature and type of containers being used to store ingredients. Some food businesses may be recycling plastic containers for storage of ingredients that are different in composition from the original contents.

It may be acceptable to use food grade liners in bulk plastic containers e.g. plastic liners can often be found in bulk drums used to store apple pulp.

Officers should not overlook the composition of spatulas and similar cooking implements that are of plastic composition.

In general there are few samples of plastic materials submitted for examination. Samples that have been submitted in the past tend to comply.

Epoxy Derivatives
Un-used articles may be submitted for specific migration testing. The scope of the analytical method includes BADGE, NODGE and BFDGE.

Vinyl Chloride monomer
Un-used articles may be submitted for specific migration testing for vinyl chloride monomer.

Associated Regulations

The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012

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

General Product Safety Regulations 2005

Further Information

Food Standards Agency Guidance notes

Guidance on Ceramic articles in contact with food

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) No. 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

Council Directive 85/572/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/EU

Council Directive 78/142/EEC

Commission Regulation (EU) No. 10/2011

Commission Regulation 1183/2012

Medical Food Regulations (NI) 2000 (SR No. 187)

Scope

These regulations implement the provisions of Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Notification of medical foods to the Food Standards Agency is a statutory requirement under Medical Food Regulations (Northern Ireland) 2000 (SR 2000 No. 187).

Notification is required when a medical food is first placed on the market in the UK.

Ingredients/Products

The term 'medical food' means food coming within the classification of dietary foods for special medical purposes for which the compositional and labelling requirements are laid down in Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Article 1 of the directive defines 'dietary foods for special medical purposes' as a category of food for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. 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 adapted for a particular disease, 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 not suitable as the sole source of nourishment.

The duty to notify falls on:

- The manufacturer if the product is manufactured in the UK; or
- The importer if the product is manufactured abroad and imported into the UK.

It is an offence to sell a medical food in the UK if it has not been so notified.
An application form can be downloaded from the FSA web site.

2000 SR No. 187 Ver 2

Medical foods are foods specially processed or formulated for the dietary management, under medical supervision, of patients who require a special diet.

Articles 3 and 4 of the directive set out the requirements for formulation, composition, and instructions for use of such food, and for its naming and labelling. It is an offence to sell medical foods that fail to meet these requirements.

Labelling Requirements

In addition to the labelling provisions of the EU Food Information to Consumers Regulation 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 100g or 100ml as appropriate
- Average quantity of each mineral substance and each vitamin mentioned in the annex expressed in numerical form per 10g or 100ml as appropriate
- Selectively the contents of components of protein, carbohydrate and fat and or/of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use expressed in numerical form per 100g or 100ml as appropriate
- Information on the osmolality or osmolarity of the product
- Information on the origin and the nature of the protein and or protein hydrosylates contained in the product.

Mandatory labelling

The following mandatory information must be provided on the label:

- '…Product must be used under medical supervision…'
- Whether the product is '…suitable for use as the sole source of nourishment…'
- As appropriate '…product is intended for a specific age group…'
- As appropriate '.product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended…'
- '...For the dietary management of …' (Blank space indicating the nature of the medical condition)
- Adequate precautions and contra-indications
- Description of the properties and or characteristics that make the product useful in particular, as the case may be relating to the nutrients
- Warning that the product is not for paternal use
- Instructions for the appropriate preparation, use and storage of the food.

2000 SR No. 187 Ver 2

Public Analyst Observations

Unless there is a producer in the authority region there are unlikely to be issues. Manufacturing company issues tend to focus on labelling rather than composition.

Associated Regulations

Medical Food Regulations (Northern Ireland) 2000 SR No. 187

The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (NI) 2007 SR No. 408

Further Information

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

Guidance notes on the Notification of Marketing of Foods for Particular Uses, Medical Foods and Infant Formula http://multimedia.food.gov.uk/multimedia/pdfs/parnuts

2000 SR No. 187 Ver 2

Section N
Legislation Under N

N

Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015 SR No. 365

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** on the quality of water intended for human consumption in relation to water intended to be labelled and sold as "spring water" and "bottled drinking water.

- **Commission Directive 2003/40/EC** 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.

- **Commission Directive 2009/54/EC** of the European Parliament and of the Council 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 water bottled and labelled as "spring water".

- **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.

Ingredients/Products

The regulations cover the exploitation and marketing of ***three distinct types*** of bottled product described under the EU regime e.g.

Natural Mineral Water: as defined in regulation 2(1) and recognised in accordance with regulation 4(2)

Water bottled and labelled spring water: in accordance with regulation 14 and schedule 7

Bottled drinking water: Water which is bottled in accordance with regulation 19 and schedule 7

Exemptions
Exemptions apply to:
- water which is a medicinal product within the meaning of Directive 2001/83;
- 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.

Recognition of Natural Mineral Water (Regulation 4)
Natural mineral water may only be sold as natural mineral water if it is extracted from the ground in:
- **Northern Ireland** and the district council has granted recognition in accordance with Schedule 1 Part 1.
- The **United Kingdom** and the responsible authority recognises it pursuant to Directive 2009/54
- A **Non EEA state** and the Agency grants recognition in accordance with Part 2 of Schedule 1 or it has an equivalent recognition given by a responsible authority of another part of the United Kingdom or non EEA State
- an **EEA State** (other than the UK), and has been officially recognised by a responsible authority of that EEA State pursuant to EC Directive 2009/54.

(EU web page link - http://ec.europa.eu/food/food/labellingnutrition/water/index_en.htm)

Schedule 1 Part 1: Recognition of a Natural Mineral Water in Northern Ireland and **Schedule 1 Part 2:** Natural mineral water extracted from the ground in a country other than an EEA state require the district council (part 1) or the FSA (part 2) publish an announcement of such recognition and the grounds on which it has been granted in the Belfast Gazette (part 1) or the London, Edinburgh and Belfast Gazette (part 2) (Recognised Sources).

Requirements and criteria for recognition as a natural mineral water are set out in Schedule 1 Part 3 and include:

- a geological and hydrogeological surveys
- the physical, chemical and physico-chemical surveys
- microbiological analyses
- clinical and pharmacological analysis

Declining to grant or withdrawing recognition (Regulation 5)
The district council or FSA can withdraw recognition on the grounds that the minimum requirements are not being met. Where a district council or the FSA 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 land owner on which the spring is situated) may within 6 months of being notified of the decision, seek a review of the decision by a person appointed by the Agency.

The review by the appointed person must be completed within 3 months in writing with recommended action.

The Agency must confirm the decision with reasons or direct the district council to grant or restore or itself restore recognition.

If a district council is directed by the Agency to grant or restore recognition then they must comply immediately.

Application to withdraw recognition (Regulation 6)
A person who exploits recognised natural mineral water from a spring may apply to have that recognition withdrawn.

Notification of Changes (Regulation 7)
A district council must immediately notify the Agency if it grants, restores or withdraws a 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.

Exploitation of natural mineral water springs and treatment (Regulation 8)
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 9)
There are four treatments that are allowed for natural mineral water

- filtration or decanting (subject to the limitations set out in regulation 9(1)(a)(i);
- physical elimination of free carbon dioxide;
- fluoride removal authorized in accordance with Schedule 2;
- ozone-enriched air oxidation authorized in accordance with Schedule 3.

Details of these treatments and under what circumstances they are allowed to be carried out are contained in the Regulations.

No other treatments are permitted if you want to sell the water as natural mineral water. In particular, no process that reduces the viable colony count (the amount of bacteria in the water) is permitted.

Natural mineral water used as an ingredient in a soft drink (Regulation 9 (2))
Regulation 9(2) permits the use of natural mineral water in the manufacture of soft drinks.

Bottling of natural mineral water (Regulation 10)
Regulation 10 and Schedules 4 & 5 set out the requirements for bottling natural mineral water. They include a requirement that natural mineral water can only be transported from the spring to the bottling plant in containers authorised for distribution to the ultimate consumer unless it was transported in containers not for distribution to the ultimate consumer (eg tankers) on or before 17th July 1980. Schedule 5 sets out maximum limits for certain constituents of natural mineral water which must not be exceeded at time of bottling.

Labelling requirements for natural mineral water (Regulation 11)
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 (regulation 11(1)):

- 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 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 possess.

Permitted indications on the label of natural mineral water (Regulation 11(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 physico-chemical analysis and pharmalogical, 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 regulation 11(2):-

- 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 11(3))

Statement of the analytical composition indicating the characteristic constituents;
- Name of the spring and the place of its exploitation;
- Indication "fully de-carbonated" or "partially de-carbonated" regulation when appropriate;

- Indication "water subjected to an authorised ozone-enriched air oxidation technique" in proximity to the analytical composition when appropriate;
- Indication when fluoride concentrations > 1.5 mg/l, "contains more than 1.5 mg/l of fluoride; not suitable for infants and children under 7 years of age" and the presentation of actual fluoride content in the location specified in the regulations.

Mandatory requirements for advertising natural mineral water (regulation 12)
In accordance with the source name labelling requirements of Regulation 11, 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 is given to the trade description.

Sale of natural mineral water
Requirements for sale of water bottled and labelled "natural mineral water" including the microbiological criteria that natural mineral water is required to meet when placed on sale are set out in Regulation 13 and Schedule 4.

Brand names and sources (Regulation 13(4))
It is forbidden to sell natural mineral water from one and the same spring under more than one trade description.

WATER INTENDED TO SOLD AS "SPRING WATER"

Requirements for exploitation of springs and bottling of water intended to be labelled and sold as "spring water" are set out in Regulation 14 Schedule 4 and 7.

Water sold as "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 4 and 7.

"Spring water" may only be transported from the spring to the bottling plant in containers authorised for distribution to the ultimate consumer unless it was transported in containers not for distribution to the ultimate consumer (eg tankers) from that spring on or before 13th December 1996.

The right to tanker is linked to the spring, not the bottler.

Treatments and additions for water intended to be labelled and sold as "spring water" (Regulation 15)
There are four treatments that are allowed for spring water
- filtration or decanting (subject to the limitations set out in regulation 15(1)(a)(i))
- physical elimination of free carbon dioxide;
- fluoride removal authorised in accordance with Schedule 2
- ozone-enriched air oxidation authorised in accordance with Schedule 3

Details of how these treatments are allowed to be carried out are contained in the Regulations.

You may introduce or re-introduce carbon dioxide to make water bottled and labelled as "sparkling spring water" or use water bottled and labelled as "spring water" in the manufacture of soft drinks.

In Northern Ireland and Wales, no other treatments are permitted if you want to sell the water bottled and labelled as spring water. In particular, no process that reduces the viable colony count (the amount of bacteria in the water) is permitted.

Labelling of water as "spring water" (Regulation 16)
The water in a bottle labelled "spring water" must meet the requirements of regulation 14(1) and if treated the treatment must be permitted by regulation 15.

Labelling description for spring water (Regulation 16(2)(a) & (b))
If a bottle of water is labelled as "Spring Water":

- a trade description must not include the name of the locality unless it refers to water the spring of which is 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 largest letters used for the trade description.

Regulation 16(3)
Water marked and labelled as "Spring water" is required to state the name of the spring and the place of its exploitation on the label and where it has undergone an ozone enriched air treatment the prescribed wording must appear on the label.

Advertising of water as spring water (Regulation 17)
In accordance with the source name labelling requirements of Regulation 16; 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 is given to the trade description.

Sale of water as "spring water" (Regulation 18)
Sets out restrictions on the sale of water as "spring water". It is forbidden to sell water bottled and labelled as "spring water" from one and the same spring under more than one trade description.

BOTTLED DRINKING WATER

Bottling of bottled drinking water (Regulation 19)
Bottled drinking water must satisfy the requirements of Schedule 7. There are no other restrictions on specific treatments of bottled drinking water in these regulations.

Labelling, marketing and trade description of bottled drinking water (Regulations 20, 21 & 22)

There are no restrictions on the selling of bottled drinking water under more than one trade description. However, these descriptions should not be liable to cause confusion of the water with a natural mineral water. The description "mineral water" must not appear. The labels must also comply with EU Food Information to Consumers Regulation No. 1169/2011.

MONITORING AND SAMPLING REQUIREMENTS

EU requirements for monitoring of radioactivity in water

Council Directive 2013/51/Euratom which came into force on 28 November 2015 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 (See regulation 25(1)(b) and Schedule 11).

Monitoring and sampling (Natural Mineral water) (Regulation 23)

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 constant and satisfies Schedule 1 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 24)

Regular monitoring of the quality of the water must be carried out to ensure it satisfies the requirements of Directive 98/83 and complies with the parametric values set in accordance with Schedule 7 and any disinfection treatment for bottled mineral water is effective. District Councils must carry out monitoring in accordance with Schedule 8 or 9 as appropriate.

Additional monitoring, must be carried out on a case-by-case basis, in relation to any property, element, substance or organism other than a parameter specified in Schedule 7, if the district council 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.

Sampling and analysis (Regulation 25) - water bottled and labelled as "spring water" and bottled drinking water)

Each district council must take samples at the point at which the water is bottled when carrying out their sampling regime.

For the purpose of monitoring water bottled and labelled as "spring water" and bottled drinking water, each district council must carry out sampling and analysis in accordance with Schedule 10 to check compliance with the parametric values specified in Parts 2 and 3 of Schedule 7; and sampling and analysis in accordance with Schedule 11 to check compliance with the parametric value for indicative dose specified in Part 4 of Schedule 7.

Remedial action (Regulation 26) - water bottled and labelled as "spring water" and bottled drinking water

If a district council determines that water bottled and labelled as "spring water" or bottled drinking water does not comply with the parametric concentrations or values specified in the sampling and analysis as above (Schedule 7) they must

- immediately investigate the non-compliance in order to identify the cause;
- assess whether the non-compliance poses a risk to human health which requires action;
- require the business operator to take remedial action as soon as possible to restore the quality of the water where that is necessary to protect human health;
- in respect of any parameter (indicator, microbiological or chemical)specified in Parts 2 and 3 of Schedule 7, notify the general public of the remedial action taken, unless the district council considers that non-compliance with the parametric value is trivial
- In respect of any parameter specified in Part 4 of Schedule 7 (Parametric Radon, tritium and ID), notify the general public of the risks and remedial action taken and advise the general public on any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.

If water bottled and labelled as "spring water" or bottled drinking water constitutes a potential danger to human health, irrespective of whether it meets the relevant parametric values in Schedule 7, the district council must-

- prohibit or restrict the supply of that water in its area or take such other action as is necessary to protect human health
- inform the general public promptly of that fact and provide advice where necessary

In prohibiting or restricting the supply of that water which constitutes danger to human health the district council must have regard to any risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.

Treatments monitoring (Regulation 27)

Each district council 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 28)

The district council must ensure that each sample is representative of the quality of the water concerned consumed throughout the year in which the sample is taken.

Enforcement

The method of enforcement will be via improvement notice served under Article 9 of the Food Safety (NI) Order 1991 as applied by these regulations. An improvement notice can also be served under Article 9 for breach of any of regulations 8-22s and certain provisions of Commission Regulation (EU) 115/2010 specified in Schedule 12 paragraph 1 of these regulations.

Improvement Notices would be used as a part of the hierarchy of enforcement when informal measures are no longer appropriate and the labelling contravention or issue should be elevated to formal action. If the conditions set by an improvement notice are not met then the non-compliance with those conditions will constitute a criminal offence. Improvement Notices can be appealed to a Court of Summary Jurisdiction.

Public Analyst Observations

Sources of recognised natural mineral water need to be regularly assessed for compliance with stability requirements including evidence of freedom from pollution. Officers who have sources that require to be tested need to inform the Public Analyst of their intention to sample as it will be necessary to supply you with specially prepared sample containers especially when tests are to be done for evidence of organic contaminants.

Associated Regulations

Council Directive 98/83/EC relating to the quality of water intended for human consumption (OJ No L330, 3,11,98, p.32) so far as it applies to water intended to be labelled and sold as "spring water" and bottled drinking water.

Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (Recast) (OJ No L 164,26.6.09, p45)

Commission Directive 2003/40/EC 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 water bottled and labelled as "spring water" (OJ No. L 126, 22.5.03 p 34)

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 (OJ No L 296, 7.1113, p12)

The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015

Further Information

Zam Zam water

EC Recognised Natural Mineral Water Sources

Novel Foods and Novel Food Ingredients Regulations (NI) 2004 (SR No. 33)

Scope

These Regulations provide for the enforcement and execution of certain specified provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients.

New Novel Foods Regulations are due to come into operation in early 2018 which will revoke these regulations. The new Regulations will implement EU Regulation No 2015/2283, which introduces a centralised EU risk assessment by EFSA for Novel Foods, simplifies notification procedures and introduces improvement notices.

Ingredients/Products

Under the Novel Foods Regulation a novel food is defined as a food that does not have a significant history of consumption within the EU prior to 15th May 1997.

The definition will include new products obtained from natural sources (animals, plants, micro-organisms) and by chemical synthesis. Regulation (EC) 258/97 does not apply to food additives, flavourings, extraction solvents or processing aids.

A company wishing to market a novel food or novel food ingredient in the EU must submit an application to the Competent Authority in the Member State where it first intends to market their product. Novel foods are subject to a pre-market safety assessment before a decision is made on EU-wide authorisation.

These Regulations designate the Food Standards Agency as the food assessment body for the purposes of Regulation (EC) No. 258/97 and appoint district councils 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.

Chia seeds

Chia seeds are considered to be a novel food. Under the Novel Foods Regulation (Regulation (EC) No 258/97) a novel food is defined as a food that does not have a significant history of consumption within the European Union before 15 May 1997. Such foods are subject to a pre-market safety assessment before a decision is made on an EU wide authorisation.

If a company wishes to use chia seeds they will need to source it from an authorised supplier or gain authorisation themselves. An authorisation under the Novel Foods Regulation is company specific. We would normally advise that the person first placing the product on the market that needs to gain authorisation. This could be an importer or producer. Anyone further down the food chain would need to ensure that they were using seeds from an authorised source and that the seeds were being used in line with the authorisation. If the company did not wish to apply for authorisation and wish to use an authorised supplier instead, all authorised chia seed suppliers can be found on the Commission website. http://ec.europa.eu/food/safety/docs/novel-food_notifications_en.pdf

Many companies now have authorisations to supply chia for the approved uses through the simpler substantial equivalence route. Companies who have notified the Commission in line with the regulation will be listed at the link. New companies are getting authorised all the time and they should be able to provide evidence that their seeds have been assessed by a member state and found to be equivalent even if the list has yet to be updated.

UK practice

The Food Standards Agency (FSA) is the responsible body in the UK for the purpose of novel food applications. The fees for a full application are £4000 whilst a request for a substantial equivalence will cost £1725.

The risk assessment is conducted by the Advisory Committee on Novel Foods and Processes (ACNFP).The FSA will discuss with the applicant before the dossier is submitted and each application will be published for public comment (28 days). Committee papers and minutes are also published and a draft assessment report is also published for public comment (10 days).

Public Analyst Observations

Issues arise in relation to new food types that have not been on the European market. Questions were raised concerning Goji berries but market checks revealed that there was evidence of its presence in Europe prior to 15th May 1997.

Associated Regulations

Novel Foods and Novel Food Ingredients Regulations (NI) 2004 (SR No. 33)

Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients

Further Information

Advisory committee on Novel Foods and Processes

European Food Safety Authority (EFSA)

ACNFP Full Application List

Examples of products refused approval by the European Commission include:

- Betaine
- Nangai Nuts and
- Stevia Rebaudiana Bertoni

Commission Novel Food Catalogue

2004 SR No.33 Ver 1

Nutrition and Health Claims Regulations (NI) 2007 (SR No. 349)

Scope

The regulations implement the provisions of the EC Regulation 1924/2006 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. foods for specific groups then these specific rules take precedence over the Nutrition and Health Claims Regulations.

The regulations ensure that any claim made on a food label is clear, accurate and substantiated so that consumers may make informed and meaningful choices when it comes to buying 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. However, from 13 December 2016 nutritional labelling must be provided for most prepacked foods whether a claim has been made or not.

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, which 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 http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/authorised_health_claims_en.htm can be used on food and only if the product meets with any specific conditions of use as well as the requirements of the regulations. Health claims cannot be made where any nutrient does not meet the criteria set by the nutrient profile.

Only authorised claims can be added to the community register.

The Regulation puts in place three ways to get claims authorised and added to the EU Register:

1) Before 31st January 2008, Member States submitted lists of claims based on generally accepted scientific evidence to the European Commission which, on the advice of the European Food Safety Authority (EFSA), must decide if claims can be included in the list of authorised health claims in the EU Register. The claims submitted before 31/01/2008 had to be accompanied by references to the relevant scientific justification and conditions of use applying to them. The UK list of candidate health claims was submitted to the European Commission on 30th January 2008.

2) Claims based on new or emerging science and / or proprietary data need to be accompanied by a dossier of information in support of the claim. EFSA will assess this evidence before advising the Commission on a decision. Applicants should send all new dossiers on such health claims to the National Competent Authority of the Member State rather than EFSA.

3) Health Claims which refer to a reduction in the risk of a disease or to the children's development and health also need to be submitted with information in support of the claim for assessment by EFSA. Applicants should send all new dossiers on such health claims to the National Competent Authority of the Member State rather than 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.
- Include a statement for persons who may need to avoid such foods.
- Include a 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 Nutrition and Health Claims (Amendment) Regulations (NI) 2010 (SR No. 259)

The primary regulations were amended by the Nutrition and Health Claims (Amendment) Regulations (NI) 2010 to introduce an ambulatory reference to Regulation (EC) No. 1924/2006 the effect of which is to avoid the necessity of numerous amendments to national legislation each time the list of approved claims changes in these EU rules.

Caffeine Health Claims

Some caffeine health claims are still 'on hold' pending EFSA's opinion on the safety of caffeine (potentially to be published by summer this year) and they can be used while they are still in this state.

The list of claims on hold is at http://ec.europa.eu/nuhclaims/ at the link to Some 'function claims', for which the assessment by EFSA or the consideration by the Commission is not finalised

The caffeine claims are under the heading in that document "Claims for which finalisation is pending" and they are:

Caffeine helps to increase alertness (736, 1101, 1187, 1485, 1491, 2063, 2103)
Caffeine helps to improve concentration (736, 1485, 1491, 2375)
Caffeine contributes to an increase in endurance performance (737, 1486)
Caffeine contributes to an increase in endurance capacity (1488)
Caffeine contributes to a reduction in the rated perceived exertion/effort during [endurance] exercise (1488, 1490).

Claims 'on hold' may be used while they are still under consideration. However, the EU Register already lists 10 caffeine claims as "non-authorised" so when a food business operator is assessing a caffeine claim he/she will need to consider whether it's the same as one of those on hold or whether it's more like one of the non-authorised ones which can no longer be used.

As to which 'national legislation' claims on hold must be in compliance with if used: they must comply with the relevant parts of Regulation 1924/2006 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF as implemented through the Nutrition and Health Claims Regulation (NI) 2007 - this includes Articles 3, 5, 6, 7, 10 of 1924/2006.

They must also comply with general food labelling legislation, including providing full nutrition labelling (see section 5 of the guidance to compliance with the claims legislation). https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods The general food labelling rules include a requirement to provide a statement about caffeine on certain foods if caffeine is present at certain levels (https://www.gov.uk/food-labelling-and-packaging/food-and-drink-warnings).

2007 SR No. 349 Ver 1

Public Analyst Observations

Article 13.1 General function Health Claims:

Many Article 13.1 general function health claims submitted to EFSA for assessment have received a negative opinion.

Nutrition claims:

Authorised nutrition claims have been included in the Community register, which can be accessed at http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/nutrition_claims_en.htm It should be possible to verify nutrition claims by analysis if necessary, please enquire when dealing with health claims. The only nutrition claims permitted are those in the Annex so "Cholesterol free" isn't permitted, but cholesterol can be declared as "nil" as part of a group 2 declaration because it's a constituent of fat.

Associated Regulations

The Nutrition and Health Claims Regulations (NI) 2007 (SR No. 349)

The Nutrition and Health Claims (Amendment) Regulations (NI) 2010 (SR No. 259)

Food Information Regulations (NI) 2014 (SR No. 223)

Food Safety (NI) Order 1991

EC Regulation 1924/2006 on nutrition and health claims made on food

Commission Regulation (EU) No. 116/2010

Commission Regulation (EU) No. 432/2012 - establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

Commission Regulation (EU) 1047/2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims

Further Information

DH Guidance to compliance with Regulation EC 1924/2006 on nutrition and health claims

DH Quick start guide to guidance on compliance with Regulation EC 1924/2006

Europa- Labelling and Nutrition

The European Union Register of nutrition claims

SCHEDULE 1

Summary table – Annex – Regulation (EC) No. 1924/2006

Nutrition Claim	Condition
Low Energy	Product not to contain > 40Kcal (170 kJ/100g {solid} or 20Kcal (80kJ/100 ml {liquid} Table top sweeteners not > 4Kcal (17kJ) per portion with equivalent sweetening properties of 6g 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 > 17kJ/100ml Table top sweeteners 4Kcal (1.7kJ) per portion with equivalent sweetening properties of 6g sucrose.
Low Fat	Not > 3g fat/100g{solids} 1.5g fat/100ml {liquid} (1.8g fat/100ml for semi skimmed milk)
Fat Free	Not > 0.5g/100g or 100ml The term "X% fat free" is prohibited.
Low Saturated Fat	The sum of saturated fatty acids and trans fatty acids must not be > 1.5g/100 or 0.75g/100ml The sum must also not exceed 10% of energy provided.
Saturated Fat Free	The sum of saturated fat and trans fatty acids must not be > 0.1g/100g or 100ml
Low Sugars	Not > 5g sugar/100g {solid} or 2.5g/100ml {liquid}
Sugars Free	Not > 0.5g sugar/100g or 100ml
With No Added Sugars	Product must not contain added mono or disaccharides or any other food for sweetening. If natural sugars are present the claim must state "CONTAINS NATURALLY OCCURRING SUGARS"
Low Sodium/Salt	Not > 0.12g sodium or equivalent/100g or 100ml. For water other than Natural Mineral Water not > 2 mg/100ml
Very Low Sodium/Salt	Not > 0.04g sodium or equivalent/100g or 100ml. Cannot be used on waters or Natural Mineral Waters.

Sodium Free or Salt Free	Not > 0.005g sodium or equivalent per 100g
Source of Fibre	Food to contain at least 3g fibre/100g or 1.5g fibre/100Kcal
High Fibre	Food to contain at least 6g fibre/100g or 3g fibre/100Kcal
Source of Protein	12% of energy value of the food must come from protein.
High Protein	20% of energy value of the food must come from protein
Source of named vitamin and or mineral	Significant amount as defined in EC Directive 90/496 or as per Article 6 EC Regulation 1925/2006
High named vitamin or mineral	Must contain twice the level of that for a "source"
Contains a named nutrient or substance	May only be made where the product complies with all the applicable provisions of the Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.
Increased Named Nutrient	Must meet the conditions for the claim "Source of" and the increase is at least 30% compared to similar food
Reduced named nutrient	Reduced by 30% compared with similar foods. Micronutients as set in Directive 90/496 10% difference is acceptable. For sodium a 25% difference is acceptable Commission Regulation (EU) No 1047/2012 inserted the following paragraphs: The claim "reduced saturated fat", and any claim likely to have the same meaning for the consumer, may only be made: (a) if the sum of saturated fatty acids and of trans-fatty acids in the product bearing the claim is at least 30% less than the sum of saturated fatty acids and of trans-fatty acids in a similar product; and (b) if the content in trans-fatty acids in the product bearing the claim is equal to or less than in a similar product. The claim "reduced sugars", and any claim likely to have the same meaning for the consumer, may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product.
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 Natural	Can only be used when the food meets the conditions for the nutrient claim

Commission Regulation (EU) No. 116/2010 inserted the following additional five claims:

Nutrition Claim	Condition
Source of Omega-3 Fatty Acids	A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer may only be made where the product contains at least 0,3g alpha-linolenic acid per 100g and per 100kcal or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.
High Omega-3 Fatty Acids	A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,6g alpha-linolenic acid per 100g and per 100kcal or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.
High Monounsaturated Fat	A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20% of energy of the product.
High Polyunsaturated Fat	A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 45% of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20% of energy of the product.
High Unsaturated Fat	A claim that a food is high in unsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 70% of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20% of energy of the product.

Commission Regulation (EU) No. 1047/2012 inserted the following additional claim:

Nutrition Claim	Condition
No added sodium/salt	A claim stating that sodium/salt has not been added to a food and any claim likely to have the same meaning for the consumer may only be made where the product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0.12g sodium, or the equivalent value for salt, per 100g or 100ml

Section O
Legislation Under O

O

Section PQ
Legislation Under PQ

PQ

Plastic Kitchenware (Conditions on Imports from China) Regulations (Northern Ireland) 2011 (SR. 2011 No. 236)

Scope

These regulations were made under the Food Safety (NI) Order 1991 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 (SML) of15mg/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 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 district councils, as set out in Regulation 5 and the district councils must execute and enforce the Regulation and inform the FSA where products analysed under the Regulations do not comply (Regulation 6).

Regulation 7 provides for expenses incurred by district councils 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 district councils 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 district council, as set out in Regulation 9. Regulation 10 provides for FSA, 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.

Public Analyst Observations

Comprehensive guidance on the sampling of polyamide and melamine kitchenware may be found in the Commission's JRC publication "Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware", which may be found using the following link:
http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/technical-guidelines-2011

As a general principal, packaged kitchenware should be submitted for analysis for specific migration of primary aromatic amines (polyamide articles) or of formaldehyde (melamine articles) within its retail packaging. Items which are being sold unpackaged may be placed in polythene plastic bags, since this will not influence the results.

(note that items submitted for overall migration testing should NOT be placed directly in contact with other plastics, but must first be securely wrapped in aluminium foil).

Any information displayed at the point of sale regarding the intended use of articles should be copied to the Public Analyst, as it may assist in the selection of appropriate test conditions.

Associated Regulations

Plastic Kitchenware (Conditions on Imports from China) Regulations (NI) 2011 SR No. 236

Commission Regulation (EU) No. 284/2011

Commission Regulation (EC) No. 882/2004

EC Directive 2002/72/EC

Commission Guidance: EU guidelines for the import of polyamide and melamine kitchenware

Commission Guidance: Technical guidelines concerning polyamide and melamine kitchenware

Preserved Sardines (Marketing Standards) Regulations (NI) 1990 (SR No. 194)

Scope

This regulation implements the provisions of EC Directive 2136/89 relating to the marketing of preserved sardines.

Ingredients/Products

A preserved sardine is described as a product:

- Covered by CN codes 1604 13 10 and ex 1604 20 50
- Exclusively from the species Sardinia Pilchardus Walbaum
- Pre-packed in an appropriate cover medium and hermetically sealed
- Sterilised by appropriate treatment

In accordance with good manufacturing practice sardines must be trimmed of head, gills, caudal fin, and internal organs other than the ova, milt, kidney and according to the marketing presentation concerned, the backbone and skin.

Labelling Requirements

There are 6 marketing presentations described in Article 4 of the Directive.

1. Sardines (basic)
2. Sardines without bones
3. Sardines without skin and bones
4. Sardine Fillets
5. Sardine Trunks
6. Any other form of presentation not covered in 1-5 above

For the purpose of trade descriptions Article 5 sets out different descriptions for cover media:

1. Olive oil
2. Refined vegetable oil
3. Tomato sauce
4. Natural juice, saline solution or water
5. Marinade with or without wine
6. Other cover media not covered by 1-5 above.

Cover media may be mixed but olive oil may not be mixed with other oils.

The final appearance for preserved sardines is set out in Article 6.

1990 SR No. 194 Ver 1

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 marinade	70%
Tomato sauce	65%
Cover media not described in 1-5 of Article 5	50%
Presentations other than set out in points 1-5 of Article 4	35%

The designation of the cover medium must form an integral part of the trade description. Oil media must be described as one of the following:

- 'in olive oil'
- 'in vegetable oil'
- 'in ...oil' indicating the nature of the oil

Preparations using homogenised sardine flesh involving the disappearance of muscle structure may contain flesh of other fish which have undergone the same treatment provided that the proportion of sardines is at least 25%.

Public Analyst Observations

Generally the issues relate to quality as measured against the marketing standards. The checks are sometimes very subjective. It is more likely to be an issue in respect of products that fall within the lower end of the market.

Associated Regulations

Preserved Sardines (Marketing Standards) Regulations (NI) 1990 (SR No. 194)

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

Preserved Tuna and Bonito (Marketing Standards) Regulations (NI) 1994 (SR No. 425)

Scope

The regulations implement the provisions of Council Regulation No. 1536/92 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 ex 1604 20 70	• Falls within CN code 1604 14 90, ex 1604 20 50, 1604 19 30 ex 1604 20 70, ex 1604 19 99 and 1604 20 90
• Prepared from the species genus thunnus Albacore or longfin Yellow fin Blue fin Big eye	• Prepared from the species genus Sarda Atlantic bonito Pacific bonito Oriental bonito
• Skip jack	• 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.

1994 SR No. 425 Ver 1

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 oil • In vegetable oil • Natural	70%
Other media	65%

In the case of culinary preparations the ratio is 25%.

Public Analyst Observations

Issues can arise in respect of the description of the product and the differences between tuna steaks and flakes etc. It may be beneficial looking at products that fall into the lower end of the market.

Associated Regulations

The Preserved Tuna and Bonito (Marketing Standards) Regulations (NI) 1994 (SR No. 425)

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 Regulations (NI) 2003 SR No 530

Scope

These Regulations implement EC Directive 96/5/EC, as amended by EC Directive 1998/36/EC, 1999/39/EC and 2003/13/EC.

The Regulations define 'baby foods' as foods for particular nutritional use fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned and by young children as a supplement to their diet or for their progressive adaptation to ordinary food, but excludes processed cereal based foods.

Regulation (EU) No 609/2013 on food for Specific Groups applied from 20th July 2016. It required the commission to adapt through a delegated act specific compositional and labelling rules for processed cereal-based foods and baby foods, replacing Directive 2006/125/EC.The delegated act has not yet been finalised. When it is the Food Safety (Information and Compositional Requirements) Regulations (NI) 2016 will need to be amended in respect to this group of foods.

Ingredients/Products

Processed cereal based foods are foods for particular nutritional use in categories of processed cereal based foods in part 1 of Schedule 1 i.e. simple cereals which are reconstituted with milk, cereals with an added protein food which have to be reconstituted with water, pastas which have to be boiled in water and rusks and biscuits which may be used directly or pulverised with the addition of water of milk.

Infants are defined as children under the age of twelve months and young children are aged between 1 and 3 years.

The Regulations do not apply to any milk which is a baby food intended for young children.

The Regulations prohibit the sale of processed cereal based foods and baby foods for infants and young children unless they comply with the manufacturing and compositional requirements in regulations 3 to 7 and the labelling requirements in regulation 8.

Manufacture and Composition

Such foods must be prepared from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data. Such foods must not contain any substance in a quantity as to endanger their health.

The Regulations detail in Schedule 1, 2 and 3 the criteria with regard to composition which must be complied with for processed cereal based foods and baby foods.

The schedules detail requirements concerning nutrients and permitted quantities in products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

Nutrients include protein, carbohydrates, fat minerals and vitamins.

Schedule 4 lists nutritional substances which may only be added during the manufacture of such foods.

Schedule 5 Part 1 provides maximum limits for added vitamins, minerals and trace elements e.g. vitamin B6 0.35mg.

Part II of Schedule 5 specifies foods and the maximum limit per 100kcal for specific nutrients when added to processed cereal based and baby foods. e.g. fruit-based dishes, fruit juices must not contain vitamin C exceeding 125mg per 100kcal.

The Regulations restrict the presence of pesticide residues in such foods. Schedule 6 lists pesticides where residues must not be present at a level exceeding 0.003mg/kg. All other pesticide residues of any individual pesticide not specified must not exceed 0.01mglkg.

Labelling Requirements

Regulation 8 provides specific labelling requirements for processed cereal based foods and baby foods. These are the appropriate age (not less than 4 months) from which the food may be used the presence or absence of gluten if the appropriate age indicated is less that 6 months

- the available energy value expressed in KJ and Kcal, and the protein, carbohydrate and fat content per 100g or 100ml of the food sold. Where appropriate, per serving information may be given

- the average quantity per 100g or 100ml of minerals and vitamins as specified in Schedule 1 and 3

- appropriate instructions for preparation if necessary and a statement as to the importance of following these instructions

- The nutrients listed in Schedule 4 may be expressed as an average per 100g or 100ml of the food or per quantified serving as consumed

- In the case of a mineral or vitamin, it is a mineral or vitamin other than one listed in part II of Schedule 1

- Vitamins and/or minerals specified in Schedule 8 which are indicated per 100g or 100ml cannot be expressed as a percentage of the reference value unless 15% or more of the reference value is present in 100g or 100ml.

2003 SR No. 530 Ver 1

Public Analyst Observations and Comments

As a general rule the major manufacturers will be aware of and comply with the rules concerning food composition.

Associated Regulations

Processed Cereal-Based foods and Baby Foods for Infants and Children Regulations (NI) 2003 SR No 530

The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (NI) 2007 SR No. 408

Further Information

EC Directive 96/5/EC

Commission Directive 98/36/EC

EC Directive 1999/39/EC

EC Directive 2003/13/EC

Products Containing Meat etc. Regulations (NI) 2014 (SR No. 285)

Scope

These regulations revoke and replace the Meat Products Regulations (NI) 2004 (MPR). The main differences are that the Products Containing Meat etc. Regulations (NI) 2014 (PMR 2014) update and simplify the provisions contained in the MPR in a way that is compatible with the EU Food Information to Consumers Regulation No. 1169/2011 (EU FIC).

The PMR 2014 applies to food which is ready for delivery to the ultimate consumer or to a catering establishment. The regulations do not apply to any food not intended for sale for human consumption or labelled clearly that it is intended exclusively for consumption by babies or young children.

The Regulations cover the following:

- 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.).

- Compositional requirements i.e. the prohibition on the use of some parts of the carcase in uncooked meat products.

Generic Definition of Meat for the purposes of labelling meat ingredients in meat products

The EU definition of 'meat' (for labelling purposes) is laid down in EU FIC (Annex VII, Part B, point 17). The definition has been carried over from Directive 2001/101/EC. It is the relevant definition when calculating meat content.

The definition:

- 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.

- Includes 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 (see note below regarding use of the term "MRM").

- 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 Collagen/Meat protein ratio

Species	% Fat	% Collagen/Meat protein ratio
Pork	30	25
Birds and Rabbits	15	10
All other red meats and mixtures	25	25

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

The PMR 2014 applies to any product containing meat, mechanically separated meat or other parts of the carcase.

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. In the PMR 2014 it states that "uncooked" in relation to a food, means a food that has not been subjected to a process of cooking throughout the whole food so that the food is sold on the basis that it will need further cooking before consumption.

Large or small intestines can be used solely to produce skin for sausages. 'Sausage' in this context includes frankfurters, salami, black pudding and any similar products.

Labelling Requirements

Reserved Descriptions

The regulations require that a product containing meat etc. offered for sale to the ultimate consumer or to a catering establishment may not be described using one of the reserved descriptions unless it meets the relevant compositional criteria laid down in Schedule 1 of the PMR 2014. 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 1 of the Regulations can be found in Annex 1 of this guide).

Labelling requirements under EU FIC

Name of Food of Meat Products Having the Appearance of a Cut, Joint, Slice, etc.
For products containing meat which look like a cut, joint, slice, portion or carcase of fresh meat the MPR required that the presence of added water and other added ingredients to be declared in the name of the food. Such foods include 'Bacon with added water' and 'Chicken with pork proteins'. These requirements are now regulated by the directly applicable EU FIC and so are not contained within the PMR 2014.

QUID Requirement

The quantifying of meat in the labelling of meat products falls within the provisions of the EU FIC and is based on the EC meat definition. Therefore, the quantitative ingredient declaration (QUID) will be required for meat products sold pre-packed; any excess fat or connective tissue present in the product cannot count towards the QUID declaration of meat content and must be declared separately in the list of ingredients.

Regulation 7 of the Food Information Regulations (NI) 2014 requires that foods containing meat and other ingredients sold loose or pre-packed for direct sale (e.g. by butchers, delicatessens, etc.) are marked with the QUID declaration of the meat ingredient(s). QUID declarations are required only for those ingredients that fall within the EC definition of 'meat'. There is no requirement to mark or label the meat content of meat products sold loose or 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 3 of the Food Information Regulations (NI) 2014 specifies foods which do not require any QUID declaration for the meat content of meat products sold loose.

These are:

1. Raw meat to which no ingredient other than proteolytic enzymes has been added.

2. Frozen and quick-frozen chicken to which Article 15 of Commission Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat applies and the water content of which does not exceed the technically unavoidable values determined as provided for in that Article.

3. Fresh, frozen and quick-frozen poultry cuts to which Article 20 of Commission Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat applies and the water content of which does not exceed the technically unavoidable values determined as provided for in that Article.

4. Sandwiches, filled rolls and filled products of a similar nature to sandwiches and filled rolls, which are ready for consumption without further processing, except for products containing meat which are sold under the name (whether or not qualified by other words) "burger", "economy burger" or "hamburger".

5. Pizzas and similar topped products.

6. Any food for which the name is "broth", "gravy" or "soup", whether or not qualified by other words.

7. A food consisting of an assemblage of two or more ingredients that has not been subjected to any processing or treatment once it has been assembled, and which is sold to the final consumer as an individual portion intended to be consumed without further processing or treatment.

Enforcement

The PMR 2014 introduces new and simpler enforcement provisions. The front line measure for the provisions of the PMR 2014 will be an improvement notice. This would be used as part of the hierarchy of enforcement when informal measures are no longer appropriate and the labelling contravention or issue should be elevated to formal enforcement action. If the conditions set by an improvement notice are not met this will be a criminal offence. Businesses will have the opportunity to appeal against an improvement notice. Appeals will be heard by a court of summary jurisdiction.

Public Analyst Observations

Officers need to pay particular attention to the food composition, ingredient listing etc. Examination of specifications outlining composition of the ingredients, particularly with regard to non-meat nitrogen which will inflate the meat content e.g. milk protein, soya, blood plasma, collagen. The composition of seasoning mixes used in butcheries and meat manufacturing plants should be examined for such information and the product and or ingredients sampled if necessary.

Associated Regulations

Products Containing Meat etc. Regulations (NI) 2014

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

Food Information Regulations (NI) 2014

Further Information

Eurofins meat calculator (for pre-packed meat products)

FSA Meat content calculator

NIFLG Guidance on Labelling for Butchers
(available on the Western Group of Councils webpage)

Desinewed meat

On 4 April 2012 the Food Standards Agency (FSA) announced a moratorium on the production and use of desinewed meat (DSM). Desinewed meat is produced using a low pressure technique to remove meat from animal bones. DSM is not a term recognised by EU food law.

DSM produced by mechanically separating residual meat from animal bones must be regarded as Mechanically Separated Meat (MSM), a product that cannot, under the provisions of European law, be produced from cattle, sheep and goat bones.

Annex 1

SCHEDULE 1
Regulation 4

RESERVED DESCRIPTIONS

Name of food	Meat or cured meat content requirements			Additional requirements
	The food must contain not less than the indicated percentage of meat, where the meat ingredient consists of the following:			
	Meat or, as the case may be, cured meat from pigs only	Meat or, as the case may be, cured meat from birds only, or a combination of birds and rabbits only	Meat or, as the case may be, cured meat from other species or other mixtures of meat	
1. Burger - whether or not forming part of another word, but excluding any name falling within items 2 or 3 of this table	67%	55%	62%	1. Where the name "burger" is qualified by the name of a type of cured meat, the food must contain a percentage of meat of the type from which the named type of cured meat is prepared at least equal to the minimum required meat content for that food 2. Where the name "burger"is qualified by the name of a type of meat, the food must contain a percentage of that named meat at least equal to the minimum required meat content for that food 3. Where the name "burger" is used to refer to a compound ingredient consisting of a meat mixture and other ingredients, such as a bread roll, these requirements apply only to the meat mixture, as if the meat mixture were the regulated product in the labelling or advertising of which the name was used as the name of the food

Name of food	Meat or cured meat content requirements			Additional requirements
	The food must contain not less than the indicated percentage of meat, where the meat ingredient consists of the following:			
	Meat or, as the case may be, cured meat from pigs only	Meat or, as the case may be, cured meat from birds only, or a combination of birds and rabbits only	Meat or, as the case may be, cured meat from other species or other mixtures of meat	
2. Economy Burger - whether or not "burger" forms part of another word	50%	41%	47%	1. Where the name "economy burger" is qualified by the name of a type of cured meat, the food must contain a percentage of meat of the type from which the named type of cured meat is prepared at least equal to the minimum required meat content for that food 2. Where the name "economy burger" is qualified by the name of a type of meat, the food must contain a percentage of that named meat at least equal to the minimum required meat content for that food 3. Where the name "economy burger" is used to refer to a compound ingredient consisting of a meat mixture and other ingredients, such as a bread roll, these requirements apply only to the meat mixture, as if the meat mixture were the regulated product in the labelling or advertising of which the name was used as the name of the food
3. Hamburger - whether or not forming part of another word	67%	Not applicable	62%	1. Where the name "hamburger" is used, the meat used in the preparation of the food must be beef, pork or a mixture of both 2. Where the name "hamburger" is qualified by the name of a type of meat, the food must contain a percentage of that named meat at least equal to the minimum required meat content for that food 3. Where the name "hamburger" is used to refer to a compound ingredient consisting of a meat mixture and other ingredients, such as a bread roll, these requirements apply only to the meat mixture, as if the meat mixture were the regulated product in the labelling or advertising of which the name was used as the name of the food
4. Chopped X - there being inserted in place of "X" the name "meat" or "cured meat" or the name of a type of meat or cured meat, whether or not there is also included the name of a type of meat	75%	62%	70%	No additional requirement

Name of food	Meat or cured meat content requirements			Additional requirements
	The food must contain not less than the indicated percentage of meat, where the meat ingredient consists of the following:			
	Meat or, as the case may be, cured meat from pigs only	Meat or, as the case may be, cured meat from birds only, or a combination of birds and rabbits only	Meat or, as the case may be, cured meat from other species or other mixtures of meat	
5. Corned X - there being inserted in place of "X" the name "meat" or the name of a type of meat, unless qualified by words which include the name of a food other than meat	120%	120%	120%	1. The food must consist wholly of meat that has been corned 2. Where the name of the food includes the name of a type of meat, the meat used in the preparation of the food must be wholly of the named type 3. The total fat content of the food must not exceed 15%
6. Luncheon meat or luncheon X, there being inserted in place of "X" the name of a type of meat or cured meat	67%	55%	62%	No additional requirement
7. Meat pie or meat pudding - 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 meat				No additional requirement
(a) based on the weight of the ingredients when the food is uncooked	12.5%	12.5%	12.5%	
(b) but if the food weighs - (i) not more than 200g and not less than 100g (ii) less than 100g	11% 10%	11% 10%	11% 10%	
Game pie (a) based on the weight of the ingredients when the food is uncooked	12.5%	12.5%	12.5%	No additional requirement
(b) but if the food weighs - (i) not more than 200g and not less than 100g (ii) less than 100g	11% 10%	11% 10%	11% 10%	

Name of food	Meat or cured meat content requirements			Additional requirements
	The food must contain not less than the indicated percentage of meat, where the meat ingredient consists of the following:			
	Meat or, as the case may be, cured meat from pigs only	Meat or, as the case may be, cured meat from birds only, or a combination of birds and rabbits only	Meat or, as the case may be, cured meat from other species or other mixtures of meat	
8. Scottish pie or Scotch pie - based on the weight of the ingredients when the food is uncooked	10%	10%	10%	No additional requirement
9. The name **"pie"** or **"pudding"** qualified by the words "meat" or "cured meat" or by the name of a type of meat or cured meat and also qualified by the name of a food other than meat or cured meat -				No additional requirement
(a) where the former (meat-related) qualification precedes the latter	7%	7%	7%	
(b) where the latter (non-meat-related) qualification precedes the former Based, in both cases, on the weight of the ingredients when the food is uncooked	6%	6%	6%	
10. Pasty, pastie Bridie or **sausage roll** - based on the weight of the ingredients when the food is uncooked	6%	6%	6%	No additional requirement
11. Sausage (excluding the name "sausage" when qualified by the words "liver" or "tongue" or both), **chipolata**, **link** or **sausage meat** -				No additional requirement
(a) where the name is qualified by the name "pork" but not by the name of any other type of meat	42%	Not applicable	Not applicable	
(b) in all other cases	32%	26%	30%	

Notes

1. In relation to items 4, 5 and 6, the percentages in column 2 are based on the weight of the raw meat used to make the food ("the raw meat ingredient") as a percentage of the weight of the cooked finished product. In relation to the other items, the percentages are based on the weight of the raw meat ingredient used to make the food as a percentage of the total weight of all the ingredients used to make the food (including the raw meat ingredient) at the time of their use as an ingredient.

2. The quantity of meat specified in the table is to be determined taking into account the provisions relating to total fat and connective tissue content in point 17 of Part B of Annex VII to FIC, including any downward adjustment needed in a case where the total fat and connective tissue content in the regulated product exceeds the values indicated in the table in point 17 of Part B of Annex VII to FIC.

Quick Frozen Foodstuffs (No.2) Regulations (NI) 2007 (SR No.110)

Scope

The regulations replace and consolidate the previous such regulations and came into force on 1st March 2007. The regulations implement the provisions of Commission Regulation 37/2005, Council Directive 89/108 and Commission Directive 92/2.

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 1st January 2006.

Existing instruments (installed before 1 January 2006) complying with previous legislation may continue to be used until 31st December 2009. All instruments must comply with the European Standards from 1st January 2010. Food operators must keep all relevant documents permitting verification that equipment/ instruments conform to the relevant European Standard(s).

Temperature recording details must be dated and kept by the food operator for at least one year or for longer depending on the nature and shelf-life of the QFF.

Exemptions

There are exemptions to this requirement of air temperature monitoring during storage in retail display cabinets and during local distribution. In these cases, the air temperature needs to be measured by at least one easily visible thermometer only.

2007 SR 110 Ver 1

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 $10m^3$ 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 district council. 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 Northern Ireland which is due to be reviewed shortly.

Associated Regulations

Quick Frozen Foodstuffs (No 2) Regulations (NI) 2007 (SR No. 110)

European Commission legislation:
Council Directive 89/108/EEC Quick Frozen Foodstuffs for human consumption

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

Section R
Legislation Under R

Section S
Legislation Under S

Specified Products from China (Restriction on first placing on the market) Regulations (NI) 2008 (SR No. 171)

Scope

Initially these regulations implemented Commission Decision 2008/289/EC on emergency measures regarding non authorised genetically modified rice Bt 63. This decision was later repealed and replaced by Commission Implementing Decision 2011/884/EU on Emergency measures requiring unauthorised genetically modified (GM) rice in rice products originating in China. Details of the list of products to which the decision applies are set out in Annex 1 of the Decision.

The national regulations and subsequent amending rules (The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (NI) 2012 SR No. 3) and The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (NI) 2013 SR No. 180) are enforced by the Department of Agriculture, Environment and Rural Affairs (DAERA) in relation to animal feed and district councils in relation to food.

Ingredients/products

The regulations relate to the first placing on the market of unauthorised genetically modified rice in rice products originating from China. The national regulations implement article 5 of the decision concerning official controls i.e

The competent authority of a Member State shall ensure that all the products within the scope of the decision are subject to documentary checks to ensure compliance with import conditions. Where a consignment of products other than those described in Article 4(2) (not containing, consisting of or produced from rice) is not accompanied by a health certificate and the analytical report provided for in Article 4, the consignment shall be re-dispatched to the country of origin or destroyed.

Where a consignment is accompanied by the health certificate and the analytical report provided for in Article 4 the competent authority shall take a sample for analysis in accordance with Annex II for the presence of unauthorised GMOs with a frequency of 100 %. If the consignment consists of several lots, each lot shall be submitted to sampling and analysis.

The competent authority may authorise onward transportation of the consignment pending the results of the physical checks. In such a case the consignment shall remain under the continuous control of the competent authorities pending the results of the physical checks. The release for free circulation of consignments shall only be allowed when, following sampling and analyses performed in accordance with Annex II, all lots of that consignment are considered compliant with Union Law.

And the first sentence of Article 7; Consignments shall not be split until all official controls have been completed by the competent authorities. The amendment regulations also allow for the Department and district councils to recover costs of official controls pursuant to Article 8.

2008 SR No. 171 Ver 1

All costs resulting from the official controls including sampling, analysis, storage and any measures taken following non- compliance, shall be borne by the food and feed business operators. The regulations also make some transitional provisions.

The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (Northern Ireland) 2013 SR No. 180)

These regulations implemented Commission Implementing Decision 2013/287/EU. The 2013 decision strengthens the 2011 decision by requiring:

- The presentation of specific import entry documents to the Border Inspection Port or the Designated Point of Entry at least one working day prior to the physical arrival of a consignment; and
- Revised sampling and analysis procedures

Public Analysts Observations

The EU Implementing Decision recommends that bulk consignments of rice should be sampled in accordance with Commission Recommendation 787/2004, resulting in a composite sample of 2.5kg that is sent for testing. This prescriptive sampling regime must be followed if formal samples are submitted to the Public Analyst. The Decision also defines the method to be followed by the analyst i.e. the construct-specific method developed by D. Mäde et al.

Associated Regulations

The Specified Products from China (Restriction on First Placing on the Market) Regulations (NI) 2008 SR No. 171

The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (NI) 2012 SR No. 3

The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (NI) 2013 SR No. 180

Further Information

COMMISSION IMPLEMENTING DECISION 2011/884 of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC

COMMISSION DECISION 2008/289 of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism 'Bt 63' in rice products

Commission Implementing Decision 2013/287 of 13 June 2013 amending Commission Implementing Decision 2011/884 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China

Specified Sugar Products Regulations (NI) 2003 (SR No. 301)

Scope

The Regulations implement the provisions of EC Directive 2001/111 relating to certain sugars intended for human consumption. The Regulations lay down reserved descriptions for the sugar products they cover and provide additional labelling requirements for these products. The Regulations also implement Commission Directive 79/796/EEC on methods of analysis for testing certain sugars.

Ingredients/Products

The Regulations apply to specified sugar products intended for human consumption and ready for delivery to the ultimate consumer or to a catering establishment. A 'specified sugar product' means one of the sugar products covered by the reserved descriptions in Schedule 1 of the Regulations. Icing sugars, candy sugars and sugar in loaf form (as defined in Regulation 2) are not covered by the scope of the Regulations. (Schedule 1 is reproduced in Annex 1 of these notes).

Reserved descriptions

A product may not be described using one of the reserved descriptions unless it meets the relevant compositional criteria laid down in Schedule 1. The name under which a specified sugar product is sold must be (or include) a reserved description. The reserved descriptions may also be used in the name of a food in the following circumstances:

(a) Where it is clear that the sugar product to which the reserved description relates is only an ingredient of the food (e.g. 'sugar mouse', 'barley sugar')

(b) Where it is clear that the food is not, and does not contain, the sugar product to which the reserved description relates (e.g. 'sugar-free gum', 'sugar snap peas')

(c) Where it is clear that the term is being used as a customary name for a food product and is not liable to mislead the consumer (e.g. 'icing sugar').

Under the general rules of EU Food Information to Consumers Regulation No. 1169/2011 (EU FIC) relating to ingredient listing, where a specified sugar product is used as an ingredient in another food, an appropriate reserved description must be used to describe that product in the list of ingredients.

Methods of analysis

The compositional and quality criteria for the specified sugar products are determined using the methods of analysis specified in Schedule 2. The Schedule stipulates which method is to be used in respect of each of the compositional criteria.

Labelling Requirements

Labelling of Specified Sugar Products

Regulation 5 provides the labelling requirements for specified sugar products. There are also a number of additional labelling provisions set out in the notes to Schedule 1, some of which are optional.

As well as the specific labelling requirements of the Regulations, specified sugar products are subject to the general labelling rules of EU FIC. In addition, Regulation 6 requires that any labelling information required by the Regulations must be provided according to the manner of marking provisions in EU FIC.

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.

Annex VII of EU FICprovides generic names that may be used to describe categories of ingredients in the list of ingredients. The Annex provides that the name 'glucose syrup' may be used to describe both glucose syrup and anhydrous glucose syrup where they appear in an ingredients list This flexibility **does not cover** glucose syrup with more than 5% fructose; these products must be labelled as described above.

Additional optional labelling provisions (Schedule 1, Notes 1, 4, 5 and 6)

The Regulations also provide a number of optional labelling provisions. These allow the reserved descriptions to be modified or supplemented with additional terms, where the product meets certain requirements, as follows:

(a) Extra-white sugar: A product meeting the requirements for the reserved description 'extra-white sugar' may alternatively carry the reserved description 'sugar' or 'white sugar'.

(b) Additional qualifying terms: Any specified sugar product may be labelled with commonly used qualifying terms in addition to the reserved description, providing this labelling is not misleading. e.g. 'granulated sugar', 'fructose: fruit sugar'.

(c) White sugar solution: The description 'white' may be used in the labelling of 'sugar solution' where the product has a colour of not more than 25 ICUMSA units. (ICUMSA stands for International Commission for Uniform Methods of Sugar Analysis).

(d) White invert sugar solution or syrup: The description 'white' may be used in the labelling of invert sugar solution or invert sugar syrup where the product has a colour of not more than 25 ICUMSA units and an ash content of not more than 0.1%.

Public Analyst Observations

There tends to be few issues identified in relation to composition of the range of sugar products.

Associated Regulations

The Specified Sugar Products Regulations (NI) 2003 (SR No. 301)

The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (NI) 2013 (SR No. 220)

EC Directive 2001/111 relating to certain sugars intended for human consumption

Further Information

FSA Guidance on specified sugar products

Sugar Traders Association

2003 SR. No. 301 Ver 1

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 nine points determined in accordance with paragraph (2) of Schedule 2
3. Extra-white sugar	The product having the characteristics referred to in paragraph 2(a), (b) and (c) of this Schedule and in respect of which the total number of points determined according to the provisions of paragraphs 2 to 4 of Schedule 2 does not exceed eight, and not more than: - four for the colour type, - six for the ash content, - three for the colour in solution
4. Sugar solution	The aqueous solution of sucrose with the following characteristics: (a) dry matter not less than 62% by weight (b) invert sugar content (ratio of fructose to dextrose = 1.0 +/- 0.2) not more than 3% by weight of dry matter (c) conductivity ash not more than 0.1% by weight of dry matter, determined in accordance with paragraph 3 of Schedule 2 (d) colour in solution not more than 45 ICUMSA units

5. Invert sugar solution	The aqueous solution of sucrose partially inverted by hydrolysis, in 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 syrup	The aqueous solution, whether or not crystallised, of sucrose that has been partly inverted via hydrolysis, in which the invert sugar content (fructose/dextrose quotient = 1.0 +/- 0.1), must exceed 50% by weight of dry matter, but which must otherwise meet the requirements laid down in paragraph 5(a) and (c) of this Schedule.
7. Glucose syrup	The purified and concentrated aqueous solution of nutritive saccharides obtained from starch and/or inulin, with the following characteristics: (a) dry matter not less than 70% by weight (b) dextrose equivalent not less than 20% by weight of dry matter and expressed as D-glucose (c) sulphated ash not more than 1% by weight of dry matter
8. Dried glucose syrup	Partially dried glucose syrup with at least 93% by weight of dry matter, but which must otherwise meet the requirements laid down in paragraph 7(b) and (c) of this Schedule.
9. Dextrose or dextrose	Purified and crystallised D-glucose containing one **monohydrate** molecule of water of crystallisation, with the following characteristics: (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

2003 SR. No. 301 Ver 1

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

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

Scope

These regulations provide for the execution and enforcement, of certain provisions of Regulation (EU) No.1308/2013 establishing a common organisation of the markets in agricultural products.

The EU 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 EU Regulation include:

(a) the requirement that milk and milk products marketed for human consumption must comply with certain specifications as to names and composition (Article 78(1)(c) and Part III of Annex VII); and

(b) the requirement that certain spreadable fats intended for human consumption must comply with specifications relating to their sales description, labelling and presentation, and use of terminology (Article78 (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
- Cream
- Butter
- Buttermilk
- Butteroil
- Caseins
- Fil
- Anhydrovs milkfat (AMF)
- Cheese
- Yogurt
- Kepher (a fermented milk drink)
- Koumiss (a fermented milk drink)
- Viili/fil

The term 'milk' and the designations used for 'milk products' may also be used in association with a word or words to designate composite products.

The origin of the milk must be stated of if it is not bovine.

2008 SR. No. 239 Ver 1

This Regulation protects consumers from the possibility of confusing butter, margarine and other spreadable fats (e.g. minarines etc) by differentiating them according to their percentage of fat content and their animal or vegetable origin.

Spreadable fats are products with a fat content of at least 10% but less than 90% by weight and which remain solid at a temperature of 20c (complete definition in Part VII of 1308/2013). To avoid any possible confusion, the regulation limits use of the terms 'butter' and 'margarine' to products with a fat content of not less than 80%.

'Reduced fat' claims

The term can be used for Spreadable fats with a fat content of more than 41% but not more than 62%. This term may also be used to replace the term "Three Quarter Fat".

Under the terms of the Regulation, the fact that the product has a reduced fat content must be mentioned clearly in the product designation. The Regulation therefore permits the use of nutritional claims which underline that the product has a reduced fat content. (Such claims consist of information relating to labelling, presentation and advertising which inform consumers about the characteristics of a foodstuff or food ingredient).

'Low fat / Light' claims

The term can be used for Spreadable fats with a fat content of 41% or less.
This term may also be used to replace the term "Half Fat".

Please note that the Regulation sets out specific criteria for the use of nutrition claims on spreadable fats. The Commission has not yet indicated when they are likely to amend these Regulations to bring the criteria for claims on Spreadable fats in line with Council Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Therefore, Food Business Operators should continue to comply with the criteria outlined in EU Regulation No. 1308/2013.

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 EU Regulation No 1308/2013.

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 Part VII of 1308/2013.

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.

Issues

There have been reports that the term Soya "milk" has been used and described as milk in some catering establishments. Soya milk is not a permitted description under the Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations (NI) 2008 (SR No. 239).

Foodstuffs intended for human consumption may only be marketed as milk and milk products if they comply with the definitions and designations laid down in EU Regulation No.1308/2013.

These have been documented in guidance issued by the Food Standards Agency. Coconut milk is an example of one such derogation; however, "soya milk" does not qualify for such derogation because it competes directly with cows' milk.

Public Analyst Observations

Typical issues concern the abuse of the term buttercream where the fat constituent must be butter and cream with artificial cream being substituted.

There are occasional problems with descriptions. The regulations focus on technical compositional and labelling terms.

Associated Regulations

The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations (NI) 2008 (SR No.239)

REGULATION (EU) No 1308/2013 of 17 December 2013 establishing a common organisation of the markets in agricultural products

FSA Guidance on legislation for spreadable fats and other yellow fat spreads

FSA Guidance on legislation on the protection of definitions and designations in respect of milk and milk products

SCHEDULE
Compositional standards set out in Appendix II to Regulation (EU) No. 1308/2013

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.	1. Butter	The product with a milk-fat content of not less than 80% but less than 90%, a maximum water content of 16% and a maximum dry non-fat milk-material content of 2%.
	2. Three-quarter-fat butter (*)	The product with a milk-fat content of not less than 60% but not more than 62%
	3. Half-fat butter (**)	The product with a milk-fat content of not less than 39% but not more than 41%.
	4. Dairy spread X%	The product with the following milk-fat contents • less than 39%, • more than 41% but less than 60%, • more than 62% but less than 80%.
B. Fats Products in the form of a solid, malleable emulsion, principally of the water-in-oil 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.	1. Margarine	The product obtained from vegetable and/or animal fats with a fat content of not less than 80% but less than 90%.
	2. Three-quarter-fat margarine (*)	The product obtained from vegetable and/or animal fats with a fat content of not less than 60% but not more than 62%.
	3.Half-fat margarine (**)	The product obtained from vegetable and/or animal fats with a fat content of not less than 39% but not more than 41%.
	4. Fat spreads X%	The product obtained from vegetable and/or animal fats with the following fat contents: • less than 39%, • more than 41% but less than 60%, • more than 62% but less than 80%.
C. Fats composed of plant and/or animal products Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived from solid and/or liquid vegetable and/or animal fats suitable for human consumption, with a milk-fat content of between 10% and 80% of the fat content.	1. Blend	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 80% but less than 90%.

	2. Three-quarter-fat blend (*)	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 60% but not more than 62%
	3. Half-fat blend (**)	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 39% but not more 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%.
C. Fats composed of plant and/or animal products Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived from solid and/or liquid vegetable and/or animal fats suitable for human consumption, with a milk-fat content of between 10% and 80% of the fat content.	1. Blend	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 80% but less than 90%.
	2. Three-quarter-fat blend (*)	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 60% but not more than 62%.
	3. Half-fat blend (**)	The product obtained from a mixture of vegetable and/or animal fats with a fat content of not less than 39% but not more 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%.

Section T
Legislation Under T

Tryptophan in Food Regulations (NI) 2005 (SR No. 440)

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 l-tryptophan at 220mg or less
- Laevoratory-tryptophan added to infant formula, follow-on formula, and processed cereal-based food or baby food
- Laevoratory-tryptophan and some derivatives added to foods for particular nutritional use

if the above substances comply with specified purity criteria.

For the purposes of the provisions of the Food Safety Order (NI) 1991 and General Food Regulations(NI) 2004, 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.

2005 SR No. 440 Ver 1

Public Analyst Observations

It is not anticipated that this type of product will be encountered in retail shops in the United Kingdom, however, where officers are aware of supplements sold in health and body building clubs checks could be made to ensure that this product is not being sold.

Associated Regulations

Tryptophan in Food (Northern Ireland) Regulations 2005 (SR No. 440)

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2009 SR No. 398

Further Information

Committee on Toxicity Report

Section UV
Legislation Under UV

UV

Addition of Vitamins, Minerals and Other Substances Regulations (NI) 2007 (SR No. 301)

Scope

There are a wide range of nutrients and other ingredients that might be used in food production such as vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts.

These regulations implement the provisions of EC Regulation No. 1925/2006 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 Directive 2002/46/EC.

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 Directive 90/496/EEC and of the total amount of vitamins and minerals present

Foods placed on the market or labelled prior to 1st July 2007 which do not comply with the regulations may be marketed until their expiry date but not later than 31st December 2009.

The primary regulations were amended by the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (NI) 2010 SR No. 292 to introduce ambulatory references the purpose of which is to avoid the necessity to make numerous amendments to national legislation each time changes are made to the EU regulations.

Public Analyst Observations

Officers who are considering sampling of this type of food need to be aware of the fact that vitamins because of their organic nature may deteriorate if exposed to air or sunlight therefore it will be preferable to sample unopened packets.

Associated Regulations

The Addition of Vitamins, Minerals and Other Substances Regulations (NI) 2007 SR No.301

The Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (NI) 2010 SR No. 292

The Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (NI) 2009 SR No. 407

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

Commission Regulation (EC) No. 1161/2011 amends the list of minerals permitted for use in food supplements, fortified food and Foods for Particular Nutritional Uses (Parnuts). From the 5 December the following substances will be permitted in fortified foods (Regulation EC No. 1925/2006):

- Ferrous Ammonium Phosphate
- Ferric Sodium EDTA
- Chromium Picolinate

Further Information

Europa – Vitamins and minerals

EFSA Tolerable Upper Intake Levels for Vitamins and Minerals

Section W
Legislation Under W

W

Section XYZ
Legislation Under XYZ

XYZ

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