Food Safety
AUTHORITY OF IRELAND

21

GUIDANCE NOTE

Food Supplements Regulations and Notifications (Revision 2)

Guidance Note No. 21
Food Supplements Regulations and Notifications
(Revision 2)

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Food Safety Authority of Ireland
Abbey Court
Lower Abbey Street
Dublin 1

Tel: +353 1 817 1300 Fax: +353 1 817 1301
Email: info@fsai.ie Website: www.fsai.ie

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1. INTRODUCTION

This guidance note is to provide information on legislation which is specific to food supplements. The legislation covers food supplements currently on sale in Ireland and those being manufactured or being imported directly, or through third parties.

This document is designed to assist manufacturers, importers, distributors and retailers of food supplements by providing information on legal requirements relating to:

- The composition of food supplements
- The labelling of food supplements
- Notification of food supplements to the Food Safety Authority of Ireland (FSAI)

2. FOOD LAW RELATING TO FOOD SUPPLEMENTS

The specific European legislation relating to food supplements is:

- Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements
- Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances
- Commission Regulation 1170/2009/EC of 30 November 2009 amending Directive 2002/46/EC as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements

This European legislation has been transposed into Irish law by:

- European Communities (Food Supplements) Regulations, 2007, S.I. No. 506 of 2007 as amended

Food supplements are foodstuffs and controlled by food law including, but not limited to:

- Regulation (EC) 178/2002 (as amended) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (transposed into Irish legislation by S.I. No. 747 of 2007 as amended)
- Regulation (EC) 852/2004 (as amended) of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (transposed into Irish legislation by S.I. No. 369 of 2006 as amended)
- Directive 2000/13/EC (as amended) of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (transposed into Irish legislation by S.I. No. 483 of 2002 as amended)
- Regulation 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (transposed into Irish legislation by S.I. No. 117 of 2010 as amended)
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
- Regulation (EC) No 258/97/EC (as amended) of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients
- Regulation (EC) No 1333/2008 concerning food additives as amended

3. DEFINITIONS

Food supplements[1] are defined in legislation as:
Foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

Nutrients[1] are defined as:
(i) vitamins (ii) minerals

Placing on the market[2] means:
The holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves

Labelling[3] is defined in legislation as:
Any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuffs

Medicinal product[4] is defined as:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

Tolerable Upper Intake Level[5] is:
The maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk to adverse health effects to humans.

Note: The UL is not a recommended level of intake.

Food business operator[2] is defined as:
The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control

[1] European Communities (Food Supplements) Regulations, 2007 (S.I. No. 506 of 2007 as amended)

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principle and requirements of food law, establishing the European Food Safety Authority and laying down the procedures in matters of food safety

[3] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

[4] Directive 2001/83/EC, as amended, on the Community code relating to medicinal products for human use

[5] Tolerable Upper Intake Levels for Vitamins and Minerals, Scientific Committee on Food Scientific, Panel on Dietetic Products, Nutrition and Allergies, European Food Safety Authority, February, 2006 http://www.slv.se/upload/dokument/efsa/upper_level_opinions_full-part33,0.pdf. Vitamin D update; EFSA Journal 2012; 10(7); 2813, Calcium update; EFSA Journal 2012; 10(7); 2814

4. FOOD BUSINESS OPERATORS TO WHOM THIS LEGISLATION APPLIES

The Regulations apply equally to all sectors of the food supplement industry: manufacturers, importers, distributors, retailers (including website sales, company mail order sales and network marketing).

In the case of direct and media marketing, although the company/product may not be of Irish origin, once it is brought onto the Irish market via any route for sale to the public (i.e. placed on the market), the importer is responsible for the notification to the FSAI of products. Sales via the internet must also comply with the provisions of the Regulations.

The Regulations also apply to food supplements intended for export outside of the EU, regardless of whether or not they are sold in Ireland. Food supplements that do not comply with the Regulations may nonetheless be exported outside the EU provided that:

(a) The competent authorities of the importing country have expressly agreed to such importation, after having been fully informed of the reasons for which and the circumstances in which the food supplements concerned could not be placed on the market in Ireland and

(b) The food supplements in question are not injurious to health

Where the provisions of a bilateral agreement concluded between the Community or the State and a third country are applicable, food supplements exported from the State to that third country shall comply with the said provisions.

If health certificates are required for exported food supplements, these can be provided by the Health Service Executive (HSE) or the FSAI.

5. FOOD SUPPLEMENT INGREDIENTS

As the legal definition outlines, food supplements are 'concentrated sources of nutrients or other substances with a nutritional or physiological effect'.

There are a wide range of nutrients and other substances used as ingredients that might be present in food supplements including, but not limited to; vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.

The legislation lays down very specific rules for vitamins and minerals used as ingredients in food supplements. Only certain vitamins and minerals can be used in food supplements, and only certain formats of these vitamins and minerals have been approved for use (see Annex I for a list of vitamins and minerals and their permitted formats compiled from Directive 2002/46/EC as amended)[1].

Specific rules concerning ingredients other than vitamins and minerals used in food supplements will be laid down at a later stage.

The Directive states that maximum and minimum levels for vitamins and minerals in food supplements will be set. Maximum levels will be set, taking into account tolerable upper intake levels (ULs) which have been recommended by the European Food Safety Authority (EFSA)[2].

[1] This list may be updated in the future.

[2] It is expected that these maximum and minimum levels will be given a legal basis by the European Commission through the procedures of the Standing Committee on the Food Chain and Animal Health.

6. FOOD SUPPLEMENTS AND MEDICINES

Sometimes a product may be considered within the definition of a medicinal product by virtue of its composition, concentration, labelling and presentation or when medicinal claims are made in association with the product. A medicinal claim states or implies that the product has the property of treating, preventing or curing a human disease. Medicinal products as defined in Directive 2001/83/EC will be dealt with under those provisions and not under food supplement controls.

The Irish Medicines Board (IMB) is the competent authority for medicinal products in Ireland. The Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (S.I. No. 540 of 2003 as amended) lists substances which are subject to prescription control in Ireland. However, some substances listed in S.I. No. 540 of 2003 may be permitted in food supplements in other EU Member States, e.g. some herbal substances, vitamins at certain levels etc.

Please note that no substance which exerts a pharmacological action (regardless of whether or not it is listed in S.I. No. 540 of 2003 as amended) is permitted in food supplements.

The food supplement Regulations do not apply where a product clearly comes under the definition of a medicinal product. Where the classification of a specific product is unclear, the FSAI will liaise with the IMB and the individual food business operator on a case by case basis, as appropriate.

7. FOOD SUPPLEMENT LABELS

The food supplements Regulations set out a number of specific labelling requirements for food supplements. The following particulars are a legal requirement for all food supplement labels:

- Products shall be sold under the name 'Food Supplement'
- The labelling, presentation and advertising of food supplements must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties
- The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general
- The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form
- The amounts of nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling
- The units of vitamins and minerals should be those as specified in the Annex to the legislation (see Annex I of this document)
- Information on vitamins and minerals shall also be expressed as a percentage of the reference values outlined in nutrition labelling legislation (see Annex II of this document)
- The labelling of food supplements must also bear the following mandatory statements:
    (a) The names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances
    (b) The portion of the product recommended for daily consumption
    (c) A warning not to exceed the stated recommended daily dose
    (d) A statement to the effect that food supplements should not be used as a substitute for a varied diet
    (e) A statement to the effect that the products should be stored out of the reach of young children

In addition, the labels of food supplements must also comply with the general food labelling requirements. Annex III contains an example of a compliant food supplement label. Up-to-date information on all labelling legislation is available on the FSAI website at www.fsai.ie/legislation.html.

8. TRACEABILITY AND COMPLIANCE

It is the responsibility of food business operators (including retailers) to ensure that the products being placed on the market are compliant with the legislation. Retailers shall be able to verify that the products they receive are of a high standard, and can achieve this by using reliable and reputable suppliers.

Food business operators, including those trading in food supplements, are required under Regulation (EC) No 178/2002 to implement a traceability system. The requirement relies on the "one step back - one step forward" approach. This means that food business operators shall have a system in place enabling them to identify the immediate supplier(s) and immediate business customer(s) of their products.

Food business operators do not have to keep details of which of their products are supplied to final consumers, e.g. sold to customers in retail outlets. The information which must be recorded in all cases and to be made available on demand is the:

- Name and address of supplier and name of products which were supplied to the food business operator by that supplier
- Name and address of business customer and name of products that were delivered by the food business operator to that customer
- Date of transaction/delivery

9. NOTIFICATION OF FOOD SUPPLEMENTS

To facilitate efficient monitoring of food supplements, the Regulations require the manufacturer or the person placing the product on the market in Ireland to notify the FSAI of the fact by forwarding a sample of the label used for the product. This requirement applies when the product is manufactured in or imported into Ireland and is being placed on the Irish market for the first time by an individual (i.e. manufacturer, distributor, importer or retailer), irrespective of product country of origin.

A separate notification is required for each flavour for products which come in different flavours. In the case of food supplements which come in different pack sizes (e.g. packs of 20, 40 & 60 tablets), these can be notified in the one notification. However, labels relating to each individual pack size must be provided with this notification.

N.B. The notification procedure is NOT an approval or authorisation procedure for marketing a food supplement in Ireland.

9.1 Responsibility for Notification to the Food Safety Authority of Ireland

It is the responsibility of the food supplement manufacturer or importer who is placing the product on the market in Ireland to notify the FSAI. Be aware that products already on the market in other EU Member States must be notified to the FSAI when being placed on the market in Ireland for the first time.

9.2 How to Notify the Food Safety Authority of Ireland

The FSAI has developed an online notification system which manufacturers and importers may use to help them with their notification. This is available at https://supplements.fsai.ie

Notification of Food Supplements is a statutory requirement under Commission Directive 2002/46/EC as transposed by S.I. No. 506 of 2007, which covers the enforcement of food legislation in the area of food supplements. This form may be used to notify the FSAI when a food supplement is placed on the Irish market for the first time.

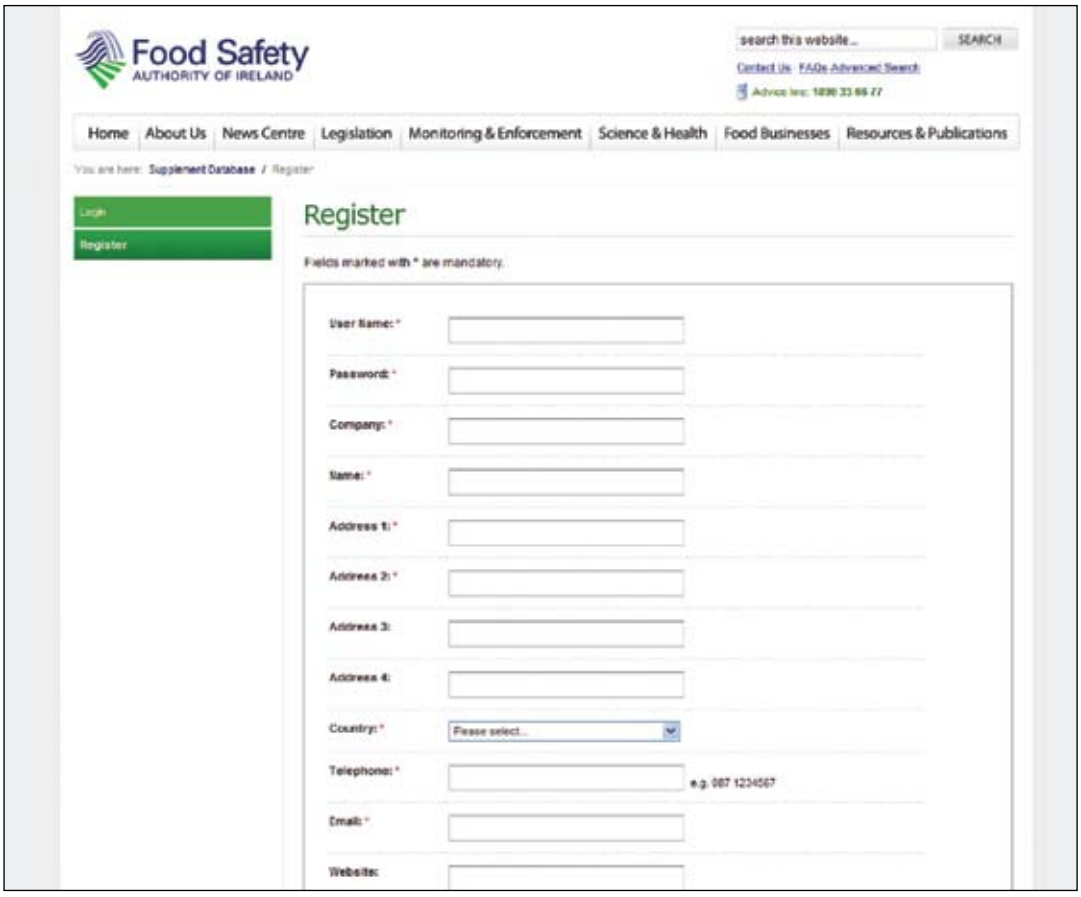
The duty to notify falls on the manufacturer if the product is manufactured in Ireland and on the importer if the product is imported into Ireland. A separate form is required for each product* and in the case of reformulation (i.e. ingredients/ingredient levels) or changes in claims.

* *In the case where a product which exists in varying pack sizes (e.g. 30, 60 and 90 capsules) is being notified, it is only necessary to fill out 1 notification, to which multiple labels can be attached (up to a maximum of 6)*

Please note: It is up to each company to maintain records of the products they have notified. We therefore suggest that each company sets up their own company specific account (using a generic email address e.g. *info@companyname.ie*, and password), for use when submitting notifications. This is to prevent loss of access to submissions that may occur if the account is set up in an individual employee's name (and email address), and that employee leaves the company.

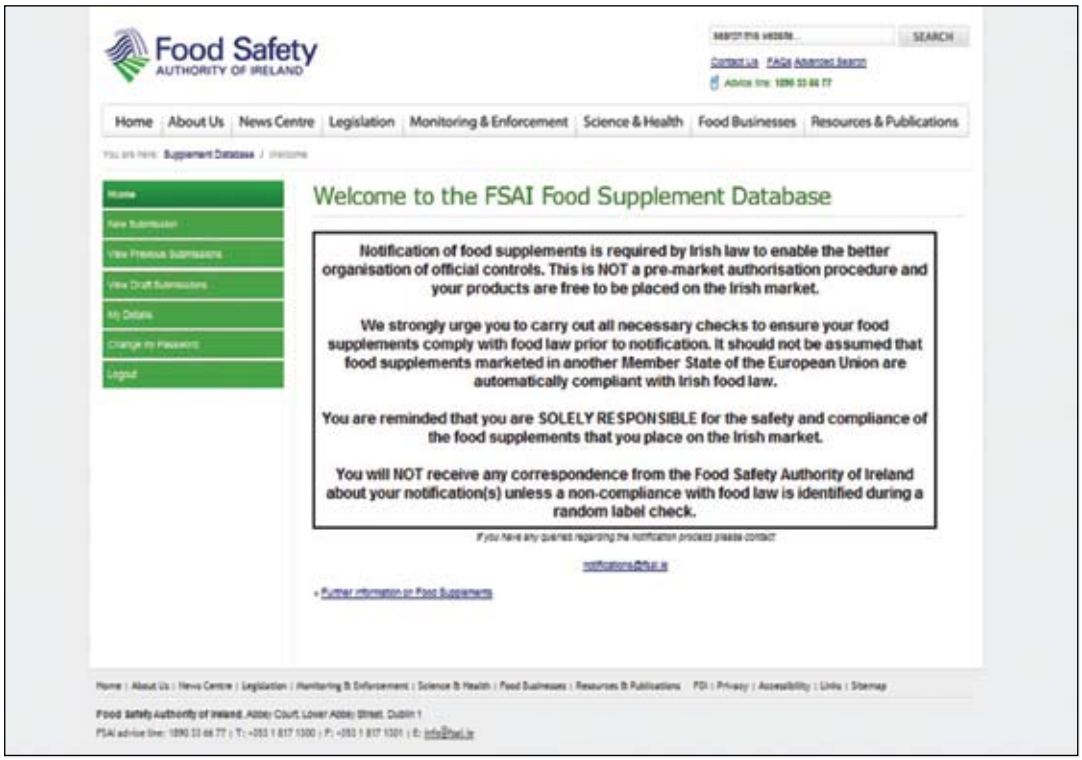
In order to use this online system, food business operators must first register as a user (see Figure 1). This will involve providing contact details as well as creating a username and password which will be used to log into the system.

Figure 1. Screenshot of Registration Page to the Food Safety Authority of Ireland Online Notification System



Once you have successfully logged onto the system you will be able: to access information on the FSAI food supplement notification system and legislation relating to food supplements, submit a food supplement notification, view a draft submission, view previous submissions and edit your details in the 'My Details' section (see Figure 2).

Figure 2. Screenshot of the Welcome Page to the Food Safety Authority of Ireland Online Notification System



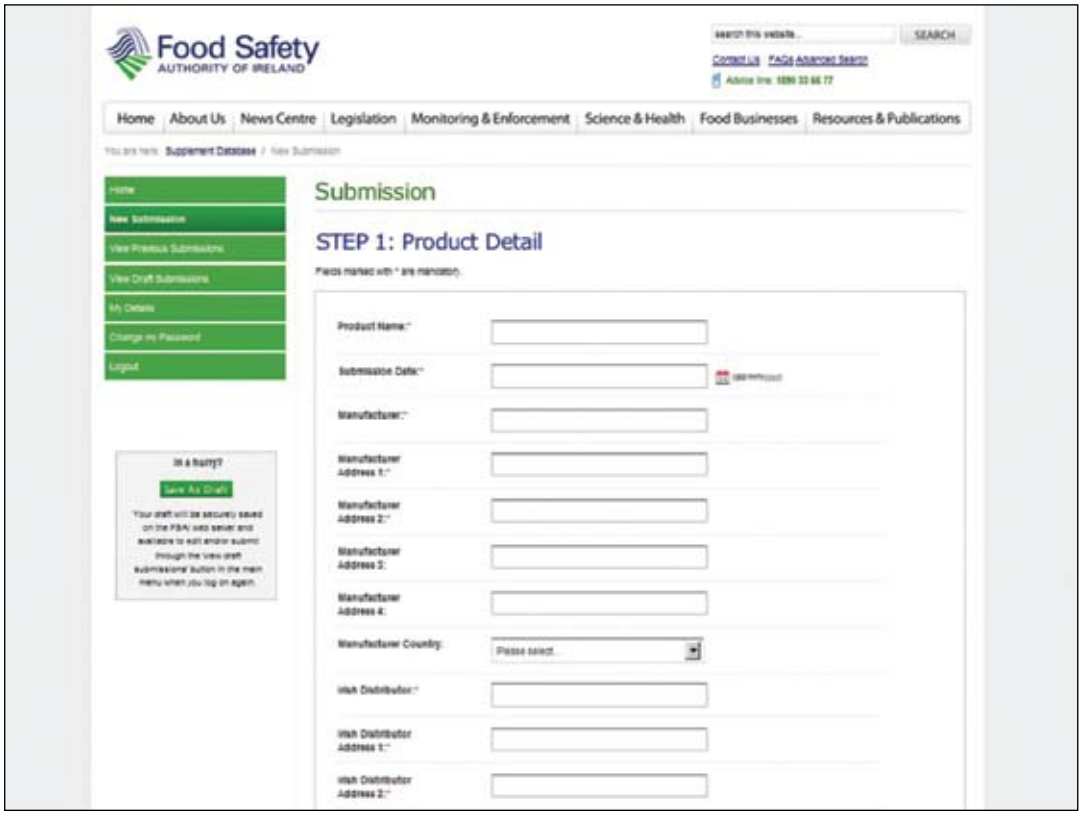
To submit a food supplement notification, you will be required to provide certain details regarding the product, i.e. product name, manufacturer/importer name and address, product description etc (see Figure 3).

You will also be required to submit a copy of the product label. This is a legal requirement under S.I. No. 506 of 2007 as amended. You may upload an electronic version of the label with your online submission (max 5MB), there is also an option to upload multiple labels (7 in total) as well as promotional material. Alternatively, a legible hard copy of the label can be sent subsequent to the online submission to: Public Health Nutrition, Food Safety Authority of Ireland, Abbey Court, Lower Abbey Street, Dublin 1, by fax to: 01 8171301 or email to notifications@fsai.ie.

If posting a copy of the label, please state clearly the reference number of your notified supplement which will be displayed on the final confirmation screen once online notification is complete.

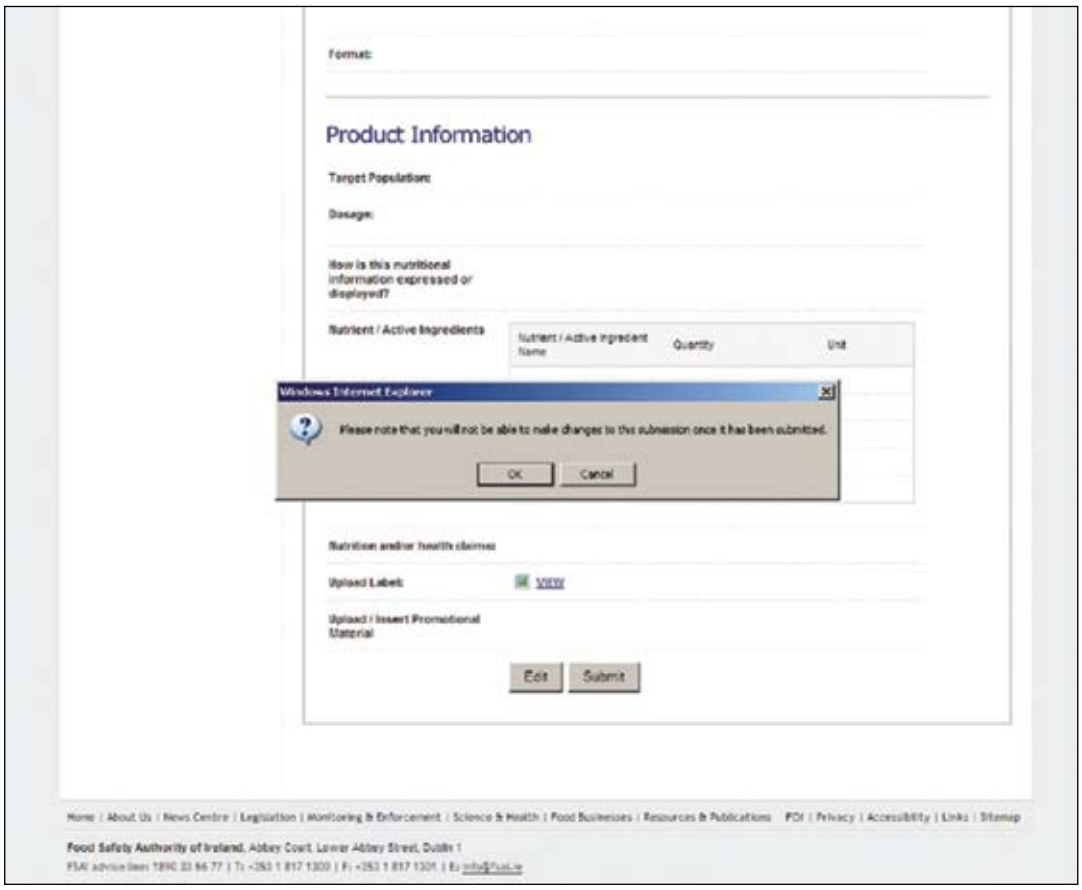
Your notification can be saved in draft format and will be available to edit and/or submit through the 'view draft submissions' button at a later stage.

Figure 3. Screenshot of Submission Page for Submitting Details



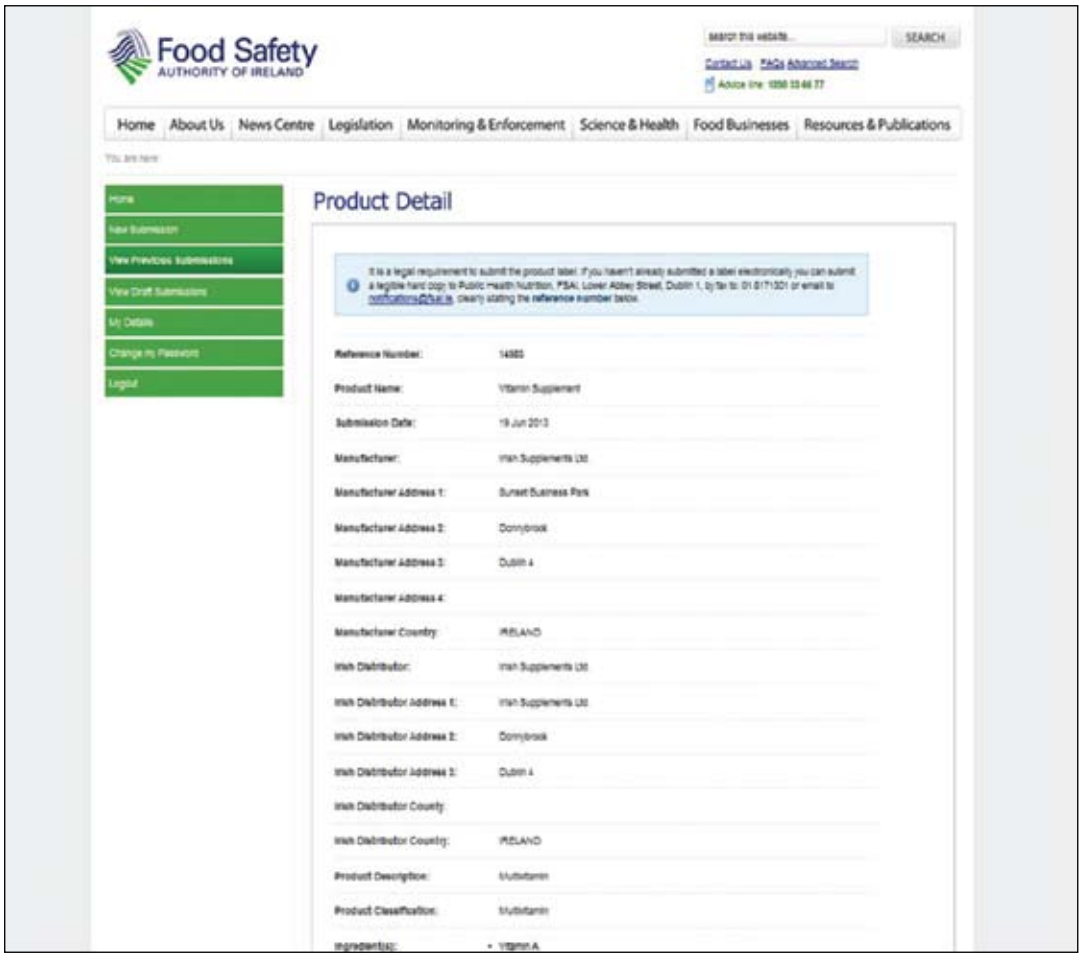
Once you have completed the submission page, you will be asked to preview your submission. You will then be able to edit the submission to correct any errors or omissions and submit your notification to the FSAI. Once you press the submit button you will not be able to make any further changes to the submission (see Figure 4).

Figure 4. Screenshot of Final View of Submission Page



Once you have submitted your food supplement notification, a reference number for your product will automatically be generated (see Figure 5), please retain this number and refer to it in any correspondence with the FSAI. You will be able to view all products notified using this online system under the section 'View Previous Submissions'.

Figure 5. Screenshot of Product Details (including reference number) Once Submission has been Completed



9.3 Food Safety Authority of Ireland Procedure for Notified Food Supplements

An email will be sent to the food business operators acknowledging receipt of the notification and highlighting legal responsibilities under relevant legislation relating to food supplements.

Some food supplement notifications will be subject to a random label compliance check by the FSAI with legislation on food supplements, novel foods, and nutrition and health claims. Not all notified food supplements receive this check. However, all notified food supplements and their labels are held in a database to facilitate official controls. Inspectors from the environmental health service (EHS) check compliance of food supplements on a random basis once they are on the market and may send samples to official laboratories for analysis

If non-compliant food supplements are identified during official controls then food business operators will be contacted. In such an event, appropriate enforcement action may be taken. This may include prosecution and product withdrawal/recall as appropriate.

N.B. You will NOT receive any correspondence from the FSAI about your notification(s) unless a non-compliance with food law is identified during a random label check

The FSAI may require the manufacturer (or where appropriate, the importer) to produce any associated marketing material to ensure that it complies with relevant requirements of food law.

The FSAI works in cooperation with the Irish Medicines Board (IMB). The IMB is responsible for enforcement of the Irish Medicines Law. Medicines law in each Member State of the European Union is different, consequently a product sold as a food supplement in one Member State may qualify as a medicine in Ireland and vice versa.

The FSAI will refer products notified as food supplements to the IMB if they contain ingredients that the IMB consider medicinal ingredients or if the food supplement makes a medicinal claim. Medicinal claims are not allowed on foods including food supplements. You will be notified if such referral has taken place and you will be faced with two compliance options:

1. Make changes to product formulation and/or label to bring product into compliance with food law

OR

2. Register the product as a medicine with the IMB

9.4 Notification of Revised Food Supplement Products

A food supplement that has been notified to the FSAI and has subsequently been reformulated or relabelled (i.e. a change in ingredients or ingredient levels or health claims) should be notified as if it were a new food supplement. Refer to the beginning of Section 9 for details on how to notify a new food supplement.

9.5 Details of Notified Products

Details about the notification, such as the product label, date of notification and contact details of the notifier, will be kept by the FSAI as confidential information, subject to the Freedom of Information Acts, 1997 and 2003.

The FSAI provides details of notified food supplements to environmental health officers of the HSE who are responsible for enforcing food legislation under contract to the FSAI.

10. ENFORCEMENT AND OFFENCES

Enforcement of the Regulations is the responsibility of the FSAI and is carried out by the HSE under contract, through the Environmental Health Services and Public Analysts' Laboratories.

The Regulations set out offences including the following:

1. Failure to comply with the Regulations
    a. Place product on market for the first time without prior notification
    b. Place product on the market for the first time with non-compliant labelling
    c. Place product on market for the first time containing vitamins and minerals not listed in Annex 1 and 2
2. To forge the certificate of analysis or other documents or use a forged document
3. To alter a certificate of analysis or other documents or use an altered document
4. Be in unlawful possession of a forged document or an altered document
5. Tamper with anything to misrepresent the substance sampled
6. Tamper or interfere with any sample taken

A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court, to imprisonment for a term not exceeding 6 months or both.

The HSE enforces the Regulations under service contract, and undertakes routine and coordinated programmes on the sampling and analysis of food supplements to check for compliance. In addition to the specific powers available in the food supplements legislation, enforcement officers have powers to seize, detain and destroy products that fail to comply with food legislation.

11. CONTACT DETAILS

Notification of foods supplements subject to these Regulations should be made through our online submission at https://supplements.fsai.ie

If you have any queries in relation to the notification process, please contact:

Public Health Nutrition,
Food Safety Authority of Ireland,
Abbey Court, Lower Abbey Street
Dublin 1

FSAI Advice Line: 1890 33 66 77
Fax: + 353 1 8171301
Email: notifications@fsai.ie

12. LEGISLATION SOURCES

Copies of all legislation mentioned in this document can be found on the FSAI website at www.fsai.ie/legislation.html

ANNEX I: VITAMINS AND MINERALS WHICH MAY BE USED IN THE MANUFACTURE OF FOOD SUPPLEMENTS

Types of Vitamins	Permitted Forms
Vitamin A (µg RE)	retinol
	retinyl acetate
	retinyl palmitate
	beta-carotene
Vitamin D (µg)	cholecalciferol
	ergocalciferol
Vitamin E (mg αTE)	D-alpha-tocopherol
	DL-alpha-tocopherol
	D-alpha-tocopheryl acetate
	DL-alpha-tocopheryl-acetate
	D-alpha-tocopheryl acid succinate
	mixed tocopherols
	tocotrienol tocopherol
Vitamin K (µg)	phylloquinone(phytomenadione)
	menaquinone
Vitamin B1 (mg)	thiamin hydrochloride
	thiamin mononitrate
	thiamine monophosphate chloride
	thiamine pyrophosphate chloride
Vitamin B2 (mg)	riboflavin
	riboflavin 5'-phosphate, sodium
Niacin (mg NE)	nicotinic acid
	nicotinamide
	inositol hexanicotinate (inositol hexaniacinate)
Pantothenic acid (mg)	D-pantothenate, calcium
	D-pantothenate, sodium
	dexpanthenol
	pantethine
Vitamin B6 (mg)	pyridoxine hydrochloride
	pyridoxine 5'-phosphate
	pyridoxal 5'-phosphate

Types of Vitamins	Permitted Forms
Folic acid (µg)	pteroylmonoglutamic acid
	calcium-L-methylfolate
Vitamin B12 (µg)	cyanocobalamin
	hydroxocobalamin
	5'-deoxyadenosylcobalamin
	methylcobalamin
Biotin (µg)	D-biotin
Vitamin C (mg)	L-ascorbic acid
	sodium-L-ascorbate
	calcium-L-ascorbate
	potassium-L-ascorbate
	L-ascorbyl 6-palmitate
	magnesium L-ascorbate
	zinc L-ascorbate

Type of Mineral	Mineral Forms
Calcium (mg)	calcium acetate
	calcium L-ascorbate
	calcium bisglycinate
	calcium carbonate
	calcium chloride*
	calcium citrate malate
	calcium salts of citric acid
	calcium gluconate
	calcium glycerophosphate
	calcium lactate
	calcium pyruvate
	calcium salts of orthophosphoric acid
	calcium succinate
	calcium hydroxide
	calcium L-lysinate
	calcium malate
	calcium oxide
	calcium L-pidolate
	calcium L-threonate
	calcium sulphate

Type of Mineral	Mineral Forms
Magnesium (mg)	magnesium acetate
	magnesium L-ascorbate
	magnesium bisglycinate
	magnesium carbonate
	magnesium chloride*
	magnesium salts of citric acid
	magnesium gluconate
	magnesium glycerophosphate
	magnesium salts of orthophosphoric acid
	magnesium lactate
	magnesium L-lysinate
	magnesium hydroxide
	magnesium malate
	magnesium oxide
	magnesium L-pidolate
	magnesium potassium citrate
	magnesium pyruvate
	magnesium succinate
	magnesium sulphate
	magnesium taurate
	magnesium acetyl taurate
Iron (mg)	ferrous carbonate
	ferrous citrate
	ferric ammonium citrate
	ferrous gluconate
	ferrous fumarate
	ferric sodium diphosphate
	ferrous lactate
	ferrous sulphate
	ferric diphosphate (ferric pyrophosphate)
	ferric saccharate
	elemental iron (carbonyl+electrolytic+hydrogen reduced)
	ferrous bisglycinate
	ferrous L-pidolate
	ferrous phosphate
	iron (II) taurate

Type of Mineral	Mineral Forms
Copper (µg)	cupric carbonate
	cupric citrate
	cupric gluconate
	cupric sulphate
	copper L-aspartate
	copper bisglycinate
	copper lysine complex
	copper (II) oxide
Iodine (µg)	sodium iodide
	sodium iodate
	potassium iodide
	potassium iodate
Zinc (mg)	zinc acetate
	zinc L-ascorbate
	zinc L-aspartate
	zinc bisglycinate
	zinc chloride*
	zinc citrate
	zinc gluconate
	zinc lactate
	zinc L-lysinate
	zinc malate
	zinc mono-L-methionine sulphate
	zinc oxide
	zinc carbonate
	zinc L-pidolate
	zinc picolinate
	zinc sulphate

Type of Mineral	Mineral Forms
Manganese (mg)	manganese ascorbate
	manganese L-aspartate
	manganese bisglycinate
	manganese carbonate
	manganese chloride*
	manganese citrate
	manganese gluconate
	manganese glycerophosphate
	manganese pidolate
	manganese sulphate
Sodium (mg)	sodium bicarbonate
	sodium carbonate
	sodium chloride*
	sodium citrate
	sodium gluconate
	sodium lactate
	sodium hydroxide
	sodium salts of orthophosphoric acid
Potassium (mg)	potassium bicarbonate
	potassium carbonate
	potassium chloride*
	potassium citrate
	potassium gluconate
	potassium glycerophosphate
	potassium lactate
	potassium hydroxide
	potassium L-pidolate
	potassium malate
	potassium salts of orthophosphoric acid
Selenium (µg)	L-selenomethionine
	selenium enriched yeast
	selenious acid
	sodium selenate
	sodium hydrogen selenite
	sodium selenite

Type of Mineral	Mineral Forms
Chromium (µg)	chromium (III) chloride
	chromium (III) lactate trihydrate
	chromium nitrate
	chromium picolinate
	chromium (III) sulphate
Molybdenum (µg)	ammonium molybdate (molybdenum (VI))
	potassium molybdate (molybdenum (VI))
	sodium molybdate (molybdenum (VI))
Fluoride (mg)	calcium fluoride
	potassium fluoride
	sodium fluoride
Phosphorus (mg)	sodium monofluorophosphate
Boron (mg)	boric acid
	sodium borate
Silicon (mg)	choline-stabilised orthosilicic acid
	silicon dioxide
	silicic acid

*These are all the chemical formats of chloride that are permitted in food supplements.

ANNEX II: LABELLING REFERENCE VALUES FOR VITAMINS AND MINERALS

NUTRIENTS	NUTRIENT REFERENCE VALUE (NRV)
Vitamin A	800µg
Vitamin D	5µg
Vitamin E	12mg
Vitamin K	75µg
Vitamin C	80mg
Thiamin	1.1mg
Riboflavin	1.4mg
Niacin	16mg
Vitamin B6	1.4mg
Folic acid	200µg
Vitamin B12	2.5µg
Biotin	50µg
Pantothenic acid	6mg
Potassium	2,000mg
Chloride	800mg
Calcium	800mg
Phosphorus	700mg
Magnesium	375mg
Iron	14mg
Zinc	10mg
Copper	1mg
Manganese	2mg
Fluoride	3.5mg
Selenium	55µg
Chromium	40µg
Molybdenum	50µg
Iodine	150µg

These NRVs are listed in Annex 1 to Directive 2008/100/EC (this Annex amends that in Directive 90/496/EEC (S.I. No. 461 of 2009)) and the Food Information to Consumers Regulation (Regulation 1169/2011) which is in force from December 13th 2014 onwards.

ANNEX III: EXAMPLE OF A COMPLIANT LABEL

Food Safety Authority of Ireland
Abbey Court, Lower Abbey Street,
Dublin 1

Údarás Sábháilteachta Bia na hÉireann
Cúirt na Mainistreach, Sráid na Mainistreach Íocht.,
Baile Átha Cliath 1

Tel: +353 1 817 1300
Fax: +353 1 817 1301
Email: info@fsai.ie
Website: www.fsai.ie

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