Food Safety
AUTHORITY OF IRELAND

Aide Memoire for Food Supplement Establishment Inspections

This document should be read in conjunction with Guidance Note No 21 Rev 1 Food Supplements Regulations and Notifications and the Food Supplement Establishment Checklist

October 2012

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INTRODUCTION

Purpose

This document and the food supplement checklist have been developed by the Food Safety Authority of Ireland (FSAI), in collaboration with the environmental health service (EHS), to aid environmental health officers (EHOs) carry out official control inspections in food supplement establishments.

As law enforcement officers, EHOs inspect against legal requirements. The legislation is mute on how food supplement manufacturers produce quality products that consistently match the label on those products. To establish the safety and consistency of food supplements produced, good manufacturing practices (GMP) or other quality management systems provide food business operators with a useful tool to ensure the safety of the products being produced.

Quality/Good Manufacturing Practices (GMP) Documents

Three levels of documents will be utilised in conjunction with the relevant legislation.

1. **Baseline document**, *Quality Guide for Food Supplements* was developed by the European Federation of Health Product Manufacturers (EHPM) with the technical assistance of expert groups from the EHPM's 26 member associations, to ensure there is a common interpretation of food supplement rules and that consumers are assured of the quality of food supplements within the EU. The document is available from the FSAI or by using the link below http://www.ehpm.org/pdfs/8990EHPM%20Report%20for%20web.pdf

2. **Food Supplements Aide Memoire** provides guidance on the use of the EHPM Quality Guide which gives the EHO a tool to establish if the food business operator's Quality, ISO 9000 or Good Manufacturing Practices (GMP) system is adequate to ensure that food supplements placed on the market meets the legal requirements. The Aide Memoire should provide the EHO with the type of questions to ask businesses and provide guidance on the evidence of compliance they should expect to see. The same section headings and numbers are used in the Aide Memoire as in the EHPM Quality Guide for ease of cross-referencing.

3. **Food Supplements Checklist** with a list of headings to prompt the EHO to use when out on an inspection (this is cross-referenced to the Aide Memoire where extra information on each heading will be provided). This checklist will provide the EHOs with evidence of the audit and the topics covered.

Please Note: These three documents can be used in conjunction with the EHS 852 Visit Record, *Guidance Note 21 Revision 1 Food Supplements Regulations and Notifications*, *Guidance Note 1 Revision 2 Guidance for the Health Service Executive on the Inspection of Food Businesses*, FSAI Training Booklet – *Information on Nutrition and Health Claims and Food Supplements* and other relevant legislation and guidance. A flow chart describing the full document hierarchy is provided in **Appendix 3.**

Use of the Quality/GMP Documents

In using these documents, the reader is reminded that GMP (or equivalent/other quality management systems) is not a legal requirement. This suite of documents incorporate mandatory requirements from European Union legislation and recommendations, based on examples of best practices, to help maintain and provide evidence of the safe and consistent production of supplements. Whilst the mandatory requirements are obligatory, the recommended best practice should be incorporated in to the production operations where appropriate and practical, as determined by the manufacturer. As part of the inspection process, the EHO should be requiring the manufacturer to provide evidence of the steps taken to ensure the safe and consistent production of food supplements. In the context of this guidance 'must' implies a mandatory requirement and 'should' implies a recommended best practice.

In establishments where there is no GMP system in place, it is the responsibility of the manufacturer to provide evidence to the EHO to demonstrate that the appropriate steps have been taken to ensure the safe and consistent production of food supplements. In establishments with no GMP system in place, this suite of documents will provide the EHO with the questions required to assess compliance with the law, and will direct them to the areas in which the food business operator must provide supporting evidence.

The businesses will vary greatly from packers to manufacturer to distributors etc. Some will have GMP others will have different quality management systems etc so it will be up to the discretion of the local EHO to apply elements of the documents the best way they see fit.

Legislation and Guidelines

Legislation, EU and international standards and official FSAI guidelines and records are the source documents to be referred to in relation to food business operator compliance during inspections. A list of the primary relevant legislation and guidelines in place at the time of issue of this document is attached in **Appendix 4**. The specific legislation that applies to each individual section is referenced at the top of the section. As legislation and guidelines are constantly being revised, EHOs should ensure that they are using the updated legislation and guidelines during inspections by checking the FSAI website for updates.

SECTION 1: PRODUCT RANGE, PERMITTED INGREDIENTS AND NOTIFICATIONS

Primary Reference Documents

Legal	**Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation*:*** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010
GMP and Guidance	FSAI *Guidance Note No 21 Food Supplements Regulations and Notifications (Revision 1)* FSAI Training Guide – *Information on Nutrition and Health Claims and Food Supplements*

Quality Principle

Food supplements **must** contain only those ingredients permitted in food supplements. Food supplements to be placed on the Irish market **must** be notified to the competent authority (FSAI) using the on line notification process or alternative system. Food business operators manufacturing or importing food supplements should recognise the potential for product cross contamination with other products and should put the appropriate controls in place.

Sub Section	
1.1	**Product Range** 1.1.1 The food business operator should provide a list of ingredients used, finished products and the target populations. At each inspection, establish if there have been any changes to the list of products manufactured or handled at the site (both food supplements and non-food supplements). 1.1.2 The technology used for the manufacture of oral medicines is the same as that used for the manufacture of food supplements and it is not unusual for a site to manufacture both. If this is the case, determine if there are adequate controls in place to prevent cross contamination and product mix-ups. A food supplement which is cross contaminated with pharmacologically active materials could create a serious public health risk. There should be segregated facilities, with access control and separate Heating Ventilation and Air Conditioning (HVAC) systems etc. 1.1.3 If a product appears to fall into the category of a medicine, consult with the Irish Medicines Board (IMB) for a final decision on classification. If the product is confirmed to be a medicine it must be controlled under medicinal legislation. Some substances listed, as medicinal ingredients, in legislation, may be

	permitted in food supplements in other EU Member States, e.g. some herbal substances, vitamins at certain levels etc. so it is particularly important to check imported products.
1.2	**Permitted Ingredients** 1.2.1 Determine if food supplement products contain only permitted ingredients at the permitted level, where these levels are specified (vitamins and minerals). See legal definitions of 'food supplement' and 'medicinal product' in the Appendix 1: Glossary (see note on permitted ingredients, and useful links in appendix 5, page 51).
1.3	**Food Supplement Notifications** 1.3.1 Check if all the food supplements manufactured or handled and placed on the Irish market have been notified to the FSAI. Food supplements marketed in Ireland **for the first time** must be notified to the FSAI, even if these food supplements are on the market in other EU states (see also Guidance Note 21 Rev1) 1.3.2 Check if some of the products notified need to be removed from the FSAI food supplements list due to re-formulation as medicines or other product group. 1.3.3 Determine if the change control system (see Section 2.3.1) is being used for the introduction of new food supplement products or processes, so that the legality of the product and suitability of the process is fully assessed in advance, see also Section 6 Product and Process Design.

SECTION 2: QUALITY MANAGEMENT

Primary Reference Documents

Legal	**General Food Law** **EC Legislation**: Regulation (EC) No 852/2004, as amended (Article 5)
GMP and Guidance	EHPM Quality Guide for Food Supplements ISO 9000 Quality Management ISO 22000 Food Safety Management Systems

Quality Principle

In order to protect consumer health and produce food supplements of consistent quality, a documented quality management system should be in place.

"As a general principle, quality management is defined as co-ordinated activities to direct and control an organisation with regard to quality, according to ISO standards. There should be a comprehensive system so designed, documented, implemented and controlled, and so furnished with personnel, equipment and other resources as to provide assurance that products will be consistently fit for their intended use. The attainment of this quality objective requires the involvement and commitment of all concerned, at all stages of manufacture, storage and distribution.

The concept of 'quality by design' is important for quality management. This means that the product should be designed and developed in a way that takes into account all the essential quality requirements.

The quality objective shall be achieved by an integrated system including Quality Assurance, Quality Control and Good Practice." EHPM

Note 1: The requirement to have a quality management system (QMS) is not specified in the legislation governing food supplements. The type of QMS in place may vary from one food business operator to another. Some may be certified to voluntary quality standards such as the ISO9000 or ISO22000 and others may operate a QMS or good manufacturing practices (GMP) system of their own design. Regardless of the type of quality management system used, there should be written specifications and instructions in place to ensure consistent manufacture or handling of food supplements and providing records to prove that these instructions and specifications have been met.

Sub Section	
2.1	**General Principle** 2.1.1 Establish the type of quality management system in place, if it addresses the quality principles above and is fully documented. 2.1.2 The contents of the QMS should cover all activities at the food business operator and any contracted activities with potential product impact. Check with the food business operator that the QMS is comprehensive and appropriate to operations, e.g. check it covers all food supplements and operations. 2.1.3 The requirements covered by sections 2 -15 of this document, which are based on the EHPM section headings, should be included in the QMS but can be in any format or design which suits the manufacturer. 2.1.4 Confirm, by reviewing records, that personnel have been trained in the requirements of the QMS relevant to their roles and that these requirements are implemented. 2.1.5 Confirm that the Quality Department has the required level of responsibility and authority to ensure compliance with the QMS and is involved in all decisions with the potential to impact on product quality.
2.2	**Good Practice for Production (GMP)** 2.2.1 All manufacturing processes should be clearly defined, and known to be capable of achieving the desired ends 2.2.2 All necessary resources and facilities should be provided (see EHPM for list) 2.2.3 Personnel should be trained 2.2.4 Further details on good p/ractice are provided throughout this document. (see sections 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14)

2.3 Quality Assurance

"The objectives of Quality Assurance are achieved when processes are defined which, when followed, will yield product that complies with its specification and the quality expected, and when the finished product:

a) contains the correct ingredients in the correct proportions;
b) has been correctly processed, according to the defined procedures;
c) is of the purity required;
d is enclosed in its proper container, which;
e bears the correct label (or is otherwise suitably marked or identified);
f) is stored, distributed and recommendations given for its subsequent handling in accordance with the recommended storage conditions, so that its quality is maintained throughout its designated or expected life." EHPM

Some of the key quality assurance systems are listed below. Many of these are referenced in Sections 3-15 of this guide but are expanded on here to provide an overview of the system and give guidance on good practices.

2.3.1 Change Control System: The Change Control system is a key input to the design of a comprehensive QMS. The Change Control system should ensure that any proposed changes are requested in writing, assessed for potential quality impacts and that appropriate actions, to minimise impacts and hazards are taken in advance of the introduction of the change. The effectiveness of major changes should also be monitored after introduction, including unintended impacts. Changes with the potential to impact on quality include, but are not limited to:

- Changes to food supplement legislation and guidelines
- New premises or changes to existing premises
- Introduction of new product categories or new food supplements
- Changes to product formulation manufacturing or packaging processes
- Changes to ingredients, packaging or to suppliers of these items
- Changes to utilities and equipment other than part-for-part replacement
- Changes to material specifications
- Changes to test methods
- Changes to storage and transportation system or conditions
- Introduction or changes to contract activities such as manufacture and testing (see also Sections 3, 5, 6, 7, 8, 9, 10, 14, 15)

2.3.2 Quality Risk Management/HACCP

The quality risk management system is another key input into the design of the QMS and contributes to the 'quality by design' expectations.

- Quality risks should be assessed during the product and process design stages and suitable actions should be put in place to prevent, minimise, monitor and control these risks prior to routine manufacture.
- Check with the food business operator if tools are used for quality risk management, e.g. Failure Mode Effect Analysis (FMEA), Fault Tree analysis etc. The use of the HACCP tool is expected under hygiene legislation and could be used for other quality risk management activities also.
- When changes are proposed, quality risk management should be used to define the potential risks associated with the proposed changes.
- Quality risk management principles should be used when making product

release decisions if deviations have occurred during the manufacture, testing or storage of the product.

- The quality risk management system and it outputs should be continuously reviewed for effectiveness and revised where necessary (see also Sections 3, 5, 6, 7, 8, 12, 14, 15).

2.3.3 Supplier Management

A documented supplier management programme should be in place. This programme should define how suppliers are selected, assessed and monitored for suitability. The supplier auditing programme should be defined, based on risk, particularly for suppliers outside the EU where the quality standards for manufacture are different or unknown. The level of testing performed on trial samples and samples for routine deliveries should be defined. The actions to be taken when a supplier fails to meet quality standards should also be stated (see also Sections 5, 6, 7 & 15).

2.3.4 Complaints, Recall and Emergency Procedures

Expectations are the same for general food stuffs and food supplements. Comments on additional QMS expectations for food supplements are provided under that section (see Section 12).

2.3.5 Deviations Management

Out of limit conditions, unusual events or failure to follow instructions should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions (CAPAs) should be put in place. The responsible manager and the Quality manager should review and approve these records. Testing results which are out of specification (OOS) or out of trend (OOT) should also be investigated using the OOS procedure. Deviations and OOS results should be trended and reviewed at quality review meetings to ensure that corrective actions and preventive actions were effective and there is no recurrence of the deviations (see also Sections 3, 7, 9, 10, 15).

2.3.6 Product Failure Investigations – Rejects and Rework

When a product failure occurs, e.g. an out of specification product, a full investigation should take place to establish the root cause and put in place corrective actions (which may include rework or reprocessing) and preventive actions. These data should be trended and discussed at quality review meetings to ensure that there is no risk posed to other batches or product due to the root cause of the initial failure (see also Section 7, 8 and 15).

2.3.7 Management of Contracted Activities

All contracted activities which have the potential to impact on product quality should be controlled (see also Section 14).

2.3.8 Managing Audit Findings – Internal, Customer, Regulatory, Supplier and Contractor

Findings from internal and customer audits and from regulatory inspections should be thoroughly investigated and appropriate corrective and preventive actions (CAPAs) should be put in place. Responses should be provided to customers and regulators and CAPAs should be implemented within the agreed time frames. The effectiveness of these actions should be reviewed at quality

	management meetings to ensure there is no recurrence. Proposed actions resulting from audits at suppliers and contractors should be tracked through to completion (see also Section 7, 13, 14). **2.3.9 Problem Investigation and Corrective and Preventive Actions (CAPAs)** When a quality system element, such as complaints, deviations, OOS, audit, etc., indicates that a problem exists, the true root cause of the problem should be established by a full investigation. Appropriate corrective and preventive actions should be proposed and approved by the quality department. A time scale for implementation of these CAPAs should be agreed and the actions should be tracked to completion. CAPA status should be reviewed at quality review meetings to ensure they are being completed in accordance with the agreed time scale and are effective, i.e. are preventing recurrence of the problem (see also Section 3, 7, 8, 9, 10, 12, 13, 14, 15). **2.3.10 Quality Review Meetings and Trending Quality Data** Regular quality review meetings should be held with all the relevant managers in attendance. A summary of quality data from key quality system elements, such as complaints, recalls, deviations, audit findings, product failures, change control requests, CAPAs etc., should be presented and reviewed. The purpose of the meetings is to ensure that quality system outputs are effectively managed to prevent recurrence of quality problems and risk to the consumer. Minutes of these meetings should be maintained (see also Section 13).
2.4	**Quality Control** **2.4.1** The authority and responsibilities of the Production Manager and the Quality Manager should be clearly defined and the quality role should be independent with a separate reporting structure. **2.4.2** Further details on expectations for facilities, staff, sampling, testing and release are provided in the Laboratory Testing Section of this document (see Section 15).

SECTION 3: FOOD PREMISES AND EQUIPMENT

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene** **EC Legislation**: Regulation (EC) No 852/2004, as amended; Regulation (EC) No 2073/2005, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011 **Food Contact Materials** **EC Legislation**: Regulation (EC) 1935/2004, as amended **National Legislation***:* S.I. No .587 of 2007, as amended
GMP and Guidance	EHPM Quality Guide for Food Supplements

Quality Principle

"Buildings should be located, designed, constructed, adapted and maintained to suit the operations carried out in them and to facilitate the protection of materials and products from contamination or deterioration. Equipment should be designed, constructed, adapted, located and maintained to suit the processes and products for which it is used and to facilitate protection of the materials handled from contamination or deterioration." (EHPM)

Note 1: The general quality principles for premises and equipment in food premises apply. Materials and articles in contact with food supplements (EC 1935/2004 as amended) **must** be inert and **must not** yield substances into the food stuff. A site hygiene plan, including a cleaning and sanitation plan, (may be broader than cleaning and sanitisation plan, e.g. HVACs, differential pressures, gowning, cleaning validation etc) should be in place to prevent or minimise contamination risks identified in the HACCP plan (EC 852/2004 as amended).

Premises and equipment used for manufacture and storage of food supplements may require additional controls outlined following.

Sub Section	
3.1	**General – Premises and Equipment** **3.1.1 Cleaning and Contamination Control:** Layout, design, construction, finish and size of premises and equipment should be such as to permit the required level of cleanliness for food supplements. Heating Ventilation Air Conditioning (HVAC) Systems may be used to minimise the risk of product contamination and cross contamination with fine dusts from micro-ingredients and products and where used should be qualified*. Maintenance and monitoring of HVACs and manufacturing rooms should be conducted. Cleaning validation should be conducted for methods used in cleaning premises and equipment.
3.1	**General – Premises and Equipment** **3.1.2 Storage Conditions:** Layout, design, construction and size of premises and HVAC systems should provide suitable processing and storage conditions, such as control of temperature and humidity, as specified during product development and as stated on the product label. **3.1.3 Planned Maintenance (PM):** PM programmes should take into account the level of maintenance required in premises and equipment to provide the specified operating parameters for utilities and equipment used in food supplements manufacture, packing and storage. PM should also be sufficient to minimise contamination from the premises or equipment. **3.1.4 Calibration:** Calibration programmes should take into account the level of calibration required to ensure that instruments used on utilities and equipment are sufficiently accurate and reliable for their intended purpose. For example, check the food business operator is calibrating instruments used for dispensing, mixing and filling of food supplements to the required level of accuracy in order to ensure accurate and uniform quantities of micro ingredients in the final product.
3.2	**Utilities/Services** **3.2.1** Critical utilities that impact on product quality should be identified in the HACCP plan and be designed, qualified*****, maintained and monitored to ensure they operate effectively and do not pose a risk of product contamination. Critical utilities may include but are not limited to: • **Heating Ventilation and Air Conditioning (HVAC) systems:** These systems should be designed, maintained and operated to provide the required level of filtration of incoming air and the conditioning of the air to provide the specified temperature and humidity levels. Localised extract units should be used in operations which generate high levels of ingredient or product dusts • **Water Systems**: Potable water is the minimum required standard for the manufacture of food stuffs. A water of higher chemical purity, such as

	Purified Water European Pharmacopoeia standard (Ph Eur), may be required for certain food supplements or for certain operations as determined by the manufacturer. Purified water systems should be qualified and monitored to ensure they meet the specified chemical purity standard. As residual chlorine has been removed, purified water systems will require routine monitoring for microbial levels. Sanitisation methods should be proven to achieve the appropriate level of microbial quality and the removal of residues of sanitising agents • **Compressed air or other gases:** Compressed air and other gases should be filtered to remove oil, dust, microbes and other contaminants **3.2.2** Utilities should be designed and qualified (validated) to prove that they can consistently achieve the specified conditions. **3.2.3** Proposed changes to utilities should be requested in writing through the change control system so that potential hazards and product impacts may be investigated and utilities re-qualified if required. **3.2.4** Maintenance and monitoring programmes for utilities should be defined in writing and records should be held. **3.2.5** Calibration programmes for critical instruments used on utilities should be defined in writing and records should be held. Instruments should be clearly identified with a unique number and status such as 'out of service' or 'calibrated' with recalibration date stated. **3.2.6** Operation, maintenance, calibration and monitoring of utilities should be defined in written procedures. Records of all these activities should be held and a chronological record such as a log book should also be maintained to facilitate investigations, in the event of deviations, product complaints, recalls etc. **3.2.7** Out of limit conditions, unusual events or failure to follow instructions should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions should be put in place. The responsible manager and the Quality Manager should review and approve these records.
3.3	**Equipment** **3.3.1** Critical equipment that impacts on product quality should be identified in the HACCP plan and be designed, located, qualified*****, maintained and monitored to ensure it operates effectively and does not pose a risk of product contamination. Critical equipment may include, but is not limited to: • Mixing or blending equipment • Granulators and fluid bed driers • Tablet presses • Filling equipment – capsule fillers, bottle fillers etc. • Packaging equipment – blister packers, labellers, cartoning equipment, cameras, bar code readers etc. • Weighing and measuring equipment.

3.3.2 As for general food stuffs, the materials of construction for all product contact equipment **must** be of suitable construction and finish and be non-reactive, non-shedding etc.(EC 1935/2004 as amended). Food supplements should typically be manufactured in equipment with non-reactive contact surfaces such as stainless steel. Valves and seals should be of a construction to facilitate thorough cleaning and minimise leaching.

3.3.3 Equipment should be designed and qualified (validated) to prove that it can consistently achieve the specified conditions.

3.3.4 Proposed changes to equipment should be requested in writing through the change control system so that potential hazards and product impacts may be investigated and the equipment re-qualified if required.

3.3.5 Equipment should be clearly identified with a unique number and status such as 'batch number x in process', 'out of service', 'clean and ready for use' etc.

3.3.6 Maintenance (PM) and monitoring programmes for equipment should be defined in writing and records should be held.

3.3.7 Calibration programmes for critical instruments on equipment should be defined in writing and records should be held. Instruments should be clearly identified with a unique number and status such as 'out of service' or 'calibrated' with recalibration date stated.

3.3.8 Equipment assembly, disassembly, maintenance, calibration, cleaning and operation should be defined in written procedures. Records of all these activities should be held and a chronological record such as a log book should also be maintained to facilitate investigations, in the event of deviations, product complaints, recalls etc.

3.3.9 Only food grade materials, such as lubricants, should be used in the maintenance and operation of product contact equipment.

3.3.10 Equipment cleaning methods should be proven to achieve the appropriate level of removal of chemical, microbial, foreign matter and cleaning agents such as detergents (cleaning validation).

3.3.11 The level of equipment cleaning required between batches of the same product and between different products should be defined in a written procedure which has been validated. Prior to commencing the next product, the level of cleanliness should be verified by inspection by the food business operator and by testing if required by their own documented procedures. Records should be maintained (see 3.1.1).

Out of limit conditions, unusual events or failure to follow instructions should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions should be put in place. The responsible manager and the Quality Manager should review and approve these records.

	***Qualification/Validation/Commissioning:** Food business operators using a GMP system will use the term **'validation'** for proving that utilities and equipment can achieve the specified operating parameters. This is achieved by a series of documented **qualification** steps. Qualification protocols and records should be in place for Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Food business operators using other systems may use the term **'commissioning'**. Documentary evidence that utilities and equipment have been proven to consistently achieve the specified operating parameters, should be requested.

SECTION 4: PERSONNEL AND TRAINING

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011
GMP and Guidance	FSAI Guidance Note No 12 The Inspection of Food Safety Training and Competence (Revision 1) EHPM Quality Guide for Food Supplements

Quality Principle

"Compatible with the size and type of business, there should be sufficient personnel at all levels with the ability training, experience, and where necessary, the professional and technical qualifications, appropriate to the tasks assigned to them." EHPM

Note 1: Food supplement manufacture and handling requires certain additional knowledge and skills beyond those required for other food stuffs. For example, the analysis of products to quantify micro-ingredients and the performance of stability studies requires specific knowledge and skills.

Sub Section	
4.1	**General (personnel)** 4.1.1 Positions and reporting structures should be defined in a document such as an organisation chart 4.1.2 Duties and responsibilities, for positions that may impact on product quality, should be clearly defined in job descriptions approved by the job holder and manager. Minimum required qualifications should be stated for each job by the food business operator. 4.1.3 Deputies should be defined to cover the absence of key personnel.

Sub Section	
4.2	**Training** In addition to standard training requirements, check that the food business operator has ensured that personnel have the required level of qualification, training and experience to understand the additional risks associated with the manufacture, storage and testing of food supplements and the ability to minimise or respond to these risks. 4.2.1 A training plan based on the job description should be in place for each individual. Check if training records match the job description and training plan and if they cover both job specific tasks and best practices (QMS or GMP) and personal hygiene. 4.2.2 Training should be provided upon employment, to all employees whose activities may impact on product quality and consideration given to language or literacy difficulties. 4.2.3 Check if training in updated instructions and refresher training on best practices is provided (particularly after errors or poor hygiene practices have been identified). 4.2.4 Trainers of food handlers and personnel conducting internal and external audits should be trained to a nationally recognised standard.
4.3	**Training of Food Supplement Handlers** 4.3.1 Food business operators **must** have systems *"to ensure that food supplement handlers are supervised and instructed and/or trained in hygiene commensurate with their work activity".* In deciding the level of risk presented by the activity, the food business operator should consider: • The nature of the food supplement, e.g. capsules, tablets, liquids, powders each of which may be subject to different contamination risks with chemical, microbial and foreign matter • How personnel handle food supplements – direct handling of product, product contact equipment or primary packaging component should not take place, gloves are usually worn

4.4	**Personal Hygiene** 4.4.1 All the statutory requirements for foodstuffs **must** be applied. 4.4.2 In addition, the following best practice requirements should be in place to minimise external contamination and cross contamination between products and be defined in a procedure: • Use of safety footwear, overshoes, suitable protective clothing (including hair and beard covers and masks where required) and laundering and inspection requirements • Suitably designed, segregated, equipped changing rooms with defined gowning and de-gowning procedures • Pre-employment medicals where required • Control of personal medications • Reporting of certain infections and of skin lesions • Policy on return to work after absences • Restrictions on wearing jewellery, cosmetics, nail varnish and carrying loose items (including mobile phones) • Removing protective clothing before leaving the production area • Hand and nail washing using bactericidal soap • Use of gloves • Controls on use of brittle material, e.g. glass, metal, plastics.

SECTION 5: HACCP - HAZARD ANALYSIS CRITICAL CONTROL POINT

Primary Reference Documents

Legal	**Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended (Article 5) **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010
GMP and Guidance	FSAI Guidance Note No 11 Assessment of HACCP Compliance (Revision 2) FSAI Guidance Note No 23 Development and Assessment of Recognised National Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles EHPM Quality Guide for Food Supplements

Quality Principle

In addition to the normal risks encountered in the manufacture of foodstuffs (such as contamination with foreign bodies, chemicals and microbes), additional risks apply to the manufacture of food supplements. Ingredients are present in minute quantities and the dose in the final product **must** be controlled to protect public health, too high or too low a dose not only misleads the consumer but could adversely impact on health. The final dosage forms, manufacturing technologies and test methods are more similar to pharmaceuticals than to food stuffs and the manufacturing process must ensure homogeneity of ingredient mixing and accuracy of filling into final units such as tablets, capsules and liquid formulations. The manufacturer should identify and prevent, eliminate or reduce these additional risks to acceptable levels and should incorporate them into a quality risk management system, such as a HACCP system. The food business operator is compliant if they have identified and controlled all risks. These must be identified and managed through procedures based on HACCP principles.

Note 1: Examples of risks/hazards unique to food supplements are presented below for guidance. This list is not all inclusive. EHOs will encounter additional risks/hazards at food establishments.

Note 2: Guidance on the expected quality system/GMP controls to minimise these risks/hazards are dealt with in the appropriate section of this document. For example, if the HACCP plan identifies hazards associated with inadequate mixing of ingredients guidance on expected control systems will be found in Section 3: Premises and Equipment, Section 6: Product and Process Development and Section 7: Manufacturing

Sub Section	**Risk Management/HACCPs** Has the HACCP system identified hazards and implemented systems to prevent, eliminate or reduce to acceptable levels the hazards associated with the following?

5.1	**Premises and Equipment (see also Section 3)** **5.1.1 Premises** Inadequate premises design and layout can increase the hazard associated with contamination or cross contamination between product categories, e.g. pharmaceutical, food supplements, or between individual food supplement products. For example, due to poor segregation and access control of activities generating fine powder dusts from ingredients or products. **5.1.2 Utilities/Services** Inadequate design, qualification, maintenance, operation and monitoring of a critical utility such as a Heating Ventilation and Air Conditioning (HVAC) system can lead to cross contamination of food supplements **5.1.3 Equipment** Inadequate design, qualification (see glossary), maintenance, cleaning, operation and monitoring of critical equipment can result in product which does not meet specification, e.g. (a) a poorly designed blender may not be capable of consistently producing homogeneous bulk materials for filling an accurate final dose (b) equipment requiring manual transfers and unloading as opposed to closed systems (direct transfer by pipe work) will present higher risks.
5.2	**Product and Process Development (see also Section 6)** **5.2.1** A risk assessment, based on HACCP principles, should be conducted from the earliest stages of product and process development to eliminate or minimise potential hazards and to aid the incorporation of effective control parameters into the product and process design. This approach is consistent with the objectives of 'quality by design' (see Glossary).
5.3	**Manufacture (see also Section 7)** **5.3.1** There is an increased risk of mix-ups due to variety of ingredients, small dosage units, and variety of printed packaging used in food supplements. **5.3.2** The number and small quantities of ingredients increase the risk of incorrectly formulated product due to incorrect dispensing or process additions. **5.3.3** There is an increased risk of cross contamination due to fine dusts and traces of physiologically active materials on equipment, surfaces and personnel. **5.3.4** Blending, filling and packing processes present increased risks as technology and skill is required to ensure accurate consistent dose and correct labelling of the finished product.
5.4	**Recovery or Re-working of Materials (see Section 8)** **5.4.1** Rework other than re-packaging can increase the risk of product contamination and of stability failure

	5.4.2 Rework such as repackaging can result in an increased probability of mix ups unless good control systems are developed in advance of the operations.
5.5	**Warehousing (Section 9)** **5.5.1** Stability of finished product will be affected by inadequate storage conditions. **Risk Management/HACCPs** Has the HACCP system identified hazards and implemented systems to prevent, eliminate or reduce to acceptable levels the hazards associated with the following?
5.6	**Transport and Distribution (Section 10)** **5.6.1** Storage and transport outside specified storage conditions may accelerate the rate of product breakdown such that the stated shelf-life is no longer valid.
5.7	**Sub-contracting (Section 14)** **5.7.1** If a sub contractor does not have adequate premises, equipment, manufacturing technology, testing facility, trained employees with necessary skills and knowledge etc. the risk of product failure increases. The HACCP plan should identify and attempt to minimise these risks by requiring audits and technical agreement etc.
5.8	**Laboratory Testing (Section 15)** **5.8.1** Sampling and testing for small quantities of nutritional ingredients and trace contaminants require additional instruments, validated test methods, systems and skills beyond those required for testing of standard foodstuffs. **5.8.2** HACCP or an equivalent system should address the risks of inaccurate results being obtained and identify the controls to be put in place to ensure that test methods, laboratory systems and analyst competence are acceptable.
5.9	**Change Control (all sections)** **5.9.1** Uncontrolled change to raw materials, raw material suppliers, critical utilities, equipment, process methods, computerised systems, test methods etc. present potential hazards.

SECTION 6: PRODUCT AND PROCESS DEVELOPMENT

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011 **Labelling** **EC Legislation**: Council Directive 2000/13/EC, as amended **National Legislation:** S.I. No. 483 of 200, as amended **Nutrition and Health Claims on Food** **EC Legislation:** Regulation (EC) No 1924/2006, as amended; Council Directive 90/496/EEC, as amended **National Legislation:** S.I. No. 461 of 2009 **Novel Foods & Ingredients** **EC Legislation**: Regulation (EC) No 258/97, as amended **Genetically Modified Foods** **EC Legislation**: Regulation (EC) No 1829/2003, as amended **EC Legislation**: Regulation (EC) No 1830/2003 **Food Contact Materials** **EC Legislation**: Regulation (EC) 1935/2004, as amended **National Legislation:** S.I. No. 587 of 2007, as amended
GMP and Guidance	FSAI Guidance Note No 11 Assessment of HACCP Compliance (Revision 2) FSAI Guidance Note No 18 Validation of Product Shelf-life (Revision 1) FSAI Guidance Note No 21 Food Supplements Regulations and Notifications (Revision 1) FSAI Guidance Note No 23 Development and Assessment of Recognised National Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles FSAI Training Guide – Information on Nutrition and Health Claims; European Federation of EHPM Quality Guide for Food Supplements

Quality Principle

The manufacturer **must** ensure that the finished product consistently complies with the product label and food supplement legislation, e.g. the stated level of folic acid or other vitamin or mineral on the label must be present in the product at the stated level throughout the product life cycle.

"A HACCP study should be applied from the earliest stages of product and process development to eliminate or minimise potential hazards and to aid the incorporation of effective control parameters into the product design. Basic checks need to be made when developing a new product or making changes to an existing product to ensure that the final product complies with current legislation regarding safety and legality and also that it meets consumer expectation within the intended circumstances of use. Testing and inspection procedures should be developed to enable the monitoring of relevant parameters and the application of corrective action should results fall outside specified limits.

Continued attention should to be paid to any changes in legislation to ensure that existing products maintain compliance in all areas of production." EHPM

Sub Section	
6.1	**General** Request the food business operators to explain the system for introducing a new product or making changes to an existing product. How do they ensure that the final product is notified to the regulator and complies with current legislation? The quality system at the food business operator should require: **6.1.1 Change Control** (see Section 2: Quality Management) The proposed change to product or process should be managed through the change control system, so that the proposed change is recorded, impacts of the change can be identified and managed and pre-approval can be obtained before product manufacture. Changes to legislation should also be put through the change control system to ensure that existing products continue to meet the requirements of the revised legislation **6.1.2 Risk Assessment** (see Section 2: Quality Management and Section 5: HACCP) A risk assessment such as HACCP should be conducted and documented to identify hazards and propose plans to eliminate or minimise these by identification of effective control parameters. The checks listed in 6.2-6.8 should be performed and documented when developing a new or changed product or process
6.2	**6.2.1 Legality and safety of ingredients and finished products** The product **must** contain only permitted ingredients. Does the documentation show evidence that **checks were performed on ingredients and finished product** to ensure compliance with safety legislation at the product design stage (if not determine when?) For example, has the following been established: • Only ingredients permitted in food supplements are included, in the permitted forms, below any stated maximum levels in the legislation • Complies with any labelling legislation

- Novel ingredients if present have received official authorisation
- GM ingredients, irradiated or other restricted ingredients comply with legal requirements of the intended market
- Upper (safety) and lower limits for quantities of vitamins, minerals and other supplements in each dosage unit. Upper safety limits for the product should take into account the target population, data from published studies and the tolerable upper intake level (refer to the Scientific Committee on Food of the European Food Safety Authority (EFSA))
- Upper and lower level of preservatives, antioxidants and other permitted, non nutritional ingredients, in the formulation
- Upper limits for chemical and other contaminants, including those specified in food legislation, for ingredients, capsule shells, intermediates and finished products
- Microbiological limits established
- BSE/TSE free certificates for at risk ingredients, e.g. gelatine capsules
- Potential allergens identified and replaced or warnings and control measures developed
- Origin of the ingredients should be risk assessed

6.2.2 Has the food business operator developed the procedures/documentation to control ingredient and product safety during routine manufacture? For example:

- Documented specifications for all ingredients (including water), packaging, intermediate materials and finished products before manufacture to specify the above
- Documented testing and inspection procedures to enable the monitoring of relevant product and process parameters and the application of corrective and preventive actions should process deviations arise or results fall outside specified limits
- Documented procedures and methods to control purchase, receipt, inspection, testing, issue and return of these ingredients in order to maintain product safety
- Instructions, specifications, process parameters and test methods to control the manufacturing and packaging process and ensure safety of finished product
- Procedures to manage deviations and results outside specified limits to ensure that appropriate corrective and preventive actions are put in place

6.3	**Stability of Formula**** **6.3.1** The product **must** meet the label declaration throughout the period of declared shelf-life. How has the food business operator established the shelf-life and assigned expiry/'best-before' dates? The food business operator can establish these by, e.g. • Stability studies should be performed, prior to product being placed on the market, using the actual product in the final pack stored under the conditions stated on the label for the proposed shelf-life (real time studies) or using accelerated (worst case) studies. • The final approved expiry date/'best-before' date should be established based on the results of these studies and should be applied to each batch of product from the date of manufacture (of the bulk formulation). • Have all the required stability parameters been monitored over the proposed shelf life including, organoleptic, chemico-physical and microbial properties, including packaging interactions and reactions between ingredients etc. and verification that claimed levels of ingredient are present at the end of shelf-life? • Has stability in-use been established when the product is repeatedly opened by the consumer, including preservative effectiveness, where appropriate? ****If suppliers or customers have specified shelf-life, the food business operator must have documentary evidence to verify the applied dates**.
6.4	**Legality of Labelling/(labelling compliance)** **6.4.1** Labels **must** bear all the required information in the format mandated by legislation. Statements/warnings **must** be provided, when appropriate, for the presence of GM ingredients, allergens, irradiated ingredients or irradiated product. Is there documentary evidence that these requirements were established? **6.4.2** How does the food business operator plan to control the legality of the label in routine manufacture? • A controlled specification for all printed packaging should be developed for each product. • Documented procedures should be developed to control receipt, inspection, issue, return and destruction of these labels, cartons or other packaging materials.
6.5	**Legality of Claims (claims compliance)** **6.5.1** Proof should be provided that the product meets the minimum levels of ingredients claimed to the end of the shelf-life. How does the food business operator plan to ensure that ingredient dose is in compliance with legislation and is supported by scientific studies? How does food business operator ensure that claims are not misleading and are substantiated by scientific evidence? • Data based on scientific studies and product test results and stability studies

	should be available to prove validity of claims on labels, packaging and advertising materials.
6.6	**Protection/Appropriateness and Legality of Packaging (packaging compliance)** **6.6.1** How did the food business operator select packaging to ensure it provides adequate protection of the product throughout its shelf-life including protection from tampering? How did the food business operator ensure that packaging will not react with the product? • Packaging specification should be in place • Routine inspection and testing of batches of packaging materials received should take place to confirm that packaging meets the legal requirements and specifications.
6.7	**Check can it be made Safely and Consistently (validation)*** **6.7.1** Product **must** meet stated label claims to the end of the shelf-life of the product. How does the food business operator plan to demonstrate compliance with this requirement for every batch produced? • The manufacturing, filling and packing processes must be carefully designed and documented to provide sufficient detail of processing steps and critical process parameters and in-process specifications. • Specifications should state the allowable upper and lower level of each ingredient and the tolerances that are applied by the food business operator. • In order to meet minimum label claims to the end of shelf-life, consideration should be given to the tolerances on raw material and finished product specifications and the ability to meet claims at extremes of the specification ranges. If 'overages' are in use, how has the food business operator established the quantity of overage allowed and ensured that maximum product safety levels will not be exceeded. • Processes should be checked to prove they produce product which meets the label claims. In particular, the homogeneity of mixing steps and the accuracy of filling steps should be checked and sufficient samples should be taken and tested to provide evidence on accurate and uniform dose throughout a batch. • Sufficient process trials must be conducted to confirm that product consistently meets specifications and label claims. Typically, a minimum of 3 trial batches are checked. • Proposed storage conditions and suitability of the pack and seal should be checked for effectiveness. *The term Validation is not used in the EHPM guide but food business operators using a GMP system are likely to use this term (see Glossary).

SECTION 7: MANUFACTURE

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011 **Labelling** **EC Legislation**: Council Directive 2000/13/EC, as amended **National Legislation:** S.I. No. 483 of 2002, as amended **Nutrition and Health Claims on Food** **EC Legislation:** Regulation (EC) No 1924/2006, as amended; Council Directive 90/496/EEC, as amended **National Legislation:** S.I. No. 461 of 2009 **Novel Foods & Ingredients** **EC Legislation**: Regulation (EC) No 258/97, as amended **Genetically Modified Foods** **EC Legislation**: Regulation (EC) No 1829/2003, as amended **EC Legislation**: Regulation (EC) No 1830/2003 **Food Contact Materials** **EC Legislation**: Regulation (EC) 1935/2004, as amended **National Legislation:** S.I. No. 587 of 2007, as amended
GMP and Guidance	FSAI Guidance Note No 10 Product Recall and Traceability (Revision 2) EHPM Quality Guide for Food Supplements

Quality Principle

"The operations and processes used in manufacture should, with the premises, equipment, materials, personnel and services provided, be capable of consistently yielding finished products which conform to their specifications and are suitably protected against contamination or deterioration." EHPM

Testing samples of batches will be insufficient to prove that the batch complies unless the process is proven to work consistently*** and process controls are also in place for each routine batch manufactured.

From the 1st January 2005, the General Food Law Regulation (EC) No 178/2002 has required food business operators to keep records of the suppliers of every lot of ingredient received, as part of the traceability system.

Records **must** be kept available for inspection by the competent authorities for the period required by national legislation. Mandatory requirements on labelling and label claims **must** be met (Directive 2001/13/EC as amended).

***The term process validation is used for this activity by food business operators using a GMP quality management system.

Note 1: Food supplement manufacture necessitates the control of certain additional risks which may not arise in the manufacture of other food stuffs such as:

- Increased risk of mix-ups due to number and variety of ingredients, small dosage units and variety of printed packaging
- Small quantities of ingredients (micronutrients) and small size of dosage units increase the risk of incorrectly formulated product
- Increased risk of cross contamination due to fine dusts and traces of physiologically active materials on equipment, surfaces and personnel
- Blending, filling and packing processes present increased risks as technology and skill is required to ensure accurate consistent doses and correct labelling of the finished product

Sub Section	
7.1	**General** **7.1.1 Product Categories:** Establish the various product categories handled in the manufacturing areas and the potential risk of cross contamination. Are the: design and layout of premises, the flow of people, equipment and materials and operational practices, sufficient to minimise these risks? **7.1.2 Personnel:** Establish if personnel responsible for the manufacturing operations are clearly defined in a document such as an organisation chart and if they have a clear understanding of the process, the risks and their personal responsibilities? Check training of operational personnel (see also Section 4). **7.1.3 Deviation System:** Out of limit conditions, unusual events or failure to follow instructions should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions should be put in place. The responsible manager and the Quality Manager should review and approve these records.

7.2	**Suitability for Production (validation and change control)** **7.2.1 Suitability:** Request evidence that trials were conducted before routine manufacture of each product to ensure that the master manufacturing instructions are correct and consistently yield product within specification. To establish consistency, at least 3 trials should be expected (this evidence may have been requested/provided under Section 6 Product and Process Development) **7.2.2 Change Control:** Establish how proposed changes to materials, equipment or manufacturing methods are controlled. There should be a Change Control system which considers if further trials are necessary prior to introduction of the change. **7.2.3 Continued Suitability:** Ask how continued suitability of the process to meet product specification is demonstrated and what evidence is available that instructions are consistently followed. Routine monitoring of the process by measuring parameters and testing of in-process samples should be taking place with trials repeated at intervals based on risk analysis. Trending of test results and deviations should be used to monitor continued suitability.
7.3	**Documentation (see also Section 11)** **7.3.1** The following documentation should be available and should have been proven, where appropriate, to produce the required result. Instructions should be clear and personnel should be trained in these instructions. Methods of confirming operator understanding and competence should be in place. • Master manufacturing formula and instructions. The master formula should be derived from the product development stage and **must** meet legal requirements (Section 6). • Master Packaging Instructions, as above • Standard Operating Procedures (SOPs) • Lot Batch Manufacturing Records • Lot/Batch Packaging Record. • Log Book providing records of critical equipment etc. • Training Records • Deviation Investigation Records • Labelling: Confirm that all materials, equipment and rooms are clearly labelled with identity and status. Product and materials should be labelled with name, code, strength, lot no., quantity and quality status.

7.4	**Raw Materials and Ingredients** **7.4.1** Suppliers: Establish if procedures are in place for supplier selection, approval and monitoring (see also Section 2.0). **7.4.2** Traceability: Check the system used to ensure that incoming ingredients are identified and best practice would require that the product and its ingredients are traceable through the process to finished product. Records of suppliers of all ingredients **must** be in place. **7.4.3** Quality status: Materials should be quarantined until they pass inspection and testing and are approved for use in manufacture following confirmation that they meet approved specifications. The extent of identity and quality testing should be based on the risk analysis in the HACCP plan. **7.4.4** Segregation: Establish how accidental use of quarantined or rejected material is prevented. **7.4.5** Bulk deliveries: Should be assessed for quality before discharge and should be traceable to source **7.4.6** Storage conditions: Confirm that receipt and storage conditions are adequate for protection, hygiene, temperature, humidity etc. **7.4.7** Materials issue/Stock rotation: Procedures should be in place to ensure the correct material is issued, in a sealed clean container and within expiry date or equivalent, on a 'first in first out' basis. **7.4.8** Dispensing: Determine if the weighing or metering equipment is sufficiently accurate and precise and is calibrated to appropriate tolerances. Dispensing should take place in an appropriate environment to minimise contamination and cross contamination. Second checks should be performed on materials dispensed by second individual or electronically. Check records for traceability. **7.4.9** Addition of ingredients: Check records of the addition of ingredients to the batch and the method of ensuring accuracy. **7.4.10** Yields: Yield variances outside limits stated on manufacturing instruction should be investigated, as deviations, prior to addition to the next stage of manufacture.
7.5	**Packaging Materials** As per general principles above but in addition: **7.5.1** Packaging **must** comply with current EU legislation on packaging and packaging waste **7.5.2** Primary packaging coming into contact with product **must** comply with EU Regulations on Materials and Articles coming into contact with Food. **7.5.3** Finished pack **must** display required statutory information and other required

	information in the required form and location. The presence of allergens, GM materials, irradiated materials etc. **must** be stated. **7.5.4** Packaging should be adequate to protect and identify finished product. **Note:** Above controls may have been established under Section 6 Product Design and Development. **7.5.5** Confirm that printed packaging is held in secure storage with controlled access. **7.5.6** Packaging controls should be in place to prevent packaging mix-ups. For example, the following should be expected: packaging codes linked to current formulations, lot numbers for each delivery, controls on issue, returns and destruction, controls on obsolete packaging and reconciliation of quantities to verify these controls are effective. **7.5.7** Packaging should be protected in storage and shelf-life should be assigned.
7.6	**Processing and Packaging** **7.6.1** Establish what controls are in place to minimise mix-ups and cross contamination between products and packaging. There should be adequate layout, segregation, status labels on rooms, lines and equipment identifying product and batch in process. **7.6.2** Procedures and records should be in place for line clearance, which is the removal from the process area materials, packaging and documentation from the previous batch/product. Is there a record that the area and equipment are checked as 'clean and ready for use' before each operation. **7.6.3** Are checks and records present to confirm the correct equipment and process set-up and that the correct materials and documentation are in place? **7.6.4** Are adequate controls in place to ensure that incorrect packaging and coded packaging with batch number and expiry date could not be used in the packaging operation – line clearance and reconciliation procedures and records? Printed coding such as batch number and expiry date should be carefully controlled at set up and throughout packaging. **7.6.5** Confirm that the process is conducted as per the Manufacturing or Packing Instruction and confirmed by product trials. Records of all process steps, key process parameters, adjustments, in-process sampling and test results should be held and checked by the Quality Department before batch release. In particular, examine the process controls, sampling and testing that ensure uniformity of the bulk material and unit doses. **7.6.6** Confirm calibration status of critical instruments. **7.6.7** Planned and unplanned deviations should be managed through the deviation system. **7.6.8** Check gowning and hygiene practices of personnel are adequate.

	7.6.9 Check the standard of housekeeping is adequate to prevent product mix-up or contamination.
7.7	**Intermediate Products (bulk powders, bulk liquids, bulk tablets or bulk capsules)** **7.7.1** Are intermediates clearly labelled, correctly stored and quarantined until release for the next stage of manufacture. Have maximum hold times been established, supported by stability data? **7.7.2** Determine which manufacturing date is used to establish the product expiry date (regardless of the individual manufacturing dates[1] of the component raw materials when they are put together into a composite food supplements product, a new manufacturing date/expiry date should apply to this new food supplement product.)
7.8	**Finished Products** **7.8.1** Establish with the food business operator how a batch is defined for purposes of sampling, testing and traceability. **7.8.2** Are finished packed products clearly labelled, correctly stored and quarantined until approval by quality control for compliance with specification? **7.8.3** In order to comply with the traceability requirements of the legislation, a system of traceability must be in place **7.8.4** Failure investigation should take place where a product fails to meet specification. **7.8.5** Failed product should be quarantined in secure storage for re-work or rejected and disposed of in accordance with procedures.
7.9	**Disposal of Waste and Effluent** **7.9.1** Check that wastes are disposed of in compliance with regulations.

[1] Manufacturing date should be assigned from the date of the blend/mix of raw materials into a bulk formulation. It could be months before finished product is manufactured from this bulk intermediate material so an extended expiry is being allowed. What have food business operators validated in terms of expiry?

SECTION 8: RECOVERY AND REWORKING OF MATERIALS

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011 **Food Contact Materials** **EC Legislation**: Regulation (EC) 1935/2004, as amended **National Legislation:** S.I. No. 587 of 2007, as amended
GMP and Guidance	EHPM Quality Guide for Food Supplements

Quality Principle

Finished product which contains recovered, reworked or reprocessed material must meet the product specification. Recovery, rework or re-processing have the potential to adversely affect product quality, efficacy and safety and should be performed only using proven* methods pre-approved by the Quality Department. Records of all operations should be held and recovered, reworked or reprocessed material must be fully traceable. Testing samples of batches containing these materials will be insufficient to prove that the batch complies unless proven methods and process controls are in place.

Note 1: Definitions of the terms rework and reprocessing may vary between food business operators (see glossary).

*The term proven implies the use of production trial, i.e. validated rework methods.

Sub Section	
8.1	**Recovered, Reworked and Reprocessed Materials** Recovered, reworked or re-processed material which might adversely affect product quality, efficacy or safety should not be used. Where certain recovered, reworked or reprocessed materials are used, appropriate controls should be in place. Request the procedure which defines the terminology and controls on recovery, rework and reprocessing. This procedure should require: • Asking the food business operator what proof he/she has that rework operations such as re-blending, re-drying etc. yield product that meets specification and does not affect stability Rework operations involving re-labelling or re-packing do not normally require proof of effectiveness but must be tightly controlled to ensure that no packaging mix-ups or quality defects occur • A documented instruction on how to perform the recovery, rework or reprocessing operation, pre-approved by the Quality Manager Procedures should require: • Full traceability of all recovered, reworked or reprocessed materials. • Additional testing where required • That the batch is not released until the original batch from which the material came has been fully tested and approved for release • Where the rework or reprocessing is necessitated by a full or partial batch failure, a full investigation should take place to determine the cause of the failure. Reprocessing to disguise a quality defect should not be allowed. For example, blending a drum of powder with high levels of foreign matter in with a batch of good quality to dilute the level of foreign matter is not acceptable.
8.2	**Returns** Request the Returns SOP. This procedure should require: • Defective finished product returned from the warehouse due to label damage etc. should be reworked (relabelled or repacked) only within the controls described above • Non defective finished product returned from the market should not be issued for resale unless critically assessed by the Quality Department to verify the integrity of the pack and that storage conditions have been maintained. Records of this evaluation should be made • Defective product returned from the market should be securely quarantined pending rejection and destruction

SECTION 9: WAREHOUSING

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011
GMP and Guidance	EHPM Quality Guide for Food Supplements

Quality Principle

The general quality principles for warehousing of foodstuffs apply. Food supplements should be stored under their specified storage conditions or products may not remain stable and meet specification for the stated shelf-life.

Sub Section	
9.1	**Storage Conditions** Storage conditions should be monitored and any deviations outside the stated storage conditions on the product label should be corrected. Storage below a specified temperature is usually stated, typically below 25°c. Some products may require storage above a minimum temperature also. Control of humidity is required for some products. Certain products are more sensitive than others to variations in storage conditions. The following controls should be in place: • Temperature mapping studies of the warehouse (RH where required) to determine the location of any 'hot' and 'cold' spots where continuous monitors should be located to establish worst case conditions • Out of limit conditions, unusual events or failure to follow instructions should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions (CAPAs) should be put in place. The responsible manager and the Quality Manager should review and approve these records. Refer to EHPM 9.1, 9.3 and 9.4

SECTION 10: TRANSPORT AND DISTRIBUTION

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** SI No 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No 344 of 2011
GMP and Guidance	EHPM Quality Guide for Food Supplements

Quality Principle

The general quality principles for transport of foodstuffs apply. Food supplements should be transported under their specified storage conditions or products may not meet specification for the stated shelf-life**.**

Sub Section	
10.1	**Transport Conditions** • The transport routes for individual products should be assessed for ability to ensure that product quality will not be impacted adversely by conditions of temperature, pressure or relative humidity. • Out of limit conditions, unusual events or failure to follow instructions should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions (CAPAs) should be put in place. The responsible manager and the Quality Manager should review and approve these records.

SECTION 11: DOCUMENTATION

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010
GMP and Guidance	FSAI Guidance Note No 10 Product Recall and Traceability (Revision 2) FSAI Guidance Note No 11 Assessment of HACCP Compliance (Revision 2) EHPM Quality Guide for Food Supplements

Quality Principle

"Good and effective documentation is an essential and integral part of Good Practice and a fundamental element of a well designed HACCP system. Its purposes are to define the materials, operations, activities, control measures and products; to record and communicate information needed before, during or after manufacture; to reduce the risk of error arising from oral communication; and to permit investigation and tracing of defective products. The system of documentation should be such that as far as is practicable the history of each lot of product, including utilisation and disposal of raw materials, intermediates and bulk or finished products, may be ascertained and thus traceability maintained." EHPM

Sub Section	
11.1	**General – Good Documentation Practices** **11.1.1** Hard copy documents should comply with the general rules on good documentation practices detailed in EHPM 11.1.The purpose of these controls is to : • Provide clear, accurate instructions, readily available to trained users • Prevent inadvertent use of superseded documents • Have accurate, legible records of activities and prevent these records being falsified

	11.1.2 Electronic records require safeguards as defined in EHPM 11.1 to ensure that data is entered correctly, is backed up and is protected from unauthorised access.
11.2	**Types of Documents** Check that all the required document types are present and comply with the general rules: • Manufacturing formulae and processing and packaging instructions • Specifications • Procedures/Standard Operating Procedures (SOPs) • Records
11.3	**Retention of Documents** Confirm that the retention time for documents is defined and that batch documents are securely stored for at least 1 year beyond the shelf-life of the batch.
11.4	**Classes of Documents** A list of the minimum classes of documents advised is provided in EHPM 11.4

SECTION 12: COMPLAINTS PROCEDURE, PRODUCT RECALL AND EMERGENCY PROCEDURE

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011
GMP and Guidance	FSAI Code of Practice No 5 Food Incidents and Food Alerts FSAI Guidance Note No 10 Product Recall and Traceability (Revision 2) EHPM Quality Guide for Food Supplements

Quality Principle

The food business operator **must** ensure the traceability of the product. The general quality principles for complaints management, recall and emergency procedures for foodstuffs apply. The food business operator **must** have procedures in place to withdraw or recall product in the event of a food safety incident in line with FSAI Guidance Note 10.

Sub Section	
12.1	**General – Complaints & Recalls** Review the complaints and recall systems. • Check food safety of any recalls that have occurred and in terms of investigations conducted to establish root cause and the corrective and preventive actions taken. • Complaints should be trended by product, type, e.g. contamination by foreign matter, incorrect quantity of ingredients, packaging defect etc., by root cause (poor equipment cleaning, supplier issue etc.) and by level of recurrence. Check the complaint summary and trends. • Check the minutes of quality review meetings to determine if these data are presented and the appropriate corrective and preventive actions are taken. • This information should help direct the EHO to areas, products or quality systems which may require closer inspection.

SECTION 13: SELF INSPECTION

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011
GMP and Guidance	EHPM Quality Guide for Food Supplements

Quality Principle

In order to ensure that the Quality/GMP system is working effectively, the food business operator should plan and conduct comprehensive internal audits at regular intervals.

Sub Section	
13.1	**General (internal audits)** Review the self inspection (internal audit procedure). • Check the annual internal audit programme and confirm that audits are being completed to the schedule. • Confirm that audits are conducted by independent and competent personnel, the outcome is recorded and appropriate corrective and preventive actions are implemented. • Check if management review meetings are held at the stated frequency, that all the appropriate quality system outputs are reviewed (complaints, deviations, internal audit findings, etc.) and that records of the required actions are maintained.

SECTION 14: DISTRIBUTORS' OWN BRAND (OWN LABEL) AND OTHER SUB-CONTRACTING

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No. 117 of 2010, as amended by S.I. No. 344 of 2011 **Labelling** **EC Legislation**: Council Directive 2000/13/EC, as amended **National Legislation:** S.I. No. 483 of 200, as amended **Nutrition and Health Claims on Food** **EC Legislation:** Regulation (EC) No 1924/2006, as amended; Council Directive 90/496/EEC, as amended **National Legislation:** S.I. No. 461 of 2009 **Novel Foods & Ingredients** **EC Legislation**: Regulation (EC) No 258/97, as amended **Genetically Modified Foods** **EC Legislation**: Regulation (EC) No 1829/2003, as amended **EC Legislation**: Regulation (EC) No 1830/2003 **Food Contact Materials** **EC Legislation**: Regulation (EC) 1935/2004, as amended **National Legislation:** S.I. No. 587 of 2007, as amended
GMP and Guidance	EHPM Quality Guide for Food Supplements

Quality Principle

Where all or part of a manufacturing or testing activity is contracted out to a third party, it is the responsibility of the contract giver to impose contractual conditions which ensure the product meets specification and is manufactured, packed, stored, distributed or tested to the required quality standards and best practice. It is the responsibility of the contract acceptor to comply with these conditions

Sub Section	
14.1	**General – Contract Activities** Check which activities are contracted out and review the systems in place for control of contracted activities. • A technical agreement should be in place (see 14.2). • Establish if an audit was conducted at the third party site to ensure suitability prior to setting up the technical agreement. Five essential objectives of the suitability audit are detailed in EHPM. • Establish how on-going compliance with the technical agreement is checked– audits, annual product quality review, other data review etc.
14.2	**Technical Agreements** • Check if current technical agreements are in place for contracted activities. • Check if technical agreements adequately define the responsibilities of each party with regard to the 5 essential objectives detailed in EHPM 14.1 and the 5 critical activities defined in EHPM 14.2.

SECTION 15: LABORATORY TESTING

Primary Reference Documents

Legal	**General Food Law** **EC Legislation:** Regulation (EC) No 178/2002, as amended **National Legislation:** S.I. No. 747 of 2007, as amended by S.I. No. 498 of 2010 and S.I. No. 500 of 2011 **Food Supplements** **EC Legislation:** Directive 2002/46/EC, as amended **National Legislation:** S.I. No. 506 of 2007, as amended by S.I. No. 355 of 2010 **Hygiene:** **EC Legislation**: Regulation (EC) No 852/2004, as amended; Regulation (EC) No 2073/2005, as amended **National Legislation:** S.I. No. 369 of 2006, as amended by S.I. No. 380 of 2009 and S.I. No. 497 of 2010 **Official Controls** **EC Legislation**: Regulation (EC) No 882/2004, as amended **National Legislation:** S.I. No.117 of 2010, as amended by S.I. No. 344 of 2011 **Labelling** **EC Legislation**: Council Directive 2000/13/EC, as amended **National Legislation:** S.I. No. 483 of 200, as amended **Nutrition and Health Claims on Food** **EC Legislation:** Regulation (EC) No 1924/2006, as amended; Council Directive 90/496/EEC, as amended **National Legislation:** S.I. No. 461 of 2009 **Novel Foods & Ingredients** **EC Legislation**: Regulation (EC) No 258/97, as amended **Genetically Modified Foods** **EC Legislation**: Regulation (EC) No 1829/2003, as amended **EC Legislation**: Regulation (EC) No 1830/2003 **Food Contact Materials** **EC Legislation**: Regulation (EC) 1935/2004, as amended **National Legislation:** S.I. No. 587 of 2007, as amended
GMP and Guidance	FSAI *Guidance Note No 21 Food Supplements Regulations and Notifications (Revision 1)* FSAI *Guidance Note No 23 Development and Assessment of Recognised National Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles* FSAI *Guidance Note No 26 Guidance for Food Business Operators on the Implementation of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs* FSAI Training Guide – *Information on Nutrition and Health Claims and Food Supplements* EHPM Quality Guide for Food Supplements

Quality Principle

The final product **must** meet all relevant food supplement legislation and meet the label declaration for the shelf-life of the product.

The testing laboratory **must** provide evidence, in the form of valid test results, to support the legal requirements for the product. If the laboratory does not operate an adequate quality/GMP system, test results may be invalid, therefore evidence of product compliance is unreliable.

These controls are necessary in order to protect public health, as too high or too low a dose not only misleads the consumer but could adversely impact on health.

Sub Section	Title
15.1	**In–house or Sub-contract Testing (see also 14.1 and 14.2)** Determine if the food business operator conducts all testing within their own laboratory or uses the services of a contract laboratory for all or some tests. How does the food business operator determine that valid results are obtained from the subcontract laboratory? • The contract giver should have a documented system for determining the suitability of the contract accepting laboratory. The sub contract laboratory should ideally be accredited for the contracted test but at the very least have a quality/GMP system suitable for the testing of food supplements. The contract giver should audit the contract acceptor to verify testing standards, especially if the laboratory is not accredited for the test. • A technical agreement should be in place defining responsibilities of the contract giver and contract acceptor in relation to testing, reporting deviations and out of specification results.
15.2	**Laboratory Accreditation** Accreditation provides additional independent assurance about the validity of test results. Determine if the food business operator laboratory and any contract laboratories have a registered QMS in place, such as ISO 17025. Does the scope of that accreditation include the relevant tests. What is the 'Measurement Uncertainty' of the test results?
15.3	**Specifications** Specifications should have been established during product and process development (Section 6). It is important to cross check specifications originally developed against those currently in place for routine testing.
15.4	**Good Laboratory Practices** In order to ensure that test results are valid, good laboratory practices should be implemented (refer to Section 15 EHPM for details).

15.5	**Food Business Sampling** **15.5.1** Has the food business operator got a suitable sampling plan in place for ingredients, packaging, water, environment, intermediate materials and finished product? **15.5.2** Is the sampling plan representative and adequate? Establish where samples are taken and how many are taken. For example, taking samples from the bulk intermediate and none from the filled units (tablets, capsules, bottles of liquid etc.) will be insufficient to prove label claim. Taking samples from both locations but with insufficient numbers may not provide sufficient evidence of homogeneity. Taking samples from the start of the fill but not during the fill or at the end will not be representative of the full batch. **15.5.3** There should be written procedures to describe sampling methods and minimise sample and material contamination or mix-up. **15.5.4** Retain samples of finished product should be held for all batches and stored appropriately for the full shelf-life of product on the market plus 1 year.
15.6	**Test Method Validation** **15.6.1** Samples should be analysed according to written procedures/test methods. **15.6.2** Test methods should be validated for the required sample matrix. A validation report should be available and retained. If the test method has not been validated it may not yield valid results. **15.6.3** Check validation of laboratory test methods for selected products and ingredient(s).

15.7	**15.7.1 Inspection and testing all materials** • Inspection and testing should be conducted on sufficient samples of the following to verify the legality and safety of the finished product and claims on certificates of analysis: o Ingredients and packaging o Intermediates o Finished product –release testing o Finished product –stability testing • Request test results and certificates of analysis (Certificate of Analysis (COA)) for selected ingredients, packaging, water and environmental samples, bulk intermediate materials and finished product batches. Check that certificates are not Certificates of Conformance only. **15.7.2 Testing of environmental samples** • Regular sampling and testing of water systems and air and surface samples should be conducted particularly when used in process by the food business operator. Alert and action limits should be set and deviation records should be raised as described below. **15.7.3 Finished product testing** • Confirm that test results for finished product are based on samples of the finished product and not extrapolated from the bulk materials test results, i.e. tablet not bulk powder. Confirm that test results provide evidence that specifications, label claims and legal requirements have been met. If test result at release is at or near upper or lower limit of specification, has allowance been made for test method measurement uncertainty? If test result is at or near lower specification limit, request evidence that result at expiry date will still meet label claim. • Determine how sample results are averaged to determine the result reported. For example, if 20 tablets are tested from each sample, what result is reported on final test certificate. Check raw data to confirm that all test results averaged fall between upper and lower specification limits before being averaged. Averaging results which are outside specification with results within specification will hide the true variability in the finished product dosage and will not provide sufficient evidence to support the label claim. • Check labels, packaging and advertising materials for claims and request the test evidence that supports these claims. **15.7.4 Deviations** • Out of limit conditions, unusual events or failure to follow instructions in laboratory testing should be recorded as deviations, investigated for product impact and for root cause and the appropriate corrective and preventive actions should be put in place. The responsible manager and the Quality Manager should review and approve these records. • Samples from wholesalers, retail outlets etc. should be accompanied by the COA for that batch/lot. Other items as described above may not be available.

15.8	**Stability and Shelf-life (see Section 6.3)** • Confirm if shelf-life and storage conditions are established using scientifically sound methods. • Request stability data and storage conditions for selected product(s). • Do stability data support the label expiry/'best-before' date? Confirm that contents for each ingredient meet the label claim to the end of the shelf-life. • Confirm that all other stability parameters, e.g. pH, viscosity, interactions with packaging, have been demonstrated to conform to end of shelf-life. • Ensure shelf-life and stability are considered by the food business operator in the event of products changes, reformulations etc.
15.9	**Handling out of Specification Results** • Out of specification (OOS) and out of trend (OOT) results in finished product testing or stability testing should be investigated. • There should be a written procedure on actions to be taken to determine if the out of specification result is due to laboratory error or manufacturing error. Laboratory error cannot be assumed. • Retesting should be justified and limited. • Re-sampling should be rare and based on scientific justification. • Failing results should never be discarded. • The possibility of manufacturing error or variance should be investigated before release decisions are made.
15.10	**Product Approval and Release** • Each batch of product, as defined by the food business operator, should be tested and formally released by a person in the Quality Department with the appropriate level of authority and responsibility. • A signed release document, such as a certificate of analysis (COA), should be available confirming that each batch of product released meets legal requirements and specifications, that manufacturing and testing documentation has been reviewed and any deviations or out of specification results have been investigated for potential impacts on product safety or quality.

See also Appendix 1: Glossary and Appendix 2: Sample of Certificates of Analysis

APPENDIX 1: GLOSSARY

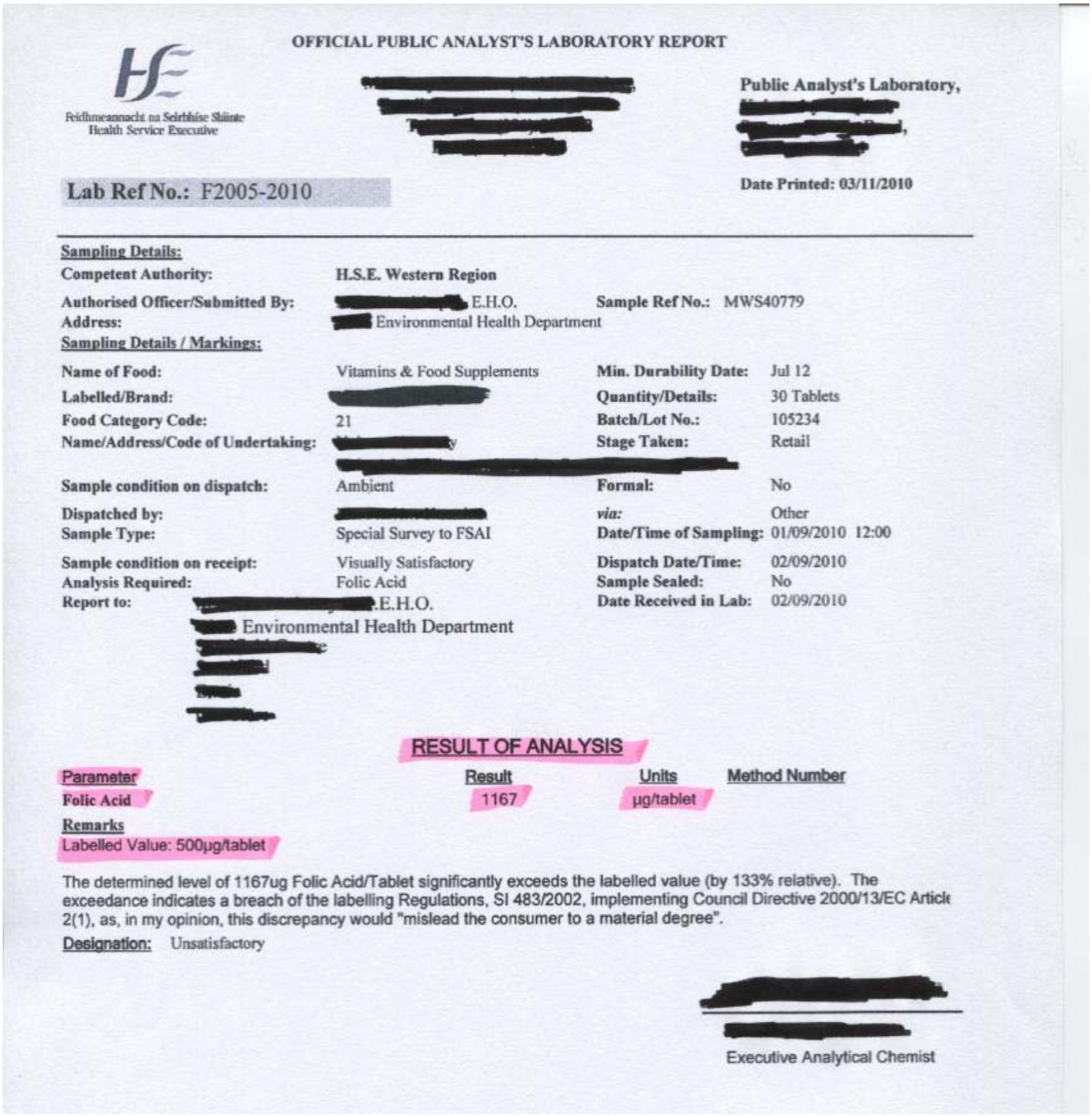
Batch	A defined quantity of starting material, packaging material or product, processed in one process or series of processes so that it could be expected to be homogenous.
Corrective and preventive actions (CAPAs)	Actions taken to correct the current cause and outcome of a problem arising from a quality system and to prevent recurrence of the problem in the future.
Certificate of Analysis (COA)	A Certificate of Analysis is a document issued and signed by a responsible individual in the Quality Department which confirms that a named batch or lot number of material has been appropriately tested and meets the specification. The specification range is stated and the actual test results for each specification parameter is recorded and checked to verify that it conforms to the specification.
Certificate of Conformance	A Certificate of Conformance is a generic statement that a typical batch of product meets the stated specification. It does not provide evidence of the test results of a specific batch or lot number of product.
Dispensing	Dispensing is a controlled process used to check ingredients against the manufacturing formula, weigh ingredients accurately on suitable, calibrated weighing equipment and dispense them into clean containers, labelled with all the required information.
Dosage Forms	Dosage forms are the units in which the final product is administered to the body. Food supplements use oral dosage forms such as tablets, capsules, liquids, powders etc.
EHPM	European Federation of Associations of Health Product Manufacturers Quality Guide for Food Supplements
Food Business Operator	*"The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control"* GN21 FSAI
Food Supplement	*"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."* EU Directive 2002/46/EC
Formula (Formulation)	The formula is the list of ingredients to be added to the bulk batch in order to achieve the required quantity of ingredient in the final dosage unit. The formula states the name, grade, code and quantity of the ingredient to be added. The term 'bill of material' may also be used.
Good Manufacturing	GMP is that part of the Quality Management System which ensures that

Practices (GMP)	products are consistently produced and controlled to the quality standard appropriate to their intended use and as required by the product specification.
Homogeneity	Homogeneity is the required outcome of a mixing or filling process and means that all ingredients of the formula are evenly distributed in the bulk products and in the final dosage form. The term uniformity is also used.
Intermediate Products	Products from a manufacturing process which are stored as intermediates awaiting the final stage of manufacture and packaging to produce the finished product such **as** bulk powders, bulk liquids, bulk tablets or bulk capsules. Intermediates are usually held in drums or other bulk containers up to a maximum validated time under those storage conditions.
Measurement Uncertainty (MU)	*"Measurement uncertainty is an estimate attached to a measurement which characterises the range of values within which the true value is asserted to lie."* (ISO/DIN 3534-1). Every test result has an uncertainty associated with it due to the variability inherent in any sampling and test method even when tightly controlled by good laboratory practices. It is usually expressed as a standard deviation or multiple of standard deviation. The true result can only be stated with a confidence level (usually 95%) to be the reported result +/- the measurement uncertainty.
Medicinal product	*"(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"* GN21 FSAI.
Out of Limit Result	A value outside the limits set for operation of a utility or piece of equipment or for environmental monitoring of air or water.
Out of Specification Result (OOS)	A result outside the specification range for a material or process.
Out of Trend Result	A result within specification but at the high or low end of the specification compared to historical data for previous batches or a stability result at a particular time point out of trend with results at other time points.
Overage	An overage is the term used by some manufacturers to describe the additional quantity of an ingredient added to a process above that necessary to achieve the required dose in the finished product dosage form. The practice of using an overage should be scientifically justified and should not result in a consumer exceeding the tolerable upper intake level for a specified food supplement ingredient.
Qualification (utilities & equipment)	Qualification is a process whereby utilities and equipment are proven to achieve the specified operating parameters (validation). Qualification

	involves a series of qualification steps: Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).
Quality Assurance	Quality assurance is that part of the Quality Management System which ensures that *" processes are defined which, when followed, will yield product that complies with its specification and the quality expected" EHPM*
Quality by Design (QbD)	The principle of designing quality into a product from the earliest stage of development by using quality risk management to identify risks and building in procedures to either prevent risks or to minimise and control risks. In this document, Section 6 is consistent with this approach.
Quality Control	Quality control is that part of the Quality Management System which is concerned with sampling, specifications and testing and with the organisation, documentation and release procedures which ensure that the necessary tests are carried out and the materials are not released for use, nor products released for sale or supply until their quality is deemed satisfactory.
Quality Management System (QMS)	*"Co-ordinated activities to direct and control an organisation with regard to quality" ISO* standards. *"A comprehensive system so designed, documented, implemented and controlled, and so furnished with personnel, equipment and other resources as to provide assurance that products will be consistently fit for their intended use. The attainment of this quality objective requires the involvement and commitment of all concerned, at all stages of manufacture, storage and distribution. The concept of 'quality by design' is important for quality management. This means that the product should be designed and developed in a way that takes into account all the essential quality requirements. The quality objective shall be achieved by an integrated system including Quality Assurance, Quality Control and Good Practice. "* EHPM
Recovered Material	Leftover material recovered from manufacturing equipment, such as dry powder recovered from a dryer following a granulation and drying operation. The powder is usually recovered after the batch itself has been discharged into containers. Recovered material may or may not meet specification.
Relative Humidity	Relative humidity is the concentration of moisture in the atmosphere surrounding a food product whether packaged or not. It is calculated as a percentage of the humidity required to completely saturate the atmosphere, i.e. saturation humidity. Typically, there will be an exchange of moisture between a food and its atmosphere which continues until the food reaches equilibrium with the surrounding atmosphere.
Re-processing	*"Using, in the manufacture of a food supplement, clean, uncontaminated, materials or product that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a food*

	supplement." (EHPM)
Re-work	*"Action on a non conforming product to make it conform to requirements".(*EHPM)
Specification	*"A document giving the description of a starting material, intermediate, bulk or finished product in terms of its chemical, physical and (if any) biological characteristics. A specification describes in detail the requirements with which the products or materials used or obtained during manufacture have to conform and normally includes descriptive clauses and numerical clauses, stating standards and permitted tolerances. It serves as a basis for quality evaluation."* EHPM
Test Method Validation	The process of proving that a method is suitable for the test parameter being measured and produces accurate and reliable test results. At a minimum, the following parameters of the method should be proven - specificity/selectivity, recovery, precision, linearity and range, accuracy and Limit of Detection (LOD)/Limit of Quantitation (LOQ).
Tolerance	When establishing a specification for the assay values of ingredients at the product release stage and at the end of shelf-life, manufacturers usually build in a tolerance due to the variation of the process and to the method uncertainty. The specification will therefore be stated as a range with an upper and lower limit. The manufacturing process will be designed to produce to the label claim (target) value but product can be released once it falls within the specification range. There are restrictions on the tolerances that can be set. For example the upper specification level cannot cause a consumer to exceed the tolerable upper intake level.
Tolerable Upper Intake Level	*"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"* GN21
Validation	*"Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled."* EHPM
Yield	The quantity of material produced by the manufacturing process is the yield. For example, the weight of powder from a blender, the number of bulk tablets or finished packs. The theoretical yield should be stated for each process on the manufacturing instruction. If the actual yield varies significantly from the theoretical yield, it should be investigated through the deviation system.

APPENDIX 2: SAMPLE PUBLIC ANALYST LABORATORY CERTIFICATE CHECK



OFFICIAL PUBLIC ANALYST'S LABORATORY REPORT

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

[redacted]

Public Analyst's Laboratory,
[redacted]

Lab Ref No.: F2005-2010

Date Printed: 03/11/2010

Sampling Details:

Competent Authority:	H.S.E. Western Region		
Authorised Officer/Submitted By:	[redacted] E.H.O.	**Sample Ref No.:**	MWS40779
Address:	[redacted] Environmental Health Department		
Sampling Details / Markings:			
Name of Food:	Vitamins & Food Supplements	**Min. Durability Date:**	Jul 12
Labelled/Brand:	[redacted]	**Quantity/Details:**	30 Tablets
Food Category Code:	21	**Batch/Lot No.:**	105234
Name/Address/Code of Undertaking:	[redacted]	**Stage Taken:**	Retail
Sample condition on dispatch:	Ambient	**Formal:**	No
Dispatched by:	[redacted]	***via:***	Other
Sample Type:	Special Survey to FSAI	**Date/Time of Sampling:**	01/09/2010 12:00
Sample condition on receipt:	Visually Satisfactory	**Dispatch Date/Time:**	02/09/2010
Analysis Required:	Folic Acid	**Sample Sealed:**	No
Report to:	[redacted] E.H.O. Environmental Health Department	**Date Received in Lab:**	02/09/2010

RESULT OF ANALYSIS

Parameter	Result	Units	Method Number
Folic Acid	1167	µg/tablet	

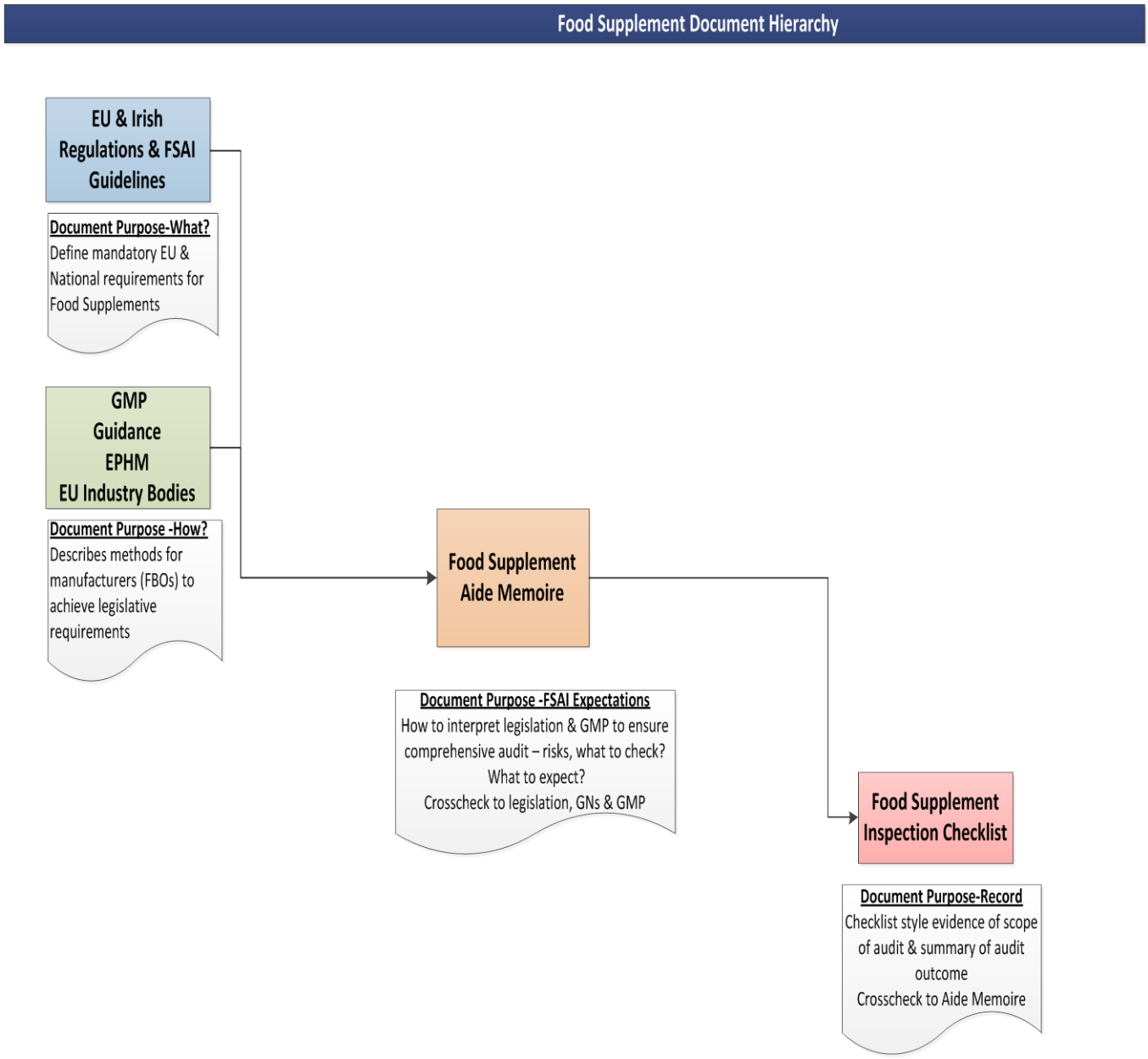
Remarks
Labelled Value: 500µg/tablet

The determined level of 1167ug Folic Acid/Tablet significantly exceeds the labelled value (by 133% relative). The exceedance indicates a breach of the labelling Regulations, SI 483/2002, implementing Council Directive 2000/13/EC Article 2(1), as, in my opinion, this discrepancy would "mislead the consumer to a material degree".

Designation: Unsatisfactory

[redacted]
Executive Analytical Chemist

APPENDIX 3: FOOD SUPPLEMENT DOCUMENT HIERARCHY



APPENDIX 4: FOOD SUPPLEMENTS LIST OF PRIMARY REFERENCE LEGISLATION AND GUIDELINES

Scope

The legislation and guidelines referenced in the FSAI Inspection Audit Aide Memoire for Food Supplements (Revision 0) are listed below. New legislation or guidelines or revisions to existing legislation & guidelines will require review and possible revision of the Aide Memoire.

General Food Law		
EU	**National**	**Guidance**
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 General Food Law Amended by: S.I. No. 498 of 2010 S.I. No. 500 of 2011	GN No. 1 Rev 2 Guidance for the Health Service Executive on the Inspection of Food Businesses (2011) GN No. 2 EU Classification of Food (2001) GN No. 10 Rev 2 Product Recall and Traceability (Jun 2010) GN No. 12 Rev 1 The Inspection of Food Safety Training and Competence (Sep 2007) GN No. 13 Use of Enforcement Powers under the Food Safety Authority of Ireland Act 1998 (April 2003) Code of Practice No 5 – Food Incidents and Food Alerts EC Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 ISO 22000:2005: Food Safety Management Systems

Food Supplements		
EU	**National**	**Guidance**
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	European Communities (Food Supplements) Regulations S.I. No. 506 of 2007	GN No. 21 Rev 1 May 2010 Food Supplements Regulation and Notifications European Federation of Associations of Health Product Manufacturers (EHPM) Quality Guide for Food Supplements 2007 International Alliance of Dietary/ Food Supplement Associations (IADSA) Global Guide to GMP for Supplements 2011
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		
Regulation 1170/2009/EC of 30 November 2009 amending Directive 2002/46/EC and regulation 1925/2006 as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements	European Communities (Food Supplements) (Amendment) Regulations, 2010 S.I. No. 355/2010	
Commission **Regulation (EU) No 1161/2011** of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods Text with EEA relevance	Not yet been given effect by an S.I.	

Hygiene of Foodstuffs		
EU	**National**	**Guidance**
Regulation (EC) 852/2004 (as amended) of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (Particularly Annex 2)	Transposed into Irish legislation by S.I. No. 369 of 2006 Amended by: S.I. No. 380 of 2009 S.I. No. 497 of 2010	GN No.11 Rev 2 Assessment of HACCP compliance (Apr 2007) GN No. 23 Development & Assessment of Recognised National Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles (Apr 2007) EC Guidance Document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses EC Guidance Document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs NSAI I.S. 341: 2007: Hygiene in Food Retailing/Wholesaling ISO 22000:2005: Food Safety Management Systems
Regulation (EC) No **2073/2005** Microbiological Criteria for Food Stuffs, as amended	Not yet been given effect by an S.I.	GN No. 26 Guidance for Food Business Operators on the Implementation of Commission Regulation (EC) No 2073/2005 Microbiological Criteria for Foodstuffs, as amended

General Labelling Provisions for Foodstuffs		
EU	**National**	**Guidance**
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 Amended by: Commission Directive 2001/101/EC Commission Directive 2002/86/EC Directive 2003/89/EC Commission Directive 2006/142/EC Commission Directive 2007/68/EC Regulation (EC) No 1332/2008 Regulation (EC) No 1334/2008 Regulation (EC) No 596/2009 Commission Directive 2005/26/EC	Transposed into Irish legislation by S.I. No 483 of 2002 S.I. No. 257 of 2003 S.I. No. 451 of 2003 S.I. No. 528 of 2003 S.I. No. 228 of 2005 S.I. No. 514 of 2005 S.I. No. 647 of 2005 S.I. No. 376 of 2007 S.I. No. 808 of 2007 S.I. No. 424 of 2008 S.I. No. 61 of 2009	
RDA for vitamins and minerals from Commission Directive 2008/100/EC (effective Nov 2009) RDA for vitamins and minerals from Council Directive 90/496/EC RDA (applicable until Oct 2012)		
Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs Amended by: **Commission Directive 2003/120/EC** and **Commission Directive 2008/100/EC**	Transposed into Irish legislation by S.I. No. 461 of 2009	
Regulation (EC) No 1829/2003 (as amended) of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed **Regulation (EC) No 1830/2003**		

Nutrition and Health Claims on Food		
EU	**National**	**Guidance**
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 Amended by: Regulation (EC) No 107/2008, Regulation (EC) No 109/2008 and Regulation (EU) No 116/2010		FSAI Training Guide 2010 - Information on Nutritional & Health Claims EU Commission Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods
Novel Foods & Ingredients		
EU	**National**	**Guidance**
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 Amended by: Regulation (EC) No 1829/2003 Regulation (EC) No 1882/2003 Regulation (EC) No 1332/2008		
Food Contact Materials (Materials And Articles Intended To Come Into Contact With Foodstuffs)		
EU	**National**	**Guidance**
Regulation (EC) 1935/2004, as amended of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food Amended by: Commission Regulation (EC) No 2023/2006 Commission Regulation (EC) No 282/2008 Regulation (EC) No 596/2009	S.I. No. 587 of 2007, as amended	
Official Control of Foodstuffs		
EU	**National**	**Guidance**
Regulation (EC) No 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 as amended	Transposed into Irish legislation by S.I. No. 117 of 2010 S.I. No. 344 of 2011 For HSE supervised establishments	Guidance on Interpretation of S.I. No. 117 of 2010 Guidance on Interpretation of S.I. No. 344 of 2011 (to be completed)

APPENDIX 5: USEFUL LINKS

FSAI Website: Food Supplements
http://www.fsai.ie/science_and_health/food_supplements.html

FSAI Website: Nutrition and Health Claims on Food
http://www.fsai.ie/legislation/food_legislation/labelling_presentation_advertising_foodstuffs/health_nutrition_claims.html

EFSA website: Tolerable Upper Intake Levels for Vitamins and Minerals
http://www.efsa.europa.eu/en/ndatopics/docs/ndatolerableuil.pdf

Commission Website: EU Register of nutrition and health claims made on foods
http://ec.europa.eu/nuhclaims/

Note regarding food supplements making a medicinal claim
Products which make a medicinal claim or which contain levels of vitamin or minerals which exceed those restricted in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540/2003) as amended fall under the definition of medicinal products and require a marketing authorisation from the IMB before being placed on the market in Ireland. Some manufacturers may apply to the IMB for a product licence for their food supplement. If granted, the product is then considered a medicine, and will have a licence number (PA number) on the packaging. Licensed products, i.e. medicines, and their manufacture are supervised by the IMB.

For further information please contact the FSAI on notifications@fsai.ie.

Note regarding permitted ingredients (from 1.2 permitted Ingredients – page 5)
There is no information on 'permitted ingredients at permitted levels' in the case of food supplements, i.e. there is no definitive list of 'permitted ingredients'. However, there are 3 lists that may be useful to refer to:

1. The vitamins and minerals allowed in food supplements, the units that they must be declared in and the chemical forms of these vitamins and minerals that are acceptable in food supplements (as in Annex I and II of Directive 2002/46/EC) http://www.fsai.ie/uploadedFiles/Cor_Reg1924_2006.pdf

2. Six vitamins have cut-off levels called 'Prescription only medicine or POM' levels as set out in S.I. No. 540 of 2003 and food supplements should not contain levels in excess of these POM levels. http://www.fsai.ie/uploadedFiles/SI_540_2007.pdf

3. The FSAI maintains a **current** list of substances which are checked for in notified food supplements and if present, the product is referred over to the IMB. This list is subject to change on an ongoing basis (usually things are only added not removed). To enquire about substances on this list, please contact the FSAI on notifications@fsai.ie.

The additives that are permitted in food supplements are listed in Regulation 1333/2008/EC (as amended). The additives permitted in food supplements are given in food category 17 of the attached Regulation. This is all of additives that are currently permitted in Directives 94/35/EC on sweeteners, 94/36/EC on colours and 95/2/EC on miscellaneous additives all now in one Regulation. This Regulation comes into force in June 2013. Category 17 covers food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children. Additives in supplements are divided into 3 further subcategories (Regulation 1333/2008/EC Annex II Part D Food Categories), i.e.

- 17.1 Food supplements supplied in solid form including capsules and tablets and similar forms, excluding chewable forms
- 17.2 Food supplements supplied in liquid form
- 17.3 Food supplements supplied in a syrup-type or chewable form

Discussions are ongoing at EU level regarding additives in food supplements for infants and young children. It is likely that a category for food supplements for children and additives permitted in them will be developed.