

EU LEGAL REQUIREMENTS FOR IMPORTS OF FRUITS AND VEGETABLES (A SUPPLIERS GUIDE)



Andrew Graffham

Fresh Insights no. 1, Report series for www.agrifoodstandards.org.

This publication was funded by the Department for International Development (DFID) of the Government of the United Kingdom as part of a project entitled “Small-scale producers and standards in agrifood supply chains: Phase 2, 2005-2008 (**AG3815**)”. However, the views expressed may not necessarily reflect that of official DFID and UK Government policy.

Citation: Graffham, A. (2006). EU legal requirements for imports of fruits and vegetables (a suppliers guide). *Fresh Insights* no. 1, DFID/IIED/NRI, www.agrifoodstandards.org.

Corresponding author: Andrew Graffham, Natural Resources Institute, UK. A.j.Graffham@greenwich.ac.uk.

CONTENTS	
Contents	i
List of tables	iii
Glossary	iv
Definitions	v
Acknowledgement	vi
Summary	1
SECTION 1: INTRODUCTION AND BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS FOR GLOBAL TRADE IN FRESH FRUITS AND VEGETABLES	2
1.1 Scope of the guide	2
1.2 How to use this guide	2
1.3 Food safety as a driver for change in global trade	2
1.4 Harmonisation of international law under WTO	3
1.5 Harmonisation of EU regulatory requirements	3
1.6 Who is responsible for ensuring food safety?	4
1.7 EU market requirements – wholesale versus retail	4
SECTION 2: MINIMUM LEGAL REQUIREMENTS FOR EXPORT OF FRESH FRUITS AND VEGETABLES TO THE EU	5
2.0 Does EU food law apply to food businesses outside the borders of the EU?	5
SANITARY AND PHYTOSANITARY (SPS) MEASURES	5
2.1 Comparison of import controls for products of non-animal and animal origin	5
2.2 Vertical traceability (EC/178/2002)	6
2.3 Hygiene rules for foods of non-animal origin (EC/852/2004)	8
Summary of hygiene requirements for primary production of fresh fruits and vegetables as specified under Annex IA of EC/852/2004	9
Summary of hygiene requirements for minimally processed (fresh or pre-cut) fruits and vegetables as specified under Annex II of EC/852/2004	10

2.4 Microbiological criteria for foodstuffs (EC/2073/2005)	13
2.5 Safe and effective use of pesticides	15
2.5.1 Pesticides banned in the EU (Directive 79/117/EEC)	15
2.5.2 Pesticides approved for use within the EU (Directive 91/414/EEC)	16
2.5.3 Harmonised MRL's for pesticides (EC/396/2005)	17
2.6 Chemical contaminants in food (EC/466/2001)	19
2.7 Phytosanitary measures (Directive 2000/29/EC)	20
2.8 Wood packaging (Directive 2004/102/EC)	21
2.9 Special restrictions on import of food of non animal origin (EC/882/2004)	21
TECHNICAL BARRIERS TO TRADE (TBT) MEASURES	22
2.10 Market grade standards (EC/2200/1996 & EC/1148/2001)	23
2.11 Organic production (EC/2092/91 & EC/1788/2001)	25
SECTION 3: EU FRUIT AND VEGETABLE IMPORT REQUIREMENTS AT A GLANCE	26
3.1 Minimum legal requirements for export to EU markets applicable to all shipments of fresh fruits and vegetables	27
3.2 Additional requirements applicable to fresh-cut (minimally processed) fruits and vegetables	36
3.3 Additional requirements applicable for commodities covered by market grade standards as defined under EC/2200/1996	37
3.4 Additional requirements applicable for organic fruits and vegetables as defined under Regulations EC/2092/91 & EC/1788/2001	38
REFERENCES	39
EU Regulations	39
UK Regulations	40
EU Directives	40
EU Commission Decisions	41
EU Commission Communications & White papers	41
Guidance on interpretation of EU food law	41
USEFUL WEBSITES	42

LIST OF TABLES

Table 1. Comparison of EU import controls for products of animal and non-animal origin	7
Table 2. Food safety and process hygiene criteria for ready to eat sprouted seeds and fresh-cut fruits and vegetables as specified under EC/2073/2005	14
Table 3. List of pesticides banned under directive 79/117/EEC	16
Table 4. Maximum residue levels for chemical contaminants in food as defined under EC/466/2001	19
Table 5. List of products of non-animal origin subject to market grade standards under EC/2200/1996	24
List of tables given as sub-sections of section 3:	
Table 3.1. Minimum legal requirements for export to EU markets applicable to all shipments of fresh fruits and vegetables	27
Table 3.2. Additional requirements applicable to fresh-cut (minimally processed) fruits and vegetables	36
Table 3.3. Additional requirements applicable for commodities covered by market grade standards as defined under EC/2200/1996	37
Table 3.4. Additional requirements applicable for organic fruits and vegetables as defined under Regulations EC/2092/91 & EC/1788/2001	38

GLOSSARY

BRC	British Retail Consortium
CAC	Codex Alimentarius Commission
CFU	Colony Forming Unit
DGSANCO	Directorate General for Health and Consumer Protection
EC	European Commission
EU	European Union
EUREPGAP	European Retailers Protocol for Good Agricultural Practice
FAO	Food and Agriculture Organisation
FHD	First Harvestable Date
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GATT	General Agreement on Tariffs and Trade
GHP	Good Hygienic Practice
HACCP	Hazard Analysis Critical Control Point
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
LOD	Limit of Detection
MDF	Medium Density Fibreboard
MRL	Maximum Residue Limit
NPPA	National Plant Protection Authority
NRI	Natural Resources Institute
PHI	Pre Harvest Interval
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
UK	United Kingdom
WHO	World Health Organisation
WTO	World Trade Organisation

DEFINITIONS

Primary production – means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

Post-harvest processing – refers to any procedure carried out on fruits or vegetables after harvesting (other than simple sorting and grading), this would include processes such as washing, trimming and cutting.

Food of non-animal origin – refers to fruits, vegetables, cereals, roots, tubers, nuts, edible fungi, drinks prepared from fruit or vegetable products, spices, condiments and food of mineral origin such as salt.

Food of animal origin – includes all forms of meat, fish, shellfish, gastropods, crustacea, milk and any products prepared from these foods.

Vertical legislation – refers to legislation that deals with specific products, currently the EU has 9 vertical Directives dealing with cocoa, chocolate, sugars, milk products, honey, fruit juices and fruit jams.

Horizontal legislation – refers to legislation on issues that are common to all foodstuffs such as hygiene, labelling, additives and chemical residues.

EU Regulation – the text of the law must be applied directly by all EU member states without changing requirements or criteria.

EU Directive – the text of the law must be interpreted and incorporated into national law by each member state, this allows member states flexibility to make changes to criteria such as setting national tolerances for chemical contaminants rather than using values given in the EU Directive.

EU Decision – a commission decision is a specific time limited measure for additional official controls, and is normally made in response to recognition of a risk to human, plant or animal health via an existing or emerging risk.

EU Communication – communications have no legal validity but serve for the EU to give opinions, guidance or indications of policy.

Sanitary and Phytosanitary (SPS) measures – refers to all measures intended to protect human, animal or plant health.

Technical Barriers to Trade (TBT) measures – refers to non-health related measures such as marking, labelling, packaging, market grade standards and conformity assessments to EU standards.

Due diligence defence – is a legal defence whereby the EU food business (importer or retailer) is able to demonstrate in court that they have taken all reasonable precautions and exercised due diligence in trying to avoid breaking the legal requirements. This defence is important for EU food businesses in terms of determining negligence and responsibility for insurance purposes. Fully documented food safety management systems with evidence of compliance in the form of detailed records and independent verification form a strong due diligence defence hence the interest by EU importers and retailers in private assurance schemes such as EUREPGAP and the BRC global technical standard.

Precautionary principle – Sanitary and phytosanitary measures are intended to be based on sound scientific evidence, however in emergencies it may not be possible to wait for scientific evidence to be available. In these cases the EU invokes the precautionary principle whereby immediate action can be taken in the absence of scientific evidence and justified at a later date when the evidence becomes available.

Traceability – refers to the ability to trace and follow a food or substance intended to be incorporated into a food through all stages of production, processing and distribution. In practice this means a system of record keeping and documentation by food businesses to enable tracing or tracking of the movement of a product or ingredient through every stage of the food chain.

Vertical traceability – refers to the ability to trace movement of food at different stages of the market chain. A good traceability system will allow food purchased by the final consumer to be traced back to an individual field, plot, orchard or block on the farm where it was grown. The minimum legal requirement for vertical traceability in the EU is the so called “one up one down principle” whereby the importer must know who they have sold food too, but also know the country of origin and name and address of their supplier.

Horizontal traceability – refers to the ability to trace all the inputs made to production and processing of the food. If accurate records are maintained that identify food from planting through to export with unique code numbers it will be possible to trace details of who worked on the crop, fertiliser, water and pesticide inputs, soil history and origin of planting material. In post-harvest processing, the identity of persons who handled the food will be traceable as will details of any washing, trimming, cutting, refrigeration, storage and transport.

Third country supplier – refers to any producer, processor or exporter in a country outside of the EU who wishes to supply foodstuffs or food ingredients to EU markets.

SUMMARY

International marketing of fruits and vegetables to fulfil demand for exotic and out of season products offers a lucrative marketing opportunity for growers, and the market opportunities offered by the European Union are some of the most financially attractive. However, accessing EU markets requires compliance with a strict regulatory framework of measures designed to ensure human and plant health within the EU that sometimes go beyond the international requirements set under the SPS and TBT agreements administered by the World Trading Organisation.

European law is not extra-territorial and thus cannot be said to apply directly to any country or business outside of the EU. However, EU importers and retailers must comply with the law and hence will specify legal minima as market requirements that the third country supplier must comply with in order to export food to EU markets. Although the legislation represents the minimum for market access, many of the larger retailers and some wholesalers require suppliers to demonstrate compliance with independently verifiable private standards such as the European Retailers Protocol for Good Agricultural Practice (EUREPGAP) and the British Retail Consortiums (BRC) Global Technical Standard as this is an effective way of verifying that suppliers have the necessary management and control systems in place.

EU LEGAL MINIMA FOR IMPORT OF FRESH FRUITS AND VEGETABLES

All consignments must comply with these criteria:

- Each consignment must be accompanied by a phytosanitary (plant health) certificate
- Labelling of consignment must state country of origin, name and contact details of exporter, name of the product and date of the transaction
- Suppliers must demonstrate on demand that they comply with the EU hygiene criteria for foods of non-animal origin
- Contamination with pesticides, lead and cadmium must not exceed the maximum levels permitted under EU law
- Pesticides banned in the EU must not be used or allowed to contaminate the food
- Wooden packaging made after 28th February 2005 complies with the international standard on wooden packaging (ISPM-15)
- Consignments that fall under the EU market grade standards have a certificate of conformity

SECTION 1: INTRODUCTION AND BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS FOR GLOBAL TRADE IN FRESH FRUITS AND VEGETABLES

1.1 Scope of the guide

This guide has been written for third country suppliers of fruits and vegetables to European Union (EU) markets and is intended to provide information on the minimum regulatory requirements for market access. Information is given for exporters of conventionally produced fresh and minimally processed fruits and vegetables, and a brief summary is provided on export of organically produced fruits and vegetables.

This guide does not cover requirements for genetically modified fruits or vegetables, products processed using quick freezing, canning or irradiation, and products containing additives, novel foods or those prepared for special nutritional purposes as these have additional regulatory requirements. Products of animal origin are not covered but a comparison is provided between the entry requirements for animal and non-animal origin products.

1.2 How to use this guide

The guide is divided into three parts, part 1 deals with general issues of food safety in global trade of fruits and vegetables and harmonisation of the EU regulatory framework for food and feed hygiene. Part 2 provides detailed explanations of all of the regulatory requirements for export of fruits and vegetables to the EU, and part 3 summarises this information into tables so that key information can be obtained rapidly without reading through all of section 2. Full references to legal texts, guidance documents and useful websites are given at the end of the guide and the contents section is followed by a glossary and selection of useful definitions.

Part 1 will provide useful background information, but for many third country suppliers the best starting point will be to refer to the summary tables in section 3 to identify the key legal requirements for market access and then refer to the relevant sub-sections in section 2 for detailed information. In some cases it would be an advantage to download some of the official guidance documents and legal texts listed in the reference and useful website sections at the end of the guide.

1.3 Food safety as a driver for change in global trade

The development of global markets for exotic and out of season fruits and vegetables, meat and fisheries products has resulted in complex market chains involving many links, long distances and significant intervals of time between harvest and delivery to the final consumer. All these factors increase the opportunity for something to go wrong resulting in risks to either human or plant health.

Major food safety incidents such as the transmission of BSE (mad cow disease) in beef, Salmonella species and antibiotic residues in poultry, toxic dyes in spices, dioxins in fats and pathogenic *E.coli* (*E.coli* O157) in meat and ready to eat sprouted seeds (bean sprouts) have all raised public concern and caused both governments and private sector to seek measures to prevent such problems occurring.

National governments have improved their official control systems and the private sector has developed and implemented private standards to ensure legal compliance. However, in some cases the increase in different measures resulted in accusations of deliberate use of sanitary regulations and standards as barriers to trade.

1.4 Harmonisation of international law under WTO

Countries meeting under the 1994 Uruguay round of talks on General Agreement on Tariffs and Trade (GATT) recognised the need for harmonisation of international standards to ensure free trade between countries. An agreement for sanitary and phytosanitary measures (SPS) was created to cover issues of human, animal and plant health and an agreement for technical barriers trade (TBT) was created to cover non-health related matters. The World Trade Organisation (WTO) was created to administer the standards and mediate in any disputes between countries over issues covered by the SPS and TBT agreements.

The Codex Alimentarius Commission (CAC) administered jointly by the Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) since 1961 was chosen as the official reference for all standards and guidelines and recommendations for SPS and TBT issues. This was a sensible step as 154 countries are members of the CAC and play an active role in developing the standards and guidelines and also make use of CAC material for development of national legislation.

All measures under the SPS and TBT agreements must be science based and make use of risk assessment (risk analysis, risk management and risk communication) techniques to assess the level of risk to human, animal or plant health objectively. Governments that sign to the SPS and TBT agreements agree to use international standards, guidelines and recommendations where they exist and not to create unnecessary barriers to trade. Members retain the option to implement higher standards than those specified by the CAC but must provide justification in the form of scientific evidence to support the need for higher standards.

The EU is a signatory to the SPS and TBT agreements as are the member states and all member states are active members of CAC hence most EU regulatory requirements comply with the SPS and TBT agreements. However, some EU measures require higher standards than those set under the WTO agreements and the EU also applies the precautionary principle which allows for emergency measures to be made without waiting for scientific evidence.

1.5 Harmonisation of EU regulatory requirements

In the year 2000, the EU published a white paper on food safety recognising that existing EU horizontal legislation on food hygiene was over complex and repetitive with legal provisions scattered over 17 European Commission Directives. Furthermore the use of Directives as legal instruments allowed members states to set national tolerances rather than following a single set of criteria established centrally by the European Commission. This lack of harmony tended to create barriers to trade both within and outside the borders of the EU. To solve these problems the EU food safety white paper proposed measures to harmonise and simplify EU food law by merging together the 17 Commission Directives to establish a single framework of harmonised food controls.

The new harmonised framework for food and feed hygiene came into effect on 1st January 2006, but many of the measures will not be fully implemented until at least August 2007 and the EU has created a series of transitional measures (EC/2076/2005) that allow member states until 31st December 2009 to adopt the framework in full. In January 2010 the European Commission will conduct a review of the implementation process. The main framework consists of the following regulations and directives:

- Single framework regulation – The General Food Law (EC/178/2002)
- Official controls for feed and food regulation (EC/882/2004)
- Consolidated hygiene regulations, general issues of hygiene applicable to all foods (EC/852/2004), additional hygiene measures for food of animal origin (EC/853/2004) and official controls for foods of animal origin (EC/854/2004)
- Feed hygiene regulation (EC/183/2005)
- Animal health rules (Directive 2002/99/EC)
- Repeal of the 17 existing Directives on 1st January 2006 (Directive 2004/41/EC)

The harmonised regulatory framework only refers to SPS measures, and is simply the basic set of rules. At a level below this framework are numerous regulations, directives and decisions dealing with specific issues of implementation of food law. In addition there are many other regulations and directives covering TBT issues but given the extremely wide range (includes non-food matters such as children's toys, electrical goods, industrial processes etc) of issues covered under TBT it comes as no surprise that there is no regulatory framework for TBT. Only those regulations and directives that deal with foods of non-animal origin will be discussed in more detail in section 2.

1.6 Who is responsible for ensuring food safety?

Under EU law there is a clear division of responsibility for food safety between the private food business operator and the competent authorities of government:

- **The food business** is charged with legal responsibility for ensuring food safety, and some establishments (those handling products of animal origin) need to be approved and registered by competent authorities;
- **The competent authorities (government)** have legal responsibility for establishing official control systems and verifying compliance with food law and food hygiene in particular.

1.7 EU market requirements – wholesale versus retail

EU legislation represents the minimum requirement for market access. However, many of the larger retailers and some wholesalers require suppliers to demonstrate compliance with independently verifiable private standards such as the European Retailers Protocol for Good Agricultural Practice (EUREPGAP) and the British Retail Consortiums (BRC) Global Technical Standard as this is an effective way of ensuring that suppliers have the necessary management and control systems in place. In addition if the EU food business faces legal action being able to demonstrate that all suppliers can demonstrate compliance with an independently verifiable standard that

meets all legal requirements is a powerful due diligence defence for the EU food business. This guide deals with regulatory requirements details of compliance requirements for EU private standards can be found in the companion volume published under the same DFID funded project.

Food safety white paper – need for harmonisation of EU regulatory requirements & a farm to fork approach

EU harmonised regulatory framework for SPS summary of the wider framework (includes animal origin material), and mention of transitional measures (deadlines) & implementation into national law (UK as an example)

SECTION 2: MINIMUM LEGAL REQUIREMENTS FOR EXPORT OF FRESH FRUITS AND VEGETABLES TO THE EU

This section is divided into two parts to separate regulatory requirements covering food safety and plant health issues (SPS measures) and those dealing with product quality and standards for niche markets (TBT measures).

2.0 Does EU food law apply to food businesses outside the borders of the EU?

The authorities of the EU are quite clear that EU food law is not extra-territorial and thus has no direct application or legal validity for non EU 3rd country suppliers.

However, the EU food business (importer or retailer) must comply with the relevant legal requirements and is charged under Article 17 of the general food law (EC/178/2002) with responsibility for ensuring food safety by satisfying the requirements of food law and verifying that these requirements are met. Under Article 19 of EC/178/2002 the EU food business must withdraw food that they believe to be not in compliance immediately and inform the competent authorities.

In practice this means that the EU importer is responsible for ensuring that all foodstuffs imported into the EU comply with the requirements of EU food law and must be able to provide evidence of compliance when required. As a result the EU importer is obliged to require third country suppliers to meet the requirements of EU food law (as discussed in detail in sections 2.1-2.11).

Hence third country suppliers (growers, processors and exporters outside the EU) of fruits and vegetables intended for EU markets must meet the specifications of EU food law as these constitute a market entry requirement that will be asked for by any reputable EU import business.

SANITARY AND PHYTOSANITARY (SPS) MEASURES

The regulatory framework for sanitary and phytosanitary measures (SPS) is designed to protect human and plant health within the EU by ensuring that imported fruits and vegetables are not contaminated with harmful levels of pesticides or other chemical contaminants, micro-organisms capable of causing harm to human health and plant pests and diseases that could harm crops, ornamentals or wild plants in Europe.

2.1 Comparison of import controls for products of non-animal origin and those of animal origin – All food safety measures within the EU are based on scientific assessment of the likely risk to health of a given hazard, for this reason products of animal origin that represent the greatest risk to health are subject to strict import controls including EU approval of exporting countries national food control systems and EU approval and registration of food businesses wishing to export to the EU or involved in production and processing of food intended for export to the EU. In

contrast products of non-animal origin such as fresh fruits and vegetables that represent a low risk to health are normally subject to a low level of control (see table 1) although this can change if a specific risk is identified leading to the introduction of special restrictions or emergency measures to control the identified hazard.

Under normal circumstances, the minimum export requirement for fresh fruits and vegetables is a plant health (phytosanitary) certificate if the crop is listed in the phytosanitary directive (2000/29/EC) and basic information on country of origin, supplier name and address and product identity for vertical traceability requirements (EC/178/2002). In the case of the commodities listed under the market grade standards regulation (EC/2200/1996) a certificate of conformity is required (see TBT measures). No other certificates are required but produce may be subject to random testing at point of entry, distribution or retail sale for the presence of pesticide residues or other chemical contaminants, and the exporter may be asked by the buyer in the EU to supply more detailed information and records on primary production and post-harvest handling to satisfy the more detailed requirements specified under EC/852/2004 and EC/2073/2005 for ensuring food safety of products of non-animal origin.

2.2 Vertical traceability (EC/178/2002) – Under Article 18 of the General Food Law (Regulation EC/178/2002) the EU food importer (and therefore logically the third country supplier) must be able to immediately provide the authorities with the following information:

- Name and address of the third country supplier, country of origin, nature of the products (for example green-beans) and the date of the transaction

In addition the EU food importer is highly recommended (under EC/178/2002) to:

- keep and make available to the authorities information on the volume or quantity of products, batch number and a detailed description of the products (pre-packed or bulk, variety, raw or processed)

Article 18 is considered as being fulfilled for imports to the EU because the importer is obliged to comply and will therefore ensure that the third country supplier supplies the information stated above. The third country supplier is bound to provide the required information for business reasons as failure to do so would result in exclusion from the EU market.

Table 1. Comparison of EU import controls for products of animal and non-animal origin

Control Measure	Non-animal Origin	Animal Origin
Exporting country must be on an EU list of approved countries	No	Yes
Exporting country must have EU approved competent authorities	No, but must provide evidence of competent authority for phytosanitary measures	No, but must provide evidence of competent authority for veterinary measures
Exporting country must submit a control plan prior to export	No	No, but must provide information on certain zoonotic diseases, veterinary medicines and other pharmacologically active substances
Exporting food business (establishment) must be on an EU list of approved establishments	No	Yes
Exporting country must have EU approved reference laboratories	No	No, but laboratories that verify compliance to EU standards must be accredited
Exporting countries national food control systems are subject to inspection by EU inspectors from the food and veterinary office (FVO)	No, new guidance will be issued by the EU in October 2006	Yes
HACCP required for primary production	No	No, but is mandatory for animal feed producers
HACCP required for post-harvest handling	Yes for processing of fresh cut products	Yes
Prior notification of export must be given for each consignment	No	Yes
Certificates must be supplied with each consignment	Yes, plant health certificate required	Yes, Animal health certificates and health and identifications marks

2.3 Hygiene rules for foods of non-animal origin (EC/852/2004) – Regulation EC/852/2004 introduces for the first time the concept of ensuring food hygiene at all stages in the food chain. The EU food importer (and therefore logically the third country supplier) must consider the following:

- EU food business must ensure food safety by preventing contamination of products from any source (air, soil, water, fertiliser, feed, chemicals, worker hygiene, storage, handling and disposal of wastes);
- Foodstuffs imported into the EU shall comply with the EU hygiene standards or with equivalent standards (Article 1g);
- The EU food business is responsible for food safety (Article 1a) and thus importers must ensure that third country suppliers of primary products meet requirements specified in Articles 1, 3, 4.1 and Annex IA. If the product is processed then the third country food processor must meet the requirements specified in Articles 4.2 and 5 and Annex II.

The specific measures for ensuring food safety and hygiene are divided into those applying to primary production (Annex IA) which in practice means the farm and those dealing with food processing (Annex II) which in practice refers to high care facilities in pack-houses for pre-cut fruit and vegetable production and facilities for production of fruit and vegetable juices. It is impossible here to give detailed descriptions of the contents of the annexes or the measures necessary to ensure food safety for a given crop or type of process but a summary can be given of the points (see EC/852/2004 for full text of the required measures) that need to be considered by primary producers of fresh fruits and vegetables and those processing fruits and vegetables to create fresh-cut ready to eat packs.

Summary of hygiene requirements for primary production of fresh fruits and vegetables as specified under Annex IA of EC/852/2004 (requirements that are only applicable to food of animal origin have been omitted):

I. Scope

- Production, harvesting, transport on farm, storage and transport to the point of export

II. Hygiene Provisions

- 2. Protect products from contamination
- 3. Control hazards including:
 - 3a. Control of contamination from air, soil, water, fertilisers, pesticides & biocides, storage & handling of wastes
 - 3b. Measures related to plant health
- 5. Specific measures
 - 5a. Keep clean and where necessary disinfect facilities, equipment, containers, crates and vehicles
 - 5b. Ensure hygiene in production, transport & storage and cleanliness of plant products
 - 5c. Use potable water or clean water where necessary to prevent contamination
 - 5d. Ensure that staff handling foodstuffs are in good health and undergo training on health risks
 - 5e. Prevent animals and pests from causing contamination
 - 5f. Store and handle waste & hazardous substances (including pesticides) so as to prevent contamination
 - 5g. To take account of results and analyses of samples of plant or other material that have importance to human health
 - 5h. To use pesticides and biocides correctly as required by relevant legislation
- 6. To take appropriate remedial actions if problems are identified during official inspections

III. Record Keeping

- 7. Must keep and retain records of measure put in place to control hazards for an appropriate period (6 months for fruits and vegetables) and make available to the authorities on request
- 9. Must keep records of:
 - 9a. Any use of pesticides or biocides
 - 9b. Presence of any pests or diseases that affect safety of the product
 - 9c. Results of analyses important to human health

Article 5 of Regulation EC/852/2004 specifies requirements for most food businesses to have a HACCP system in place. However, Article 5.3 of the regulation states that the requirement for a HACCP system does not apply to primary production and those operations associated with annex I. In practice this means that HACCP does not apply on the farm, and would not be required by a third country supplier who simply boxed up whole fresh fruits or vegetables for export without any form of post-harvest processing. However, farmers should still find aspects of the HACCP approach useful for looking a type of product, intended use, process flow, hazard analysis, control measures, monitoring, record keeping and verification that the good agricultural practice management and control system is achieving the desired outcomes in terms of food safety and hygiene.

Summary of hygiene requirements for minimally processed (fresh or pre-cut) fruits and vegetables as specified under Annex II of EC/852/2004 (chapter III that only applies to catering establishments has been omitted as have chapters or points dealing with issues not applicable to processing of pre-cut fruits and vegetables):

Chapter I General requirements for food premises

- 1. Food premises are to be kept clean and maintained in good repair and condition
- 2. The layout, design, construction, siting and size of food premises are to:
 - 2a. permit adequate maintenance, cleaning and disinfection provide space for hygienic operations and prevent airborne contamination
 - 2b. protect against accumulation of dirt, contact with toxic materials, shedding of particles into food and the formation of condensation or mould on surfaces
 - 2c. permit good hygienic practices including protection against contamination and pest control
 - 2d. where necessary provide temperature controlled handling and storage conditions and allow for monitoring and recording of temperatures
- 3. An adequate number of flush lavatories must be provided, connected to a suitable drainage system and must not open directly into areas where food is handled
- 4. An adequate number of washbasins must be provided in appropriate locations with facilities for washing and drying of hands
- 5. Ventilation must be adequate and constructed to avoid the risk of contamination passing from a contaminated area to a clean area
- 6. Toilets must have adequate natural or mechanical ventilation
- 7. Food premises must have adequate natural and or artificial lighting
- 8. Drainage facilities must be designed and constructed so as not to represent a risk of contamination for the foodstuffs, waste must not flow from a contaminated area into a clean area
- 9. Adequate changing facilities must be provided for personnel
- 10. Cleaning agents and disinfectants must not be stored in areas where food is handled

Chapter II Special requirements for rooms where foodstuffs are prepared, treated or processed

- 1. In rooms where food is prepared, treated or processed the design must permit good hygienic practices, including protection against contamination between and during operations, in particular:
 - 1a. floor surfaces must be maintained in good condition and be easy to clean and disinfect as appropriate
 - 1b. walls must be maintained in sound condition and be easy to clean and disinfect as appropriate
 - 1c. ceilings or roof interiors must be constructed to prevent accumulation of dirt, shedding of particles, condensation or growth of moulds
 - 1d. windows and other opening must be constructed to avoid accumulation of dirt, fitted with insect proof screens if open, and kept closed if opening of windows leads to a risk of contamination
 - 1e. doors must be easy to clean
 - 1f. Surfaces in food processing areas must be smooth, washable, corrosion resistant and non-toxic, be well maintained cleaned and where necessary disinfected

- 2. Adequate facilities must be provided for cleaning, disinfection and storage of working utensils
- 3. Adequate provision must be made for washing of foodstuffs with potable water and sinks must be clean and where necessary be disinfected so as to prevent disinfection

Chapter IV Transport

- 1. Vehicles must be kept clean and well maintained and where necessary disinfected and be designed to protect the foodstuff from contamination
- 2. Containers in vehicles are not to be used for transporting anything other than foodstuffs where this might cause a risk of contamination
- 3. If vehicles are used for transporting different types of food or non-food items separation must be provided to prevent contamination
- 5. If vehicles are used for different types of food or anything other than foodstuffs there must be effective cleaning and disinfection between loads to avoid the risk of contamination
- 6. Foodstuffs must be positioned so as to avoid contamination
- 7. Where necessary vehicles and containers used for foodstuffs must maintain appropriate temperatures and these must be monitored

Chapter V Equipment requirements

- 1. All articles, fittings and equipment that food comes into contact with:
 - 1a. be effectively cleaned and where necessary disinfected to avoid risk of contamination
 - 1b. be constructed of materials and properly maintained to prevent risk of contamination
 - 1c. Re-usable containers must be kept clean and in good state of repair
 - 1d. installed to all easy cleaning of equipment and surroundings

Chapter VI Food waste

- 1. Waste is to be removed from rooms where foods is present as quickly as possible to avoid accumulation
- 2. Waste products must be stored in closed containers that are easy to clean and disinfect when necessary
- 3. Provision must be made for storage of waste separate from foodstuffs and kept free of animals and pests
- 4. All waste must be disposed of in a hygienic and environmentally friendly way

Chapter VII Water supply

- 1. Adequate supplies of potable water must be provided and used to prevent contamination of the foodstuff
- 2. Where non-potable water is permitted for fire control or refrigeration the supply must be clearly labelled and not allowed to connect in any way to the potable supply
- 3. Recycled water must not represent a risk of contamination and must be of potable quality

Chapter VIII Personal hygiene

- 1. All workers must maintain a high standard of personal hygiene and to wear suitable clean protective clothing
- 2. No person suffering from illness or being a carrier of a disease that could be transmitted through food is to be permitted to handle foodstuffs or ingredients and raw materials

Chapter IX Provisions applicable to foodstuffs

- 1. Food business must not accept raw materials or ingredients that are known or expected to be contaminated with anything that represents a risk to human health
- 2. Raw materials and ingredients must be stored so as to prevent contamination and harmful deterioration
- 3. At all stages of production, processing and distribution food must be protected against contamination
- 4. Access by pests and domestic pets to food handling and storage areas must be prevented and measures taken to control any pests that manage to enter the premises
- 5. Temperatures in the cool chain must be maintained at a level that does not represent a risk to health at all points in processing and distribution of the foodstuff
- 6. Chilled foods must be cooled rapidly to a temperature that does not cause a risk to health
- 8. Hazardous/inedible materials must be properly labelled and stored separately from foodstuffs

Chapter X Wrapping & packaging of foodstuffs

- 1. Wrapping & packaging materials must not be a source of contamination
- 2. Wrapping materials stored so as to avoid contamination
- 3. Wrapping and packaging carried out so as to avoid contamination of the product
- 4. Re-usable packaging material must be easy to clean and disinfect

Chapter XII training

- 1. Food handlers are trained in food hygiene and supervised
- 2. Members of the HACCP have received adequate training on HACCP
- 3. Comply with national requirements concerning training for food workers

The measures specified in Regulation EC/852/2004 represent a convergence between regulatory requirements and voluntary private sector standards such as EUREPGAP and the British Retail Consortium (BRC) Global Technical Standard. This is particularly pertinent in the sense that in the absence of detailed guidance documents or codes of practice from either the EU or national agencies of member states, food businesses will need to make use of existing private sector codes of practice and guidance materials to decide how best to meet the requirements of the law. In connection with this, the European Commissions Directorate General for Health and Consumer Protection (DG SANCO) has stated in section 4 of their guidance document on implementation of EC/852/2004 that where the annexes of the Regulation use the terms “where necessary”, “where appropriate”, “adequate” and “sufficient” it is the responsibility in the first instance of the food business operator to decide the measures that they have in place are “necessary”, “adequate” and “sufficient” to meet the legal requirements. In doing this the food business needs to take account of the nature of the food and its intended use to determine the likely

level of risk to health and can justify their choice by taking a HACCP based approach to food safety management.

Exporters of whole unprocessed fresh fruits and vegetables need only to consider the measures for good agricultural practice (GAP) on the farm specified under Annex IA of the regulation. No certificate is required by law, but third country suppliers must keep documentary evidence including accurate records and provide these to the EU importer on request. Suppliers should be aware that the buyer may ask for evidence of certification under an independent farm-gate standard such as EUREPGAP as a suitable way to verify that appropriate measures for GAP have been implemented and are being maintained correctly.

Third country food businesses involved in any kind of post-harvest processing of fruits and vegetables must meet the requirements of both Annex IA for primary production and also the requirements of Annex II of the Regulation dealing with processing facilities. No certificate is required, but as with the farm-gate regulatory requirements suppliers must keep documentary evidence and make this available to the EU importer on request and should also be aware that the EU buyer may ask for evidence of participation in an independent certification scheme such as the BRC Global Technical Standard as a means of verifying that appropriate measures for good manufacturing practice, good hygienic practice, and HACCP have been implemented and are being maintained correctly. Those involved in processing of fruits and vegetables must also meet the requirements of the Regulation on microbiological criteria for foodstuffs (EC/2073/2005) discussed in the next section.

2.4 Microbiological criteria for foodstuffs (EC/2073/2005) – Compliance with microbiological criteria for foodstuffs are mentioned in articles 4 & 12 of Regulation EC/852/2004 whereby the food business operator is charged with responsibility for ensuring that food meets the specified microbiological criteria and that unsafe food is not placed on the market. In regulation EC/2073/2005 microbiological criteria are divided into two types namely:

- Food safety criteria – dealing with the presence of micro-organisms in the food, that represent a risk to human health;
- Process hygiene criteria – dealing with micro-organisms that can be used as indicators of the level of hygiene present in the food business.

A glance at the regulation shows that most of the criteria relate to products of animal origin as these quite rightly are considered as representing the highest level of risk to human health. Regular testing of fresh uncut unprocessed vegetables and fruits, excluding sprouted seeds is stated in EC/2073/2005 as not being useful under normal circumstances which means exporters of these products would not normally need to be concerned with the requirements of EC/2073/2005. However, if they are selling to a processing company either within or outside the EU who supplies EU markets they may be required by that company to take account of microbiological criteria if the processor is having problems with food safety or hygiene that can be traced back to contamination from the unprocessed fruits or vegetables.

Suppliers and exporters of ready to eat sprouted seeds and pre-cut (fresh cut or minimally processed) which are known to be higher risk products must meet the food safety and hygiene criteria specified in table 2.

Table 2. Food safety and process hygiene criteria for ready to eat sprouted seeds and fresh-cut fruits and vegetables as specified under EC/2073/2005

Food Category	Micro-organisms	Sampling plan		Limits CFU/g	
		N	C	M	M
Food Safety Criteria					
Sprouted seeds (ready to eat)	Salmonella	5	0	Absence in 25g	
Pre-cut fruit and vegetables (ready to eat)	Salmonella	5	0	Absence in 25g	
Unpasteurised fruit and vegetable juices (ready to eat)	Salmonella	5	0	Absence in 25g	
Process Hygiene Criteria					
Pre-cut fruit and vegetables (ready to eat)	<i>E.coli</i>	5	2	100	1000
Unpasteurised fruit and vegetable juices (ready to eat)	<i>E.coli</i>	5	2	100	1000

CFU /g = Colony Forming Units per gram of sample

n= number of units comprising the sample

c= number of sample units giving values between m & M

Interpretation of test results

For Salmonella as an important human pathogen, where 5 samples of 25g each are taken none of the samples will contain detectable levels of Salmonella

For *E.coli* as an indicator of process hygiene the following apply:

- Satisfactory if all values observed are less than 100 CFU/g (m)
- Acceptable if a maximum of c/n values are between 100 and 1000 CFU/g (m & M) and the rest of the values are less than 100 CFU/g (m)
- Unsatisfactory, if one or more values observed are greater than 1000 CFU/g or more than c/n values are between 100 and 1000 CFU/g (m & M)

Third country suppliers involved in the production, processing and distribution of ready to eat sprouted seeds, pre-cut fruits and vegetables or unpasteurised fruit and vegetable juices must ensure compliance with the criteria specified in table 2. This is to be achieved by using a combination of good hygienic practices (GHP) and Hazard Analysis Critical Control Point (HACCP) to ensure:

(a). that supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that process hygiene criteria are met;

(b). that food safety criteria applicable throughout the shelf-life of products can be met under reasonably foreseeable conditions of distribution storage and use.

(c). in the event of unsatisfactory results to make the necessary improvements in production hygiene to meet the microbiological criteria specified in table M.

In practice in order to comply with the microbiological criteria specified in EC/2073/2005 suppliers of sprouted seeds, pre-cut fruits and vegetables and unpasteurised fruit juices will need to comply with the requirements for food hygiene specified under EC/852/2004 and conduct regular sampling and analysis of products for *E.coli* and Salmonella as a means of verifying that process hygiene and food

safety are satisfactory. For pre-cut fruits and vegetables and unpasteurised fruit and vegetable juices the focus would be on the processing plant meeting the general hygiene requirements specified under Annex II of EC/852/2004. However, for sprouted seeds and in cases where problems with hygiene or safety of fruits and vegetables used for pre-cut or juice manufacture are traced to the farm it will be necessary to require the primary supplier to demonstrate that they meet the requirements specified under Annex IA of EC/852/2004.

2.5 Safe and effective use of pesticides – In the area of pesticide residues it is necessary for third country suppliers to ensure that no pesticides banned in the EU are present on the produce, and that levels of permitted pesticides do not exceed the maximum levels permitted under EU law. The legal provisions for these requirements are covered under Directives 79/117/EEC, 91/414/EEC and Regulation EC/396/2005.

2.5.1 Pesticides banned in the EU (Directive 79/117/EEC) – Directive 79/117/EEC with amendments provides a list of pesticides that have been banned in the EU on grounds of serious adverse impacts on human and animal health or the environment. Food cannot be imported into the EU if it has been treated or contaminated with any of the compounds listed under the directive (see table 3). There is no need for a certificate for export, but produce is subject to random testing at the point of entry, distribution or retail sale within the EU. Detection of any banned substance will result in rejection and destruction of the shipment and could result in prosecution of the importer and stopping of further imports from the supplier or country pending investigation by the competent authorities.

The majority of compounds found on the banned pesticides directive list are unlikely to be seen on any farm in the present day, but some supplier countries are known to be considering resumption of use of DDT as a public health measure to control Anopheles mosquitoes that carry malaria. DDT is a cheap and effective insecticide with a high level of persistence in the environment and thus could be viewed as a positive measure for malaria control. However, its persistence creates a problem as DDT can remain in the environment for decades after application and is very efficient at spreading through the food chain. If countries do resume application of DDT it seems certain that the compound will eventually be detected during routine sampling and analysis in the EU with disastrous consequences for the fresh produce export industry in the country concerned.

Producers and exporters in third countries need to ensure that banned pesticides are not present in the farm and cannot contaminate produce intended for export. In practice this means that these compounds must not be purchased, stored or used at any farm site. Industry associations need to persuade governments to avoid using any of these compounds and look for safer and more acceptable alternatives for public health campaigns such as those associated with mosquito control.

Table 3. List of pesticides banned under directive 79/117/EEC

Name of active substance or group of active substances
A. Mercury compounds <ul style="list-style-type: none">• Mercuric oxide• Mercurous chloride (calomel)• Other inorganic mercury compounds• Alkyl mercury compounds• Alkoxyalkyl and aryl mercury compounds
B. Persistent organo-chlorine compounds <ul style="list-style-type: none">• Aldrin• Chlordane• Dieldrin• DDT• Endrin• HCH containing less than 99% of the gamma isomer• Heptachlor• Hexachlorobenzene
C. Other compounds <ul style="list-style-type: none">• Ethylene oxide• Nitrofen• 1,2-dibromoethane• 1,2-dichloroethane• Dinoseb (acetate & salts)• Binapacryl• Captafol• Dicofol (containing less than 78% dicofol or more than 1g/kg of DDT)• Maleic hydrazide (other than choline, potassium or sodium salts)• Choline, potassium and sodium salts of maleic hydrazide containing more than 1mg/kg of free hydrazine• Quintozene containing more than 1g/kg of HCB or more than 10g/kg of pentachlorobenzene

2.5.2 Pesticides approved for use within the EU (Directive 91/414/EEC) –

Directive 91/414/EEC deals with approvals for active substances used in pesticides to be put on the market in the EU. Pesticide manufacturers wishing to register a pesticide and the usages of that chemical need to register with the EU and provide an extensive dossier of information from field and analytical studies to demonstrate the safety and effectiveness of the chemical for a given application and to enable maximum residue limits (MRL) to be set (see under EC/396/2005). This information is then evaluated by the EU to decide if the compound be granted approval. If approved the compound and its approved uses are added to the annexes of Directive 91/414/EEC and the MRL will be listed in the annexes to EC/396/2005. If the compound is not approved it will be declared as being withdrawn and the MRL will be set at the limit of detection (LOD) which simply means that the maximum level of the compound permitted in a food is set at the limit of sensitivity of analytical techniques used by pesticide residue laboratories.

A major review of active substances used in pesticides is underway and will not be completed until late in 2008. All substances and applications require fresh approval so pesticide manufacturers have had to decide whether to invest funds in the registration process. Manufacturers have decided not to bother registering some compounds and applications as the costs outweigh the potential income from chemical sales. The majority of these compounds are older substances long out of

patent that can be produced cheaply in generic form by chemical manufacturers outside of Europe. These compounds are automatically declared as being withdrawn from use in the EU.

Compounds that are declared as withdrawn cannot be made, sold, stored or used in the EU, but unlike the banned substances listed under Directive 79/117/EEC it is permissible for growers outside the EU to use these compounds provided that the compound and application are registered for use in the growers country. In every case the grower must ensure that the level of residue of the pesticide does not exceed the MRL set in the EU and in cases of withdrawn compounds this can create problems with ensuring that levels are below the limit of detection by EU residue laboratories.

2.5.3 Harmonised MRL's for pesticides (EC/396/2005) – Maximum residue limits (MRL) are the legal limit or maximum permitted level of a chemical contaminant in food or feed. It is important to understand that MRL's are not toxicological limits and thus a chemical detected in a food at its MRL will not represent a risk to human health. Naturally the question may be asked as to what is the difference between the MRL and the toxicological limit. MRL's are determined scientifically using field studies for each chemical and type of food and sometimes even the type of tissue is relevant. In these studies a very wide safety margin (factor) is established, typically around x800 lower than the toxicological limit. As mentioned earlier, if a active substance is withdrawn in the EU the MRL will be set at the limit of detection (LOD) that being the minimum amount of chemical that can be detected with current methods of analysis in residue laboratories.

In the past the EU established MRL's for different types of foods via 4 directives with fruits and vegetables being covered under Directive 90/642/EEC. This approach had disadvantages as member states were free to interpret the directives into national law and thus some states used the MRL's given in the directives, some set more stringent values and some set less strict MRL's. The outcome of member states setting their own national MRL's was to create barriers to trade within the EU as farmers who had grown crops to a more relaxed standard could not access markets with stricter requirements. To overcome this problem the EU has introduced a single regulation (EC/396/2005) to harmonise the setting of MRL's for pesticide residues throughout the community. When the process of setting the harmonised MRL's is complete suppliers will only need to meet one set of rules to access 25 members states markets in effect one key to fit 25 locks!

A timetable for implementation has been created with the objective of having a complete set of EU MRL's (also known as definitive tolerances) by mid 2008. In the meantime the EU is allowing for the setting of temporary EU MRL's (temporary tolerances) until the process of reviewing active substances under Directive 91/414/EEC is completed. When EC/396/2005 was published in March 2005 no annexes were provided, but the first set of annexes containing EU definitive and temporary tolerances (MRL's) is due to be published in March – April 2006, and these MRL's will come into force in September 2006. In the interim national MRL's and values set under the old directives remain in force.

Third country suppliers must ensure that shipments of fruits and vegetables to the EU meet the MRL values set within the EU. Although no certificate is required, produce is subject to random testing at the point of entry, distribution and retail sale. If violations are detected at the point of entry the shipment is liable to be rejected and destroyed at the exporters expense. If detected further down chain the level of action will depend on the severity of the non-compliance. If the violation does not represent

a risk to public health the authority may simply inform the retailer and exporter of the incident and publish full details of the incident in publicly available reports. If many violations are seen from a particular country sampling of that country's material is likely to be increased. If the violation represents a risk to public health the offending shipment will be withdrawn and destroyed.

It is also important for third country suppliers to keep track of changes in MRL values as reductions in the MRL will need changes in practice on farm to avoid violations in the EU. In 2001, the EU drastically reduced the MRL for ethephon an organo-phosphorous pesticide commonly used for de-greening of pineapples. Pineapple exporters from Ghana failed to take note of this change and lost two shiploads of pineapples at point of entry to the EU for violating the new MRL value for ethephon. It is ironic that these shipments were well within the old MRL value and thus would not have been condemned had they reached port just a few days earlier.

Maximum residue limits (MRL's) are useful as measures for verifying good agricultural practice on the farm and confirming that the produce does not represent a risk to health. However, they cannot be used on farm as sampling and analysis is an expensive and complex undertaking and takes at least a day to get results back.

In practice the grower and exporter need a method to ensure that the level of chemical will have reduced from the amount applied during spraying to below the MRL by the time the product reaches the EU. The difference in time between spraying of the pesticide and safe harvesting is known as the pre-harvest interval (PHI) or first harvestable date (FHD). Pre-harvest intervals and first harvestable dates are easily applied on farm as the farmer only requires a calendar, and a record keeping system to ensure that correct PHI or FHD are observed. Markers such as warning signs or red flags can also be placed at the four corners of the field to tell farm workers that the field is not ready for harvesting.

To make use of pre-harvest intervals it is necessary to know how persistent the pesticide is on a given crop this information is normally provided on the label or in product information sheets (care must be taken to ensure that the specified PHI relates to the EU MRL as internationally recognised MRL's set by the Codex Alimentarius Commission are sometimes less strict than those set by the EU). It is also essential to know how much pesticide has been applied over a given area of land in order for the PHI to be usable. Therefore the following factors must be taken into account when preparing to spray pesticides:

- The field area in hectares (may be less than 1 hectare);
- The percentage of active ingredient in the formulation & correct dilution factor;
- The sprayer must be calibrated and properly maintained to deliver the correct amount of pesticide;
- The tractor or spray-man must move forwards at a steady rate to ensure uniform spraying throughout the crop;
- Crops must be planted in rows to facilitate easy access for pesticide spraying.

Records must be kept of the date of spraying of the crop, PHI and FHD, when harvesting takes place the member of staff responsible for preparing the shipment must check the date of harvest against the PHI or FHD to ensure against premature harvesting. If these measures are taken into account the producer and exporter have assurance that they are unlikely to experience problems with MRL testing in the EU. In the case of sea-freight an extra safety margin is added as the level of pesticide residues in the fruits or vegetables will continue to fall during the journey. This is

significant for pineapple exports from West Africa to Europe where journey times last from 9-14 days depending on the port of entry into the EU. The maintenance of proper records of application of pesticides will also help to satisfy the requirements for record keeping specified under point 9a of Annex IA of regulation EC/852/2004.

2.6 Chemical contaminants in food (Regulation EC/466/2001) - The contaminants in food regulation establishes the maximum permitted levels of chemical contaminants (other than pesticides) such as nitrates, mycotoxins (fungal toxins), heavy metals (lead, cadmium & mercury) and 3-monochloropropane-1,2-diol (3-MCPD) in a range of foods of both animal and non-animal origin. The contaminants of interest for fruits and vegetables are nitrates, lead and cadmium (see table 4).

Table 4. Maximum residue levels for chemical contaminants in food as defined under EC/466/2001

Product	Maximum level of nitrate (mg / kg)
Fresh spinach	Harvested 1/11-31/3 – 3,000 Harvested 1/4-31/10 – 2,500
Preserved, deep frozen spinach	2,000
Fresh lettuce (protected & open-grown)	Harvested 1/10-31/3 – 4,500 Harvested 1/4-30/9 – 3,500 With the exception of open-grown lettuce harvested from 1/5-31/8 – 2,500
Product	Maximum level of lead (mg / kg)
Vegetables, excluding brassica, leafy vegetables, fresh herbs and all fungi. For potatoes the maximum level applies to peeled potatoes	0.1
Brassica, leafy vegetables and all cultivated fungi	0.3
Fruit, excluding berries and small fruit	0.1
Berries and small fruits	0.2
Product	Maximum level of cadmium (mg / kg)
Vegetables & fruits, excluding leafy vegetables, fresh herbs, all fungi, stem vegetables, root vegetables and potatoes	0.05
Leafy vegetables, fresh herbs, celeriac and all cultivated fungi	0.2
Stem vegetables, root vegetables and potatoes (peeled) excluding celeriac.	0.1

As with pesticide residues the levels given are the maximum permitted by law in the EU but do not represent levels that would cause risk to human health as a wide safety margin was factored in when the levels were calculated. It is the responsibility of the exporter to ensure that these levels are not exceeded in products sent to the EU. No certificate is required with the shipment, but random sampling and analysis may occur at point of entry, distribution or retail sale within the EU. If levels of the specified contaminants are found to exceed permitted levels the shipment will be rejected and destroyed at the exporters expense. Random sampling programmes will only cover a very small percentage of produce entering the EU. However, if several violations are detected from the same exporting country the European Commission may decide to apply special restrictions or emergency measures to control the identified risk (see below) and this involves considerable expense for loss

of reputation for the exporting country and economic loss for producers and exporters in that country. Special conditions and emergency measures have been applied to imports of non-animal origin on 6 occasions over the last 6 years, 5 of these involved violations of mycotoxin levels in nuts and dried fruits as specified under EC/466/2001 and remaining emergency measure applied to illegal dyes (sudan-1 and para-red) in chilli and chilli products in 2005. As a result of this incident EC/466/2001 was amended to cover these dyes.

It clearly pays to avoid violation of the chemical contaminants regulation, but how is this achieved in practice. Laboratory testing of end products for the presence of chemical contaminants is useful for verifying that food safety management measures are working but cannot be used to control the hazard in the field. For nitrate sensitive crops it is necessary to determine the existing levels of nitrate available in the soil and then take account of all inputs of inorganic and organic nitrogen (manures, mulches and composts) to calculate the correct amount to apply so as to ensure that levels are not exceeded. Visual indications of excess nitrogen levels can be seen in crops that have darker green foliage than usual and thicker stems and greater leaf development than expected.

For heavy metals it pays to conduct a risk assessment of the farm and farming practice to determine how heavy metals could contaminate the land. Heavy metals could already be present in the soil in areas where mining for lead or cadmium has been conducted on an extensive basis. Application of sewage sludge should be avoided as sludge is often contaminated with high levels of heavy metals. Heavy metals can also reach the crop via contaminated air/dust and water. In practice this is most often due to water draining from busy roads and dust and fumes from the road and vehicles travelling along it. This material is contaminated with heavy metals from petroleum and motor car by-products. The obvious solution to this is to avoid planting too close to major roads and avoiding abstracting water for irrigation from sources that have proved to be contaminated with high levels of lead or cadmium. It is strongly recommended that soil and water tests are carried out as part of the farm risk assessment. This is a requirement for compliance with private sector standards such as EUREPGAP but also makes commercial sense for suppliers seeking to meet EU regulatory requirements.

2.7 Phytosanitary measures (Directive 2000/29/EC) – The plant health directive (2000/29/EC) is designed to regulate entry and spread of plant pests and diseases within the EU. The accidental introduction of exotic plant pests and diseases into the EU as part of shipments of imported plant products is a serious matter as many of the exotic species have the potential to become established in Europe and could cause serious economic damage especially where no natural predators exist to control the pest. As a result the EU requires all countries wishing to export to member states that they have a competent national plant protection authority (NPPA) capable of conducting phytosanitary inspection and certification prior to export.

All exporters of products of plant origin listed in annex V of Directive 2000/29/EC must submit their shipment for inspection by officers of their NPPA and obtain a plant health (phytosanitary) certificate issued in accordance with the requirements of Directive 2000/29/EC to certify that the products (specified under annex V of the Directive) are free of the prohibited pests and diseases listed in annexes I and II of the directive. A plant health certificate is required with every shipment, inspection and signature by an official of the NPPA must occur less than 14 days prior to dispatch and non English language certificates must be accompanied by an official translation. Random checks will be made at the point of entry into the EU to confirm

the validity of the information provided on the certificate. Shipments violating plant health requirements are liable for rejection and destruction at exporters expense.

It is imperative that exporters conduct their own quality control checks to ensure that shipments are free of pests and it also pays to work with the authorities to ensure that official inspections are conducted correctly. In some cases countries have been known to issue certificates without inspecting the shipment. This is a high risk strategy and if detected by inspectors in the EU can affect all exporters from a given country as loss of confidence degrades the value of certificates and assurances of quality control.

2.8 Wood packaging (Directive 2004/102/EC) – The wood packaging directive was introduced on 1st March 2005 so that the EU would be in compliance with the International Standard for Phytosanitary Measures (ISPM15) developed by the International Plant Protection Convention (IPPC) that provides guidelines for regulating wood packaging materials in international trade.

This directive is a phytosanitary measure intended to prevent plant pests and diseases from being carried from one country to another in wood packaging materials such as packing cases, crates, drums, pallets, load boards and pallet collars. As of March 1st 2005 all wood packaging materials of greater than 6mm in thickness are required to either be heat treated at 56°C for 30 minutes or fumigated with methyl bromide. The directive does not apply to processed woods manufactured using combinations of glue, heat and pressure such as plywood and MDF, and wood packaging materials made prior to 28th February 2005 are also exempt.

All wood packaging material falling within the scope of the directive must be stamped with an ISPM15 mark bearing the logo of the IPPC, and code letters to denote the country of origin & treatment, producer identity and type of treatment used. Implementation of the directive is a paperless system whereby inspectors in the EU will simply be looking for evidence of the ISPM15 mark on any wooden packaging materials, no certificate is required with the shipment. Non compliance could result in rejection and destruction of the entire shipment, but inspectors have considerable discretion in deciding what action is necessary on a case by case basis.

As an additional measure Directive 2004/102/EC specified that from 1st March 2006 all wood packaging materials would have to be de-barked, however the scientific basis for this requirement has been disputed and as a result the EU has postponed introduction of the requirement for debarking until January 1st 2009 (specified in Directive 2006/14/EC) to allow time for the IPPC to evaluate the scientific evidence for the debarking requirement.

2.9 Special restrictions on the import of food of non-animal origin (EC/882/2004 & specific commission decisions) – Products of non-animal origin are normally considered as representing a low level of risk to human health and thus are not subject to the systems for approval and prior notification associated with products of animal origin. However, the EU has made provision for dealing with high risk situations associated with products of non-animal origin. Under Article 15 of the Official feed and food controls regulation (EC/882/2004) the commission reserves the right to establish a list of products of non-animal origin where on the basis of known or emerging risks stricter controls are required in the form of approval to export, designation of entry points and prior notification of shipments. The European Commission has not developed this list yet, but special restriction measures are implemented on an individual basis via publication of Commission Decisions in the Official Journal of the European Union (series L). In every case the decision deals

with specific commodities and countries of origin and an identified risk to health requiring restrictions on imports to the EU. The measures are time limited and are cancelled when the risk has been satisfactorily controlled.

As an example in 2004 unacceptable levels of fungal toxins (Aflatoxins and Aflatoxin B1) were detected in pistachio nuts and pistachio nut products imported from Iran. Inspectors from the EU Food and Veterinary Office (FVO) visited Iran and found unsatisfactory hygiene practices representing a risk for aflatoxin formation and problems with product traceability making restriction of imports of pistachios from Iran necessary until the hygiene and traceability problems could be rectified. In January 2005 a Commission Decision was published (Commission Decision 2005/85/EC) imposing special conditions on the import of pistachios and certain products derived from pistachios originating in or consigned from Iran. These measures included specification of a list of approved entry points to the EU, mandatory requirement for each shipment to be accompanied by a health certificate issued by the Ministry of Health of the Government of Iran, specifying results of official sampling and analysis of the product for aflatoxin and each consignment must have an identification code number applied to all packages and to the health certificate.

Six of these Commission Decisions on products of non-animal origin were published between 1999 and 2005 (2000/49/EC, 2002/79/EC, 2002/80/EC, 2003/493/EC, 2005/85/EC & 2005/402/EC) and thus it is not a routine situation for products of non-animal origin to be subject to strict import controls. In every one of the incidents covered by the EU Commission Decisions mentioned above the cause of the restriction could have been avoided if the producers and exporters were operating proper food safety management and control systems from primary production through to point of export to the EU.

As all the economic costs for sampling, testing and issuing of approval to export, destruction of rejected shipments and loss of reputation all fall upon the food business, it makes practical sense to invest in good agricultural practices and good hygienic practices to ensure product safety and traceability and unrestricted access to EU markets rather than waiting for a problem to occur.

TECHNICAL BARRIERS TO TRADE (TBT) MEASURES

The majority of regulatory requirements for accessing EU markets deal with food safety and phytosanitary issues and thus come under SPS measures. However, exporters of selected commodities are required to meet quality specifications defined under the market grade standards regulation (EC/2200/1996) with proof of compliance with the standards coming in the form of a certificate of conformity (EC/1148/2001). Producers of organic products must meet the requirements laid down in the organic regulation (EC/2092/91).

2.10 Market grade standards (EC/2200/1996) and certificate of conformity with market grade standards (EC/1148/2001) – Regulation EC/2200/1996 defined the need for quality standards for fresh fruits and vegetables to ensure that produce offered to the consumer is of acceptable quality, accurately labelled and that produce of unsatisfactory quality is kept off the market. Produce subject to a market standard under EC/2200/1996 can only be sold by a retailer if it conforms with the specified standards, which require as a minimum that:

- Produce of all classes should be sound, clean and free of foreign smell or taste;
- Each container or display should be clearly marked with the correct information.

Currently there are 43 products subject to market grade standards (see table 5), each product has its own standard (for example beans are covered by standard EC/912/2001) that provides a detailed quality specification covering issues such as colour, size, shape, freshness and surface defects. Copies of the standards with detailed annexes stating the exact quality requirements required can easily be obtained from the website of the Horticultural Marketing Inspectorate of the United Kingdom Government. As can be seen from table 5 many of the tropical exotics such as pineapples, passion fruit, chilli peppers and okra do not have EU market standards (although Codex standards exist in most cases – see section 1.4).

For commodities where a standard exists, quality is divided into three classes (extra class, class 1 & class 2) with the requirements for each class being detailed in the annex to the relevant standard. From 31st March 2003 it has been mandatory to demonstrate compliance by providing a certificate of conformity (defined under EC/1148/2001) with each shipment of any of the 43 listed commodities.

Table 5. List of products of non-animal origin subject to market grade standards under EC/2200/1996

Vegetables	Extra Class	Class 1	Class 2
Artichokes (globe)	✓	✓	✓
Asparagus	✓	✓	✓
Aubergines		✓	✓
Beans	✓	✓	✓
Brussels sprouts		✓	✓
Cabbages		✓	✓
Carrots	✓	✓	✓
Cauliflowers	✓	✓	✓
Celery		✓	✓
Chicory (witloof)	✓	✓	✓
Courgettes	✓	✓	✓
Cucumbers	✓	✓	✓
Cultivated mushrooms (Agaricus)	✓	✓	✓
Garlic	✓	✓	✓
Leeks		✓	✓
Lettuce, endives and batavia		✓	✓
Onions		✓	✓
Peas (including mangetout & sugar-snap)		✓	✓
Spinach		✓	✓
Sweet peppers		✓	✓
Tomatoes	✓	✓	✓
Fruit	Extra Class	Class 1	Class 2
Apples	✓	✓	✓
Apricots	✓	✓	✓
Avocados	✓	✓	✓
Cherries	✓	✓	✓
Kiwifruit	✓	✓	✓
Lemons	✓	✓	✓
Mandarins	✓	✓	✓
Melons		✓	✓
Nectarines	✓	✓	✓
Oranges	✓	✓	✓
Peaches	✓	✓	✓
Pears	✓	✓	✓
Plums	✓	✓	✓
Satsumas, clementines, tangerines & similar citrus hybrids	✓	✓	✓
Strawberries	✓	✓	✓
Table grapes	✓	✓	✓
Watermelons		✓	✓
Nuts	Extra Class	Class 1	Class 2
Hazelnuts in shell	✓	✓	✓
Walnuts in shell	✓	✓	✓

The easiest way to get electronic copies of any of these standards and their annexes is to go to UK Governments Horticultural Marketing Inspectorate website (www.defra.gov.uk/hort/hmi.htm) and click on market standards.

Under EC/1148/2001 three routes are defined by which third country suppliers can obtain a certificate of conformity, these are as follows:

- Send shipment to the EU for inspection and certification by an inspector at the point of entry. This is the most obvious route but risks delay to shipments at the port waiting for an inspector to be available (a very real risk within the EU given the limited resources available for inspection) with consequent loss of quality and reduction in shelf-life for sensitive commodities.
- Import products via an EU importer having authority to inspect and issue certificates of conformity via the bonded warehouse system. This route avoids the risk of delays at port of entry, but locks the exporter into a relationship with a given importer which may prove commercially unattractive under certain conditions.
- The government of the non-EU exporting country applies to the EU mission in their country for authority to issue certificates of conformity prior to export to the EU. Certificates can be issued by government bodies or the government may specify in its application to the EU an intention to delegate authority for inspection and certification to the private sector. In this case private sector might mean an export agency, private certifier or large export companies. Obviously in these circumstances the government would need to specify a procedure for random checks by competent authorities of the private sector body to ensure inspection and certification procedures remain compliant to the requirements of EC/1148/2001.

Gaining permission to issue certificates of conformity prior to export is a straightforward process that has the advantage of eliminating the risk of delays at point of entry and retaining maximum flexibility of choice of importer for the third country supplier. Currently India, Israel, Morocco, New Zealand, Switzerland and South Africa have all successfully applied for approval to issue certificates of conformity under EC/1148/2001.

2.11 Organic production (EC/2092/91 & EC/1788/2001) – It is not the intention of this paper to look in detail at the requirements for export of organic fruits and vegetables but a brief summary would still be useful. Third country suppliers wishing to export fruits and vegetables under an organic label must meet all the requirements for organic production specified in Regulation EC/2092/91. To demonstrate compliance the food business must register with an EU approved organic certification body and implement an organic certification scheme incorporating independent verification of compliance on an annual basis. Eight countries have successfully demonstrated to the EU that they have equivalent national systems for control of organic production and free importation of organic products is allowed from these countries. Individual businesses in the majority of countries that have not demonstrated national equivalence of systems for organic production require prior approval for export and a certificate of importation (issued by a national or international body recognised by the EU) to accompany every shipment. Details of the certificate of importation and procedures for access by organic produce to EU markets are given in Regulation EC/1788/2001.

Third country suppliers of organic fruits and vegetables must also comply with all of the regulatory requirements for SPS & TBT specified for conventional production under sub-sections 2.1-2.10 with specific requirements being determined by whether the product is processed or comes under the market grade standards.

SECTION 3: EU FRUIT AND VEGETABLE IMPORT REQUIREMENTS AT A GLANCE

This section is laid out in the form of four quick reference tables covering the EU regulatory minima (Table 3.1) that apply to all imports of fruits and vegetables, additional measures applicable only to processed products (Table 3.2), products covered by the market grade standards (Table 3.3) and products marketed under an “organic” label (Table 3.4). Each table provides answers to common questions on regulatory requirements and provides reference to tables and sub-sections with page numbers in section 2 of the guide as well as giving the relevant regulation or directive number. You are strongly recommended to look at these tables first and then refer to the relevant sub-sections of section 2 for more detailed information.

Table 3.1 covers the minimum legal requirements for import of fresh unprocessed fruits and vegetables into the EU, for ease of use the table is subdivided into the following sub-sections and page references:

- General issues 27
- Vertical traceability 28
- General hygiene 28
- Microbiological criteria 29
- Safe and effective use of pesticides 29
- Chemical contaminants (other than pesticides) in food 32
- Phytosanitary measures to ensure plant health 35
- Special restrictions on the import of foods of non-animal origin 35

Table 3.1 Minimum legal requirements for export to EU markets applicable to all shipments of fresh fruits and vegetables

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
GENERAL ISSUES			
As my business is outside of the EU how can EU law apply to me?	EU law cannot apply directly outside the EU, but your buyer in the EU must comply with the law for all foodstuffs including imports and therefore will require you to meet the same criteria as a requirement for market access.	EC/178/2002	Sub-section 2.0 page 5
Does my country need official approval from the EU before I can export fruits and vegetables to EU markets?	NO – The approved countries list only applies to food of animal origin.	EC/882/2004	Sub-section 2.1 pages 5-6 & Table 1, page 7
Does my country need to get EU approval for its competent authorities?	NO – This measure only applies to food of animal origin, but your country must provide evidence of a competent authority for phytosanitary measures.	EC/882/2004 Dir 2000/29/EC	Sub-section 2.1 pages 5-6 & Table 1, page 7
Does my country need to submit a control plan before any exports of fruits and vegetables go to the EU?	NO – This measure only applies to food of animal origin.	EC/882/2004	Sub-section 2.1 pages 5-6 & Table 1, page 7
Does my business need to be on a list of EU approved establishments before I can export?	NO – This measure only applies to food of animal origin.	EC/882/2004	Sub-section 2.1 pages 5-6 & Table 1, page 7
Does my country need to have EU approved reference laboratories before I can export?	NO – This measure only applies to food of animal origin.	EC/882/2004	Sub-section 2.1 pages 5-6 & Table 1, page 7
Is my countries official food control system subject to inspection by the EU?	NO – This measure only applies to food of animal origin, but new guidance will be issued by the EU in October 2006.	EC/882/2004	Sub-section 2.1 pages 5-6 & Table 1, page 7
Do I need to give prior notification to the authorities in the EU prior to export of each consignment?	NO – This measure only applies to food of animal origin.	EC/882/2004	Sub-section 2.1 pages 5-6 & Table 1, page 7

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
Do I need any certificates to accompany each shipment?	Yes – You must have a phytosanitary certificate issued by the plant health authority in your country to accompany each shipment.	Dir 2000/29/EC	Sub-section 2.7 pages 20-21
VERTICAL TRACEABILITY			
What are the minimum labelling requirements for each consignment?	You must label your consignment with your company name, full address and contact details, country of origin, nature of the product (name of the product) and date of the transaction.	EC/178/2002	Sub-section 2.2 pages 6-7
GENERAL HYGIENE REQUIREMENTS			
What hygiene requirements do I need to meet in order to export fresh unprocessed fruits and vegetables to the EU?	<p>You must ensure food safety by preventing contamination of products from any source (air, soil, water, fertiliser, feed, chemicals, poor worker hygiene, storage, handling and disposal of wastes at any point in production through to export of the foodstuff.</p> <p>This is achieved by complying with the hygiene requirements for primary production specified in annex IA of EC/852/2004.</p>	EC/852/2004	<p>Sub-section 2.3 pages 8-13</p> <p>Summary of requirements under Annex IA see page 9</p>
Do I need to put HACCP in place on farm?	NO – Under Article 5 of EC/852/2004 you only need HACCP for post-harvest processing (see section 3.2).	EC/852/2004	Sub-section 2.3 pages 8-13
Do I need a certificate of compliance with the requirements of EC/852/2004?	NO – Official certificates are not required, but you must keep detailed records and documentation of the hygiene measures applied on farm and make these available to your EU buyer on request. Some EU buyers may ask for evidence of participation in an independently verified farm assurance scheme such as EUREPGAP as a means of ensuring compliance with EU legal requirements.	EC/852/2004	Sub-section 2.3 pages 8-13

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS			
Do I need to comply with the regulation on microbiological criteria for foodstuffs in order to export fresh unprocessed fruits and vegetables to the EU?	NO – with the exception of sprouted seeds (see 3.2) these criteria only apply to minimally-processed ready to eat fruits and vegetables.	EC/2073/2005	Sub-section 2.4 pages 13-15
SAFE AND EFFECTIVE USE OF PESTICIDES			
Are there any pesticides banned in the EU that I must avoid using or allowing to contaminate my crops?	YES – The EU has banned certain compounds on grounds of proven harm to human/animal health or environmental damage. These chemicals are listed in Directive 79/117/EEC and must not be present on the farm.	Dir 79/117/EEC	Sub-section 2.5.1 pages 15-16 & Table 3, page 16
Do I need a certificate of compliance with the banned pesticides directive?	NO – There are no official certificates for pesticide usage, verification of compliance is by random sampling and analysis at the point of entry, distribution or sale in the EU.	Dir 79/117/EEC	Sub-section 2.5.1 pages 15-16
What happens if banned pesticides are detected on my produce by the authorities in the EU?	If this occurs your consignment will be condemned and destroyed at your expense, you and your buyer will be informed, and you will risk not being allowed to make further exports to the EU. If the offence occurs for several suppliers from your country, the EU will consider introducing special restrictions on imports from your country (see section 2.9).	Dir 79/117/EEC	Sub-section 2.5.1 pages 15-16 & Table 3, page 16

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
<p>I hear that the EU has withdrawn many common pesticides from use can I still use these chemicals on crops intended for export to the EU?</p>	<p>YES – Compounds withdrawn under Directive 91/414/EEC cannot be produced, sold, stored or used within the EU, but you can use them on produce intended for the EU as long as the chemical and intended use is approved by the authorities in your country.</p> <p>In addition you must comply with EU maximum residue limits (see section 2.5.3) which will be set at the limit of detection for all withdrawn chemicals. It may prove difficult or impossible to achieve such a low level of residue whilst complying with manufacturers criteria for correct application.</p> <p>Although not an EU regulatory requirement your EU buyer may choose to make it a market requirement that chemicals withdrawn in the EU are not used on any produce intended for export to the EU.</p>	<p>Dir 91/414/EEC</p>	<p>Sub-section 2.5.2 pages 16-17</p>
<p>Do I need a certificate of compliance with the requirements of directive 91/414/EEC?</p>	<p>NO – There are no official certificates for pesticide usage, verification of compliance is by random sampling and analysis at the point of entry, distribution or sale in the EU.</p>	<p>Dir 91/414/EEC</p>	<p>Sub-section 2.5.2 pages 16-17</p>

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
What are the legal limits for pesticide on my produce when it reaches the EU?	The maximum permitted levels of pesticide are known as maximum residue limits (MRL's) which are established for chemicals and crops on the basis of scientific evidence. The EU is undergoing a major process to review licensing of chemicals under Dir 91/414/EEC and to create a single set of harmonised MRL's that will apply across the EU. This process is due for completion in mid 2008, but in the meantime a mixture of temporary and definitive MRL's listed in the annexes to EC/396/2005 will apply. Due to the review process the annexes will not start to appear until March-April 2006.	EC/396/2005	Sub-section 2.5.3 pages 17-19
How do I ensure compliance with the legal limits for pesticides on my produce?	MRL's are a useful verification measure but cannot be used directly by the farmer in the field. For field use the farmer needs to know the correct pre-harvest interval (PHI) and first harvestable date (FHD) to ensure that the amount of chemical left on the crop at the time of harvest meets legal requirements. PHI's are given in manufacturers literature but to be accurate the farmer must taken certain factors into account (see page 19).	EC/396/2005	Sub-section 2.5.3 pages 17-19

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
<p>What happens if the authorities in the EU detect pesticides at levels that exceed the permitted amounts specified under EC/396/2005?</p>	<p>If the level of pesticide exceeds the MRL and represents a risk to human health, the shipment will be condemned and destroyed at your expense, you and your buyer will be informed, and you will risk not being allowed to make further exports to the EU. If the offence occurs for several suppliers from your country, the EU will consider introducing special restrictions on imports from your country (see section 2.9).</p> <p>If the level of pesticide exceeds the MRL but is not a risk to human health, the shipment may be rejected and destroyed at your expense if detected at the port of entry. If detected at point of distribution or retail sale, you and your buyer will be informed and your details are likely to be published on publicly available electronic databases but no further action is likely to be taken because there is no risk to human health.</p>	<p>EC/396/2005</p>	<p>Sub-section 2.5.3 pages 17-19</p>
CHEMICAL CONTAMINANTS IN FOOD (OTHER THAN PESTICIDES)			
<p>Which chemical contaminants are important for fruits and vegetables?</p>	<p>For the majority of fresh fruits and vegetables the only contaminants with maximum levels specified under EC/466/2001 are lead and cadmium.</p> <p>For spinach and lettuce there are restrictions on the amount of nitrate in the product.</p>	<p>EC/466/2001</p>	<p>Sub-section 2.6 pages 19-20 & Table 4, page 19</p>

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
How do I ensure compliance with the legal limits for chemical contaminants in my produce?	<p>For lead and cadmium it is important to conduct a risk assessment to determine the risk of contamination. The level of risk can be dramatically reduced by avoiding the use of sewage sludge, not using land or water sources close to areas where lead and cadmium mining has occurred and avoiding planting too close to major roads or using surface water for irrigation if a risk exists of contamination of the water supply with run-off from a major road. Soil and water tests need to be conducted to determine the practical level of risk for a given site.</p> <p>For nitrate sensitive crops it is necessary to determine the level of nitrate in the soil and then take account of the amount of nitrate in any proposed inputs of fertilisers, manures, composts or mulches to calculate how much of these inputs can be used without exceeding the maximum levels permitted in the crop. Visual indications of excessive nitrate levels such as abnormally dark green foliage, thick stems and greater leaf development should be acted upon.</p>	EC/466/2001	Sub-section 2.6 pages 19-20
Do I need a certificate to demonstrate compliance with the requirements of EC/466/2001?	NO – There are no official certificates for chemical contamination, verification of compliance is by random sampling and analysis at the point of entry, distribution or sale in the EU.	EC/466/2001	Sub-section 2.6 pages 19-20

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
<p>What happens if the authorities in the EU detect pesticides at levels that exceed the permitted amounts specified under EC/466/2001?</p>	<p>If the level of contamination exceeds the MRL and represents a risk to human health, the shipment will be condemned and destroyed at your expense, you and your buyer will be informed, and you will risk not being allowed to make further exports to the EU. If the offence occurs for several suppliers from your country, the EU will consider introducing special restrictions on imports from your country (see section 2.9).</p> <p>If the level of contamination exceeds the MRL but is not a risk to human health, the shipment may be rejected and destroyed at your expense if detected at the port of entry. If detected at point of distribution or retail sale, you and your buyer will be informed and your details are likely to be published on publicly available electronic databases but no further action is likely to be taken because there is no risk to human health.</p>	<p>EC/466/2001</p>	<p>Sub-section 2.6 pages 19-20</p>

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
PHYTOSANITARY MEASURES TO ENSURE PLANT HEALTH			
Do I need a plant health (phytosanitary) certificate in order to export fresh fruits and vegetables to the EU?	<p>A phytosanitary certificate issued by your plant health authority is required to be sent with every shipment of produce specified under annex V of Directive 2000/29/EC to certify that none of the pests or diseases mentioned in annexes I and II of the directive are present in the consignment.</p> <p>The validity of the certificate may be checked by random sampling and analysis at the point of entry into the EU, non-compliant shipments will be rejected and destroyed at the exporters expense if they represent a serious risk to plant health within the EU.</p>	Dir 2000/29/EC	Sub-section 2.7 pages 20-21
What are the plant health requirements for wooden packaging?	<p>All wooden packaging manufactured from natural timber of greater than 6mm thickness after 28th February 2005 must be treated to comply with ISPM-15 and be stamped with an ISPM-15 compliance stamp. All wooden packaging must be de-barked as of January 1st 2009.</p> <p>Non-compliant packaging can be rejected and could result in rejection of the entire consignment.</p>	Dir 2004/102/EC	Sub-section 2.8 page 21
SPECIAL RESTRICTIONS AND EMERGENCY MEASURES			
What are special restrictions to imports of food of non-animal origin into the EU?	Food of non-animal origin is normally considered to be of low risk. However, if repeated violations of the law are detected that represent a risk to human health, the EU will introduce measures to restrict imports until the risk is eliminated or reduced to an acceptable level.	EC/882/2004	Sub-section 2.9 pages 21-22

Table 3.2 Additional requirements applicable to fresh-cut (minimally processed) fruits and vegetables

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
What are the minimum requirements for export of fresh-cut fruits and vegetables to the EU?	Exporters of fresh-cut ready to eat fruits and vegetables and sprouted seeds must comply with all of the measures described in section 3.1 and additional measures specified below.	See section 3.1	
What are the basic hygiene requirements for fresh-cut fruits and vegetables?	<p>You must ensure food safety by preventing contamination of products from any source (air, water, chemicals, poor worker hygiene, storage, handling and disposal of wastes at any point in processing, storage or transport of the foodstuff through to export.</p> <p>This is achieved by complying with the hygiene requirements for processing and preparation of foodstuffs specified in annex II of EC/852/2004.</p>	EC/852/2004	<p>Sub-section 2.3 pages 8-13</p> <p>Summary of requirements under Annex II see page 10</p>
Do I need HACCP in place in the processing facility?	Under Article 5 of EC/852/2004 food businesses conducting processing operations must put a HACCP system in place that meets the requirements specified under the regulation.	EC/852/2004	Sub-section 2.3 pages 8-13
Do I need to comply with microbiological criteria for foodstuffs?	Suppliers of ready to eat minimally processed fruits and vegetables and sprouted seeds must comply with hygiene and food safety criteria (see table 2, page 14). In practice this is achieved by putting in place and maintaining all of the good hygienic practices (GHP) specified under annex II of EC/852/2004 and a HACCP system. The success of the GHP & HACCP for controlling hazards is verified by regular sampling for <i>E.coli</i> and Salmonella and judging results against the criteria given in EC/2073/2005.	EC/2073/2005	Sub-section 2.4 pages 13-15 & Table 2, page 14

Table 3.3 Additional requirements applicable for commodities covered by market grade standards as defined under EC/2200/1996

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
What are the minimum requirements for export of fruits and vegetables covered by EU market grade standards?	Exporters of fruits and vegetables covered by market grade standards must comply with all of the measures described in section 3.1 and additional measures specified below.	See section 3.1	
What are market grade standards?	Market grade standards are quality standards covering issues such as colour, length, shape and surface defects. They DO NOT cover human or plant health issues.	EC/2200/1996	Sub-section 2.10 pages 23-25
Which commodities are covered by market grade standards?	43 commodities are currently list as having an EU market grade standard.	EC/2200/1996	See Table 5, page 30
Do I need a certificate to export fruits and vegetables covered by market grade standards to the EU?	YES – A certificate of conformity is required this certificate need not be issued prior to export but reliance on certification at the point of entry into the EU can lead to unnecessary delays to release into the market.	EC/1148/2001	Sub-section 2.10 pages 23-25
Do I need to get a certificate before I export?			

Table 3.4 Additional requirements applicable for organic fruits and vegetables as defined under Regulations EC/2092/91 & EC/1788/2001

Question	Minimum EU requirement for market access	EU Regulation or Directive	For detailed information see:
What are the minimum requirements for export of organic fruits and vegetables to the EU?	Exporters of organically produced fruits and vegetables must comply with all of the measures described in section 3.1 and additional measures specified below.	See section 3.1	
What additional measures are required for organic products and how do I demonstrate compliance?	Produce labelled as organic must be produced according to criteria established under EC/2092/1991. To demonstrate compliance the food business must register with an EU approved organic certification body and implement an independently verified organic certification scheme.	EC/2092/1991	Sub-section 2.11 page 25
Do I need an organic certificate for each consignment in order to export?	YES – A certificate of importation is required to meet the requirements of EC/1788/2001 issued by a competent authority approved by the EU.	EC/1788/2001	Sub-section 2.11 page 25
Do I need to give prior notice to the authorities in the EU of intention to export?	YES – Exporters in countries that have not received EU approval to freely export organic produce to the EU must give prior notification of each shipment.	EC/1788/2001	Sub-section 2.11 page 25

REFERENCES

EU Regulations

Commission Regulation EC/2076/2005 of 5th December 2005 laying down transitional arrangements for the implementation of regulations EC/853/2004, EC/854/2004 and EC/882/2004 of the European Parliament and of the Council and amending regulations EC/853/2004 and EC/854/2004. Official Journal of the European Union, Series L, issue 338, 22.12.2005, pages 1-26.

Commission Regulation EC/2073/2005 of 15th November 2005 on microbiological criteria for foodstuffs. Official Journal of the European Union, Series L, issue 338, 22.12.2005, pages 1-26.

Regulation EC/396/2005 of the European Parliament and of the Council of 23rd February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. Official Journal of the European Union, Series L, issue 70, 16.3.2005, pages 1-16.

Regulation EC/183/2005 of the European Parliament and of the Council of 12th January 2005 laying down requirements for feed hygiene. Official Journal of the European Union, Series L, issue 35, 8.2.2005, pages 1-22.

Corrigendum to Regulation EC/854/2004 of the European Parliament and of the Council of 29th April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Official Journal of the European Union, Series L, issue 226, 25.6.2004, pages 83-127.

Corrigendum to Regulation EC/853/2004 of the European Parliament and of the Council of 29th April 2004 laying down specific hygiene rules for food of animal origin. Official Journal of the European Union, Series L, issue 226, 25.6.2004, pages 22-82.

Corrigendum to Regulation EC/852/2004 of the European Parliament and of the Council of 29th April 2004 on the hygiene of foodstuffs. Official Journal of the European Union, Series L, issue 226, 25.6.2004, pages 3-21.

Corrigendum to Regulation EC/882/2004 of the European Parliament and of the Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Official Journal of the European Union, Series L, issue 191, 28.5.2004, pages 1-52.

Regulation EC/178/2002 of the European Parliament and of the Council of 28th January 2002 laying down the principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Communities, Series L, issue 31, 1.2.2002, pages 1-24.

Commission Regulation EC/1788/2001 of 7th September 2001 laying down detailed rules for implementing the provisions concerning the certificate of inspection for imports from third countries under Article 11 of Commission Regulation EC/2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. Official Journal of the European Communities, Series L, issue 243, 13.9.2001, pages 3-14.

Commission Regulation EC/1148/2001 of 12th June 2001 on checks on conformity to the marketing standards applicable to fresh fruits and vegetables. Official Journal of the European Communities, Series L, issue 156, 13.6.2001, pages 9-27.

Commission Regulation EC/912/2001 of 10th May 2001 laying down the marketing standard for beans. Official Journal of the European Communities, Series L, issue 129, 11.5.2001, pages 4-7.

Commission Regulation EC/466/2001 of 16th March 2001 setting maximum levels for certain contaminants in foodstuffs. Official Journal of the European Communities, Series L, issue 77, 16.3.2001, pages 1-13.

Council Regulation EC/2200/1996 of 28th October 1996 on the common organisation of the market in fruit and vegetables. Official Journal of the European Communities, Series L, issue 297, 21.11.1996, pages 1-38.

Council Regulation EC/2092/1991 of 24th June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. Official Journal of the European Communities, Series L, issue 198, 22.7.1991, pages 1-95.

United Kingdom Regulations

The Official Feed and Food Controls (England) Regulations 2006. Statutory Instrument 2006, No. 15. The Stationery Office, ISBN 0110738896. pages 1-43.

The Food Hygiene (England) Regulations 2006. Statutory Instrument 2006, No. 14. The Stationery Office, ISBN 0110738888. pages 1-54.

EU Directives

Commission Directive 2006/14/EC of 6th February 2006 amending annex IV to Council Directive 2000/29/EC on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community. Official Journal of the European Union, Series L, issue 34, 7.2.2006, pages 24-25.

Commission Directive 2004/102/EC of 5th October 2004 amending annexes II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community. Official Journal of the European Union, Series L, issue 309, 6.10.2004, pages 9-25.

Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21st April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC. Official Journal of the European Union, Series L, issue 195, 2.6.2004, pages 12-15.

Council Directive 2002/99/EC of 16th December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption. Official Journal of the European Communities, Series L, issue 18, 23.1.2003, pages 11-20.

Council Directive 2000/29/EC of 8th May 2000 on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community. Official Journal of the European Communities, Series L, issue 169, 10.7.2000, pages 1-112.

Council Directive 91/414/EEC of 15th July 1991 concerning the placing of plant protection products on the market. Official Journal of the European Communities, Series L, issue 230, 19.8.1991, pages 1-194.

Council Directive 79/117/EEC of 21st December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances. Official Journal of the European Communities, Series L, issue 033, 8.2.1979, pages 36-39.

EU Commission Decisions

Commission Decision 2005/85/EC of 26th January 2005 imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran. Official Journal of the European Union, Series L, issue 30, 3.2.2005, pages 12-18.

EU Commission Communications & White Papers

COM (2000) 1 final Communication from the Commission on the precautionary principle. Commission of the European Communities, Brussels, 2.2.2000, pages 1-28.

COM (1999) 719 final. White paper on food safety. Commission of the European Communities, Brussels, 12.1.2000, pages 1-52.

Guidance on the interpretation of EU food law

Health and Consumer Protection Directorate General (2006) Guidance document on certain key questions relating to import requirements and the new rules on food hygiene and on official food controls. European Commission, Brussels, 5.1.2006, pages 1-28.

FSA General guidance for food business operators – EC Regulation 2073/2005 on microbiological criteria for foodstuffs. Food Standards Agency, United Kingdom, January 2006, pages 1-23.

Health and Consumer Protection Directorate General (2005) Guidance document on the implementation of certain provisions of Regulation EC/852/2004 on the hygiene of foodstuffs. European Commission, Brussels, 21.12.2005, pages 1-16.

FSA Guidance on the requirements of food hygiene legislation – working draft. Food Standards Agency, United Kingdom, 1st December 2005, pages 1-72

Health and Consumer Protection Directorate General (2005) Guidance document on the implementation of procedures based on the HACCP principles and on the facilitation of the implementation of the HACCP principles in certain food businesses. European Commission, Brussels, 16.11.2005, pages 1-27.

EC marketing standards for fresh fruits, vegetables, salad crops and nuts – a guide for retailers. Horticultural Marketing Inspectorate, Department for Environment Food and Rural Affairs (DEFRA) of the Government of the United Kingdom, September 2005, pages 1-7.

Health and Consumer Protection Directorate General (2005) Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of regulation EC/178/2002 on general food law. European Commission, Brussels, 20.12.2004, pages 1-30.

Guidance for importing organic produce – Guide on implementing Commission Regulation EC/1788/2001 and the organic products & imports from third countries regulations 2003. Department for Environment Food and Rural Affairs (DEFRA) of the Government of the United Kingdom, 6.1.2004, pages 1-36.

USEFUL WEBSITES

Eur-lex: http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en official website offering plain text searches of the Official Journal, Legislation in force, Consolidated legislation, Community preparatory acts and treaties, documents can also be searched for by number within the sections.

Official Journal: <http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en> Official Journal series “L” for legislation and “C” for information and notices, document searches are most readily carried out by entering the regulation or directive reference number such as EC/852/2004.

Legislation in force: <http://europa.eu.int/eur-lex/lex/en/repert/index.htm> organised into 20 chapters, 03 deals with agriculture (agriculture, biotechnology, organic farming, foodstuffs etc), chapter 15 covers environment, consumers and health protection.

Consolidated texts: <http://europa.eu.int/eur-lex/en/consleg/index.html> Consolidated texts are useful because they present the text of the law with all amendments added thus saving a lot of time on cross-referencing.

SCADPlus: <http://europa.eu.int/scadplus/leg/en/s84000htm> provides official EU summaries of legislation, sections include, controls and food hygiene rules, imports from third countries, specific provisions (all meat related) and production and placing on the market of foodstuffs.

EU Guidance documents:

<http://europa.eu.int/comm/food/food/foodlaw/guidance/index.htm> Official guidance documents on food law, clarifying the requirements for food businesses.

Health and Consumer Protection Directorate General (DGSANCO):

http://europa.eu.int/comm/dgs/health_consumer/index_en.htm DG SANCO is responsible for food safety and hygiene within the EU, and this website offers excellent coverage of food safety issues and global listings of EU approved countries, establishments and laboratories.

United States Foreign Agriculture Service (USEU): www.useu.be/agri/usda.html

well organised website of easy to read information designed to help US producers and exporters selling into the EU, includes information on EU regulations and implications for third country suppliers, import regulatory guides for each EU member state (FAIRS) with all procedures and contacts given, certification requirements, reports and articles.

Food Standards Agency: www.food.gov.uk provides guidance documents on EU food laws and United Kingdom interpretation of EU legislation, some guidance documents are more detailed than those found on EU sites and FSA also provides code of practice.

Horticultural Marketing Inspectorate: www.defra.gov.uk/hort/hmi.htm United Kingdom government site, containing very useful information on import requirements for fresh produce and excellent coverage of market grade standards (EC/2200/1996) and conformity certificates under EC/1148/2001. Individual EU grade standards are easily accessed from a list of commodities subject to market grade standards.

EU MRL: Useful websites on pesticides – A selection of websites offering access to EU MRL's, pesticide safety data and government testing programmes with results published on a quarterly basis.

http://europa.eu.int/comm/food/plant/protection/pesticides/index_en.htm

http://www.pesticides.gov.uk/psd_databases.asp

<http://www.chm.bris.ac.uk/safety/msds.htm>

Codex Alimentarius Commission: www.codexalimentarius.net provides access to electronic copies of all of the Codex Alimentarius Commission international standards, guidance documents and manuals consisting of combined texts developed jointly by the 154 member states of the Codex Alimentarius Commission. Codex maximum residue limits for pesticides and veterinary drugs are provided via user friendly databases that can be searched by commodity or compound. The Codex documents are the official reference texts for the WTO administered SPS and TBT agreements that set the framework for regulation of international trade.

FAO International Portal on Food Safety, Animal and Plant Health (IPFSAP): www.ipfsaph.org/En/default.jsp The IPFSAP offers an alternative route for accessing Codex documents, but more importantly the portal has a searchable database of official documents (downloadable as PDF files) on SPS issues submitted by signatories to the WTO administered SPS and TBT agreements. These documents can be invaluable for checking national regulatory requirements either within the producer country or for checking the regulatory requirements for access to a new export market.

World Trade Organisation: www.wto.org provides access to copies of the SPS and TBT agreements that form the basis for harmonisation of international regulation of food safety, quality, animal and plant health in global trade. WTO quarterly reports are also accessible covering trade and regulatory issues and disputes between members of the WTO.

Dr Andrew John Graffham
Food Safety & Quality Specialist
Natural Resources Institute
University of Greenwich at Medway
Central Avenue
Chatham Maritime
Kent, ME4 4TB
United Kingdom

Email: a.j.graffham@gre.ac.uk or andrew.graffham@btopenworld.com

Tel: 00 44 1634 88 32 39 or 00 44 77 43 82 06 57