

Standard setting and/or benchmarking organisations

Unsafe food shall not be placed on the market.



4 Standard setting and/or benchmarking organisations

With trade relations becoming globally intertwined, producers, processors and traders need coherent conditions that facilitate business relations across boundaries. Since the ever expanding system of standards might hamper international trade, there is a need for coordination and harmonisation. The European Union consequently follows the principle that, where applicable, international standards take priority over EU standards, and with proceeding harmonisation of the internal market, EU standards take priority over EU Member States' standards.

The vast number of laws, regulations, standards, good practices and codes leaves everybody confused who is not working with these issues on a regular basis and thus cannot keep up with the developments. With a view of facilitating the orientation in this labyrinth, the following box gives an overview of relevant standard ruling and setting organisations, which will be presented in more detail in the subsequent chapters (the hyperlinks allow direct access to the respective chapters). Readers interested to access original standard texts and further related information, will find useful links both at the end of every section and in chapter 7.

Food Quality Standards	Food Safety Standards	Social & Ecological Standards
WTO - Rules for Standard-Sett multilateral - public - mandatory		
Technical Barriers to Trade Agreement (TBT)	Sanitary and Phytosanitary Agreement (SPS)	
Trade Related Intellectual Property Rights (TRIPS)		
WTO – recognized Standards multilateral – public – reference standards for WTO members		United Nations multilateral – public – mandatory for signatory countries
Codex Allmentarius Comission	(CAC)	International Labour Organisation (ILO)
	International Plant Protection Convention (IPPC)	
	World Organisation for Animal Health (OIE)	
International Organization for Standardization (ISO)		
EU – Legislation regulating co supranational – public – mandato		
Common Market Organisation (CMO)	EU General Food Law	Generalised System of Preferences (GSP+)
		Cross-Compliance
EU – Legislation regulating ma supranational – public – voluntar		
Organic Farming		Organic Farming
EU Member States – Legislatio national – public – mandatory at	n regulating commercial activities national level	
Marketing Standards*	e.g. Food and Feed Code (Germany)	
Collective Standards (sub-sect private – voluntary	or networks, company networks and alik	ce)
	Global Food Safety Initiative (GFSI) – recognized standards: BRC, Dutch HACCP, SQF, IFS, NZ GAP	International Social and Environmental Accreditation and Labelling Alliance (ISEAL) – recognized standards: FLO, FSC, IFOAM, MAC, MSC, RA, SAI
	EurepGAP – Scope Fruit & Vegetables – recognized standards: AMAGAP, ChileGAP, Mais Doux, México Supreme Quality GAP, Naturane, QS- GAP, etc.	
	others: Label Rouge, etc.	others: EurepGAP, Global Compact, etc.
Corporate Standards (individu private – voluntary	al companies)	
Company Codes/Company Spo	ecifications	Corporate Social Responsibilities (CSR)

^{*} National marketing standards are only applicable where no EU norms have been established.

Box 1: Inventory of food standards

4.1 Multilateral organisations

Standards are not only based on scientific values but also represent a political consensus between diverging interest and pressure groups. Thus, a balance has to be found between economic and social needs, between wishful thinking and economic feasibility. This is a recognised basic principle of international trade policy, on which consensus was achieved within the World Trade Organization.

4.1.1 World Trade Organization (WTO)

The WTO itself does not establish standards but

- · sets rules to be applied by WTO member countries when setting national standards and
- recognises reference standards to be applied in trade between WTO member countries.

The WTO was founded on 1 January 1995 as an umbrella organisation for an expanded world trade system including trade in goods (GATT – General Agreement on Tariffs and Trade), cross-border services (GATS – General Agreement on Trade in Services) and the protection of intellectual property rights (TRIPS – Agreement on Trade-related Aspects of Intellectual Property Rights). The WTO has been designed as a flexible agreement to adapt to a continuously changing international trading system. It aims at reducing tariffs and other trade barriers as well as abolishing discriminatory behaviour in international trade.

Due to the increasing number of products covered by the WTO, the issue of standardisation has invited growing attention.

4.1.1.1 WTO - General provisions

Central pillars

- General Agreement on Tariffs and Trade (GATT of 1 January 1948)
- General Agreement on Trade in Services (GATS of 15 April 1994)
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS of 15 April 1994)
- Understanding on Rules and Procedures Governing the Settlement of Disputes (Disputes Settlement Understanding – DSU of 15 April 1994)

Key WTO principles Every member of the WTO is bound to fulfil its obligations deriving from the Agreements regulating the trade in goods and services as well as the protection of intellectual property rights ("single undertaking" 15).

The key principles of the WTO are:

 Most-favoured-nation (MFN): treating other WTO members equally (GATT Article I, GATS Article II, TRIPS Article 4):
 Each member country that grants market access or other special benefits to another member country has to grant the same rights to all other member countries. In simple terms, a special benefit granted to one country (such as a lower customs tariff) has to be granted to all other WTO Members.

The principle of "single undertaking" refers to the obligation of members to adopt all WTO agreements without exception.

- National Treatment: treating foreigners and locals equally (GATT Article III):
 A member country may require that imported products comply with the same product regulations as domestic products ('like products'¹⁶); discrimination of imported products offends against the GATT principle. In simple terms, imported and locally-produced goods have to be treated equally with regard to competitive opportunities in the import market.
- Reciprocity: making equivalent concessions (GATT, GATS, TRIPS):
 The political principle of reciprocity applies to tariff negotiations (GATT Article XXVIII) and protective measures (GATT Article XIX:3). The negotiations regarding the reduction of tariffs are to be held on a reciprocal and mutually beneficial basis. With respect to developing countries, GATT does not expect reciprocity in tariff concessions or the reduction of other trade barriers.

The Doha Development Round In November 2001, the declaration of the Fourth Ministerial Conference in Doha, Qatar, provided the mandate for negotiations on a range of subjects including those on agricultural market access and domestic support. Members agreed to dedicate this second round of WTO negotiations to the development goals of less developed countries. Called the 'Doha Development Round', it aimed at free global trade by cutting industrial and agricultural tariffs and reducing farm subsidies, with a special focus on achieving concrete benefits for developing countries. The original mandate was refined at the conferences in Cancún (2003), Geneva (2004), and Hong Kong (2005). For the developments since then see succeeding paragraph.

Agreement on Agriculture The WTO's Agreement on Agriculture (AoA) was negotiated in the 1986-1994 Uruguay Round and is a significant first step towards fairer competition and a less distorted sector. It includes specific commitments by WTO member governments to improve market access by reducing tariffs and eradicating non-tariff barriers as well as trade-distorting subsidies in agriculture. These commitments are being implemented over a six year period (10 years for developing countries) that began in 1995.

The revision of the WTO Agreements was supposed to be finalised by 1 January 2005. But all negotiations are on halt since July 2006 because of unbridgeable differences in Agriculture. There are still wide gaps in the positions among negotiators regarding fundamental aspects of the further reform programme (in particular among industrial countries like the EU and the US on market access, export competition, domestic support, provisions for special and differential treatment). There is already significant support for exempting least-developed countries from some commitments, but details are not yet specified.

Environmental protection and Ethical trade (social and environmental standards)

Introducing the objective of sustainable development into the WTO preamble has led to an intense debate on the linkages between trade policy and environmental policy since the signing of the 'Final Act of the Uruguay Round of Multilateral Trade Negotiations' in Marrakech on 15 April 1994. Proposals from WTO members, such as the EU and Norway, explicitly call for more environmental concerns to be incorporated into the international trade framework. Other governments propose reductions in subsidies linked to production in agriculture, energy, mining and fishing. These proposals are essentially driven by environmental concerns. Generally, there is growing recognition (both in advanced and developing economies) that the removal of certain trade restrictions and distortions would lower environmental damage.

At the Fifth Ministerial Conference in Hongkong in December 2005, Ministers reaffirmed their commitment to negotiations on specific trade obligations set out in multilateral environmental agreements and welcomed the work undertaken by the WTO Committee on Trade and Environment.

Adherents to the scientific approach oppose the application of non-product related Process and Production Method (PPM) requirements within the GATT/WTO context since they consider the risk of rising (disguised) protectionism particularly high. Adherents to the precautionary approach, however, aim at including social and environmental standards into GATT/WTO agreements. They assume that there is an international responsibility for a fair working environment and for global protection of natural resources.

Definition see chapter 2

Aid for Trade

Many poor countries lack the basic infrastructure to take advantage of the market access opportunities resulting from a successful outcome to the Doha Round of trade negotiations. In this context, Aid for Trade provides trade-related technical assistance and capacity building to help developing and least-developed countries to participate more efficiently in international trade with a special focus on fostering bilateral and multilateral development cooperation in trade-related fields. Funds for trade promotion have been pledged by the EU Commission ¹⁷⁾ and the US¹⁸⁾.

Emerging issues

- World Trade Report 2005:
 - In chapter II 'Trade, Standards and the WTO', the report refers to recent developments in fields such as (i) the economics of standards, (ii) institutions and policy issues, and (iii) standards in the multilateral trading system (see further readings).
- Geographical indications: increasing interest of the private sector to gain a competitive edge by producing food of specific characteristics associated with specific localities (linked to the discussion in the TRIPS (intellectual property) Council on geographical indications; see below)
- Non-trade concerns (agricultural multifunctionality, environmental protection, animal
 welfare and others), labelling and trade distortion:
 discussion over whether voluntary and mandatory labelling would be a way to deal with
 some non-trade concerns without distorting trade (e. g. animal welfare, information on
 genetically modified organisms etc.)
- Process and Production Methods (PPM):
 with competitiveness concerns being on the rise, the private sector in major target
 markets increasingly imposes PPM-related social and environmental standards ('ethical
 trade') on suppliers in developing countries independent from any WTO-decisions

Further readings

EC: Aid for Trade

http://ec.europa.eu/trade/issues/bilateral/regions/acp/pr161006_en.htm

EC: EU & WTO – The Doha Development Agenda http://ec.europa.eu/trade/issues/newround/doha_da/index_en.htm id21 (2005): Harnessing trade for development

http://www.id21.org/insights/insights59/index.html

World Bank and International Monetary Fund (2006): Trade Progress Report – The Doha Development Agenda and Aid for Trade: Hongkong and beyond

http://siteresources.worldbank.org/DEVCOMMINT/Documentation/20890708/DC2006-0005 (E)-TradeProgress.pdf (EVCOMMINT/Documentation/20890708/DC2006-0005 (E)-TradeProgress.pdf (EVCOMMINT/Documentation/EVCOMMINT/Do

WTO: Agriculture: Work in the WTO – The current negotiations

http://www.wto.org/english/tratop_e/agric_e/negoti_e.htm

WTO: WTO News

http://www.wto.org/english/news_e/news_e.htm

WTO: Understanding the WTO: Basics - Principles of the trading system

 $http://www.wto.org/English/thewto_e/whatis_e/tif_e/fact2_e.htm\\$

WTO: Understanding the WTO: The Agreements – Agriculture: fairer markets for farmers

http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm3_e.htm

WTO: Doha Development Agenda
http://www.wto.org/English/tratop_e/dda_e/dda_e.htm
WTO: Legal Texts – the WTO agreements
http://www.wto.org/english/docs_e/legal_e/final_e.htm

WTO: World Trade Report 2005

http://www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report05_e.pdf

The following agreements, which are designed to minimise discriminatory and adverse effects of international and national regulations, are of special interest with regard to food standards (see chapters 4.1.1.2 to 4.1.1.5):

- Agreement on Technical Barriers to Trade (WTO TBT)
- Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS)
- Agreement on Trade-related Aspects of Intellectual Property Rights (WTO TRIPS)

¹⁷ 2 billion US\$ per annum until 2010

¹⁸ 2,7 billion US\$ per annum until 2010

WTO TBT and WTO SPS both acknowledge the importance of harmonising standards internationally in order to reduce the risk of sanitary, phytosanitary and other technical standards becoming a barrier to trade.

A fourth agreement is important regarding settlement procedures for disputes between members:

 Understanding the Rules and Procedures Governing the Settlement of Disputes (WTO DSU) (see chapter 4.1.1.6)

Specific health issues and relevant WTO agreements are summarised in the following box.

Box 2: Specific health issues and most relevant WTO agreements						ts	
WTO Rule or Agreement Health Issue	Agriculture	SPS	TBT	TRIPS	Services (GATS)	GATT Art. XX(b)	Others
Infectious Disease Control		X	X			X	
Food Safety		X					
Tobacco Control	X		×	×	X	X	
Environment		X	×			X	
Access to Drugs				X			
Health Services					X		X
Food Security		X				X	
Emerging Issues							
Biotechnology		X	X	X			
Information Technology				X	X		
Traditional Knowledge				X			

Source: WHO/WTO 2002 http://www.wto.org/english/news_e/pres02_e/pr310_e.htm

4.1.1.2 WTO TBT – Agreement on Technical Barriers to Trade

Relevance

The objective of the TBT Agreement is to prevent the unjustified use of national or regional technical requirements, or standards in general, as technical barriers to trade. It requires non-discriminatory application of mandatory product standards on imported products. The TBT Agreement covers all technical regulations and conformity assessment procedures including those related to food such as standards of quality, nutritional requirements, labelling and methods of analysis. It includes measures designed to protect the consumer against deception and economic fraud.

The TBT Agreement

- recognises that international standards and conformity assessments contribute considerably to improve efficiency of production and facilitate trade
- aims at harmonising standards by encouraging all standardising bodies to participate in the preparation of international standards

With the signing of the TBT Agreement, WTO members agree that

- their central governmental standardising bodies comply with the WTO Code of Good Practice for the Preparation, Adoption and Application of Standards (see below)
- they take reasonable measures to ensure that local governmental, non-governmental and standardising bodies also apply this code

Principles

Legitimate objective:

Legitimate objectives include inter alia: national security requirements, prevention of deceptive practices, protection of human health or safety, protection of animal and plant life or health or the environment.

Avoidance of unnecessary obstacles to trade:

"The Agreement on Technical Barriers to Trade (TBT) provides that such mandatory product standards should not be so applied by countries as to cause unnecessary obstacles to international trade. Furthermore, they should be based on scientific information and evidence." (see box 2 p. 29)

Transparency:

Members must notify their TBT measures (technical regulations, conformity assessment procedures) to the WTO when two conditions apply:

- (i) whenever a relevant international standard or guide or recommendation does not exist, or the technical content of the measure goes beyond and
- (ii) if the measure may have a significant effect on the trade of other Members. Enquiry Points must be established to answer reasonable questions of other WTO members.

Harmonisation:

- (i) "From the viewpoint of the Agreement, technical regulations do not create unnecessary barriers to trade if they are based on internationally agreed standards.
- (ii) "Voluntary standards ... may pose problems in international trade if they differ widely from country to country. The Code of Good Practice for the Preparation, Adoption and Application of Standards, an integral part of the Agreement on TBT, therefore urges countries to use their best endeavours to require national standardising bodies to use the same principles and rules in preparing and applying voluntary standards as are laid down for mandatory standards."

Equivalence:

"A complementary approach to technical harmonisation is known as equivalence. Technical barriers to international trade could be eliminated if Members accept that technical regulations different from their own fulfil the same policy objectives even if through different means". WTO members are encouraged to formally recognise equivalence by mutual recognition agreements.

Special and differential treatment:

The TBT Agreement pays attention to the specific situation of developing countries, in particular with respect to implementation periods and to the obligation of developed countries to provide technical assistance to developing countries.

Organisations accepting the Code of Good Practice

The WTO TBT Standards Code Directory lists standardising bodies that have notified acceptance of the 'Code of Good Practice for the Preparation, Adoption and Application of Standards'

Emerging issues

· Conformity Assessment:

With a view to improving implementation of the TBT Agreement and to promoting a better understanding of conformity assessment systems in member countries, the WTO organised a workshop in March 2006 to discuss the different approaches to conformity assessment, including the acceptance of conformity assessment results.

- Supplier's Declaration of Conformity (SDoC):
 - The 2005 workshop on SDoC came to the following conclusions:
 - (i) SDoC contributes to reducing costs for regulators allowing them to spend more on post market surveillance
 - (ii) SDoC may be beneficial to exporters/suppliers by reducing their expenses and fostering their competitiveness and may facilitate exports to developed countries (iii) developing countries are concerned with their capacities to use SDoC (lack of technical infrastructure, products liability regimes and market surveillance system) and need technical assistance

Further readings

EC: DG Enterprise - Technical Barriers to Trade - Database, Library, News, Useful Links

http://ec.europa.eu/enterprise/tbt/index.cfm?dspLang=en

EC: EU and WTO

http://ec.europa.eu/trade/issues/global/index en.htm

FAO (2003): WTO Agreement on Agriculture: The Implementation Experience

- Developing Country Case Studies

http://www.fao.org/DOCREP/005/Y4632E/Y4632E00.HTM
FAO: Trade in Agriculture Fisheries and Forestry – WTO Negotiations

http://www.fao.org/trade/negoc dda en.asp

ISO (2006): Standardising Bodies having notified Acceptance of the WTO TBT Code Practice for the Preparation, Adoption and Application of Standards as of September 2006 http://www.iso.org/iso/en/comms-markets/wto/pdf/TbtList_2006-09-16.pdf or http://www.iso.org/iso/en/comms-markets/wto/pdf/scd2006-07-en.pdf

WTO: A Training Package - Module 3 - Goods: Rules on Non-Tariff Measures (NTMs)

http://www.wto.org/English/thewto_e/whatis_e/eol/e/wto03/wto3.pdf WTO: Code of Good Practice for the Preparation, Adoption and Application of Standards

http://www.iso.org/iso/en/comms-markets/wto/pdf/tbt-a3.pdf WTO: Electronic circulation of TBT notifications

http://www.wto.org/english/tratop_e/tbt_e/tbt_mailing_list_e.htm

WTO: Legal texts: the WTO agreements http://www.wto.org/english/docs_e/legal_e/final_e.htm

WTO: TBT workshop on the different approaches to conformity assessment http://www.wto.org/English/tratop_e/tbt_e/meeting_march06_e/tbt_conformity_16march06_e.htm

WTO: Technical Barriers to Trade

http://www.wto.org/English/tratop_e/tbt_e/tbt_e.htm

WTO: Training Courses

http://www.wto.org/english/tratop_e/devel_e/train_e/train_e.htm

4.1.1.3 WTO SPS - Agreement on the Application of Sanitary and Phytosanitary Measures

Relevance

The SPS Agreement builds the legal international framework on how to set and apply sanitary and phytosanitary (SPS) measures in the international trading environment. The overall objective of the agreement is to minimize trade distorting effects of SPS measures. At the same time, the SPS Agreement respects the individual countries' rights to implement SPS-related border measures regarded as appropriate to protect human, animal and plant life or health.

Sanitary and Phytosanitary regulations/measures can be

- applied rigorously to imports from countries where specific diseases or pests are prevalent
- taken to restrict imports on a provisional basis, as a precautionary step, where there is imminent risk of the spread of diseases but the scientific evidence is insufficient

Principles

Sovereignty of WTO member countries:

"Countries ... require the compliance of imported agricultural products with their national sanitary and phytosanitary regulations. The primary aim of these regulations is to protect human, animal or plant life or health from pests and diseases that may be brought in by imported agricultural products. The rules which the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) lays down are similar to those applicable to mandatory product standards.

Source: International Trade Centre UNCTAD/GATT (ITC) and Commonwealth Secretariat (CS) (1999), p. 82

Appropriate level of protection:

At national level, WTO Members may adopt a level of (human, animal, plant) health/consumer protection they regard as appropriate, provided this does not constitute disguised protectionist measures restricting competition for the benefit of domestic producers.

Regionalisation:

WTO members are encouraged to differentiate SPS measures on a regional basis and recognise pest or disease free areas for food, animal and plant products of their trading partners where they are objectively disclosed.

Scientific justification:

To minimise negative trade effects, all SPS measures have to be based on a risk assessment taking into consideration scientific evidence. In cases where adequate scientific evidence is not yet available, an importing country may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information; the measures must be reviewed within a reasonable period of time ("precautionary principle").

Transparency:

In order to assure transparency, proposed national SPS measures must be notified to the WTO before being enforced. This provides

- (i) time for adjustment if the measure will be accepted or
- (ii) time for comments and discussion if the measure is challenged.

Disputed measures are discussed in the WTO's SPS Committee and justified objections examined in order to avoid the need for recourse to the WTO's formal dispute settlement mechanisms.

Harmonisation:

The WTO does not set standards but allows each state to set its own standards by stipulating that member countries will align their standards with those considered adequate by the relevant multilateral organisations¹⁹⁾. In doing so, the SPS Agreement calls for a programme of harmonisation of national requirements based on multilateral standards and by laying down procedural rules for the formulation and application of SPS standards in WTO member countries.

Equivalence:

Members shall accept the SPS measures of other members as equivalent, even if these measures differ from their own or from those used by other members trading in the same product, if the exporting member objectively demonstrates that its measures achieve the importing member's appropriate level of SPS protection. They shall recognise such measures as equivalent through mutual recognition agreements (MRA).

Special and differential treatment:

In the preparation and application of sanitary or phytosanitary measures, members shall take account of the special needs of developing country members. The SPS Agreement pays attention to the specific situation of developing countries in particular with respect to phased and prolonged implementation periods. It also encourages developed countries to provide technical assistance to developing countries.

International Standards as reference frame The SPS Agreement itself does not establish standards, but leaves this task to relevant international organisations or the member countries. WTO members are encouraged to base their measures on international standards, guidelines and other recommendations adopted by the

- Codex Álimentarius Commission (CAC)
- International Plant Protection Convention (IPPC)
- Office Internationale des Epizooties (OIE)

The WTO recognises these standards as scientifically founded and compatible with the SPS Agreement. These standards are not legally binding but are used as a frame of reference by the WTO in disputes and cases of arbitration. Whereas these standards cannot be challenged, national SPS measures are challengeable.

SPS and Codex Alimentarius The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Codex Alimentarius Commission (CAC) was established in 1962 to establish standards for food quality and safety (see chapter 4.1.2.1).

Emerging issues

Specific trade concerns

- ACP countries and the Economic Partnership Agreements (EPA):
 SPS measures are of relevance in the negotiation of ACP-EU Economic Partnership Agreements and bilateral trade agreements (see further readings: Doherty, 2005).
- Developing countries and SPS measures: The Standards and Trade Development Facility (STDF), which offers trade- and SPS-related technical assistance for capacity building to developing countries, was launched at the fourth Ministerial Conference in Doha on 11 November 2001. The STDF is a global programme of the WTO, the FAO, WHO, CAC, OIE and the World Bank Group with the strategic aim to assist developing countries to enhance their expertise and capacity to analyse and implement international SPS standards, to improve their human, animal and plant health situation and thus their ability to gain and maintain market

WTO recognised standards: Codex Alimentarius Commission (CAC), International Office of Epizootics (OIE), International Plant Protection Convention (IPPC) – see chapter 4.1.2

access. In September 2004, the partners agreed on the STDF business plan, and inflow of funds has grown since then from US\$ 1.4 mn to US\$ 5.3 mn. Eligible countries, preferably Least Developed Countries (LDC), can apply for projects and project preparation grants (see further readings).

· Novel food:

Developing countries are concerned about a proposed revision of the EU Regulation on novel foods due to take effect in 2007. Mainly Latin American countries, supported by India and Benin, are concerned that the new regulation will affect their ability to export exotic traditional products sourced from their rich biodiversity. In line with this, EU companies advocate for marketing of foods with as little regulation and intervention as possible. The EU Commission now argues that the new regulation does not target biodiversity products but new technologies and new products.

Regionalisation:

Discussion of the concept of regionalisation. EU and other members call for application of science-based decisions or international standards for regionalisation to disease outbreaks like mad cow disease (BSE) and avian influenza in order to recognise that risks are more likely bound to regions than to countries/territories. Two standard-setting bodies, the International Plant Protection Convention (IPPC) and the World Organization for Animal Health (OIE) are currently (March 2006) elaborating on related concepts.

- National Food Control Systems:
 The World Health Organisation recently up-dated its 'Guidelines for Developing an Effective National Food Control System' (see the further readings).
- Private standards:
 Relevance of private standards (like EurepGAP see chapter 4.3.4.1) has become a
 subject of discussions in the WTO SPS Committee.

Further readings

Doherty, M. (2005):

ACP-EU Economic Partnership Agreements – Sanitary and Phytosanitary Measures http://spiderman.ecdpm.org/Web_ECDPM/Web/Content/Download.nsf/0/30D4360E1CC3B0AEC12570BC004332F5 /\$FILE/05-68e-Martin%20Doherty.pdf

EC: The Sanitary and Phytosanitary (SPS) Export Database

http://madb.europa.eu/sps/index.html

EC: Trade in agricultural goods and fishery products

- The SPS sector in DG TRADE: SPS export issues

http://ec.europa.eu/trade/issues/sectoral/agri_fish/sps/spsei_en.htm

EC: Trade in agricultural goods and fishery products

- The SPS sector in DG TRADE: SPS trade related assistance

http://ec.europa.eu/trade/issues/sectoral/agri_fish/sps/trta_en.htm

EC: Sanitary, Phytosanitary and biotechnology trade issues - Newsletter

http://ec.europa.eu/trade/issues/sectoral/agri_fish/sps/newsletter.htm

FAO (2003): WTO Agreement on Agriculture: The Implementation Experience

- Developing Country Case Studies

http://www.fao.org/DOCREP/005/Y4632E/Y4632E00.HTM

FAO: Trade in Agriculture Fisheries and Forestry – WTO Negotiations

http://www.fao.org/trade/negoc_dda_en.asp

FAO/WHO/WTO et al - Standards and Trade Development Facility (STDF)

Assistance to developing countries to establish and implement appropriate SPS measures

http://www.standardsfacility.org/

ISO (2006): Standardising Bodies having notified Acceptance of the WTO TBT Code Practice for the Preparation, Adoption and Application of Standards as of September 2006 http://www.iso.org/iso/en/comms-markets/wto/pdf/TbtList_2006-09-16.pdf or http://www.iso.org/iso/en/comms-markets/wto/pdf/scd2006-07-en.pdf

UNCTAD (2005): Training Module on the WTO Agreement on SPS Measures http://www.unctad.org/en/docs/ditctncd20043 en.pdf

WHO: Guidelines for Developing an Effective National Food Control System

http://www.who.int/foodsafety/publications/fs_management/guidelines_foodcontrol/en/WTO: A Training Package – Module 3 – Goods: Rules on Non-Tariff Measures (NTMs) http://www.wto.org/English/thewto_e/whatis_e/eol/e/wto03/wto3.pdf

WTO: Code of Good Practice for the Preparation, Adoption and Application of Standards http://www.iso.org/iso/en/comms-markets/wto/pdf/tbt-a3.pdf

WTO: Committee on Sanitary and Phytosanitary Measures – Summary of specific trade concerns brought to the Committee's attention since 1995 – 25 February 2005 http://docsonline.wto.org/DDFDocuments/t/G/SPS/GEN204R5.doc

WTO: Committee on Sanitary and Phytosanitary Measures – Specific trade concerns: Novel debate on EU's food regulation – 29th/30th March 2006

http://www.wto.org/English/news_e/news06_e/sps_march06_e.htm

WTO: Legal texts – the WTO agreements http://www.wto.org/english/docs_e/legal_e/final_e.htm WTO: Notifications of SPS measures proposed by WTO members

http://www.wto.org/English/tratop_e/sps_e/sps_e.htm

WTO: Notifications of SPS measures

 Example Egypt – imported potato seed – G/SPS/N/EGY/20–22nd September 2006 http://www.sfs.fi/files/wtonotif/spsnotif/egy20.doc

WTO: SPS: Article 6 (Regionalisation) – Example European Union http://www.wto.org/English/tratop_e/sps_e/meet_jan06_e/ec_regionalisation_e.ppt

WTO: SPS Committee: Novel debate on EU's food regulation http://www.wto.org/English/news_e/news06_e/sps_march06_e.htm

WTO: SPS Committee: SPS and private standards (EurepGAP)

http://www.wto.org/english/news_e/news05_e/sps_june05_e.htm

WTO: SPS Measures: Introduction, Mandate, Work in the SPS Committee

http://www.wto.org/English/tratop_e/sps_e/sps_e.htm

WTO: Training Courses

http://www.wto.org/english/tratop_e/devel_e/train_e/train_e.htm

4.1.1.4 Difference between SPS and TBT measures

The TBT Agreement is similar to the SPS Agreement in its content and format. Both agreements encourage the use of international standards (harmonisation) and the principle of equivalence in the development of non-tariff measures. In implementing these measures, both agreements promote the concepts of non-discrimination and the avoidance of unnecessary obstacles to trade. The transparency provisions are also very similar.

The difference between the two agreements is primarily one of coverage and the underlying basis for the application of a measure. In general terms, under the SPS Agreement, a measure has to be scientifically justified while under the TBT Agreement, a measure has to be based on a legitimate objective. This is the case when governments impose special requirements on imports of armaments (national security) or restrict imports of endangered species (environment), and when they mandate that labels on cigarette packs should warn consumers of the hazards of smoking (human health) or prescribe labelling in order to protect consumers against deceptive practices. These measures would not fall within the scope of the SPS Agreement as they do not meet the definition of an SPS measure as set out in the following box.

Box 3: Difference between SPS and TBT measures

TBT Agreement

The TBT Agreement (Article 1.5) states that the provisions of the TBT Agreement do not apply to measures as defined in Annex A of the SPS Agreement. In other words, the measures mentioned within the "To protect from?" column below are not covered by the TBT Agreement.

SPS Measures (Annex A Definition)

To protect what?	To protect from?			
human or animal life	risks arising from additives, contaminants, toxins or disease-causing organisms in their food, beverages, feedstuffs (contaminants include pesticide and veterinary drug residues and extraneous matter)			
human life	plant- or animal-carried diseases (zoonoses)			
animal or plant life, including fish, forests and wild animals or plants	pests (including weeds), diseases, or disease- causing organisms			
a country	damage caused by the entry, establishment or spread of pests (including weeds)			

Source: WTO (2002) http://www.wto.org/english/news_e/pr310_e.htm

4.1.1.5 WTO TRIPS - Agreement on Trade-Related Aspects of Intellectual Property Rights

General relevance

The TRIPS Agreement is a complex multilateral framework of principles, rules and disciplines aiming at coordinating, integrating, adjusting and reorganizing stipulations regarding the protection of intellectual property rights.

Food sector

- protection for geographical indications: geographical indications are defined as indications which identify a product as originating in the territory of a member state or a region or locality of the same, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin (article 22 TRIPS)
- patent protection for innovative foodstuff: TRIPS obliges WTO members to grant patents for innovations in all fields of technology in a non-discriminatory manner (art. 27 TRIPS).

Pharmaceutical products

WTO members adopted a separate declaration on TRIPS and Public Health in order to enable members to take measures protecting public health, when necessary. Emphasising the flexibility built into the TRIPS Agreement (including compulsory licensing and parallel importing), member governments agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

Wines and spirits

- "Additional protection for geographical indications for wines and spirits":
 An extended protection prohibits also descriptions such as 'kind', 'type', 'style', 'imitation' or the like. Misleading geographical indications may also not be registered as trade marks." (art. 23 [1] TRIPS)
- "In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system." (art. 23 [4] TRIPS)

Emerging issues

Geographical indications:

The EU submitted two proposals in 2002, which are still pending:

(i) high-quality goods that are protected in a Member State should be registered in a central databank in order to reduce costs;

(ii) protection for names/origins of wines and spirits shall be extended to other regional-specific goods (e. g. Indian Darjeeling Tea, Spanish Jamon de Huelva). The EU – in line with other proponents – argues that the protection of high-quality regional-specific goods will have positive effects both for developing and for developed countries. The goods benefit from the increased reputation and thus gain sales potential, while the consumer will not be confused by misleading indications. Members' positions on this issue polarised during WTO consultations in April 2006. While the EU, Bulgaria, India, Sri Lanka and Switzerland favour an extension of the geographical indication protection for wines and spirits to other products (under art. 23), Argentina, Australia, Brazil, Canada, New Zealand and the US argue that current provisions under Article 22 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights are sufficient.

· Pharmaceutical patents:

Regarding pharmaceutical products, WTO members assigned the TRIPS Council to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries (being mentioned under "Paragraph 6" of the Doha declaration on TRIPS and public health, this issue is sometimes referred to as "Paragraph 6" agenda).

Further readings

FAO: Trade in Agriculture Fisheries and Forestry – WTO Negotiations

http://www.fao.org/trade/negoc_dda_en.asp

WTO: Legal texts – the WTO agreements http://www.wto.org/english/docs_e/legal_e/final_e.htm

http://www.wto.org/english/docs_e/legal_e/final_e.htm
WTO: TRIPS – Fact Sheet TRIPS and Pharmaceutical Patents: Obligations and exceptions
http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm

WTO: TRIPS - Geographical Indications - Background and the current situation

http://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm#protection or http://www.wto.org/english/docs_e/legal_e/27-trips_04b_e.htm

WTO: TRIPS – Material on the WTO website http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

4.1.1.6 WTO DSU – Understanding on Rules and Procedures Governing the Settlement of Disputes

Scope

"The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognise that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law."

Organisation structure

- Dispute Settlement Body (DSB):
 - The DSB administers the rules and procedures under the WTO DSU Agreement and the consultation and dispute settlement provisions of the covered agreements. Accordingly, the DSB shall have the authority to establish panels, adopt panel and Appellate Body reports, maintain surveillance of implementation of rulings and recommendations, and authorise suspension of concessions and other obligations under the covered agreements.
- Panels:

Upon the request of the complaining party, a panel shall be established composed of well-qualified and independent governmental and/or non-governmental individuals. The task of the panels is to examine the matter referred to the DSB in the light of the relevant provisions. Furthermore, the panels assist the DSB in making recommendations or in giving the rulings provided for in the respective agreements.

Compensation and suspension

"Compensation and the suspension of concessions or other obligations are temporary measures available in the event that the recommendations and rulings are not implemented within a reasonable period of time. However, neither compensation nor the suspension of concessions or other obligations is preferred to full implementation of a recommendation to bring a measure into conformity with the covered agreements. Compensation is voluntary and, if granted, shall be consistent with the covered agreements."

Source: Understanding on Rules and Procedures Governing the Settlement of Disputes

Dispute cases

Nearly 400 disputes have been raised under the WTO dispute settlement system, thereof 84 cases by the US and 73 by the EU as complainants.

Further WTO: DSU – Disputes by Country

readings http://www.wto.org/English/tratop_e/dispu_e/dispu_by_country_e.htm

WTO: DSU - Disputes by Subject

 $http://www.wto.org/English/tratop_e/dispu_e/dispu_subjects_index_e.htm$

WTO: DSU – Dispute Settlement Gateway http://www.wto.org/English/tratop_e/dispu_e/dispu_e.htm WTO: Legal texts – the WTO agreements http://www.wto.org/english/docs_e/legal_e/final_e.htm

4.1.2 WTO-recognised standards (voluntary standards for benchmarking)

As indicated above, the WTO does not set standards, but it recognises standards elaborated by other organisations as benchmark for WTO members. Under the SPS Agreement the relevant international organisations are

for food safety: Codex Alimentarius Commission (CAC)

for plant health: International Plant Protection Convention (IPPC)

for animal health: Office Internationale des Epizooties (OIE)

The WTO applies the voluntary standards of these three organisations (so called 'three sisters') as reference in arbitration cases. No WTO member country is forced to apply these standards, but deviations of national standards from these references have to be well-reasoned.

4.1.2.1 Codex Alimentarius Commission (CAC)

The Codex Alimentarius Commission (CAC) is an international body established jointly by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO). All MEDA-countries (except the Palestinian Areas) are members of the Codex Commission, as are the 25 Member States of the EU and the European Commission. "The Codex Alimentarius, or the food code, has become the seminal global reference point for consumers, food producers and processors, national food control agencies and the international food trade. The code has had an enormous impact on the thinking of food producers and processors as well as on the awareness of the end users – the consumers. Its influence extends to every continent, and its contribution to the protection of public health and fair practices in the food trade is immeasurable." ²⁰⁾

FAO and WHO complement the Commission's activities significantly. To adopt Codex standards, countries require an adequate food law as well as a technical and administrative infrastructure with the capacity to implement it and ensure compliance. For many years, FAO and WHO have been providing assistance to developing countries to enable them to take full advantage of the Commission's work. This effort has been enhanced to a considerable degree by the financial and technical support provided by industrialised countries.

Source: CAC – Understanding the Codex Alimentarius – Preface http://www.fao.org/docrep/w9114e/W9114e01.htm#TopOfPage

Codex Alimentarius Commission (CAC)

Name Codex Alimentarius (Latin) means 'food code'

General facts

The Codex Alimentarius Commission is the international food standards setting body of the

United Nations, a joint venture of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It is the longest standing

example of interagency cooperation in the UN system.

The CAC has got 173 member states and one member organisation (the European Community), who, with the advice of independent technical experts selected by FAO and

WHO, develop food standards, guidelines and recommendations.

Purpose The fundamental mandate of the CAC is to develop international standards for consumer health protection and fair practices in food trade.

The Codex philosophy embraces consumer protection, fair practice and facilitation of international trade through reduction of trade barriers/harmonisation of standards.

Underlying rationale

"The 'Strategic Framework for FAO: 2000–2015' accords high priority to promoting policy and regulatory frameworks for food at the international and national levels. Similarly, the ... World Health Assembly recognised the need to highlight health considerations in international food trade and acknowledged the importance of the CAC for assuring the highest levels of consumer health protection. The resolution also urged WHO to work towards integrating food safety as one of its essential public health functions with the goal of developing sustainable, integrated food safety systems for the reduction of health risk along the entire food chain."

Source: FAO/WHO (2002)

Scope

The CAC includes standards for a wide range of products, whether processed, semi-processed or raw, for distribution to the consumer. The Codex includes provisions with respect to food hygiene, food additives, pesticide residues, contaminants, labelling and presentation, methods of inspection, analysis and sampling. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures.

The standards of the Codex Commission are not legally binding, and national adoption of Codex standards is thus voluntary. Nevertheless, an increasing number of countries are aligning their national food standards, or parts of them (especially those relating to food safety), with those of the Codex Alimentarius. Codex Standards serve as benchmark for national regulations and in international food law disputes submitted to the WTO.

The Codex recognises the importance of minimising the effect of regulatory provisions on food trade.

Harmonisation process

The harmonisation of food standards is a prerequisite for the protection of consumer health and facilitation of international trade. The Uruguay Round Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) thus both encourage the international harmonisation of food standards.

In practice, it is difficult for many countries to fully adopt Codex standards. Currently, there are three forms of acceptance: full acceptance, acceptance with minor deviations and free distribution. Though this situation impedes the progress of harmonisation, the process of harmonisation is gaining impetus thanks to the strong international desire to facilitate trade.

Commodity Committees

Commodity standards

('horizontal')

Commodity Committees have responsibility for developing standards for specific foods or classes of food. Commodity standards have been developed, among others, for:

cereals, pulses and legumes

- cocoa products and chocolate
- · fats and oils
- fresh fruits and vegetables
- processed fruits and vegetables
- · vegetable proteins

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General Subject General Subject Matter Codex Committees develop standards, codes of practice or Committees

quidelines that apply to all commodities, for example:

food additives (permitted maximum levels for food additives)

General Standards ('vertical')

- contaminants in foods (maximum or guideline levels for contaminants and naturally occurring toxins in food and animal feed)
- food hygiene (basic provisions on food hygiene for all foods)
- food import and export certification systems (principles and guidelines)
- food labelling (labelling provisions, consideration of issues of mislabelling)
- general principles (rules and procedures referred to by the CAC)
- methods of analysis and sampling (except for residues of pesticides, veterinary drugs)
- nutrition and foods for special dietary uses (provisions on nutritional aspects for foods, quidelines, general principles and standards)
- pesticide residues (maximum limits for pesticide residues for specific food)
- residues of veterinary drugs in foods (maximum residue limits)

Principles, Guidelines and Codes of Practice

In addition to the food commodity and general standards CAC has developed principles, guidelines and recommended codes of practice, for example:

- general methods of analysis for contaminants
- recommended methods for the analysis of pesticide residues
- · recommended methods of analysis and sampling
- general principles for the use of food additives
- general principles for food import and export inspection and certification
- general principles for the addition of essential nutrients to foods
- · guidelines for the production, processing, labelling and marketing of organically produced
- guidelines for the establishment and application of microbiological criteria for foods
- quidelines for radionuclides in foods following accidental nuclear contamination for use in international trade
- · guidelines for vitamin and mineral food supplements
- recommended international code of practice general principles of food hygiene
- codes of hygienic practice numerous applications
- · code of ethics for international trade in food
- codes of practice for the prevention and reduction of mycotoxin contamination
- code of practice for the packaging and transport of tropical fresh fruit and vegetables

Maximum Residue Limits (MRL) of pesticides

Maximum Residue Limits (MRLs) of pesticides are the maximum level of named active ingredients in foods that can be legally sold for human consumption.

Codex MRLs for pesticides are recommended on the basis of appropriate residue data obtained mainly from supervised trials. These residue data reflect registered or approved usage of the pesticide in accordance with GAP. Owing to differences in local pest control requirements, the usage might vary from region to region. Consequently, residues in food may also vary. In establishing Codex MRLs, these variations in residues are taken into consideration. Codex MRLs are established only where evidence is given about food risks for human use. Codex MRLs thus represent residue levels which are toxicologically acceptable.

Extraneous Maximum Residue Limit (EMRLs) of pesticides

The Codex EMRLs refer to residues of compounds, which are no longer registered but arise from environmental contamination (including former agricultural use of pesticides) or uses of these compounds other than agricultural uses (e.g. DDT in malaria control). These residues are treated as contaminants. Codex EMRLs represent acceptable residue levels which are intended to facilitate international trade in food while protecting the health of the consumer.

Ad hoc Intergovernmental Task Forces Ad hoc Intergovernmental Task Forces are Codex Committees with very limited terms of reference established for a fixed period of time – current task forces:

- animal feeding
- · food derived from biotechnology
- fruit and vegetable juices
- antimicrobial resistance
- · processing and handling of quick frozen foods

Expert Scientific Bodies

FAO and WHO jointly established three independent expert scientific bodies, in which government and academia experts assist Codex Committees in specific fields of expertise:

- The Joint FAO/WHO Expert Consultantion in Food Additives (JECFA) evaluates the safety of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food.
- The Joint FAO/WHO Meeting in Pesticide Residues (JMPR) conducts scientific
 evaluations of pesticide residues in food. It provides advice on the acceptable levels of
 pesticides in food traded internationally.
- The Joint FAO/WHO Experts on Microbiological Risk Assessment (JEMRA) conducts
 microbiological risk assessment of specific pathogen-commodity combinations, develops
 guidelines for the assessment of microbiological risks arising from food and water and
 provides assistance for risk management.

Emerging issues

• Vitamin and mineral supplements:

Recognising vitamin and mineral supplements in 2005, the Codex recommends to base levels of vitamins and mineral on risk assessment rather than Recommended Dietary Intake (RDI) as currently used in some countries.

Food Additives and Contaminants:
 The Codex Committee on Food Additives and Contaminants (CCFAC)²¹⁾ proposed new food additive standards, on which members are requested to comment until September 2006.

· Trans fat:

The WHO proposes in its action plan for the standards rule-making body CAC to reduce trans-fats (partially hydrogenated oils). Trans-fats are mainly found in (partially) hydrogenated vegetable oil and are linked with raising blood cholesterol levels and promoting atherosclerosis and heart disease. The CAC will draft specific rules based on discussions with stakeholders. Deadline for comments: 15 October 2006.

Trans fat:

"Over £ 1.5 billion worth of food products in the UK are being reformulated in order to eliminate harmful trans fats, according to a food industry body. The Food and Drink Federation (FDF) has claimed that hundreds of well-known household names, including Hula Hoops, Mars Bars, Nestle, Cheerios and Weetabix, have been redesigned to take into account growing health concerns. ... The European food industry is obviously concerned about the negative publicity such findings can generate. ... The pre-emptive reformulation of products is therefore something the food industry wants to push, as Hunt implicitly acknowledges." ²²⁾

Acrylamide:

The UK and the US drafted a code of practice on acrylamide (potential carcinogen in processed potatoes and other foods resulting from a reaction between specific amino acids and sugars during high temperature cooking). The draft was presented at a Codex committee meeting in April 2006.

Genetically Modified Organisms (GMO):

In July 2003, CAC adopted guidelines to introduce uniform analysis and management of risks related to foods derived from biotechnology across member countries (including pre-market safety evaluations, product tracing for recall purposes and post-marketing monitoring).

· Codex Trust Fund:

In 2003, the Codex Trust Fund was launched seeking US\$ 40 million over a 12-year period to help developing countries and countries in transition to participate in the Codex work. Deadline for applications: 31 October each year.

FAO Nutrition and Consumer Protection Division:

Reflecting the global shift in paradigm towards assurance of food quality and safety 'from farm to fork', FAO established a new unit beginning 2006, the Nutrition and Consumer Protection Division.

Further readings

CAC: Codex Alimentarius homepage

http://www.codexalimentarius.net CAC: Current Official Standards

http://www.codexalimentarius.net/web/standard_list.do?lang=en or

http://www.ipfsaph.org/En/default.jsp

In 2007, the CCFAC Committee will split into the CCFA (Codex Committee on Food Additives) and the CCFC (Codex Committee on Food Contaminants).

Source: http://www.foodnavigator.com/news/ng.asp?n=71328&m=1FNEO17&c=tywzvtovrizosnn

CAC: Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 45-2003)

http://www.codexalimentarius.net/download/standards/10007/CXG 044e.pdf

Codex Trust Fund

http://www.who.int/foodsafety/codex/trustfund/en/index.html

FAO: Pesticide Management Unit – Pesticide MRL search machine (see also JMPR)

http://www.fao.org/ag/AGP/AGPP/Pesticid/default.htm

International Portal for Food Safety, Plant and Animal Health (IPFSAPH) http://www.ipfsaph.org/En/default.jsp

JECFA (Joint FAO/WHO Expert Committee on Food Additives)

http://www.fao.org/ag/agn/jecfa/whatisnew_en.stm or http://www.who.int/ipcs/food/jecfa/en/index.html

JECFA: Flavouring agents database

http://apps3.fao.org/jecfa/flav_agents/flavag-q.jsp

JEMRA (Joint FAO/WHO Experts on Microbiological Risk Assessment)

http://www.fao.org/ag/agn/jemra/index_en.stm

JMPR (Joint FAO/WHO Meeting in Pesticide Residues)

http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm

WHO - Regional Office Europe - Technical assistance

http://www.euro.who.int/foodsafety/assistance/20020418_1

4.1.2.2 International Plant Protection Convention (IPPC)

Purpose

The purpose of the international treaty IPPC is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. The IPPC covers both direct and indirect damage by pests, including weeds. The provisions extend to cover conveyances, containers, storage places, soil and other objects or material capable of harbouring plant pests.

The IPPC is governed by the Commission on Phytosanitary Measures (CPM) which adopts International Standards for Phytosanitary Measures (ISPMs). The IPPC Secretariat coordinates the activities of the Convention and is hosted by FAO.

Scope

The International Plant Protection Convention (IPPC)

- presents a multilateral agreement (convention) for cooperation in plant protection
- is a global instrument for harmonising phytosanitary measures
- sets standards that are recognised by WTO-SPS
- applies mainly to guarantine pests involved with international trade

The New Revised Text of the IPPC (1997) entered into force on 2 October 2005. As of 3 October 2006, the IPPC has 159 contracting parties.

Commission on Phytosanitary Measures (CPM)

The Commission governs the implementation of the IPPC. It is presently composed of representatives from the National Plant Protection Organizations (NPPO) from both contracting parties to the IPPC and FAO members. The Commission provides a forum for the discussion of international plant protection issues.

Activities

- standard setting phytosanitary standards
- information exchange coordination of regional plant protection organisations
- dispute settlement facilitation of arbitration
- technical assistance support to developing countries NPPOs

Types of standards

- reference standards
 - e.g. International Standards for Phytosanitary Measures (ISPM); Glossary of Phytosanitary Terms
- conceptual standards
 - e.g. Requirements for the Establishment of Pest Free Areas
- guidelines
 - e.g. Guidelines for Pest Risk Analysis; Guidelines for Surveillance; Guidelines for Phytosanitary Certificates
- · codes of conduct
 - e.g. Code of Conduct for the Import and Release of Exotic Biological Agents

Trade related standards

- ISPM (International Standards for Phytosanitary Measures art. 10)
- phytosanitary certificates (art. 5)
- arbitrage (art. 8)
- import requirements (art. 7)

Technical assistance

Contracting parties to the IPPC agree to promote the provision of technical assistance to other contracting parties with the objective of facilitating the implementation of the Convention. In particular, IPPC encourages support to developing countries in order to improve the effectiveness of their National Plant Protection Organisations (NPPOs) and increase the potential for them to realize the benefits of safe trade. The Convention also encourages participation in regional plant protection organisations as the basis for cooperation in achieving the aims of the IPPC at the regional level (see further readings).

Emerging issues

ISPM 15 – wood packaging material:

Striving to harmonise EU procedures with the IPPC standard on wood packaging material (prevention of bringing in pests via wooden packaging material), the EU intended to enforce the respective Commission Directive 2004/102/EC by March 2005. Following interventions from several member countries that failed to harmonise national law, the enforcement was first extended until March 2006 and finally to 2009.

Further readings

IPPC: Adopted ISPMs (International Standards for Phytosanitary Measures) https://www.ippc.int/servlet/CDSServlet?status=ND0xMzM5OSY2PWVuJjMzPSomMzc9a29z

IPPC: ISPM 15 – Guidelines for regulating wood packaging material in international trade

https://www.ippc.int/servlet/CDSServlet?status=ND0zNTlyNSY2PWVuJjMzPSomMzc9a29z IPPC: International Phytosanitary Portal (IPP) – official website of the IPPC

https://www.ippc.int/IPP/En/default.jsp IPPC: Technical Assistance

https://www.ippc.int/servlet/CDSServlet?status=ND0xMzM4MSY2PWVuJjMzPSomMzc9a29z

WTO: IPPC standard-setting work programme (as of CPM-1, April 2006)

http://www.wto.org/English/tratop_e/sps_e/sps_e.htm – search documents online: G/SPS/GÉN729, 11 October 2006

WTO: IPPC update on technical assistance activities October 2006

http://www.wto.org/English/tratop_e/sps_e/sps_e.htm – search documents online: G/SPS/GEN730, 12 October 2006

4.1.2.3 Office Internationale des Epizooties (OIE)

The OIE (Organisation Mondiale de la Santé Animale/World Organisation for Animal Health) will only be presented very briefly, since the present study focuses on food of non-animal origin.

Purpose

- securing transparency in animal health worldwide
- collecting, analysing and disseminating veterinary information
- defining minimum health standards for international trade within its WTO mandate
- contributing expertise to respond to the occurrence of diseases
- encouraging coordination

Scope

According to WTO SPS, importing country can apply sanitary measures to protect human health and life as well as the life and health of animals and plants

- to the adequate level of protection and
- consistently

Sanitary measures must be based on

- scientific principles and should not be maintained without sufficient scientific evidence
- · international standards, if such exist
- risk analysis if more stringent measures are scientifically justified or if the country decides on a higher level of protection

In this context, OIE

- promotes transparency by reporting on the occurrence of diseases and epidemics
- contributes to improved knowledge on the animal health situation worldwide (in particular information necessary for safe trade)
- · runs official 'disease-free' recognition procedures

Commissions

- · commission on the international animal health code
- standards commission
- · commission for foot and mouth disease and other epizooties
- · commission for fish diseases
- · working groups and ad hoc groups

Types of standards

- health standards for animal and animal products trade
- · biological standards

Further readings

OIE homepage

http://www.oie.int/eng/en_index.htm

4.1.3 Other multilateral standard setting organisations (voluntary standards)

Although the standards described in this chapter are voluntary by character and thus not legally binding, some of them (e.g. some ISO standards) have become quasi obligatory in international trade since they have (partly) been integrated into national law and/or into codes established by the private industry or the retail trade.

4.1.3.1 United Nations Economic Commission for Europe (UN/ECE)

Purpose

UN/ECE aims at fostering sustainable trade relations between its 56 member countries by providing a forum for communication among members, addressing trade, transport and environment issues and supplying statistics, economic and environmental analyses.

UN/ECE commercial standards are meant to

- · facilitate fair international trade
- · encourage high quality production
- · improve producers' profitability
- protect consumers' interests

Scope

Quality is the key to international markets. UN/ECE commercial quality standards are used as a common trading language for buyers and sellers and as a reference for quality control.

Although UN/ECE standards are voluntary multilateral standards (see chapter 3, graph 2), they are of special interest in international trade since they

- define a common trading language
- fill the gap between food safety regulations and marketing
- · define commercial quality for foodstuffs

UN/ECE standards are used by governments, producers, importers and exporters as well as other international organisations as basis for the definition of regulations, guidelines and codes of practice.

Standards

Quality is defined as comprising the following elements:

- food safety²³⁾, nutrition aspects, production methods
- shape, presentation, colour, taste, ripeness

UN/ECE has been working for more than 50 years on commercial quality standards for a wide range of agricultural products:

- · fresh fruit and vegetables
- · dry and dried produce
- potatoes
- cut flowers

Source: http://www.unece.org/trade/agr/info/layout/layfresh_e.doc

Characteristics related to food safety: "produce affected by rotting or deterioration such as to make it unfit for consumption is excluded, practically free of any visible foreign matter, practically free from pests, practically free from damage caused by pests."

Further readings UN/ECE: Working Party 7 - Working Party on Agricultural Quality Standards

http://www.unece.org/trade/agr/welcome.htm

UN/ECE: Standard layout for UN/ECE standards concerning the marketing and commercial quality control of Fresh Fruit and Vegetables

http://www.unece.org/trade/agr/info/layout/layfresh e.doc

UN/ECE: Working Party on Agricultural Quality Standards - Fresh fruit and vegetables http://www.unece.org/trade/agr/standard/fresh/fresh_e.htm

UN/ECE: Working Party on Agricultural Quality Standards – Dry and dried produce

http://www.unece.org/trade/agr/standard/dry/dry_e.htm
UN/ECE: Working Party on Agricultural Quality Standards – Potatoes

http://www.unece.org/trade/agr/standard/potatoes/pot_e.htm

UN/ECE: Working Party on Agricultural Quality Standards – Cut Flowers

http://www.unece.org/trade/agr/standard/flowers/flower e.htm

UN/ECE: Working Party on Agricultural Quality Standards - Acceptance of UN/ECE

standards by countries

http://www.unece.org/trade/agr/info/accept.htm

International Organization for Standardization (ISO) 4.1.3.2

Purpose

Consensus agreements between national delegations representing all economic stakeholders (suppliers, users, government regulators, consumers, etc.) on specifications and criteria to be applied consistently in the classification of materials, in the manufacture and supply of products, in testing and analysis, in terminology and in the provision of services.

Scope

International Standards provide a reference framework between suppliers and their customers – which facilitates trade and the transfer of technology.

As the leading developer of international standards, ISO cooperates in a participatory way with public and private stakeholders worldwide to lay down requirements for state-of-the-art products, services and processes, for conformity assessment as well as for managerial and organisational practices.

ISO standards are voluntary. However, certain ISO standards - mainly health, safety and/or environmental standards - have been adopted in some countries as part of the national regulatory framework, or are referred to in legislation. However, although ISO standards are voluntary, they may become a market access requirement, for example in the case of ISO 9000 quality management systems.

WTO and ISO

In its World Trade Report 2005, the WTO acknowledges that ISO and its partners IEC and ITU (International Telecommunication Union) are the most important organisations defining voluntary standards based on consensus²⁴.

Member structure

ISO is a network of national standards bodies of 157 countries (by August 2006). ISO member institutes are either part of the governmental or private sectors (e.g. industry associations) in their respective countries. In such a way, ISO is able to facilitate consensus agreements on solutions that meet the requirements of the business community as well as those of other stakeholders, such as consumers or the society in general.

Standards

ISO-standards cover the following fields:

- terminology
- laboratories
- · accreditations
- inspections
- certification of personnel
- · certification of products
- · certification of management systems
- · environmental management systems
- multilateral agreements (MLAs)
- suppliers of conformity declarations

Source: http://www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report05_e.pdf

- · quality management systems
- conformity tests (also guidelines)

The ISO list currently contains more than 16,000 standards (by August 2006).

Generic management system standards

Whereas most ISO standards are specific to particular products, materials or processes, the so-called 'generic management system standards' constitute international reference requirements for quality management systems, which can be applied to any organisation, regardless of type, size and product in any sector or business activity, in public administration, in government institutions or private sector organisations.

The ISO 9000 (quality management) and ISO 14000 (environmental management) families are the core of generic management system standards. ISO 9000 and ISO 14000 are among the most widely spread international standards.

Quality management principles

The following quality management principles form integral part of the basic understanding of ISO 9000 and ISO 14000:

- principle 1: customer focus
- principle 2: leadership
- principle 3: involvement of peopleprinciple 4: process approach
- principle 5: system approach to management
- principle 6: continual improvement
- principle 7: factual approach to design making
 principle 8: mutually beneficial supplier relationships

ISO 9000 family

ISO 9000 is an international reference for quality requirements in business to business relations. Quality management comprises all activities of an organisation that contribute to enhancing customer satisfaction, fulfilling customer and regulatory requirements and continuously improving the organisation's performance with regard to customer satisfaction.

The ISO 9000 family serves

- · organisations seeking a competitive edge
- organisations seeking reliable suppliers
- common understanding among suppliers, customers and regulators
- common understanding among auditors, regulators, certification/registration bodies
- common understanding among consultants and trainers
- · fundamental information for developing related standards

As a generic standard, the ISO 9000 family is not branch-specific and has thus to be adapted to the features of the individual company.

Structure of the ISO 9000 family:

- (1) The ISO 9000 family consists of 3 norms:
 - ISO 9000 fundamentals and vocabulary
 - ISO 9001 requirements for quality management systems
 - ISO 9004 guidelines for performance improvements

Structure of ISO 9000:2000:

- (2) vocabulary:
 - quality, management, organisation, process and product, characteristics, conformity, documentation, assessment, audit, quality assurance in measurement processes
- (3) fundamentals:
- objectives of quality management systems (QMS), requirements (QMS, products), establishing a QMS, process-oriented approach, quality policy and objectives, management, documentation, assessment of QMS, continuous improvement, statistical processes, other management systems, best practices

Structure of ISO 9001:2000:

- (4) quality management system: general requirements for QMS, requirements for documentation (general, quality management handbook, managing documentation and reporting
- (5) responsibility of the management: commitment of the management, customer orientation, quality policy, planning (quality objectives, planning the QMS), responsibility, authorisation and communication, management assessment

- (6) management of resources: availability of resources, personnel (general, capacities, awareness and training), infrastructure, facilities and equipment, finances, information and knowledge
- (7) product realisation: planning the product realisation, client-interaction, examination of contracts, after sales service, product and process design, input management, product and service related processes (including traceability and liability), management of control and measurement
- (8) measurement, analysis and (continuous) improvement: internal audit, process related measurements, product related measurements, analyses of data, improvements, continuous improvements, corrective measures, preventive measures

ISO 9004:2000 applies the structure of ISO 9001:2000 and is meant to facilitate the implementation and continuous improvement of quality management systems. ISO 9004:2000 serves to assess the quality of a QMS and describe quality-related processes as well.

ISO 14000 family

ISO 14000 is an international reference for environmental management systems (EMS). It is a systematic approach towards minimising environmental effects of an organisation's activities and achieving continuous improvement of the organisation's environmental performance. An EMS enables organisations of any size or type to control the impact of its activities, products or services on the natural environment.

Principles of ISO 14000 standards:

- facilitate better environmental management
- be applicable in all different types of national environments
- promote the broad interests of the general public and the users of the standards
- be cost effective, non-prescriptive, flexible to meet needs of different organisations
- · be suitable for internal or external verification
- be scientifically based
- · be practical, useful and useable

Structure of ISO 14000 standards:

- · continuous improvement of the environmental management system
- · respect of all environment-related regulations
- · economically justifiable use of best technologies
- standardised ecological audits
- · management review

The ISO 14000 family addresses:

- Environmental Management Systems (EMS)
- Environmental Auditing and Related Investigations (EA & RI)
- Environmental Labels and Declarations (EL)
- Environmental Performance Evaluation (EPE)
- Life Cycle Assessment (LCA)
- Terms and Definitions (T & D)

ISO 22000:2005

In September 2005, ISO published the standard 'Food Safety Management Systems – Requirements for any Organisation in the Food Chain' (ISO 22000:2005).

Adapting the generic management systems' approach of the ISO 9001 and 14000 series, which resulted in a paradigm shift of quality and environmental management systems of organisations worldwide, ISO 22000:2005 is the first management system giving sub-sector specific guidance for assuring food safety along the food chain. It is a new international standard designed to ensure safe food supply chains from "farm to fork" (including primary producers, food manufacturers, animal feed producers, wholesalers, retailers, caterers and food service operators as well as producers of agricultural chemicals, food additives, food manufacturing equipment, food transport and warehousing operators packaging materials, service providers).

The standard ensures food safety 'from farm to fork' based on generally recognised elements:

Interactive communication:
 a structured two-way information flow up- and downstream the food supply chain as well
 as external communication as innovative and essential tool for risk management to
 quarantee effective control of hazards

- System management: control of the interaction of operators 'from farm to fork', which guarantees efficient and effective coordination and cooperation
- Good practices:
 Good Agricultural Practices, Good Manufacturing Practices and Good Hygiene Practices, maintenance programmes and procedures, pest control programmes
- HACCP principles: control of food safety hazards through pre-requisite programmes (good practices) and HACCP plans
- · Continuous improvement and updating of the management system

Implementation guidelines (ISO 22004:2005):

Food safety management systems – Guidance on the application of ISO 22000:2005.

Guidance for accreditation and certification bodies (ISO 22003):

Food safety management systems – Requirements for bodies providing audit and certification of food safety managament systems (scheduled for publication in September 2006).

Guidance for traceability (ISO 22005):

Traceability in the feed and food chain – General principles and guidance for system design and development (to be circulated as a draft international standard).

ISO is also preparing a checklist for small businesses and developing countries.

Conformity assessment

Conformity assessment is the evaluation whether products, materials, services, systems or people meet the specifications set by a relevant standard.

Issues related to conformity assessment are managed by the ISO Committee on Conformity Assessment (CASCO) in cooperation with the International Electrotechnical Commission (ICE). Standards related to conformity assessment are therefore named ISO/IEC standards.

The majority of products in industrialised countries require testing for compliance with technical specifications, safety requirements and other regulations before they are eligible to be marketed. Increasing trade across borders makes conformity assessment indispensable. ISO offers standards, against which products are assessed for conformity, as well as standardised test methods that allow the meaningful comparison of test results necessary for international trade.

3 levels of conformity assessment can be distinguished:

- First-party assessment Suppliers Declaration of Conformity (SDoC):
 The assessment of conformity to a standard, specification or regulation is carried out by the supplier organisation itself (self-assessment).
- Second-party assessment:
 The conformity assessment to a standard, specification or regulation is carried out by a customer of the supplier organisation (e.g. a potential customer verifies the conformity of the supplier's products to relevant ISO product standards).
- · Third-party assessment:

The conformity assessment to a standard, specification or regulation is carried out by a body that is independent of both supplier and customer organisations (e.g. ISO 9000 certification, where an organisation's quality management system is assessed by an independent certification or registration body).

List of ISO/IEC standards related to conformity assessment (for detailed descriptions see paragraphs below):

• ISO/IEC 17000:2004	_	Conformity assessment –
		vocabulary and general principles
 ISO/IEC 17011:2004 	_	General requirements for bodies providing assessment
		and accreditation
 ISO/IEC 17020:1998 	_	General criteria for the operation of various types of
		bodies performing inspection
 ISO/IEC 17021:2006 	_	Conformity assessment – requirements for bodies
		providing audit and certification of management systems
 ISO/IEC 17025:2005 	_	General requirements for the competence of calibration
		and testing laboratories

• ISO/IEC 17050:2004 Supplier's declaration of conformity

(SDoC)

 ISO/IEC Guide 60:2004 Conformity assessment -Code of Good Practice

• ISO/IEC Guide 62 (and 66)-General requirements for bodies operating assessment

and certification/registration of quality systems General requirements for bodies operating

ISO/IEC Guide 65:1996

product certification systems

• ISO/IEC Guide 68:2002 Arrangements for the recognition and acceptance of

conformity assessment results

ISO/IEC 17000:2004

Vocabulary and general principles

The standard ISO/IEC 17000:2004 - conformity assessment - specifies general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and to the use of conformity assessment to facilitate trade. The standard has been established by a joint project of the ISO Committee on Conformity Assessment (CASCO) in cooperation with the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC - see following chapter).

The standards describe the functional approach to conformity assessment to facilitate common understanding among users of conformity assessment, conformity assessment bodies and their accreditation bodies, in both voluntary and regulatory environments.

ISO/IEC 17011:2004

Accreditation

ISO/IEC 17011 – general requirements for bodies providing assessment and accreditation - is an internationally recognised standard stating general requirements for accreditation bodies accrediting conformity assessment bodies.

Accreditation is the procedure, by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Accreditation refers to formal recognition of conformity assessment bodies as competent to carry out ISO 9000 or ISO 14000 certification in specific business sectors as well as testing laboratories, inspection bodies and product certification bodies.

In some countries, accreditation is a legal requirement for conformity assessment bodies. In countries where accreditation is not a legal requirement, conformity assessment bodies may want to gain a competitive edge by having their competence recognised against international criteria.

IAF (International Accreditation Forum):

Accreditation bodies, which are members of the International Accreditation Forum (IAF), are required to operate at the highest standard and require the bodies they accredit to comply with appropriate international standards. Certificates issued by bodies accredited by members of the IAF Multilateral Recognition Arrangement (MLA) are relied upon all over the world because the MLA assures customers that the certificate is credible.

ISO/IEC 17020:1998

Inspection

ISO 17020 – general criteria for the operation of various types of bodies performing inspection – is an internationally recognised standard for the competence of inspection bodies. Product inspection is an activity that compares one or more characteristics of a product with specified requirements in order to determine if the product meets these requirements. Inspection refers to evaluation of parameters like quality, fitness for use or safety in operation.

Third-party national and multinational inspection bodies examine products, materials, installations, plants, processes, work procedures and services, both for the private and the public sector. The overall aim is to reduce risk to the buyer, owner, user or consumer of the item being inspected. The general requirements for the operation of various types of inspection bodies are given in the joint International Standard ISO/IEC 17020.

It should be noted that ISO 9001 is not accepted as alternative to ISO 17020, since it does not require evaluation of the technical competence of an inspection body.

ISO/IEC 17021:2006

Audit and Certification of QMS

ISO/IEC 17021:2006 - conformity assessment - requirements for bodies providing audit and certification of management systems - contains principles and requirements for the competence, consistency and impartiality of the audit and certification of management systems of all types (e.g. quality management systems or environmental management systems) and for bodies providing these services. Certification bodies operating to this International standard do not have to offer all types of management system certification.

ISO/IEC 17025:2005

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Calibration and Testing Laboratories

The international standard ISO/IEC 17025 – general requirements for the competence of testing and calibration laboratories – is recognised as standard for accreditation of laboratories including chemical analysis. Accreditation to ISO 17025 is frequently required for analysis in the context of international trade. For some regulatory fields of activities (e.g. testing of pesticides, feed), the more demanding accreditation of laboratories to Good Laboratory Practices (GLP) is mandatory in OECD countries (see chapter 4.1.3.4).

Testing is a very common form of conformity assessment, which can include activities like measurement and calibration. Testing also provides the basis for e.g. product certification.

ISO/IEC 17050:2004 ISO/IEC 17050 – supplier's declaration of conformity (SDoC) – specifies the general criteria for self-declarations of conformity.

Supplier's Declaration of Conformity (SDoC) Self-declaration saves the costs of third-party assessment provided that the supplier's reputation is high and that the customers accept an SDoC. Self-declaration might not be appropriate where health, safety or environmental risks are at stake. A self-declaration does not exempt the supplier from its responsibility to meet relevant regulations – for example, in relation to product liability – and such declarations generally need to be accompanied by effective post-market surveillance.

ISO/IEC Guide 60:2004

Code of Good Practice The ISO/IEC Guide 60:2004 – code of good practice – recommends good practices for all elements of conformity assessment, including normative documents, bodies, systems, schemes and results. It is intended for use by individuals and bodies who wish to provide, promote or use ethical and reliable conformity assessment services. The Guide has been designed to facilitate trade at the international, regional, national and sub-national levels.

ISO/IEC Guide 62 (66)

Certification/ Registration of QMS ISO/IEC Guide 62 – general requirements for bodies operating assessment and certification/registration of quality systems – states the general requirements for certification bodies carrying out assessment and certification/registration of quality systems.

ISO/IEC Guide 66 refers to general requirements for bodies operating assessment and certification/registration of environmental management systems.

ISO/IEC 65:1996

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Product Certification ISO 65:1996 – general requirements for bodies operating product certification systems – describes the requirements for a certification/registration process, through which a third party extends a written assurance that a product (including services), process, personnel, organisation or system conforms to specific requirements.

In the ISO 9000 and ISO 14000 context, certification and registration are used interchangeably, and they both signify the same. One term is preferred over the other depending on the country. Likewise, the bodies that issue ISO 9000 or ISO 14000 certificates are referred to in some countries as certification bodies and in others as registration bodies or registrars.

ISO itself does neither assess the conformity nor issue certificates of conformity to standards. Certification is carried out independently from ISO by more than 800 certification or registration bodies active at the national or international levels. ISO does not control the certification bodies, but it contributes to best practice and consistency in their activities through ISO/IEC Guide 62 (see above).

Accompanying standards:

- ISO/IEC Guide 28:2004: general rules for a model third-party certification system for products
- ISO/IEC Guide 53:2005: approach by which certification bodies can develop and apply product certification
- schemes
 ISO/IEC 17024:2003: specifies requirements for a body certifying persons against specific requirements, including the development and maintenance of a certification scheme for personnel
- ISO/IEC Guide 67:2004: guidance on product certification systems facilitating to understand, develop, establish or compare third-party product certification systems

ISO/IEC Guide 68:2002

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Mutual Recognition Agreements (MRA's) ISO/IEC Guide 68:2002 – arrangements for the recognition and acceptance of conformity assessment results – explains how to develop, issue and operate accords and reports of recognition and acceptance related to international trade. Cross-border cooperation between conformity assessment and accreditation bodies can be formalised through Mutual Recognition Agreements (MRA's), in which the partners agree to recognise the results of each other's testing, inspection, certification or accreditation.

The primary objective of MRAs is to reduce repeated conformity assessment controls for internationally traded goods and services and hence conformity assessment costs. MRAs are intended to increase confidence of both private customers and public regulators in the work of conformity assessment and accreditation bodies in other countries. Since MRA's facilitate the acceptance of goods and services everywhere on the basis of a single assessment in one country, they contribute to the efficiency of the international trading system to the benefits of suppliers and customers alike.

Emerging issues

- Good management and organisation practices:
 e.g. guidelines on social responsibility, guidelines for supply chain security
- Supply chain security management systems: ISO/PAS 28000 applies the management system's approach to facilitate security of global supply chains
- Management system certification: New ISO/IEC standard to increase confidence in management system certification (ISO/IEC 17021:2006)
- Environment:
 - e.g. ISO 14064 and 14065 standards reflecting new requirements such as greenhouse gas verification (climate change mitigation)
- Cost and benefits of compliance: ISO 10014 standard explains how to realise financial and economic benefits with ISO 9001:2000

Further readings

International Accreditation Forum (IAF)

http://www.iaf.nu

International Organization for Standardization (ISO)

http://www.iso.ch

ISO: ISO 14000 model

http://www.iso.org/iso/en/prods-services/otherpubs/iso14000/model.pdf

ISO: ISO 22004:2005

http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=39835&ICS1=67&ICS2=20&ICS3

ISO: ISO 22000

http://www.iso.org/iso/en/iso9000-14000/msstandards/pdf/food_1.pdf or http://www.iso.org/iso/en/iso9000-14000/msstandards/pdf/food_3.pdf

ISO: ISO/PAS 28000

http://www.iso.org/iso/en/iso9000-14000/msstandards/pdf/supply_1.pdf

ISO: TC207 Environmental Management

http://www.tc207.org/

ISO: Action Plan for developing countries

http://www.iso.org/iso/en/prods-services/otherpubs/pdf/actionplan_2005-en.pdf

ISO: ISO in brief

http://www.iso.org/iso/en/prods-services/otherpubs/pdf/isoinbrief_2006-en.pdf

ISO: How conformity assessment works

http://www.iso.org/iso/en/comms-markets/conformity/iso+conformity-02.html

ISO: List of ICS (International Classification for Standards)

http://www.iso.org/iso/en/CatalogueListPage.CatalogueList

ISO: Quality management – Guidelines for realising financial and economic benefits http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=37263&ICS1=3&ICS2=120&ICS3=10

ISO: Quality Management Principles

http://www.iso.org/iso/en/iso9000-14000/understand/qmp.html

ISO: Selection and use of the ISO 9000:2000 family of standards http://www.iso.org/iso/en/iso9000-14000/understand/selection_use/selection_use.html

ISO: Strategic Plan 2005-2010

http://www.iso.org/iso/en/aboutiso/strategies/isostrategies_2004-en.pdf

OECD (2005): Standards and Conformity Assessment in Trade:

Minimising Barriers and Maximising Benefits

http://www.oecd.org/dataoecd/19/27/36223999.pdf

TÜV Sued: Lebensmittel: Welche Chancen bietet die ISO 22000?

 $http://www.tuev-sued.de/presse/pressearchiv/tuev_sued-thema_lebensmittel_welche_chancen_bietet_die_iso_22000$

World Standards Network (WSSN) http://www.wssn.net/WSSN/index.html

European Committee for Standardization (CEN) and 4.1.3.3 **European Committee for Electrotechnical Standardization (CENELEC)**

Background

The Treaty of Rome (25 March 1957) already stipulated that technical barriers to trade within the Community should be removed. But as late as mid of the 1980s, first steps were taken to elaborate on standards at the Community level. As a result of the so called 'new approach', the EEC ratified on 7 May 1985 the 'Directive of the Council for harmonisation and standardisation'.

The Comité Européen de Normalisation (CEN – European Committee for Standardisation) and the Comité Européen de Normalisation Electrotechnique (CENELEC – European Committee for Electrotechnical Standardisation) have been officially recognised as the European Standards Organisation in their fields by the European Commission through Directive 83/189/EEC.

Scope

Main reasons for standardisation at EU level:

- existing high risks, for which no standards have been elaborated so far
- differing national standards, which need to be harmonised at EU level
- need for deregulation and simplification of standards to achieve better transparency

According to the CEN/CENELEC rules of procedures, the national standardisation institutes of the following EU Member States are obliged to integrate European standards: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Switzerland, Spain and the United Kingdom.

Standards of CEN bear the label 'EN', standards of the German Standardisation Institute (DIN – Deutsches Institut fuer Normung) are labelled 'DIN', and standards that are approved at both levels bear a combined label 'DIN EN ...'.

Legal Basis

The legal bases for the activities of CEN in food-related issues are laid down e.g. in the Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery' (basic requirements for safety and health for specific machine types such as food processing machines).

Technical Committees (TC)

TC related to food processing:

- CEN/TC 132 aluminium and aluminium alloys
- CEN/TC 144 tractors and machinery for agriculture and forestry
- CEN/TC 146 packaging machines
 CEN/TC 149 power operated warehouse equipment
- CEN/TC 150 industrial trucks
- CEN/TC 153 food Processing Machinery Safety and Hygiene Requirements
- CEN/TC 172 pulp, paper and board
- CEN/TC 174 fruit and vegetable juices methods of analyses
- CEN/TC 194 utensils in contact with food
 CEN/TC 197 pumps
 CEN/TC 225 bar coding

- CEN/TC 275 food analysis horizontal methods
- CEN/TC 284 greenhouses
- CEN/TC 307 oilseeds, vegetable and animal fats and ... methods of sampling
- CEN/TC 334 irrigation techniques

Food processing machines

Since hygiene requirements are of outstanding importance both for machine constructors as for users and control institutions, the most important standard is the 'DIN-EN 1672 food machines - general guidelines'. Machines and equipment that conform to European standards can be labelled 'CE'.

Further readings

European Committee for Electrotechnical Standardization

http://www.cenelec.org/

European Committee for Standardization

http://www.cenorm.be/

European Committee for Standardization: Members http://www.cenorm.be/standardization/tech_bodies/cen_tcs.htm

European Committee for Standardization: Online catalogue

http://www.cenorm.be/cenorm/standards_drafts/onlinecataloguewithlinkstomembers/index.asp

4.1.3.4 Organization for Economic Cooperation and Development (OECD)

Background

The OECD elaborates common criteria (procedures, rules, standards) with the objective of facilitating international trade.

Scope

The OECD produces internationally agreed instruments, decisions and recommendations to facilitate the adaptation of quality standards to present production, trade and marketing conditions, the promotion of uniform quality control procedures and the dissemination of quality assurance quidelines.

The OECD supplies reference for the certification and standardisation of certain agricultural commodities (fruit and vegetables) and inputs (seeds). Depending on countries, various schemes exist ranging from direct enforcement to accreditation procedures.

The OECD also elaborates on different codes of conduct in general such as the Code of Conduct for Multinationals of the OECD.

Standards for fruit and vegetables

The OECD Scheme for the Application of International Standards for Fruit and Vegetables facilitates the adaptation of quality standards (production, trade and marketing) by promoting uniform quality control procedures and dissemination of quality assurance guidelines. Further benefits of the scheme:

- promotion of the use of an internationally recognised control certificate
- · improvement of conditions for maintaining the quality during transport and handling
- promotion of international standardisation of packaging and labelling
- improvement of quality assurance operations

The scheme assists producers, traders and quality inspectors to

- develop and revise standards in co-operation with the UN/ECE
- · develop explanatory brochures of standards
- develop tools for gauging the skin colouring of various products
- provide guidance for the application of quality assurance and inspection systems

Standards for qualityguaranteed seed

The OECD scheme for varietal certification of seed moving in international trade ensures the varietal identity and purity of seed. Under the scheme, appropriate requirements and controls throughout the cropping, seed processing and labelling operations have been elaborated (e.g. generation control [pre-basic, basic and certified seed], isolation distances, purity standards, field inspections, lot sampling, post-control plots, compulsory official laboratory analysis for each certified seed lot). The OECD certification provides for official recognition of quality-guaranteed seed, thus facilitating international trade. Certified seeds are produced and officially controlled according to common harmonised procedures in 55 participating countries.

Pesticides Programme

Assistance to OECD governments to co-operate in assessing and reducing the risks of agricultural pesticides and to improve the efficiency and effectiveness of pesticide regulations in OECD countries. The program supports pesticide regulation by

- harmonising the testing and assessment of health and environmental risks
- improving the way governments record their product evaluations
- developing tools to measure progress in risk reduction
- · creating mechanisms that help governments communicate and work together

The program also addresses special issues, such as

- the contribution of integrated pest management to pesticide risk reduction
- the problem of obsolete pesticide stockpiles in developing countries
- the economic impacts of pesticide risk reduction in commercial farming

Good Laboratory Practices (GLP)

Alongside the relevant ISO standards, the OECD GLP requirements are also important for laboratory accreditation. The OECD criteria for GLP focus strongly on the documentation of how results have been obtained, although it goes without saying that proof of the technical competence of the laboratory also has to be furnished.

The analysis of chemicals (e.g. plant protection products or pharmaceuticals) for licensing purposes must be done with due regard of GLP principles.

Principles of Corporate Governance The OECD Principles of Corporate Governance were endorsed at the May 1999 OECD Ministerial meeting. The principles are non-binding on OECD members. In cooperation with the World Bank and other international organisations, the OECD established a Global Corporate Governance Forum, a Private Sector Advisory Group and regional corporate governance roundtables to promote an effective and continuing dialogue on corporate governance.

Economic analysis

The OECD assesses costs and benefits of compliance for meeting regulatory requirements in international trade (OECD 2000, 2005a and 2005b – see further readings). Some findings of the company poll implemented in four different countries:

- harmonisation of standards would lead to reduced costs of product testing/re-design
- · conformity assessment costs vary significantly between countries
- mutual recognition agreements have yielded a beneficial effect on costs of compliance
- time is an important additional indirect cost of conformity assessment
- meeting voluntary requirements is seen as more challenging than mandatory standards
- small companies face difficulties to adapt quickly to changing requirements

The OECD also developed a standard cost model manual (SCM – see further readings) comprising, among others, a step-by-step approach for the implementation of a standard cost analysis and for cross-country benchmark and comparison studies (SCM – see further readings).

Further readings

OECD (2000): Assessment of the Costs for ... Regulatory Requirements

http://www.olis.oecd.org/olis/1999doc.nsf/linkto/td-tc-wp(99)8-final

OECD: Environment Directorate – Chemical Safety – Good Laboratory Practices

http://www.oecd.org/department/0,2688,en_2649_34381_1_1_1_1_1_0.0.html OECD: Fruit and vegetables – Publications and documents

http://www.oecd.org/findDocument/0,2350,en_2649_33907_1_1_1_1_1_1,00.html

OECD: The OECD Guidelines for Multinationals

http://www.oecd.org/dataoecd/56/36/1922428.pdf

OECD: Seeds - Publications and documents

http://www.oecd.org/findDocument/0,2350,en_2649_33909_1_1_1_1_1_1,00.html OECD: List of Varieties eligible for Seed Certification (2004/2005) http://www.oecd.org/findDocument/0,2350,en_2649_33909_1_119699_1_1_1,00.html

OECD (2005a): Funding Environmental Compliance Assurance – Lessons Learned from

International Experience

http://www.oecd.org/dataoecd/51/58/35139072.pdf

OECD (2005b): Standards and Conformity Assessment in Trade: Minimising Barriers and

Maximising Benefits

http://www.oecd.org/dataoecd/19/27/36223999.pdf and http://www.oecd.org/dataoecd/6/35/35602222.pdf SCM Network: International Cost Model Manual

http://www.oecd.org/dataoecd/32/54/34227698.pdf

4.1.3.5 Environmental and social standards

Environmental and social aspects gain considerably in importance in international trade, in particular for exports to the European market. Besides governmental legislation and regulations, a strong consumer movement forces the food industry to react, in particular in the Northern parts of the EU (Scandinavia, Germany, The Netherlands, UK). Alongside aspects such as price, food quality and food safety, environmental and social issues may well become important determinants for success in the EU market.

At the same time, conflicts on environmental issues within the WTO (see also 'like products') have increased and possibly jeopardised the process of trade liberalisation. Many open questions need to be tackled by WTO and related international organisations: e.g. the impact of trade liberalisation on the environment, the consideration of production and process measures (PPMs) to protect the environment, the relationship between WTO and multilateral environmental agreements (MEAs), or the role of alternative environmental policy approaches including the elimination of subsidies.

Environmental and Social Standards/Eco-Labelling²⁵⁾

Promotion

The EU promotes environmentally sound production methods not only through legal provisions but also awards tariff preferences to third country exporters applying respective production methods. On the other hand, the EU follows 'the polluter pays' principle, placing responsibilities and costs for pollution prevention and clean-up on polluters. European importers facing such problems will oblige suppliers to share these costs.

Definition

Eco-labelling (or environmental labelling) identifies products and services as less harmful to the environment than similar products or services used for a specific function. Eco-labelling is a guide for consumers to choose goods that cause less damage to the environment. Eco-labelling is intended to reward eco-leadership; eco-labelling does not imply setting minimum standards or requirements.

Benefits

Improving the environmental performance of products and production processes can lead to both internal (improved efficiency) and external (perceived image) advantages for companies. As a consequence, 'green' marketing tools such as eco-labels (for products) and environmental management standards (for the organisations) have been created both by governments and private parties.

The Generalised System of Preferences (GSP) of the EU (Regulation [EC] No 2501/2001) promotes work and environmental standards through an incentive system (preferential margin of 8.5%). Though, countries risk their status as GSP country if they seriously violate such standards.

Eco-labels

Eco-labels have been developed both at EU level, applicable throughout Europe, and at the national level, such as the Netherlands 'Milieukeur', the 'Blue Angel' in Germany or the 'NF Environnement' in France. The criteria pay specific attention to crop protection, the use of energy and the minimisation of waste. 'Fair trade labels' such as the Netherlands 'Max Havelaar' label, the 'Transfair International' label and the MIGROS (leading Swiss retailer group) label aim to provide fair working conditions for workers in developing countries. Environmental aspects play only a secondary role for these labels, although growers are encouraged to apply bio-dynamic production methods. The market share of eco-labelled products remains relatively small to date.

Eco-labelling programmes can provide effective incentives for producers to reduce negative environmental impacts. They are generally acknowledged by the WTO as long as they do not discriminate trade ('like products'). National eco-labelling programmes are meanwhile operating in most OECD countries and also in many non-OECD countries like the People's Republic of China, India, Indonesia, Thailand or Zimbabwe.

Environmental management systems

Whereas eco-labelling indicates that the product has a reduced impact on the environment (product standard), Environmental Management Systems like ISO 14001 are generic management system standards. This standard has been explicitly developed for environmentally sound processing methods. Although not many companies are certified to date to ISO 14001, it is expected that this standard will have an impact similar to the ISO 9000 Quality Management Systems Series in the near future.

UN Global Compact Formally launched in July 2000, the UN Global Compact stands for an agreement between the UN and leading businesses to uphold and promulgate a set of core values in the areas of human rights, labour standards and environmental practices.

Corporate Social Responsibility (CSR)

Increased outsourcing in the food sector might put at risk the brand reputation of European manufacturers if subcontractors do not adhere to the same international standards (particularly in terms of labour rights and product safety). Corporate Social Responsibility throughout the entire value added chain thus gains importance.

Scope for improving the social and environmental conditions on less developed smallholdings mainly comprises sustainable agriculture methods and ethical trade issues. Apart from the joint Flower Label Program initiative and the UK Ethical Trade Initiative there is relatively little guidance as regards good practices in CSR. Examples are listed in the

²⁵ Source: Guenther (2002)

IBLF document 'Food for thought - Corporate social responsibility for food and beverage manufacturers' cited below.

There is relatively little practical guidance available to help companies respond to wider social responsibilities. Tools that do exist tend to apply to any company and can therefore be somewhat generic; there is almost no guidance that spells out the wider social responsibilities faced by companies in specific industry sectors.

Impact on third country exporters

While there is some evidence that eco-labelling programmes have adverse impacts on producers and exporters in developing countries (especially in pulp and paper, footwear, textiles and timber markets), eco-labelling may also increase the international competitiveness of products from third countries supplying the European market and safeguard national environmental and economic interests in accordance with international trade practices (e.g. the Indian eco-label on the niche market for jute).

Emerging issues

For fresh fruit and vegetables as well as primary produce for the processing industry, social and environmental standards are expected to be integrated into existing private industry and trade standards (mainly GAP), which are currently being developed.

Further readings

European Union Eco-label Homepage http://ec.europa.eu/environment/ecolabel/index_en.htm

ADB – Asian Development Bank (2006): Core Labor Standards Handbook – Guidelines,

Handbooks, and Manuals

http://www.adb.org/Documents/Handbooks/Core-Labor-Standards/CLS-Handbook.pdf

Worldbank – CSR within the food industry http://web.worldbank.org/WBSITE/EXTERNAL/WBI/WBIPROGRAMS/CGCSRLP/0,,contentMDK:20333979~pagePK:

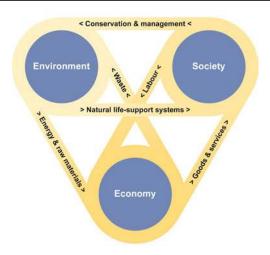
64156158~piPK:64152884~theSitePK:460861,00.html

see also following chapter

4.1.3.6 International Social and Environmental Accreditation and Labelling Alliance (ISEAL Alliance)

At the United Nations Conference on Environment and Development in Rio de Janeiro in 1992, 178 nations adopted the vision of sustainable economic, social and ecological development. On this occasion, representatives of industrialised and developing countries agreed that vigorous action was necessary to prevent aggravation of environmental problems (in particular climate change) by generating job opportunities, improving public health and quality of life. It was concluded that successful economies will be those, which succeed to manage the transformation to more efficient and sustainable use of natural resources.

Being aware that regulatory control by governments often lacks effective enforcement, economic and socio-environmental concerns are not sufficiently addressed in many countries. The following graph perfectly depicts the triangle of interdependent pillars of socially equitable, environmentally sound and economically viable global economic development.



Graph 3: Triangle of socially equitable, environmentally sound and economically viable global economic development Source: GTZ Programme on social and ecological standards ²⁶⁾

The ISEAL Alliance provides a platform for initiatives wishing to create an environment where ecological sustainable and social justice are the normal conditions of business.

Purpose

"The ISEAL Alliance is an association of leading international standard-setting, certification and accreditation organisations that focus on social and environmental issues. Taken individually, the standards and verification systems of ISEAL members represent efforts to define issue-specific elements of social and environmental sustainability. Taken together, they represent a holistic movement that has the potential to change the way the world does business. The ISEAL Alliance provides the framework to support the growth of that movement."²⁷⁾

Scope

ISEAL assists its members to govern and promote the legitimacy of their programmes. ISEAL serves as a platform for cooperation and exchange of experiences among members with the intention to enable members to improve their standard schemes, to increase the compatibility between standards and to reduce duplication. ISEAL represents its members in international trade fora and monitors policy on regulatory issues of common concern.

Services

ISEAL services to members:

- capacity building tools
- policy monitoring and analysis
- · peer review
- common platform for collaboration

Code of Good Practice

The ISEAL Code of Good Practice aims at improving the quality of standard-setting processes by establishing objective criteria for standard setting, capacity-building of members as well as by obliging members to continuous improvement of their programmes and to participate in internal peer reviews against ISO/IEC Guide 17011.

Membership

• full members (organisations meeting requirements for good practice in either their international standard-setting or international accreditation practices):

FLO – Fairtrade Labelling Organizations (see below)

FSC - Forest Stewardship Council (see below)

IFOAM – International Federation of Organic Agriculture Movements (see below)

Source: http://www.gtz.de/en/themen/uebergreifende-themen/sozial-oekostandards/2471.htm

Source: http://www.isealalliance.org/about/index.htm

MAC – Marine Aquarium Council MSC – Marine Stewardship Council

RA - Rainforest Alliance

SAI – Social Accountability International (see below)

 associate members (organisations being in the process of meeting these requirements for good practice):

IATP – Institute for Agriculture and Trade Policy

 affiliate members (organisations subscribing to the ISEAL Code of Ethics interested to participate in ISEAL primarily as an information sharing and awareness raising exercise): Chemonics International

GEN - Global Ecolabelling Network (see below)

Further readings

Liu et al (2004): Voluntary standards and certification for environmentally and socially responsible agricultural production and trade; FAO Commodities and Trade Technical Paper 5

http://www.gtz.de/de/dokumente/en-standards-in-agricultural-production-and-trade.pdf

ISEAL: Code of Good Practices for Setting Social and Environmental Standards

http://www.isealalliance.org/programs/code.htm

ISEAL: Guidance Document

http://www.isealalliance.org/documents/pdf/P020_PD3.pdf

ISEAL: Members

http://www.isealalliance.org/membership/founding.htm

Fairtrade Labelling Organizations International (FLO)

Scope

The Fairtrade Labelling Organizations International (FLO) is part of a worldwide network of Fair Trade organisations supporting producers, awareness raising and campaigning for changes in the rules and practices of conventional international trade. Established in 1997, FLO unites 20 labelling initiatives that promote and market the Fairtrade label in their countries

FLO International is constituted by two organisations:

• FLO International e.V.:

publicly recognised non-profit multi-stakeholder association involving the 20 member organisations (labelling initiatives), producer organisations, traders and external experts. FLO International e.V. develops and reviews standards and assists producers to capitalise market opportunities.

FLO-Cert GmbH:

limited company that coordinates all tasks, processes and information related to inspection and certification of producers and traders (accredited certification body according to ISO/IEC 65).

Purpose

As the leading Fairtrade standard setting and certification body, FLO intends to enable sustainable development and empowerment of disadvantaged producers and workers in developing countries.

Tasks

FLO International e.V.

- · sets international Fairtrade standards
- facilitates and develops Fairtrade business
- · advocates for trade justice

FLO Cert GmbH regularly inspects and certifies about 508 producer organisations in more than 50 countries in Africa, Asia and Latin America.

Generic

General principles:

Producer Standards

- social development
- economic development

• environmental development

Principles

Principles specific to small farmers' organisations only:

- members must be Small Producers
- democracy

Principles specific to Hired Labour situations only:

- management of the Fairtrade Premium
- forced labour & child labour

- freedom of association & collective bargaining
- working conditions

Minimum and progress requirements:

The Generic Standards distinguish between minimum requirements, which producers must meet to be certified, and progress requirements that encourage producer organisations to continuously improve in all areas related to standards and to invest in the development of the organisations and their producers/workers.

Generic Trade

Trade standards stipulate that traders that buy directly from Fairtrade producer organisations must:

Standards

 pay minimum prices to producers that cover the costs of sustainable production (Fairtrade Minimum Price)

Principles

- pay a premium that producers can invest in development (Fairtrade Premium)
- partially pay in advance (on request of producers)
- sign contracts that allow for long-term planning and sustainable production practices

Product Specific Standards

Product Specific Standards for small farmers' organisations and traders of their products have been elaborated for:

bananas, cacao, coffee, dried fruit, fresh fruit (except bananas) and fresh vegetables, herbs

and spices, fruit juices, honey, nuts and oil seeds, quinoa, rice, cane sugar, tea, wine

grapes and seed cotton

Further readings FLO: Fairtrade Labelling Organizations International

http://www.fairtrade.net/ FLO: Standards

http://www.fairtrade.net/standards.html

Forest Stewardship Council (FSC)

The Forest Stewardship Council (FSC) is an international non-profit organisation founded in Scope

1993 to support environmentally appropriate, socially beneficial, and economically viable management of the world's forests. FSC accredited certification bodies are required to evaluate all forests aiming for certification according to the FSC Principles and Criteria for Forest Stewardship. Purchasing forest products carrying the FSC logo promotes forest management that meet these internationally recognised principles and criteria.

Further

Forest Stewardship Council (FSC) http://www.fsc.org/en/about/about fsc/mission readings

FSC: Principles, Policies and Standards http://www.fsc.org/en/about/policy_standards

International Federation of Organic Agriculture Movements (IFOAM)

Scope

The International Federation of Organic Agriculture Movements (IFOAM) is an umbrella organisation of the organic agriculture movement founded in 1972 with approximately 750 member organisations in 100 countries around the world.

Purpose

IFOAM's mission is leading, uniting and assisting the organic movement in its full diversity. IFOAM's goal is the worldwide adoption of ecologically, socially and economically sound systems that are based on the principles of organic agriculture.

In order to fulfill its mission, five goals were set by the World Board for the medium term:

- · IFOAM builds the global platform for the organic movement
- IFOAM develops, communicates and defends the principles of organic agriculture
- IFOAM advocates and facilitates the adoption of organic agriculture
- IFOAM promotes the development of organic markets
- IFOAM ensures an effectively managed organisation with sufficient and sustainable resources

Principles of Organic Agriculture

- principle of health:
 - organic agriculture should sustain and enhance the health of soil, plant, animal, human and planet as one and indivisible
- principle of ecology: organic agriculture should be based on living ecological systems and cycles, work with them, emulate them and help sustain them
- principle of fairness:
 organic agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities
- principle of care: organic agriculture should be managed in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment

IFOAM

IFOAM Basic Standards (IBS):

Basic Standards (IBS) The IBS provide a framework for standard-setting and certification bodies to develop their own certification standards based on specific local conditions. While continuously adopting newly developed organic practices worldwide, the IBS reflect the current state of organic production and processing methods.

IFOAM Accreditation Criteria (IAC)

IFOAM Accreditation Criteria (IAC):

The IAC establish the requirements for conducting organic certification. The IAC are based on the ISO 65:1996 for the operation of certifying bodies and are developed to reflect the particular circumstances of certifying organic production and processing.

IAC along with the IBS lay the foundations for accreditation of certification bodies.

Internal Control Systems (ICS) for Group Certification "An Internal Control System (ICS) forms part of a documented quality assurance system that allows an external certification body to delegate the periodical inspection of individual group members to an identified body or unit within the certified operator. This means that the third party certification bodies only have to inspect the well-functioning of the system, as well as to perform a few spot-check re-inspections of individual smallholders." 28)

IFOAM Farmers' Group Initiative

The IFOAM Farmers Group is an organ within IFOAM, organising farmers' and farmworkers' organisations with the objectives:

- to pursue IFOAM's objectives among organic farmers and farm-workers
- to represent its affiliates within IFOAM
 to represent its affiliates to the outside
- to give farmers a voice in IFOAM
- to build bridges between farmers from north to south and from east to west

Further readings

International Federation of Organic Agriculture Movements (IFOAM)

http://www.ifoam.org/index.html

IFOAM: IFOAM Programme 2008

http://www.ifoam.org/about_ifoam/inside_ifoam/pdfs/IFOAM_Program_2008.pdf IFOAM: Internal Control Systems for Group Certification http://www.ifoam.org/about_ifoam/standards/ics.html

IFOAM: Organic Standards and Certification http://www.ifoam.org/about_ifoam/standards/index.html
IFOAM: Principles of Organic Agriculture http://www.ifoam.org/about_ifoam/principles/index.html
IFOAM: The IFOAM Accreditation Programme http://www.ifoam.org/about_ifoam/standards/accreditation.html

IFOAM: The Norms Documents Library

http://www.ifoam.org/about_ifoam/standards/norms/norm_documents_library/norms_documents_library.html

IFOAM: The IFOAM Farmers' Group Initiative http://www.ifoam.org/about_ifoam/initiatives/farmers_group.html

Social Accountability International (SAI)

Scope

Rising public concern about inhumane working conditions in developing countries led to the creation of the Council on Economic Priorities Accreditation Agency (CEPAA) in 1997. In 2000, CEPAA became Social Accountability International (SAI), which promotes workers' rights based on the International Labour Organization (ILO) standards and the United Nations Human Rights Conventions.

Source: http://www.ifoam.org/about_ifoam/standards/ics.html

Purpose

Develop voluntary standards governing social responsibility and certify companies that agree to meet these standards. The first such standard is SA 8000, which governs employees' working conditions. SAI's mission is

- to work with companies, non-governmental organisations, labour and trade unions
- to cooperate with a global network of auditing organisations/certification bodies
- to incorporate third-party monitoring and innovative management systems
- · to provide a sustainable framework for improved social performance
- · to improve ethical workplace conditions while improving business productivity
- · to be represented globally
- · to incorporate the most robust principles with regard to workplace human rights

SA8000

The SA8000 is a standard for socially responsible employment practices. It is modelled on the ISO 9000 quality standard. However, unlike ISO 9000, it prescribes specific performance standards. SA8000 is designed for

- retailers who commit themselves to only doing business with socially responsible partners
- manufacturers/suppliers who have to apply standards in 9 key areas (child labour, forced labour, health and safety, freedom of association and collective bargaining, discrimination, disciplinary practices, working hours, compensation, management systems)

Published in late 1997 and revised in 2001, the SA8000 Standard and verification system is a credible, comprehensive and efficient tool for assuring humane workplaces. The SA8000 system includes:

- factory-level management system requirements for ongoing compliance and continual improvement
- independent, expert verification of compliance by certification bodies, which are accredited by SAI
- involvement of stakeholders: workers, trade unions, companies, socially responsible investors, non-governmental organisations and governments
- public reporting on SA8000 certified facilities and Corporate Involvement Programme (CIP) annual progress reports through postings on the SAI website
- integration of consumer and investor concerns through the SA8000 Certification and Corporate Involvement Program
- training partnerships for workers, managers, auditors and other interested parties in effective use of SA8000
- research and publication of guidance on the effective use of SA8000
- · complaints, appeals and surveillance processes to support the system's quality

SA8000 Elements:

- · child labour
- forced labour
- · health and safety
- · freedom of association and right to collective bargaining
- · discrimination
- · discipline
- working hours
- compensation
- management systems

Benefits for Workers, Trade Unions and NGOs:

- opportunities to organise trade unions and bargain collectively
- · tool to educate workers about core labor rights
- · opportunity to work directly with business on labor rights issues
- public awareness on companies committed to assuring humane working conditions.

Benefits for Business:

- drives company values into action
- enhances company and brand reputation
- improves employee recruitment, retention and productivity
- supports better supply chain management and performance

Benefits for Consumers and Investors:

- · assurance for ethical purchasing decision
- identification of ethically produced goods and companies committed to ethical sourcing
- · coverage of product categories and production geography

SA8000 is widely accepted as a comprehensive international ethical workplace management system.

Further readings Business and Sustainable Development: A Global Guide

http://www.bsdglobal.com/tools/systems_sa.asp

Social Accountability International (SAI)

http://www.sa-intl.org/

SAI: Overview of SA 8000

http://www.sa-intl.org/index.cfm?fuseaction=Page.viewPage&pageId=473

Global Ecolabelling Network (GEN)

Scope

The Global Ecolabelling Network (GEN) is a non-profit association of third-party, environmental performance labelling organisations founded in 1994 to improve, promote, and develop the "ecolabelling" of products and services.

Purpose

The mission of the GEN is to:

- serve stakeholders to improve, promote and develop the ecolabelling of products, the credibility of ecolabelling programs
- foster co-operation, information exchange and harmonisation with regard to ecolabelling
- · facilitate access to information about ecolabelling standards from around the world
- participate in certain international organisations in order to promote ecolabelling generally
- encourage the demand for/supply of environmentally responsible goods and services
- set criteria for/certify products and services with lower environmental impact
- provide information, advice and technical assistance to organisations and the public
- represent the interests of ecolabelling in international meetings and events

Definition Ecolabelling

Ecolabelling is a voluntary environmental performance certification and labelling, which is awarded by an impartial third-party certification body assessing against environmental standards.

ISO has identified three broad types of voluntary labels, with ecolabelling fitting under the Type I designation. Voluntary Environmental Performance Labelling – ISO Definitions:

Type I:

voluntary, third party license authorising the use of environmental labels on products indicating environmental preferability of a product based on life cycle considerations

Type II:

informative environmental self-declaration claims

Type III:

voluntary programs providing environmental data of a product, under parameters set by a qualified third party and based on life cycle assessment

Further readings Global Ecolabelling Network (GEN)

http://www.gen.gr.jp/index.html GEN: What is Ecolabelling?

http://www.gen.gr.jp/eco.html

GS1 The Global Language of Business 4.1.3.7

- solutions for bar codes and traceability

GS1 and GS1 US, formerly known as European Article Number (EAN) and Uniform Code Council (UCC), offer an integrated system of global standards that provide for identification and communication on products, assets, services and locations for supply chain management. Of major interest for the food industry are the solutions on bar codes and traceability.

Scope

GS1 designs and implements standards and solutions to improve the efficiency and transparency of supply chains worldwide and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world.

GS1 cooperates with official bodies such as the United Nations and the European Commission, ISO and other international organisations. The member organisations of GS1 are in general national associations providing tools and support to enable member companies to manage their supply chains more efficiently.

Purpose

"GS1's goal is to simplify global commerce by connecting the flow of information with the flow of goods."

"GS1 will lead the design and implementation of global standards to improve the supply and demand chain." ²⁹⁾

Activities

- allocation of unique numbers
- provision of training and support
- supply of information on standards
- · continuous improvement of GS1 standards

Elements

· GS1 Bar codes:

Globally recognised GS1 identification keys allowing automatic identification for example of trade items, locations, logistic units, and assets.

GS1 eCom:

Global standards for electronic business messaging allowing rapid, efficient and accurate automatic electronic transmission of business data between trading partners.

• GS1 GDSN:

The Global Data Synchronisation Network™ (GDSN™) enables partners in the supply chain to have automatic and consistent item data for effective category management.

GS1 EPCglobal:

Global standards system combining RFID (Radio Frequency Identification) technology, existing communications network infrastructure and the Electronic Product Code (EPC) to enable immediate and automatic identification and tracking of an item through the entire supply chain for improved efficiency of and transparency in the supply chain.

GS1 Traceability:

GS1 traceability integrates several GS1 products and is a robust solution for tracking and tracing items through the food supply chain.

Further readings

GS1/ANECOOP: Traceability Implementation Case Study http://www.gs1.org/docs/traceability/traceability_case_study_anecoop.pdf

GS1: Banana Supply Chain Traceability

http://www.gs1.org/docs/traceability/GS1_banana_traceability.pdf

GS1/EAN International: Fresh produce Traceability Guidelines

http://www.gs1.org/docs/traceability/GS1_fresh_produce_traceability.pdf

GS1: GS1 Germany

http://www.gs1-germany.de/internet/content/ueber_gs1_germany/index_ger.html

GS1: Products and Solutions http://www.gs1.org/productssolutions/

GS1: Publications

http://www.gs1.org/services/publications/online/index.html

GS1: Supply Chain Management Tools for the Packaging Industry

http://www.gs1.org/docs/traceability/traceability_case_study_anecoop.pdf

GS1: Wine Supply Chain Traceability

 $http://www.gs1.org/docs/traceability/GS1_fresh_produce_traceability.pdf$

4.2 European Union (EU)

Extending their scope in several stages, the EU agriculture and food policies have developed from the focus on establishing the common market to the assurance of high levels of food safety. For a better understanding of past structures and shortcomings, lessons learned, on-going reforms and

Source: http://www.gs1.org/about/visionmission.html

probable future developments, it might be worth to have a brief look at the history of the EU's agricultural and food policies.

Period 1 (1957–1986): With the establishment of the EU in 1957, rules were adopted for certain agricultural products under the EU's Common Agricultural Policy (CAP). Although, the Treaty of Rome establishing the European Economic Community (the 'EEC Treaty') initiated the establishment of a Common Market, mainly through adaptation of the legislation, it did not confer on EU institutions any specific power to adopt food legislation. Since the envisaged harmonisation process slowed down at the beginning of the 1980ies, in 1985, Member States' governments placed new political emphasis on establishing a single Internal Market within the EU in which goods, services, people and capital could move freely.

Period 2 (1987–1992): This period saw the adoption of a vast array of new legislation, all designed to eliminate obstacles to cross-border trade within the EU by harmonising most divergent national laws. As a result, many of the controls previously administered on intra-EU borders were abolished and transferred to the external borders of the EU, i. e. the borders between EU and the so called third countries (non-EU) countries. The completion of the single Internal Market was officially scheduled for 31 December 1992. To achieve this goal, Member States granted further powers to EU institutions, notably in the areas of consumer protection and public health.

Period 3 (1993–today): In 1995, Austria, Finland and Sweden became EU members, and Norway, Iceland and later Liechtenstein concluded agreements with the EU to apply all Internal Market rules to the combined territory of those three countries and the EU Member States. This area is called European Economic Area (EEA) and most EU food legislation applies to the EEA as a whole. With the accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia by 1 May 2004, followed by Bulgaria and Romania in January 2007, the EU accounts for 27 Member States. Other applicants for membership are Croatia, Macedonia and Turkey. The geographical outreach of the EU makes its laws all the more important for non-EU (third) countries, which aspire to keep their export shares or to gain new shares in the EU market.

In the early 1990s, the mad cow disease crisis shocked the internal market. EU institutions were called to enforce and improve the national legislation on safety of food products. Political pressure increased with a series of subsequent food scares, notably the dioxin contamination in animal feed and EU-wide concerns over the use of genetically modified organisms (GMO) in foods. While prior to these scares, food safety had been largely a Member State matter, it suddenly took centre stage on the Commission's agenda. Developed over more than four decades in an uncoordinated and inharmonious way, the European Union required a fundamental restructuring and harmonisation of Member States food safety regulations based on common principles. To this end, the Commission of the European Communities published the White Paper on Food Safety in January 2000 (see following chapter).

4.2.1 Brief introduction to EU legislature

The European Communities' core objective of achieving European unification is based exclusively on the rule of law. Community law is an independent legal system which takes precedence over national legal provisions. A number of key players are involved in the process of implementing,

monitoring and further developing this legal system for which a variety of procedures apply. In general, EU law is composed of three different, but interdependent, types of legislation as described below.

Primary legislation

The Treaties constitute the European Union's 'primary legislation', which is comparable to constitutional law at national level.

The treaties lay down the fundamental features of the Union, in particular the responsibilities of the various actors in the decision-making process and the legislative procedure under the Community system and the powers conferred on them. The treaties themselves are the subject of direct negotiations between the governments of the Member States, after which they have to be ratified in accordance with the procedures applying at national level (in principle by the national parliaments or by referendum). Treaties can only be changed by other primary laws (new treaties, basic principles of international law).

The Treaties establishing the European Communities (EC):

- Treaty establishing the European Economic Community ('EEC Treaty', Rome, 1958) amended in particular by the:
- Single European Act (1987)
- Treaty of Maastricht ('Treaty on European Union', 1993)
- Treaty of Amsterdam (1999)
- Treaty of Nice (2003)

Secondary legislation

Secondary legislation is based on the Treaties, and implies a variety of procedures defined in different articles thereof:

- Regulations
- Directives
- Decisions

Regulations are adopted by the Council in conjunction with the European Parliament or by the European Commission (EC) alone. A regulation is directly applicable, which means that it creates law which takes immediate effect in all the Member States in the same way as a national instrument, without any further action on the part of the national authorities.

Directives are adopted by the Council in conjunction with the European Parliament or by the Commission alone. In contrast to regulations, directives are only binding on the Member States with regard to the result to be achieved. Some Directives are very general in nature, whilst others set out in detail particular controls and provisions that are to be applied in the national legal systems of the Member States.

Directives are effectively instructions to Member States to enact laws in their proper national systems to meet the objectives prescribed in the Directive, but leave Member States the choice of the form and method they adopt to realise the Community objectives within the framework of their internal legal order. The evolving scope of discretion used by the national authorities of the Member States often results in divergences, which further complicate the harmonisation process of food laws within the EU.

Decisions are adopted either by the Council, by the Council in conjunction with the European Parliament or by the Commission. A Decision is the instrument, by which the Community institutions give a ruling on a particular matter. Decisions are fully binding on those to whom they are addressed.

Case law

Case-law includes judgments of the European Court of Justice and of the European Court of First Instance, for example, in response to referrals from the Commission, national courts of the Member States or individuals.

Further readings

EUR-Lex – EU Law definitions

http://europa.eu.int/eur-lex/en/about/pap/process_and_players2.html

EUR-Lex - Process and Players

http://eur-lex.europa.eu/en/droit_communautaire/droit_communautaire.htm#1.1.3

4.2.2 The EU's Food Safety and Quality Legislation – an overview

The following compilation outlines the EU's Food Safety and Quality legislation and institutional setup. The different parts will be explained in the indicated chapters in more detail.

Box 4: Inventory of the EU's Food Safety and Quality Legislation		
Food Safety (chapter 4.2.3) Mandate: European Commission Directorate General Health and Consumer Protection (DG SANCO)		
Policy Papers and Legislation	Content	Chapter
White Paper on Food Safety	Policy Paper of the European Communities providing a framework for the restructuring of the European Union's food safety legislation and institutional set-up	4.2.3.1
Regulation (EC) No 178/2002 (popular name: General Food Law)	Principles of the General Food Law	4.2.3.2
	Institutional set-up	4.2.3.3
	Horizontal legislation (mandatory)	4.2.3.4
	Vertical legislation (mandatory)	4.2.3.5
Food Quality (chapter 4.2.4) Mandate: European Commission Directorate General Agriculture and Rural Development		
Common Market Organisation (CMO)	Introduction	4.2.4.1
	Marketing standards (mandatory standards)	4.2.4.2
	Protection for geographical indications (voluntary)Organic farming (voluntary)	4.2.4.3

4.2.3 Food Safety

4.2.3.1 The White Paper on Food Safety

By publishing the White Paper on Food Safety on 12 Janauary 2000, the Commission of the European Communities initiated an ambitious restructuring programme for the food safety system of the EU and its Member States. Implementation started with unprecedented drive. A new legal framework was drafted to cover the entire food chain (including feed production), the European Food Safety Authority (EFSA) was established to provide independent scientific advice, food safety controls were harmonised between EU Member States on the basis of best practices and legal provisions for consumer information have been improved.

As the Community is the world's largest importer and exporter of food, the White Paper furthermore emphasised the EU's active role in international bodies as being indispensable to communicate developments on food safety to trading partners.

The White Paper aimed to restore and maintain consumers' confidence in food. Although the European food processing chain is one of the most secure in the world, there certainly is room for improvement. Modernising the food law of the Community will lead to a more coherent, clearer, more flexible and thus even more secure food supply to consumers.

White Paper on food safety

Purpose

"Assuring that the EU has the highest standard of food safety is a key policy priority for the Commission ... This process is driven by the need to guarantee a high level of food safety." 30)

Key elements

The policy paper clearly identifies many weaknesses in the hitherto existing system. Among the weaknesses identified are: lack of scientific support for the system of scientific advice, inadequacies in monitoring and surveillance on food safety issues, gaps in the rapid alert system and lack of coordination of scientific cooperation and analytical support.

Institutional set-up:

The White Paper calls for the establishment of a European Food Authority based on the principles of independence, scientific excellence and transparency in its operations. Therefore the Authority must be guided by best science, be independent of economic and political interests, be open to rigorous public scrutiny, be scientifically authoritative and shall work closely with national scientific bodies.

A key element is the functional separation of scientific risk assessment and risk management decisions

- the responsibility for risk management decisions remains with the European Commission, European Parliament and European Council as politically responsible institutions
- the responsibility for risk assessment and risk communication is the task of the European Food Safety Authority (EFSA – for more details see chapter 4.2.3.3)

Food safety legislation:

In parallel to the establishment of the Authority, legislative provisions for food safety have to be improved in order to gain in coherence and integrate all aspects from farm to table. Due to the developments in both food production and processing during the past decades, standards and control measures have to be adapted in order to ensure food safety. A clear need to up-date existing European legislation has been identified and a new legal framework has been proposed in the White Paper under consideration of the principles of food safety mentioned below.

Main elements of the new legal framework:

- food safety (see principles of food safety below)
- animal feed
 - (e.g. declaration of input used in animal feed)
- animal health and welfare
 - (e.g. transforming safety measures against BSE into legislation)
- hygiene
 - (e.g. guiding principle of full responsibility of food operators throughout the food chain and the implementation of HACCP)
- contaminants and residues
 - (e.g. definition of standards for contaminants in order to harmonise the system EU-wide, the Commission also aims at progressively setting limits for all pesticide/commodity combinations)
- novel food
 - (e.g. adoption of an implementing regulation to clarify the procedures laid down in the Novel Food Regulation (EC) No. 258/97)
- additives, flavourings, packaging and irradiation
 (e.g. maintaining lists of authorised additives and status of enzymes, up-dating lists of colouring matters, sweeteners and other additives)
- · emergency measures
 - (e.g. legislative proposal to adopt a single emergency procedure applicable to all types of food and feed)
- decision making process
 - (e.g. streamlining and simplifying the decision making process in order to ensure efficacy, transparency and rapidity)

Source: Commission of the European Communities (2000) http://ec.europa.eu/dgs/health_consumer/library/pub/pub/6_en.pdf

Food Safety Controls:

Since the implementation and enforcement of Community legislation differs considerably between Member States, the same level of protection across the EU cannot be guaranteed. Therefore, the White Paper proposes to develop a Community framework for the development and operation of national control systems (based on performance criteria and clear guidelines).

Controls of imports at borders of the Community will be extended to cover all feed and foodstuffs and action taken to improve coordination between inspection points.

Consumer Information:

The Community will promote a dialogue with consumers to encourage their involvement in food policy matters and will in particular improve the information system on food quality and food risks.

International Dimension:

Being the world's largest importer/exporter of food products, the Community is obliged to explain the implications of the developments in food safety to the EU trading partners.

Principles of food safety

Comprehensive and integrated approach:

- throughout the food chain: from farm to table
- · across all food sectors
- between the Member States
- at the EU external frontier and within the EU
- in international and EU decision-making

Primary responsibility of food and feed operators for food safety:

 food and feed operators are surveyed and controlled by EU Member Statescontrolcapacities and capabilities in Member States are tested by the EU Commission through audits and inspections

Traceability of food and feed and their ingredients:

- adequate procedures to withdraw products from the market where a risk to consumer health is posed
- adequate records at all stages of the food chain so that a source of a problem can be identified

Transparency:

- · constant review of the food policy
- adaptation of the food policy to respond to short-comings and developments in the production chain
- involvement of all stakeholders having the right to contribute to policy decision

Risk Analysis must form the foundation on which food safety is based – three components:

- risk assessment (scientific advice and information analysis)
- risk management (regulation and control)
- · risk communication

The Guidelines for Risk Analysis of the Commission for governments and legislative bodies in Member States comprise criteria for the

- identification of the degree of scientific insecurity by an objective risk assessment
- integration of all stakeholders into decisions on alternative risk management measures
- relation between measures and existing risk
- · cost-benefit relation of measures

Further readings

Commission of the European Communities: White Paper COM (1999) 719 final http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf
EUR-Lex: The Access to European Union Law – Legislation in Force – 03. Agriculture

http://eur-lex.europa.eu/en/repert/index_03.htm

4.2.3.2 General Food Law

- Regulation (EC) No 178/2002

Existing food law principles and procedures must be adapted in EU Member States by 1 January 2007 in order to comply with the general framework (so-called General Food Law) established by **Regulation (EC) No. 178/2002** of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

General Food Law - Introduction

Principles of the General Food Law The General Food Law does not clearly define its principles. Under General Food Law – Principles, the Commission's Directorate General (DG) Health and Consumer Protection states the following ³¹⁾:

General Objectives:

The food law aims at ensuring a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment. This integrated farm to fork approach is now considered a general principle for EU food safety policy.

- Food law, both at national and EU level, establishes the rights of consumers to safe food and to accurate and honest information
- The EU food law aims to harmonise existing national requirements in order to ensure the free movement of food and feed in the EU.
- The food law recognises the EU's commitment to its international obligations and will be developed and adapted taking international standards into consideration, except where this might undermine the high level of consumer protection pursued by the EU.

Risk Analysis:

The Regulation establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA).

Regulation EC 178/2002 establishes in EU law that the three inter-related components of risk analysis provide the basis for food law as appropriate to the measure under consideration:

- · risk assessment
- risk management
- · risk communication

Transparency:

Food safety and the protection of consumer interests are of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. Therefore, the Regulation establishes a framework for the greater involvement of stakeholders at all stages in the development of food law and establishes the mechanisms necessary to increase consumer confidence in food law.

In view of establishing and maintaining consumer confidence (primary goal), the EU and its Member States are currently harmonising their regulations based on the following criteria:

- transparent legislation
- effective public consultation
- efficient evaluation and explanation of potential risks and efficient communication about food safety

Basic requirements for imports

Compliance or equivalence:

Imported food must comply with the relevant requirements laid down in the General Food Law or checked for compliance under conditions recognised by the EU to be at least equivalent therto.

³¹ Source: http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm

Traceability:

Unless specific provisions for traceability are in place, businesses are required to identify the immediate supplier of the product and the immediate subsequent recipient (one step back – one step forward). Importers are hence required to identify the exporter in the country of origin as their immediate supplier.

Responsibilities of importers:

Importers like any business operator in the supply chain are responsible that foods satisfy the requirements of food law. Where imported foodstuff is assumed not to comply, importers shall immediately initiate procedures to withdraw the food from the market and inform the competent authorities thereof.

Fundamental goals of the General Food law

- ensure a high level of protection of public health and safety and of consumer protection
- ensure the free movement of goods within the single market
- base legislation on scientific evidence and risk assessment
- ensure the competitiveness of the European industry and enhance export prospects
- place the primary responsibility for safe food with industry, producers and suppliers
- ensure that legislation is consistent, rational and clear

Regulation (EC) No. 178/2002

of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Aim and Scope

- The regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food. The regulation takes into account the diversity of foods including traditional products, whilst ensuring the effective functioning of the internal market.
- The regulation establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

Art. 2 Definition of food

For the purpose of this regulation 'food' or 'foodstuff' means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Foods include water, drinks, chewing gum and intentionally incorporated substances; foods shall **not** include:

- feed
- live animals, unless they are prepared for placing on the market for human consumption
- · plants prior to harvesting
- medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC
- cosmetics, tobacco and tobacco products, narcotic and psychotropic substances, residues and contaminants

Art. 6 Risk analysis

Food Law is science-based in accordance with WTO law. In order to achieve a high level of protection of human health and life, measures adopted by the Member States and the Community governing food shall generally be based on risk analysis except where this is not appropriate to the circumstances.

Risk analysis consists of 3 interconnected components:

Risk assessment:

Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Risk assessment is the main task of **EFSA** (European Food Safety Authority).

Risk management:

Determination of measures taking account of the results of risk assessment and other legitimate factors relevant to the matter including societal, economic, traditional, ethical and environmental factors and feasibility of controls done by the **European Commission**.

Risk communication:

Interactive exchange of information and opinions throughout the risk analysis process with interested parties such as assessors, business, academia and consumers. It also includes the explanation of risk assessment findings and risk management decisions. Risk communication is the task of **EFSA**.

Art. 7 Precautionary principle

To mitigate food-related risks, regulators should take proportionate action: In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified, but scientific uncertainty persists, provisional risk management measures may be adopted to ensure the high level of health protection in the Community.

Measures have to be:

- proportionate
- not more trade-restrictive than necessary to achieve the high level of health protection
- · technically and economically feasible
- limited to a reasonable period of time (depends on the nature of the risk and the needed scientific information to clarify the risk)

Art. 8 Consumer protection

Food Law shall protect the interests of consumers by providing a basis for them to make informed choices in relation to the food they consume. Fraudulent or deceptive practices, the adulteration of food as well as any other misleading practices shall be prevented.

Art. 11/12 Imported/ exported foods

Food imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

Exported Food from the Community shall comply with the relevant requirements of food law, unless

- otherwise requested by authorities of importing country or established by laws or standards of importing country
- in other circumstances (except in case of unsafe products) the authorities of the country of destination have expressively agreed after full information
- the exported food comply with bilateral agreements

Art. 14 Food safety requirements

Food shall not be placed on the market if it is unsafe. Food shall be deemed unsafe if it is considered to be

- · injurious to health
- · unfit for human consumption

When determining whether any food is unsafe, regard shall be given

- to normal conditions of use of the food by consumers and at each stage of the food chain
- to the information provided to the consumer

A foodstuff is **unfit** for human consumption

• if it is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay

It is assumed that all food in the same lot/consignment is unsafe until it proves to the contrary.

Art. 17 Responsibilities

Food and feed business operators at all stages of production, processing and distribution are responsible for following the food law. Penal responsibility in food law is limited to faults/defects, which happened in the own sphere of influence (business operation) or have been obvious at the time of delivery.

EC Member States are responsible for enforcement from farm to fork (controls, communication and penalties).

Art. 18 Traceability

The traceability of food, feed, food-producing animals and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal or any substance intended to be, or expected to be, incorporated into a feed or food ('one step back')

Food and feed business operators shall have in place systems and procedures to identify the other business to which their products have been supplied ('one step forth') Art. 19 Responsibilities of food business operators If a food business operator considers or has reason to believe that a food which he has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, he shall

- initiate immediately procedures to withdraw the food (if it has left its immediate control)
- inform the competent authorities of the measures taken
- inform the consumers of the reasons for the withdrawal (if the product already reached the consumer); possibly recall

A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health (including information of the measures taken).

Art. 21 Liability

Art. 50–52 Rapid Alert System for Food and Feed (RASFF) see chapter 4.2.3.3

Further readings

Doherty, M. (2005): ACP-EU Economic Partnership Agreements Sanitary and Phytosanitary Measures; ECDPM Discussion Paper 68 with CTA; Maastricht www.ecdpm.org/dp68

EC – DG Health and Consumer Protection – Guidance on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No. 178/2002 http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf

EUR-Lex: The Access to European Union Law – Legislation in Force – 03. Agriculture http://eur-lex.europa.eu/en/repert/index_03.htm

Official Journal of the European Communities No. L 31 of 1st February 2002 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

4.2.3.3 General Food Law

- Institutional set-up (EC DG SANCO, EFSA, RASFF, FVO)

Overall responsibility for food safety stays with the EC's **Directorate General Health and Consumer Protection (DG SANCO)**, which has the task of keeping EU laws on food safety, on consumers' rights and on the protection of public health up to date and of checking that the rules are being applied properly in all EU Member States³²⁾. According to the Regulation (EC) No 178/2002, the EU's risk analysis system builds on three pillars comprising risk assessment, risk management and risk communication. The following organisations are mandated with implementing the EU's risk analysis scheme (for further details see succeeding paragraphs):

- the European Commission (EC) with the Food and Veterinary Office (FVO) as its own
 inspection service, which is responsible for promoting and auditing Member States'/third
 countries' food control systems
- the European Food Safety Authority (EFSA) as independent body, which is responsible for risk assessment and risk communication
- the Rapid Alert System for Food and Feed (RASFF) is a network involving the Commission,
 EFSA and Member States of the EU and EFTA (European Free Trade Association) established to exchange information on measures relevant to food safety

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See http://ec.europa.eu/dgs/health_consumer/index_en.htm

Food and Veterinary Office (FVO)

Mission

Established by the Commission in April 1997, the FVO's mission is to monitor the observance of food hygiene, veterinary and plant health legislation within the EU and in third countries, and to contribute towards the maintenance of confidence in the safety of food offered to EU consumers.

Status

Forming part of the EU Commission's Directorate General for Health and Consumer Protection (DG SANCO – Directorate F), the FVO acts as the Commissions own inspection service.

Tasks

The FVO conducts monitoring and control programmes for both food products originating from EU Member States and third countries

- to promote effective control systems in the food safety and quality, veterinary and plant health sectors
- to check on compliance with the requirements of EU food safety and quality, veterinary and plant health legislation within the EU and in third countries exporting to the EU
- to contribute to the development of EU policy in the food safety and quality, veterinary and plant health sectors
- to prompt stakeholders to eliminate weak points through informing them of the outcome
 of evaluations

For imports from third countries, the FVO has the task of ensuring that the imported goods are produced under conditions at least equivalent to those in the EU. This involves the auditing of control systems and the implementation of on-the-spot checks on food production plants in non-EU countries.

Based on the experience gained from inspections, the FVO also gives recommendations to other Commission Services on legislation that needs to be clarified, amended or where new legislation is required.

Structure

The number of staff working in the FVO has increased from 74 in 1997 to its present complement of 163. Of these, 81 are inspectors, who participate regularly in on-the-spot inspection missions, with the balance consisting of management and support staff. Organisational chart of 16th June 2006:

Unit F1: country profiles, coordination of follow-up

Unit F2: food of animal origin (mammals)
Unit F3: food of animal origin (birds and fish)

Unit F4: food of plant origin, plant health; processing and distribution

Unit F5: animal nutrition, import controls, residues

Unit F6: quality, planning and development

Competent Authorities The FVO's main activity is to carry out inspections in Member States and third countries as well as to verify the implementation and enforcement of EU legislation by Competent Authorities.

Inspection programme and reports

Each year, the FVO develops an inspection programme identifying priority areas and countries for inspection. The findings of each inspection carried out under the programme are set out in an inspection report. Both the inspection programme and the reports are published on the website of the FVO. Recommendations are made to the country's Competent Authority to address shortcomings revealed during the inspections. The Competent Authority is requested to present an action plan to the FVO explaining intended measures to address the shortcomings. Together with other Commission services, the FVO evaluates this action plan and monitors its implementation.

Emerging issues

- Over recent years, the FVO has developed its working methods moving away from focusing on sectoral evaluations towards assessing the performance of the relevant Competent Authority in operating national control systems. Where specific problems are to be addressed, the FVO inspects on the basis of sectoral and/or establishment visits in addition to the general audits. This approach has been stipulated in Regulation EC 882/2004 on Official Food and Feed Controls which entered into force on 1 January 2006 (see below).
- Historically, FVO inspections have been principally in the veterinary sector and, to a
 much lesser extent, in the feed sector (mainly restricted to aspects related to BSE). With
 the new Regulation EC 882/2004 (see chapter 4.2.3.4) the Commission's responsibility

will be extended to the plant-based food and plant health sectors, which will also be reflected in the role and responsibilities of the FVO.

Further readings

European Commission – DG Health and Consumer Protection – Food and Veterinary

Office

http://ec.europa.eu/food/fvo/index_en.htm

EFSA - European Food Safety Authority

Mission The primary responsibility of the Authority is to provide independent scientific advice on all

matters with a direct or indirect impact on food safety.

Legal entity

The new food safety legislation establishes EFSA as a Community body with own legal identity. EFSA is funded from the Community budget but operates independently of the

Communities' institutions.

Scope

The Authority has been given a wide brief as to cover all stages of food production and supply, from primary production to the safety of animal feed, right through to the supply of food to consumers. EFSA gathers information from all parts of the globe, keeping an eye on new

developments in science.

EFSA shares its findings and listens to the views of others through a vast network of experts and decision-makers at many levels. A key task of the Authority is to communicate directly with the public on its areas of responsibility. The Authority carries out assessments of risks to the food chain and can carry out scientific assessment on any matter that may have a direct or indirect effect on the safety of the food supply, including matters relating to animal health,

animal welfare and plant health.

Legal basis The Council of the Ministers of Agriculture of the EU ratified on 28th January 2002 the Regulation EC No. 178/2002 of the European Parliament and of the Council laying down the 'General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety' (see chapter 4.2.3.2).

Tasks According to this Regulation, EFSA shall

- provide independent scientific advice on food safety issues (incl. advice for policy formulation and legislation)
- collect and analyse data relevant to any potential risks and monitor safety along the food chain
- identify emerging risks and provide early warning
- · cooperate closely with similar bodies in Member States
- · assist the Commission (as necessary) in crises management
- communicate to the general public

Art. 49
Participation of third countries

"The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation."

Implications for third countries

Concluding arrangements with EFSA according to Article 49 will facilitate

- to participate in the networks operated by the Authority
- to be included in the list of competent organisations, to which certain tasks may be entrusted
- to access financial contributions and staff training

Emerging issues

- An independent evaluation report in 2005 states that EFSA has done well in the first two
 years of its existence, but that the undeniable success is achieved under organisational
 conditions and staff workload that are not sustainable. Given the restrictive budgetary
 context, prioritisation is strongly recommended and 6 priority areas have been defined:
 - (i) develop active networking and stronger cooperation with Member States
 - (ii) enhance EFSA's organisation
 - (iii) strengthen EFSA's relationship with its institutional and stakeholder partners
 - (iv) enhance impact and effectiveness of EFSA communications
 - (v) develop/clarify EFSA's role in nutrition issues
 - (vi) define EFSA's medium and long-term vision (roadmap for the next 10 years)

- Harmonising the EU's national risk assessment plans:
 In December 2006, the EU's national regulators agreed to coordinate their risk assessment plans, to increase the exchange of scientific data and information and to build a European database on food safety. It is expected that the establishment of a more conistent approach to food safety within the EU will ease some of the regulatory burden for companies operating across the bloc.
- EFSA completed the 2nd stage of the EU-wide peer review of active substances used in plant protection products (commonly referred to as pesticides) and issued conclusions on 50 substances by October 2006. It is expected that the Commission and the Members States will determine within the next 6 months whether these substances can continue to be used in the EU. EFSA started the 3rd stage of the peer review covering 137 substances, which is to be completed by 2008.
- In 2006, NGOs criticised EFSA for
 (i) employing industry-friendly scientists, having particular interest in promoting GMOs and
 (ii) employing scientists with conflicts of interest, who while sitting on national food safety committees and elaborating national proposals later judge on the same in EFSA panels
 (iii) not enforcing EU law requiring EFSA panel scientists to declare any interests
- Environment Ministers from several Member States also criticised EFSA for not accepting their scientific objections against GMOs

Further readings

Direction General (DG) Health and Consumer Protection

 Training activities in third countries in the field of animal health and food safety http://ec.europa.eu/food/training/training2007_en.htm

European Food Safety Authority (EFSA)

http://www.efsa.eu.int/

EFSA (2005): Evaluation of EFSA – Final Report

http://www.efsa.europa.eu/etc/medialib/efsa/mboard/122.Par.0004.File.dat/final_report_evaluation1.pdf

EFSA (2005): Evaluation of EFSA – Annex

http://www.efsa.europa.eu/etc/medialib/efsa/mboard/122.Par.0006.File.dat/final_report_evaluation_annexes1.pdf

EFSA (2005): Evaluation of EFSA - Recommendations

 $http://www.efsa.europa.eu/etc/medialib/efsa/mboard/122.Par.0014.File.dat/mb_recommendations_evaluation.pdf$

EFSA: Members of the EFSA Management Board

http://www.efsa.europa.eu/en/mboard/members.html

EFSA: Pesticide risk assessment peer review (PRAPeR)

http://www.efsa.europa.eu/en/science/praper.html

EFSA: Press release – EFSA completes 2nd stage of EU-wide pesticides peer review process http://www.efsa.europa.eu/en/press_room/press_release/pr_praper-2nd-stage.html

Meulen, Bernd van der and Menno van der Velde (2004):

Food Safety Law in the European Union – An introduction

http://www.wageningenacademic.com/books/foodlaw.htm

RASFF - Rapid Alert System for Food and Feed

Purpose

The purpose of the RASFF is to provide the control authorities with an effective tool for exchange of information on measures taken to ensure food safety.

Scope

The RASFF is primarily a tool for exchange of information between food and feed central competent authorities in cases where a risk to human health has been identified and measures have been taken, such as withholding, recalling, seizure or rejection of the products concerned. This quick information-exchange allows the members of the network to immediately identify whether they are also affected by a problem, take the appropriate measures, thereby ensuring coherent and simultaneous actions and consumer safety.

Legal basis Regulation (EC) No. 178/2002, Article 50 establishes the Rapid Alert System for Food and Feed as a network involving the Member States (EU and EFTA/EEA), the European Commission and the European Food Safety Authority (EFSA).

Tools

Information notifications
 are established and disseminated for food and feed, for which a risk has been identified,
 but for which no immediate action has to be taken, since the product has not yet reached
 the market. Information notifications mostly concern consignments that have been tested
 and rejected at the point of origin or at the point of entry to the EU. The intention is to
 prevent imports through another border point.

Alert notifications

are sent out when immediate action is required since the product presenting a risk is already in the market. By notifying all members of the network about the risk, alert notifications enable the competent authorities to verify whether the product already entered their markets and to take all necessary preventive measures.

To avoid the recurrence of problems detected, RASFF informs countries of origin/third countries in a systematic way via the Commission Delegations.

When repeated serious problems are detected, RASFF sends a letter to the competent authority of the country concerned. As a consequence, third country authorities are supposed to guarantee that they take appropriate measures to prevent further incidents (e.g. delisting of establishments, suspension of exports, intensification of controls or change of legislation). In parallel to measures taken in the country of origin, Member States intensify checks at the point of entry. In case the guarantees given by the country of origin are not sufficient, the Commission may take measures such as systematic control at the EU borders, mandatory presentation of health certificates and eventually prohibition of import.

The European Commission's Food and Veterinary Office (FVO – see chapter 4.2.3.3) uses, among other criteria, the information transmitted by the RASFF to identify the priorities for its inspection programmes.

Third country notifications

In 2005, the following number of notifications for products originating from third countries were issued:

information notifications - 1,733
 alert notifications - 351

thereof:

additional information – 185
 contamination products – 278

Recurrent problems, for which the Commission sent out letters requiring specific guarantees from third countries:

Turkey – aflatoxins on fruit and vegetables, herns and spices, nuts and nut products

• Turkey — sulphites on fruit and vegetables

Thailand - Salmonella and Escherichia coli on vegetables and herbs
 China - migration of various chemicals on food contact materials

• China — illegal import of various products of animal origin

Further readings

Rapid Alert System for Food and Feed (RASFF)

http://ec.europa.eu/food/food/rapidalert/index_en.htm

RASFF: Annual Report 2005

http://ec.europa.eu/food/food/rapidalert/report2005_en.pdf

RASFF: Leaflet

http://ec.europa.eu/food/food/rapidalert/leaflet02_en.pdf

RASFF: Weekly overview

http://ec.europa.eu/food/food/rapidalert/index_en.htm

4.2.3.4 EU Food Safety (mandatory standards)

- Horizontal legislation

Horizontal legislation provides for rules across the food chain encompassing all aspects from farm to fork, which are common to all foodstuffs, such as food hygiene, food and feed control, contaminants, labelling, etc.

Food hygiene and food control

Food Hygiene

(so-called Hygiene Package)

Regulations (EC) 852/2004 (EC) 853/2004 (EC) 854/2004

Directive 2004/41/EC The so-called **Hygiene Package** consisting of three Regulations and one Directive were adopted in April 2004 and entered into force on 1 January 2006:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption³³⁾
- Directive 2004/41 repealing previous Directives or, in some cases, amending still existing legislation

The new regulations merge, harmonise and simplify the detailed and complex hygiene requirements previously contained in a number of Council Directives covering the hygiene of foodstuffs and the production and placing on the market of products of animal origin. They innovate in making a single, transparent hygiene policy applicable to all food and all food operators right through the food chain 'from the farm to the fork', together with effective instruments to manage food safety and any future food crises throughout the food chain.

Principles of the hygiene regulations:

- primary responsibility with food operators (self-regulation, self-control)
- food safety from farm to table, including primary production
- procedures based on HACCP principles
- · application of basic common hygiene requirements
- · registration or approval for certain food establishments
- · development of guides to good practices for hygiene or for HACCP principles

Flexibility in the implementation of the new hygiene rules with regard to:

- derogations to facilitate small and medium enterprises to adopt the regulations
- national measures to adapt the requirements for:
 - (i) continued use of traditional methods
 - (ii) special geographic conditions (remote areas)
 - (iii) establishments with low throughput

Official food and feed controls

Regulation 178/2002 defines the basic responsibilities of EU Member State authorities and those of food and feed businesses to ensure that all food and feed for sale in the EU is safe, accurately described and, where appropriate, complies with defined standards.

Regulation (EC) 882/2004

Directive 2002/99/EC The hygiene package is accompanied by:

- Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
- Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

Official food and feed controls (Regulation (EC) 882/2004):

- complements the framework Regulation (EC) 178/2002 by establishing how the basic principles will be interpreted, implemented and enforced by the EU and Member States' authorities via official controls of both EU-produced and imported food and feed
- applies to most activities covered by food and feed law, including not only food and feed safety but also animal health and animal welfare
- introduces a harmonised EU-wide regime for official control of all food and feed products, the same for domestic products and imports
- encourages third countries to develop their capacities to provide detailed information as
 required by the EU Commission about the general structure and management of their food
 and feed sanitary control systems, and guarantees that products destined for the EU meet
 EU safety standards or those considered equivalent. Information requested by the
 Commission will need to be proportionate to the nature of any risks

The new Regulation effectively extends the current requirements for food of animal origin into a number of **non-animal products**, which are associated with particular – especially microbial – risks (see emerging issues).

including sampling and analysis methods

Provisions for official controls:

- · regular inspections with a frequency based on risk assessment
- without prior warning (as a general rule)
- · at any stage of production, processing, distribution
- · including imports/exports

Provisions for import controls:

- food of animal origin (Art. 14)
 - (i) border inspection posts
 - (ii) advance warning
 - (iii) verification of documentation and identity, physical check (Decision 94/360/EC)
- food of non-animal origin (Art. 15):
 - (i) regular controls with frequency based on risk assessment
 - (ii) at any place (point of entry, importers' premises, retail)
 - (iii) verification of documentation and identity, physical check

Implementing and transitional Regulations

(EC) 2073/2005 (EC) 2074/2005

(EC) 2076/2005

The remaining implementing and transitional measures supporting the application of the EU hygiene legislation were published on 22 December 2005:

- Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs³⁴⁾³⁵⁾, which is relevant for (i) sprouted seeds (ready-to-eat)
 - (ii) pre-cut fruit and vegetables (ready-to-eat)
- (EC) 2075/2005 (iii) unpasteurised fruit and vegetable juices (ready-to-eat)
 - (iv) food safety hazards related to Salmonella
 - (v) process hygiene hazards related to Escherichia coli
 - Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under 853/2004 and for the organisation of official controls under 854/2004 and 882/2004, derogating from 852/2004 and amending 853/2004 and 854/2004
 - Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for trichinella in meat
 - Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of 853/2004, 854/2004 and 882/2004 and amending 853/2004 and 854/2004

Guidance Documents

The Commission elaborated a number of guidance documents to help food business operators and official control understand what needs to be done to comply with the new regulations (see further readings):

- guidance document on the implementation of regulation No 178/2002
- guidance document on the implementation of Regulation No 852/2004
- guidance document on the implementation of Regulation No 853/2004
- guidance document on the implementation of the HACCP principles
- guidance document on import requirements and the new rules on food hygiene and official controls

Emerging issues

• Integration of primary producers – Good Agricultural Practices:

The call for subjecting primary producers to HACCP was rejected by the EU Agriculture Ministers. Instead, they agreed on establishing guides to Good Agricultural Practice to encourage the use of appropriate hygiene practices at farm level. However, the feasibility of extending HACCP to primary production will be one element of the review that the Commission will carry out following implementation of Regulation (EC) 852/2004.

• Third country control systems:

Third countries will need to produce and retain more documented records of their control systems, their management and day-to-day operation than it is required to date. Greater emphasis is also likely to be placed on formal accreditation of laboratories and control systems by independent, internationally recognised bodies. Frictions from overlaps with existing private control schemes are probable.

• Stricter control for products with 'high risk profiles':

The following fruit and vegetable products may be subject to the same strict rules as already exist for products of animal origin such as meat, livestock and fish. The concept of

Microbiological criteria have been developed in accordance with internationally recognised principles such as Codex Alimentarius.

Regulation (EC) No 2073/2005 provides for sampling plans, limits, analytical reference methods and stages where the criterions apply.

listed countries, approved plants and certified products may be established for products with high risk profiles such as sprouted seeds, pre-cut fruit and vegetables, unpasteurised fruit juices and other 'risky' products.

Training strategy:

Regulation 882/2004 contains provisions to provide aid, training and practical guidance on the best methods to achieve Community standards. A white paper outlining the training strategy has been published in September 2006 (see further readings).

Training programmes for third countries:

Training programmes have been developed and are open to third countries. Developing countries should take a pro-active approach regarding the new regulations, seizing them as a good opportunity to bring their national food control systems in line with those of their trading partners. Developing countries should use the training offers which, for the first time, have been integrated into an EC Regulation (Article 51 of Regulation (EC) 882/2004).

Microbiological criteria:

In March 2005, the Community published a discussion paper on a strategy for setting microbiological criteria for foodstuffs in Community legislation. The proposal includes principles for the development and application of criteria and proposals for measures to be

Further readings

Doherty, M. (2005): ACP-EU Economic Partnership Agreements Sanitary and Phytosanitary Measures; ECDPM Discussion Paper 68 with CTA; Maastricht

www.ecdpm.org/dp68 DG SANCO³⁶⁾ – CD "Food hygiene and safety"

http://ec.europa.eu/food/dyna/hygiene_safety/index_en.cfm

DG SANCO - Council Directives concerning Legislation on Food Hygiene

http://ec.europa.eu/food/food/biosafety/hygienelegislation/directives_en.htm

DG SANCO - EC: discussion paper on a strategy for setting microbiological criteria for foodstuffs in Community legislation

http://ec.europa.eu/food/biosafety/salmonella/discussion_paper_en.pdf

DG SANCO - Guidance on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No. 178/2002

http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf

DG SANCO - General Food Law - Introduction

http://ec.europa.eu/food/food/foodlaw/index_en.htm

DG SANCO - Guidance Document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs

http://ec.europa.eu/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf

DG SANCO - Guidance Document on the implementation of certain provisions of

Regulation (EC) No 853/2004 on the hygiene of food of animal origin

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf

DG SANCO - Guidance Document the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

DG SANCO - Guidance Document - Key questions related to import requirements and the new rules on food hygiene and official food controls

http://ec.europa.eu/food/international/trade/interpretation_imports.pdf

DG SANCO - Online magazine "Food hygiene and safety"

http://ec.europa.eu/food/biosafety/hygienelegislation/dvd/index.html
DG SANCO – Training Strategy – Better Training for Safer Food

http://ec.europa.eu/food/training/whitepaper en.htm

Food Standards Agency – Background to the 2006 food hygiene legislation

http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg

Food Standards Agency - Guidance on new EU Official Feed and Food Controls Regulation http://www.food.gov.uk/news/newsarchive/2005/nov/offcganotes

Food Standards Agency - Regulation 882/2004 - Q & A notes for enforcement authorities on the feed and food elements

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

Food Standards Agency – Regulation (EC) No 178/2002

http://www.food.gov.uk/scotland/regsscotland/regulations/scotlandfoodlawguide/sflg200501/

Direction General Health and Consumer Protection - Food and Feed Safety

Further horizontal legislation

Harmful Organisms including

including Phytosanitary Certificate Imports of fresh fruit and vegetables from third countries are subject to phytosanitary control with regard to protecting the domestic agriculture against imported pests and diseases. Third country exporters have to present a phytosanitary certificate as guarantee that the product is in a healthy condition (inspection for insects and diseases), issued by the food inspection authority of the country of origin.

Directive 2000/29/EC

Phytosanitary certificates are required for (listed in Part B of Annex V to Directive 2000/29/EC):

annona, apples, apricots, berries, blueberries, cherries, citrus, guavas, mangoes, nectarines, passion fruit, peaches, pears, persimmon, plums, quince

Special provisions apply to trials or scientific purposes and for work on varietal selections.

Further readings:

Council Directive 2000/29/EC of 8 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

http://europa.eu/eur-lex/en/consleg/pdf/2000/en_2000L0029_do_001.pdf#122 or http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0029:EN:HTML

Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections

 $\label{lem:http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0044&model=guichett$

Commission Directive 97/46/EC of 25 July 1997 amending Directive 95/44/EC establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections

http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapilcelexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997L0046&model=guichett

Packaging

Directives 94/62/EC 75/106/EEC 76/211/EEC 80/232/EEC Packaging of products to be marketed in the EU must comply with the general requirements, which aim at protecting the environment, and with specific provisions, which aim at preventing any risk to the health of consumers:

- General requirements related to packaging and packaging waste laid down in Directive 94/62/EC, which obliges Member States to introduce systems for the return and/or collection of used packaging material
- Specific provisions related to package sizing, established in Directives 75/106/EEC, 76/211/EEC and 80/232/EEC
- Regulations (EC) 1935/2004
- Special rules for materials and articles intended to come into contact with foodstuffs, covered by Regulation (EC) 1935/2004

The Directive 94/62/EC lays down essential requirements as to the composition and the reuse, recovery and recycling of packaging material:

- no later than 30 June 2001 between 50 and 65 % by weight of packaging waste will be recovered or incinerated at waste incineration plants with energy recovery
- no later than 31 December 2008 60 % as a minimum by weight of packaging waste will be recovered or incinerated at waste incineration plants with energy recovery
- no later than 30 June 2001 between 25 and 45 % by weight of the totality of packaging materials contained in packaging waste will be recycled (with a minimum of 15 % by weight for each packaging material)
- no later than 31 December 2008 between 55 and 80 % by weight of packaging waste will be recycled
- no later than 31 December 2008 the following recycling targets for materials contained in packaging waste must be attained: 60 % by weight for glass, 60 % by weight for paper and board, 50 % by weight for metals, 22.5 % by weight for plastics and 15 % by weight for wood

Further provisions:

- mixes of different types of fresh fruit and vegetables in the same sales package: (EC) 6/2005 stipulates rules for mixes (maximum sizes, labelling)
 use of the EU Eco-Management and Audit Scheme (EMAS) logo³⁷:
- use of the EU Eco-Management and Audit Scheme (EMAS) logo³⁷:
 Commission Decision 2006/193/EC regulating the use of the EMAS logo in exceptional cases on transport packaging and tertiary packaging

Emerging issues:

- Harmonisation of the provisions for pre-packaged goods:
 With a view of further simplifying EU regulations and reducing costs for businesses, the EU reached a political agreement on a draft directive. Following the proposal, national restrictions on package sizes will be abolished with a phase-out period for certain goods.
 Mandatory nominal quantities decided at FC level would remain only for wine and spirits.
 - Mandatory nominal quantities decided at EC level would remain only for wine and spirits. On 25 September 2006, the Council unanimously agreed upon the draft directive, which would repeal Directives 75/106/EEC and 80/232/EEC and amend Directive 76/211/EEC.
- Packaging traceability:
 - By 27 October 2006, processors are required to have a traceability system in place for packaging materials. According to article 17 of Regulation (EC) 1935/2004 (see the succeeding paragraph on food contact materials), processors must be able to provide regulators with records documenting packaging material through all stages of manufacturing, processing and distribution.
- Wood packaging material:
- The implementation of a new requirement for the removal of bark (de-barking) from all wood packaging material entering the EU has been postponed from 1 March 2006 (initially 1 March 2005) to 1 January 2009. The respective Commission Directive 2004/102/EC on protective measures against the introduction of organisms harmful to plants or plant products and against their spread within the Community is based on the FAO International Standard for Phytosanitary Measures (ISPM n°15 see chapter 4.1.2.2).
- Active and intelligent packaging:
 - A draft legislation has been elaborated that would regulate the use of active and intelligent packaging used to indicate when shelf life expires or to extend shelf life of foodstuffs (including packaging materials that release or absorb substances).
- Good Manufacturing Practices (GMP) for packaging materials:
 The GMP aim mainly at adapting production methods with regard to preventing that substances from packaging material migrate into foods. The GMP set out guidelines in terms of quality assurance, training of staff, suitability of premises, documentation and production and will also apply to active and intelligent materials used in packaging (see above).

Further readings:

EC: Amended proposal for a Directive of the European Parliament and of the Council laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0171en01.pdf

EC: Commission Regulation (EC) 6/2005 of 4 January 2005 correcting regulations (EC) No 46/2003 and (EC) No 27/2003 as regards mixes of different types of fresh fruit and vegetables in the same sales package

http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/I_002/I_00220050105en00030003.pdf

EC: Commission Directive 78/891/EEC of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on prepackaging http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31978L0891&model=quicheti

EC: Commission Directive 2004/102/EC of 5 October 2004 amending Annexes II, III 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

http://europa.eu.int/eur-lex/lex/Lex/UriServ/site/en/oj/2004/I_309/I_30920041006en00090025.pdf

EC: Council Directive 80/232/EEC of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31980L0232&model=guicheti or

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31980L0232:EN:HTML

³⁷ EU Eco-Management and Audit Scheme (EMAS) http://ec.europa.eu/environment/emas/about/summary_en.htm

EC: Commission Decision 2006/193/EC of 1 March 2006 laying down rules, under Regulation (EC) No 761/2001 of the European Parliament and of the Council, on the use of the EMAS logo in the exceptional cases of transport packaging and tertiary packaging http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/l 114/l 11420010424en00010029.pdf

EC – DG Health and Consumer Protection: An overview on wood packaging material http://ec.europa.eu/food/resources/import_conditions/woodpackaging.pdf

EC – Enterprise and Industry: Harmonised standards – Packaging and packaging waste http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/packagin.html

EMAS: Guidance on the use of the EMAS logo

http://ec.europa.eu/environment/emas/pdf/guidance/guidance03_en.pdf

EU - ScadPlus: Technical harmonisation - Waste management - Packaging and packaging waste

http://europa.eu/scadplus/leg/en/lvb/l21207.htm

PackagingLaw.Com – The on-line resource for packaging law http://www.packaginglaw.com/index_news.cfm

ScadPlus: Prepacked products - Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products

http://europa.eu/scadplus/leg/en/lvb/l32029.htm

Food Contact Materials

The EU legislation on food contact materials as laid down in the Framework Regulation (EC) No 1935/2004 and accompanying Specific Directives has been harmonised to serve two main objectives:

Regulation (EC) 1935/2004 (EC) 1895/2005

- the protection of consumers' health
- the removal of technical barriers to trade

Regulation (EC) 1935/2004 lays down procedures for

- the authorisation of substances to be used in food contact materials and articles
- · the safety assessment and authorisation by EFSA
- the opinion of the Standing Committee on the Food Chain and Animal Health (SCFCAH)

Directives 78/142/EEC 80/766/EEC 81/432/EEC 82/711/EEC 85/572/EEC 93/11/EEC 2002/72/EC 2004/19/EC 2005/31/EC

Food contact materials are all materials and articles that come into contact with foodstuffs (e.g. packaging material, dishes, cutlery, processing machines, containers). Food contact materials should be safe and components should not migrate into the foodstuff in unacceptable quantities. To ensure consumers' health protection and to avoid migration into foodstuffs, two types of limits have been established for plastic materials:

- the Overall Migration Limit (OML) of 60 mg (of substances)/kg (of foodstuff or food simulants) applying to all substances that can migrate from food contact materials to the foodstuffs
- the Specific Migration Limit (SML) applying to individual authorised substances fixed on the basis of the toxicological evaluation of the substance

Manufacturers are supposed to issue declarations of compliance and submit supporting documentation to substantiate the declarations. Conformity of the documentation is inspected through official control.

Specific Directives:

- Council Directive 2005/31/EC migration limits for cadmium and lead for ceramics
- Commission Directive 2002/72/EC lists of authorised substances like monomers and
- Council Directive 82/711/EEC basic rules for migration tests
- Council Directive 85/572/EEC list of food simulants to be used in migration tests
 Council Directive 78/142/EEC Vinyl Chloride Monomer (VCM)
- Commission Directives 80/766/EEC and 81/432/EEC methods of analysis for VCM
- Commission Directive 93/11/EEC specific migration limits for nitrosamines
- Commission Regulation (EC) 1895/2005 restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

As supporting documents, the European Commission published (see further readings):

- Food Contact Materials A Practical Guide for Users of European Directives
- Newsletter Subject: Food Contact Materials

Emerging issues:

 The 'Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs' lays down that the list of authorised additives will become a positive list in two steps:

- (i) deadline 31.12.2006: submission of dossier to EFSA for all additives currently on national lists which have not yet been evaluated by EFSA
- (ii) deadline 31.12.2007: the Commission will establish a provisional list of additives which may continue to be used subject to national law until EFSA has evaluated them. Only additives that were permitted in one Member State and for which a valid petition has been received by EFSA until 31.12.2006 can be included in the provisional list.
- According to two desk studies implemented by the FVO in 2004 evaluating official
 controls in Member States relating to food additives, flavourings and food contact
 materials, official controls (inspection and sampling) of food contact materials are poor
 and need improvement. This is especially true with regard to relevant experiences and
 skills of inspectors. It is envisaged to prepare an enforcement campaign in late 2007 or
 beginning 2008 to control compliance with this Regulation.
- The EU currently reviews in how far new packaging systems (active and intelligent packaging – see above) and the use of recycled packaging material are addressed by the existing legislation for food contact material.

Further readings:

Regulation (EČ) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/framework_en.htm or

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/I_338/I_33820041113en00040017.pdf

Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs http://ec.europa.eu/food/chemicalsafety/foodcontact/leg_files/2004-19_en.pdf

EC: Food Contact Materials - Legislative List:

Framework Regulation, Specific Directives, Plastic Directives, Legislation on individual substances

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm#84-500

EC: Food Contact Materials – A Practical Guide for Users of European Directives http://ec.europa.eu/food/chemicalsafety/foodcontact/practical_guide_en.pdf

EC: Food Contact Materials – Substances listed in EU Directives on plastics in contact with food

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_substances_en.pdf

EC: Newsletter - Subject: Food Contact Materials

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/newsletter_en.pdf

FVO: Annual Report 2004 – Special Topic – Additives, flavourings, food contact materials http://ec.europa.eu/food/fvo/annualreports/ann_rep_2004_en.pdf

Food Contaminants

Contaminants are substances, which are not intentionally added to food but may be present in food as a result of production, packaging, transport processes or of environmental contamination.

Regulations 315/93/EEC (EC) 466/2001 (EC) 401/2006

Council Regulation 315/93/EEC of 8 February 1993 lays down the following basic principles of the EU legislation on contaminants:

Decision 2006/504/EC

- food containing a contaminant level unacceptable for human health or even at a toxicological level shall not be placed on the market
 contaminant levels shall be kept as low as can reasonably be achieved following
- recommended good working practices
- maximum levels must be set for certain contaminants in order to protect public health

Recommendation 2005/108/EC

The EU has set **maximum levels** for certain contaminants in foodstuffs, which might represent a risk for food safety and human health and for the quality of foodstuffs:

- maximum levels of certain contaminants in foodstuffs: certain foodstuffs (e.g. fruit, vegetables, nuts, cereals, fruit juices) must not, when placed on the market contain higher contaminant residues than those specified in Regulation (EC) 466/2001
- maximum levels of pesticide residues in and on food: pesticides in food are regulated under Regulation (EC) No 396/2005 (see following paragraph on Plant Protection Products (PPP) and Pesticide Residues)
- maximum residues of radioactive contamination of foodstuffs: maximum permitted levels are laid down in Regulations (EC) 3954/1987 and (EC) 944/1989
- Materials intended to come into contact with foodstuffs:
 materials and articles intended to come into contact with foodstuffs must be
 manufactured in a way that ensures that no harmful quantities migrate into the foodstuffs
 (for the respective Regulations and Directives see preceding paragraph)

The Commission Regulation 466/2001/EC of 8 March 2001 and following Amendments set maximum levels for certain contaminants in foodstuffs:

- Commission Regulation (EC) 563/2002 nitrate in lettuce and spinach
- Commission Regulations 257/2002, 472/2002 aflatoxins in nuts, dried fruit, cereals, spices, milk
- Commission Regulations 221/2002, 78/2005 heavy metals (lead, cadmium and mercury) and 3-monochloropropane diol (§-MCPD) in soy sauce and hydrolysed vegetable protein
- Council Regulation 2375/2001 dioxins in a range of foods
- Commisssion Regulation 472/2002 ochratoxin A in cereals, ceral products and dried vine fruit
- Commission Regulation 1425/2003 patulin in apple juice and other beverages
- Regulation (EC) No 208/2005 benzo(a)pyrene in certain foods
- Recommendation 2005/108/EC further investigations into the levels of polycyclic aromatic hydrocarbons in foods
- further proposals for maximum levels under consideration: fusarium toxins (deoxynivalenol, trichothecenes, zeaalenone, fumonisins)

The 'Commission Decision 2006/504/EC of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins' assembles five Commission Decisions from 2000 up to 2005 on foodstuffs imported from Brazil, China, Egypt, Iran and Turkey bearing a risk of aflatoxin contamination in groundnuts, Brazil nuts, pistachios, figs, hazelnut and foodstuffs processed thereof.

Provisions for official controls (sampling and analysis):

- Commission Regulation (EC) No 401/2006 methods of sampling and analysis for the
 official control of the levels of mycotoxins in foodstuffs
- Commission Directive 2001/22/EC methods of sampling and analysis for the official control of the levels of heavy metal and 3-MCPD
- Commission Directive 2003/78/EC methods of sampling and analysis for the official control of the levels for patulin levels
- Commission Directive 2005/10/EC methods of sampling and analysis for the official control of the levels for benzo(a)pyrene

Emerging issues:

Acrylamide:

Acrylamide is a chemical present in food as a result of cooking practices, in particular starchy foods (potato, cereal products) are affected. The Commission has initiated several projects to assess the risk acrylamide might have on public health, to analyse chemical effects of processing and cooking and to identify appropriate measures to reduce levels of acrylamide in food. The Commission and EFSA coordinate these activities and participate in international initiatives such as those of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the WHO's International Network on Acrylamide and the US Joint Institute for Food Safety & Applied Nutrition (JIFSAN). The Confederation of the Food and Drink Industries of the EU (CIAA) elaborated a guidance on ways to lower acrylamide (CIAA Acrylamide Toolbox – see further readings).

Aflatoxin originating from Iran:
 Following repeated notifications by the EU's Rapid Alert System in Food and Feed (RASFF) and rejection of consignments of pistachios of Iranian provenance, the FVO inspectors visited Iran to analyse facilities and provisions for control of aflatoxin. It was found that Iran's producers applied neither internationally recognised food safety standards nor good production and manufacturing practices. Since the Iranian control facilities and inspectors' skills were also assessed to be deficient, Iran may face stricter border controls and even a ban on pistachio exports to the EU.

• Sudan Dyes:

The illegal, potentially carcinogenic Sudan I to IV dyes in spices (mainly chili) and other food products (e.g. palm oil) have only in 2005 resulted in 42 RASFF notifications, which forced the UK industry to carry out its biggest food recall in history, costing one single UK manufacturer a total of € 200 million³⁸). More than 600 processed food products were recalled in the UK in February 2005 alone³⁹). The EU requires all imports of chilli

Source: http://www.foodnavigator.com/news/ng.asp?n=63342-sudan-testing

Source: http://www.foodnavigator.com/news/ng.asp?n=61647-sudan-contamination-irradiation

and chilli products be accompanied with a certificate proving that products are free of illegal chemical dyes.

Further readings:

CIAA (Confederation of the Food and Drink Industries of the EU): CIAA Acrylamide Toolbox

http://www.ciaa.be/documents/brochures/ciaa_acrylamide_toolbox_oct2006.pdf

Commission Decision 2006/504/EC of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:199:0021:01:EN:HTML

EC: Food Contaminants – Legislation: Basic principles, maximum levels, official control http://ec.europa.eu/food/chemicalsafety/contaminants/legisl_en.htm

EFSA: Panel on contaminants in the food chain (CONTAM Panel) http://www.efsa.europa.eu/en/science/contam.html

Plant Protection Products (PPP) and Pesticide Residues

Plant Protection Prodcuts (PPP):

The marketing and use of Plant Protection Products (PPP) and their residue in food is regulated by EU legislation. Council Directive 91/414/EEC stipulates that active substances cannot be used in plant protection products unless they are included in a **positive EU list** (Annex I to the Directive). To set up this list, the European Commission launched a review process in 1992 aiming at scientific assessment of all active ingredients used in PPPs in the European Union.

Regulation (EC) 396/2005

Directives 91/414/EEC 2002/63/EC The EFSA Pesticide Risk Assessment Peer Review (PRAPeR) Unit co-ordinates the peer review of active substances used in plant protection products in collaboration with Member States (see further readings). The review includes a notification procedure for the industry to provide further support for the continued use of their active substances proving that the substances could be used safely regarding human health, the environment, ecotoxicology and residues in the food chain. As a result of notifications received, EFSA (in charge of risk assessment since 2003) was assigned to evaluate more than 400 substances. EFSA has also been charged with the evaluation of new active substances. The risk assessment programme will be **completed by 2008**.

Based on the evaluation results, the European Commission (in charge of risk management) will decide, which active substances will be included in the positive list. Member States may then authorise the use of products containing these active substances.

Active substances mainly cover pesticides but also other products, such as growth regulators or pheromones used in agriculture. Pesticides used in other areas than agriculture, for example, as veterinary drugs or biocides, are regulated by other legislation.

Pesticide Residues:

Pesticide residues in food have been harmonised under Regulation (EC) No 396/2005, which rules the setting, monitoring and control of pesticide residues in products of plant and animal origin. The Community has set **Maximum Residue Levels (MRLs)** for about 150 plant protection products (for MRLs by pesticide, by crop groups and by commodities see further readings). Since the legislation has not yet been harmonised, Member States may regulate (and have done so) national MRLs.

Official controls:

The Commission also gives directives and guidelines regarding control systems and procedures (see further readings):

- 'Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC'
- guidance documents for residue analytical methods, quality control procedures for pesticide residue analysis, etc.

Emerging issues:

Harmonisation of EU provisions for Plant Protection Products (PPPs):
 The lack of a harmonised Community system for MRLs is considered to be a barrier to trade between Member States because unharmonised MRLs contradict the principle of free trade based on mutual recognition. As a consequence, the Commission of the European Communities submitted a 'Proposal for a Regulation of the European

Parliament and of the Council concerning the placing of plant protection products on the market' on 12 July 2006 (see further readings).

 WTO SPS and withdrawal of active substances by the EU: Having received many enquiries on the withdrawal of PPPs, the European Communities' SPS Enquiry Point drafted a paper 'Questions and Answers on the procedure to obtain import tolerances and the inclusion of active substances for plant protection uses in the European Communities' list on 29 March 2005 (see further readings).

Cumulative risk assessment:

The EU regulations on MRLs of pesticides have not yet provided for an agreed framework for combined risk assessment of pesticides. With a view of initiating a scientific debate at the European and international levels on approaches for cumulative risk assessment of pesticides, EFSA will organise a colloquium in November 2006 (see further readings).

Further readings:

EC: Plant Protection - Evaluation and Authorisation

http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm

EC: Plant Protection - Guidance documents and technical reports: PPP, MRLs, control procedures

http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council EC: Plant Protection – Legal Framework

http://ec.europa.eu/food/plant/protection/evaluation/framework_en.htm

EC: Plant Protection – Pesticide Residues – Legislation: PPP, MRLs, official control http://ec.europa.eu/food/plant/protection/pesticides/legislation_en.htm

EC: Plant Protection - Pesticide Residues: EU MRLs by pesticides, by crop group, by commodity

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

EC: Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market

http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0388en01.pdf

EFSA: Colloquium 7 – Cumulative Risk Assessment of pesticides to human health: The Way forward

http://www.efsa.europa.eu/en/science/colloquium series/colloquium 7.html

EFSA: EFSA completes 2nd stage of EU-wide pesticides peer review process

http://www.efsa.europa.eu/en/press_room/press_release/pr_praper-2nd-stage.htm

EFSA: Panel on plant protection products and their residues (PPR)

http://www.efsa.europa.eu/en/science/ppr.html

EFSA: Pesticide risk assessment peer review (PRAPeR)

http://www.efsa.europa.eu/en/science/praper.html

freshfel Europe - Fresh Quality Guide: Interpretative Guide Maximum residue levels in pesticides

http://www.freshquality.org/english/general_info.asp?id=34

freshfel Europe, COLEACP et al: Press release "imperativeness of a prompt MRL harmonisation"

http://www.freshfel.org/site/actueel/Suppliers%20Press%20Release%20on%20GAP%2027.09.06.pdf

freshfel Europe, CIAA, OEITFL et al: Joint Food-Chain Briefing on MRLs for PPP (Pesticides)

http://www.freshquality.org/files/Food%20chain%20position%20on%20MRL%20exceedances%2021.09.05.pdf OEITFL: OEITFL position on the implementation of new, modified or temporary MRLs http://www.oeitfl.org/ - publications and positions

WTO SPS: Questions and Answers on the procedure to obtain import tolerances and the inclusion of active substances for plant protection uses in the European Communities list http://useu.usmission.gov/agri/GEN557.doc

Food Irradiation

Directives

1999/2/EC 1999/3/EC Irradiation, a physical treatment of food with high energy ionising radiation can be used to

- prolong the shelf life of food products
- prevent the germination and sprouting of potatoes, onions and garlic
- disinfect by killing or sterilising insects which infest grains, dried fruit, vegetables or nuts
- retard ripening and ageing of fruit and vegetables
- · prevent food-borne diseases by reducing the number of viable micro-organisms
- reduce micro-organisms in spices and herbs

The European Parliament and Council Framework Directive 1999/2/EC sets out general and technical aspects for the process of ionising radiation, labelling and conditions for authorising radiation. The implementing Directive 1999/3/EC complements the EU approach towards radiation by establishing a list of food and food ingredients authorised for radiation (currently only: dried aromatic herbs, spices and vegetable seasonings).

National authorisations as well as restrictions or bans on irradiated foods can be maintained until the completed EU-wide list of products authorised for irradiation enters into force. Foodstuffs may only be irradiated in EU-approved irradiation facilities (this applies also to third countries). In spite of being authorised in many countries, use of irradiation is rather limited.

Member States have to validate or standardise the analytical methods used to detect irradiated foods. Respective standards have been developed by the European Committee for Standardisation (CEN - see further readings).

Emerging issues:

 In April 2003, a revised opinion on food irradiation has been presented, which proposes that only those specific irradiation doses and food classes should be endorsed, for which adequate toxicological, nutritional, microbiological and technical data are available.

Further readings:

EC: Food and Feed Safety - Food Irradiation http://ec.europa.eu/food/food/biosafety/irradiation/index_en.htm

EC: Food and Feed Safety - Food Irradiation - Community legislation

 $http://ec.europa.eu/food/food/biosafety/irradiation/comm_legisl_en.htm$

EC: Food and Feed Safety - Food Irradiation - Analytical methods

http://ec.europa.eu/food/food/biosafety/irradiation/anal_methods_en.htm

Food **Supplements**

Directive 2002/46/EC

Food supplements are defined as concentrated sources of nutrients or other substances with a nutritional or physiological effect (primarily vitamins and mineral salts) marketed 'in dose' (e.g. capsules, tablets, liquids) in order to supplement nutrient intake in a normal diet. Foods for particular nutritional uses and proprietary medicinal products covered by Directive 89/398/EEC and 65/65/EEC are excluded.

'Directive 2002/46/EC of the European Parliament and Council of 10 June 2002 on the approximation of the laws of Member States relating to food supplements' aims at harmonising the legislation and at ensuring that food supplements are safe and labelled in a way that consumers can make informed choices. Annex II of the Directive lists permitted vitamin or mineral preparations that may be added for specific nutritional purposes. Additional substances have been included through the Commission Directive 2006/37/EC. As from 1 August 2005, trading of products containing vitamins and minerals not listed in Annex II is prohibited.

On 8 May 2000, the European Parliament and the Council submitted a 'Proposal on the approximation of the laws of the Member States relating to food supplements' with a view of harmonising the rules governing the definition, composition and labelling of food supplements, guaranteeing a high level of consumer protection and ensuring the free movement of foodstuffs.

Emerging issues:

The Directorate General Health and Consumer Protection has drafted a discussion paper on the setting of maximum and minimum amounts of vitamins and minerals in foods (the consultation process ended on 30 September 2006).

Further readings:

EC: Food and Feed Safety - Food Supplements

http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm or http://europa.eu/scadplus/leg/en/lvb/l21102.htm

Flavourings

Regulation

2232/96/EC

Flavourings are substances used to give taste and/or smell to food. The EU distinguishes: natural and natural identical or artificial flavouring substances

- flavouring preparations of plant or animal origin
- · process flavourings evolving flavour after heating smoke flavourings

Directives 88/388/EEC 91/71/EEC

The Council Directive 88/388/EEC as completed by Commission Directive 91/71/EEC elaborates on relevant definitions, general rules for the use of flavourings, requirements for labelling and maximum levels for substances which raise concern for human health.

Decisions 2000/489/EC 2002/113/EC

The European Parliament and Council Regulation (EC) No 2232/96 sets out the basic rules for the use of flavourings in or on foodstuffs in the EU as well as the procedure for establishing an EU-wide positive list of flavouring substances. Commission Decision

2000/489/EC adopts a register of flavouring substances and Commission Decision 2002/113/EC amends preceding Decisions as regards the register of flavouring substances used in or on foodstuffs.

Emerging issues:

The EC proposes to harmonise the legislation on food enzymes, flavourings and additives and to simplify common approval procedures for food additives, flavourings and enzymes based on scientific opinions from EFSA.

Further readings:

EC: Legislation on Authorised flavourings

http://europa.eu/scadplus/leg/en/lvb/l21072.htm

EC: Legislation on source materials and substances used in the preparation of flavourings http://europa.eu/scadplus/leg/en/lvb/l21073.htm

EC: Legislation on defined chemical flavouring substances

http://europa.eu/scadplus/leg/en/lvb/l21081.htm

EC: Food and Feed Safety – Food Flavouring – Listed legislation http://ec.europa.eu/food/chemicalsafety/flavouring/listedlegislation_en.htm

EC: Food and Feed Safety – Food Flavouring – Scientific advice

http://ec.europa.eu/food/food/chemicalsafety/flavouring/scientificadvice_en.htm

EC: Food and Feed Safety – Food Flavouring – Package of proposals for new legislation on food additives, flavourings and enzymes

http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm

Food **Additives**

Directive 89/107/EEC A food additive is a substance that is normally not consumed as a food itself, but becomes an ingredient by intentional addition to foodstuffs for example to perform as colouring, sweetener or as preservative. Food additives are defined in Community legislation as "any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose results in it or its by-products becoming directly or indirectly a component of such foods".

The framework 'Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives for use in foodstuffs intended for human consumption' is intended to harmonise national legislation related to food additives and their conditions of use in order to protect consumer health and guarantee the free circulation of goods in the EU. The Directive establishes categories of authorised EU food additives and general criteria for their use. Specific lists of food additives authorised for circulation in the EU are contained in subsequent Specific Directives, adopted pursuant to Article 3(3) of the Additives Directive:

- sweeteners • Directive 94/35/EC • Directive 94/36/EC - colourings

• Directive 95/2/EC - miscellaneous additives

All authorised food additives have to fulfil purity criteria which are set out in Commission Directives 95/31/EC (last amendment 2004/46/EC), 95/45/EC (last amendment 2006/33/EC) and 96/77/EC (last amendment 2002/82/EC).

Emerging issues:

see preceding chapter on flavourings

Further readings:

EC: Food and Feed Safety - Food Additives - Application for Authorisation

http://ec.europa.eu/food/food/chemicalsafety/additives/appli_authoris_en.htm

EC: Food and Feed Safety - Food Additives - Introduction

http://ec.europa.eu/food/chemicalsafety/additives/index_en.htm
EC: Food and Feed Safety – Food Additives – Community legislation

http://ec.europa.eu/food/food/chemicalsafety/additives/comm_legisl_en.htm

EC: Food and Feed Safety - Food Additives - Labelling

http://ec.europa.eu/food/food/chemicalsafety/additives/add_labelling_en.htm

EC: Food and Feed Safety - Food Flavouring - Package of proposals for new legislation on food additives, flavourings and enzymes

http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm

EFSA: Panel on food additives, flavourings, processing aids and food contact materials

http://www.efsa.europa.eu/en/science/afc.html

Novel Food and Novel Food Ingredients

Regulation 258/97 (under revision) The 'Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients' is meant to authorise the placing of novel foods and novel food ingredients on the market within the Community while taking account of requirements regarding public health, the environment and consumer information.

Revision of Regulation (EC) No 258/97:

The Regulation (EC) No 258/97 on novel food and novel food ingredients is currently under revision with a view to (according to the EC):

- reflect that genetically modified (GM) food no longer falls under its scope
- create a more favourable legislative environment for innovation in the food industry
- improve internal and external trade in foodstuffs.
- · widen the choice of safe novel foods for consumers

On 2 June 2006, the Commission launched an online consultation aiming at gathering views from the general public, stakeholders and Member States seeking feedback on how to create a more streamlined authorisation procedure, which takes into account, for example, particular needs of traditional exotic food from third countries. The consultation process was closed on 1 August 2006.

Provisions of the current Regulation (EC) No 258/97:

- The current regulation applies to foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 1997 and which fall under one of the following categories:
 - (i) produced from genetically modified organisms or contain such organisms (see separate paragraph below)
 - (ii) presenting a modified primary molecular structure
 - (iii) consisting of micro-organisms, fungi or algae
 - (iv) isolated from plants or isolated from animals
 - (v) underwent significant changes of their nutritional value, metabolism or level of undesirable substances by the production process
- Foods and food ingredients obtained by traditional propagating or breeding practices
 that have a history of safe food use are exempted. However, underutilized crops may fall
 under the Novel Food Regulation, especially when their history of safe use cannot be
 proven convincingly.
- Before being authorised for placement on the market, novel foods and novel food ingredients as defined above have to be assessed by the Community. The authorisation defines the scope of the authorisation and specifies, where appropriate, the conditions of use, the designation of the food of food ingredient, its specification and the specific labelling requirements.

Emerging Issues:

 Developing countries and the Novel Food Regulation (NFR): At the WTO SPS meeting on 29-30 March 2006, representatives from 14 developing countries expressed strong concern that the current provisions and proposed revision of the Novel Food regulation seriously affect their ability to export "small exotic traditional products based on their rich biodiversity" to the European Union market (see further readings: WTO SPS - Communication of Peru of 5 April 2006 and the EU's answer under WTO SPS Communication from the EC of 8 June 2006). Since the EU considers any food newly introduced to the European market since 1997 as novel, developing countries' exporters have to invest important amounts of money to gain market access for such products to the EU. The United Nations Conference on Trade and Development (UNCTAD) initiative BIOTRADE and other development partners (e.g. CBI⁴⁰⁾, IPGRI⁴¹⁾, GTZ) support the developing countries' request for better market access. They prepared, amongst others, a proposal for a development-friendly revision of the NFR (see further readings). Responses from a wide range of stakeholders to the Discussion Paper can be accessed via the Communities' Food and Feed Safety website (see further readings).

Further readings:

EC: Food and Feed Safety – Novel Foods – Authorisations http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm

⁴⁰ Centre for the Promotion of Imports from Developing Countries

⁴¹ International Plant Genetic Resources Institute

EC: Food and Feed Safety - Novel Foods - Legislation

http://ec.europa.eu/food/food/biotechnology/novelfood/legisl_en.htm

EC: Food and Feed Safety - Novel Foods - Notified foods

http://ec.europa.eu/food/food/biotechnology/novelfood/notified_en.htm

EC: Food and Feed Safety – Novel Foods – Review of Regulation EC No 258/97 (including Responses to the Discussion Paper)

http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm

UNCTAD/CBI (2005): The EU Novel Food Regulation – Impact on the Potential Export of Exotic Traditional Food to the EU: Suggestions for Revision

http://www.biotrade.org/Events/events_docs/events-dec05-Novelfoods-CBIUNCTADpaperonEUNovelFood Regulation.pdf

WTO SPS – Communication of Peru of 5 April 2006 – Regulation 258/97 of the European parliament and of the Council concerning Novel Foods

http://www.biotrade.org/BTFP/BTFP-docs/EU_NF_Communication_gen681_en.PDF

WTO SPS – Communication of European Communities of 8 June 2006 – Reply of the European Communities to the Communication from Peru concerning Regulation 258/97 on Novel Foods

http://www.biotrade.org/BTFP/BTFP-docs/EU NF Peru WTO EU Response G SPS Gen 699 en.PDF

GM Food and Feed (Genetically Modified Food and Feed)

Genetically Modified Organisms (GMOs) are organisms (plants, animals) whose genetic material has been altered/modified by using modern gene technologies. The food and feed containing or consisting of such GMOs or produced from GMOs are called genetically modified (GM) food or feed.

Regulations 1829/2003 1830/2003 From 1998 to 2004, the European Union maintained an unofficial moratorium on approvals of GMO crops and foods. During the moratorium, the EU refused the experimental or commercial growth of new gene crops or imports of new GMO-based food products. In or before 1998, approval was given to 18 GM products, including maize, rapeseed, chicory and soybeans under the Novel Food Regulation. Moreover, another 9 GM products, including the use as or in feeding stuffs, were approved under the EU environmental legislation.

Directive 2001/18/EC

In May 2003, the United States, Canada and Argentina requested consultations with the EC and eventually brought the case to the WTO dispute settling body. The complainants alleged that the moratorium was posing an unjustified trade barrier in violation of various WTO Agreements (TBT, SPS and TRIPS). In its final ruling, which was released in September 2006, the WTO panel concluded that general and product-specific moratoria had led to an "undue delay" in the completion of the EU's approval procedures for biotech products, thus breaching Brussels' obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). The parties to the dispute have so far left open whether they would appeal the ruling. The 1,000-page document will not have immediate effects, since it concerns the EU GMO moratorium, which ended in April 2004. It may however affect the way, in which the EU deals with GMOs in the future.

Currently, the following legal provisions apply:

- 'Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed'
- 'Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms'
- 'Commission Regulation (EC) 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms'
- 'Commission Regulation (EC) 641/2004 of 6 April 2004 on detailed rules for the
 implementation of Regulation (EC) 1829/2003 of the European Parliament and of the
 Council as regards the application for the authorisation of new genetically modified food
 and feed, the notification of existing products and adventitious or technically unavoidable
 presence of genetically modified material which has benefited from a favourable risk
 evaluation'
- 'Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC'

Specific provisions as stipulated in the aforementioned regulations and directive:

- all authorisations have to be entered into the Community Register of GM Food and Feed
- GM food and feed products require specific traceability and labelling requirements
- traces of yet unauthorized GM material may be present in conventional food and feed,

which is tolerated up to a maximum of 0,5% for a limited number of events and on condition of a favourable risk evaluation (see further readings: Tolerance of adventitious presence of unauthorised material)

Emerging issues:

- NGOs critically assess the EU's GM Food and Feed policy: Environmental non-governmental organisations (NGOs) and the European Food Safety Authority (EFSA) have got fundamentally different views of the EU's GMO policy and enforcement of existing provisions. According to some NGOs, the EC withholds sensitive information on GM safety studies and approves potentially hazardous GM products.
- WTO competence:

NGOs like Greenpeace and Friends of the Earth Europe do not consider the WTO as the right place for settling such a political dispute as the one on GMOs; likewise not for many other environment-related trade disputes.

 GMOs and their effects on developing countries: see further readings: Gruère (2006)

Further readings:

EC: Food and Feed Safety - GM Food and Feed - Authorisation

http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm

EC: Food and Feed Safety - GM Food and Feed - Community Register of GM Food and

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

EC: Food and Feed Safety – GM Food and Feed – Legislation

http://ec.europa.eu/food/food/biotechnology/gmfood/legisl_en.htm

EC: Food and Feed Safety - GM Food and Feed - Questions and Answers

http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf

EC: Food and Feed Safety - GM Food and Feed - Tolerance of adventitious presence of unauthorised material

http://ec.europa.eu/food/food/biotechnology/gmfood/tolerance_en.htm

EFSA: GMO consultations

http://www.efsa.europa.eu/en/science/gmo/gmo consultations.html

EFSA: Panel on genetically modified organisms (GMO Panel)

http://www.efsa.europa.eu/en/science/gmo.html

Friends of the Earth Europe: U.S. did not win transatlantic GM trade dispute –

Friends of the Earth: WTO still wrong place to settle such rows

http://www.foeeurope.org/press/2006/AB_11_May_WTO.htm
Gruère, G.P. (2006): An Analysis of Trade Related International Regulations of Genetically Modified Food and their Effects on Developing Countries http://www.ifpri.org/divs/eptd/dp/papers/eptdp147.pdf

WTO: Dispute Settlement (Dispute DS293) -

European Communities - Measures Affecting the Approval and Marketing of Biotech **Products**

http://www.wto.org/English/tratop_e/dispu_e/cases_e/ds293_e.htm

Labelling, Presentation and

All food products have to comply with EU labelling rules, which aim at assisting consumers to make informed decisions on which foodstuffs to purchase and consume.

Advertising of **Foodstuffs**

Mandatory labelling requirements are laid down

• in the 'Directive 2000/13/EC of the European Parliament and the Council of 20 March 2000 on the approximation of the laws of the Member States. Labelling, presentation and advertising of foodstuff' are supposed to facilitate consumer information and

Directives 2000/13/EC 90/496/EEC

protection, to harmonise Community legislation and to enable free movement of foodstuffs.

- · in specific provisions for certain product groups:
- (i) labelling of Genetically Modified (GM) food (see separate paragraph below)
- (ii) labelling of Novel Food (see separate paragraph below)
- (iii) labelling of foodstuffs for particular nutritional purposes (see below)
- (iv) labelling of food additives and flavourings
- (v) labelling of materials intended to come into contact with food (see separate paragraph below)
- (vi) labelling of particular foodstuffs (e.g. nutritional claims, organic labelling)

The Directive 2000/13/EC applies to pre-packaged foodstuffs as delivered to the final consumer or to restaurants, hospitals, canteens and other similar mass caterers. It does not apply to goods intended to be exported from the EU to third countries. This Directive gives rules of a general nature, while rules for particular food products are set down in a number of product-specific Directives or Regulations. For fruit and vegetables, labelling requirements are contained in the marketing standards.

Compulsory labelling particulars:

- · name, under which the product is sold
- list of ingredients
- net quantity
- · date of minimum durability
- · special conditions for keeping or use
- name or business name and address of the manufacturer, packager or importer
- place of origin or provenance
- instructions for use (where appropriate)
- indication of the acquired alcoholic strength (for beverages containing more than 1,2% by volume)
- lot marking (on pre-packaged foodstuffs)

Manufacturers or distributors may include additional information on a voluntary basis provided that it is accurate and does not mislead the consumer. Nutritional labelling for example is not obligatory unless a nutritional claim (e.g. 'low fat', 'high fibre') is made on the label or in the advertising material. Formats for nutritional claims are provided for in Council Directive 90/496/EEC.

Further readings:

EC (2006a): Labelling: competitiveness, consumer information, better regulation for the EU http://ec.europa.eu/food/fabellingnutrition/betterregulation/competitiveness consumer info.pdf

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

http://europa.eu/scadplus/leg/en/lvb/l21090.htm or

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/I_109/I_10920000506en00290042.pdf

EC: Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC

http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31994L0054:EN:HTML or http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1994/L/01994L0054-19960425-en.pdf

EC: Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs

http://europa.eu/scadplus/leg/en/lvb/l21092.htm or

http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1990/L/01990L0496-20040109-en.pdf

EC: Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31989L0396&model=guichett or

http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1989/L/01989L0396-19920311-en.pdf

EC: General guidelines for implementing the principle of Quantitative Ingredients
Declaration (QUID) – Article 7 of Directive 79/112/EEC as amended by Directive 97/4/EC
http://ec.europa.eu/food/fs/fil/fil02_en.pdf

University of Reading: Foodlaw Reading – Food Labelling in the European Union http://www.foodlaw.rdg.ac.uk/label.htm

Dietetic Food

Directive 1999/41/EC

Dietetic foods are foodstuffs intended to satisfy particular nutritional requirements of specific groups of the population (e.g. food for infants and young children, food for weight reducing diets or food for special medical purposes). Dietetic foods might as well be referred to as 'dietary foods' or 'foods for particular nutritional purposes' (PARNUTS).

'Council Directive 1999/41/EC of the European Parliament and of the Council sets out a framework of rules for the composition, marketing and labelling requirements of dietetic foods, including measures to ensure the appropriate use of such foods and to exclude any risk to human health'. The Directive defines rules by groups of dietary foods and specifies the nutritional substances that are allowed to be added to food for particular nutritional uses.

Further readings:

EC: Food and Feed Safety - Dietetic Food

http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm

4.2.3.5 EU Food Safety (mandatory standards)

Vertical legislation

Vertical legislation applies to provisions for specified products or product groups (such as fresh fruit and vegetables, frozen fruit and vegetables, fruit juices, wine, honey, edible oil, chocolate, meat, fish etc.).

Quick-frozen Food

Quick-frozen foodstuffs are products subject to a quick-freezing process, in which the temperature zone of maximum crystallisation is spanned as rapidly as possible and the final product is held (after thermal stabilisation) at a temperature of –18 °C or lower.

Directive 89/108/EEC

The harmonised 'Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption' lays down the rules for quick-freezing, packaging, labelling and inspection of quick-frozen foodstuffs.

The Council Directive is accompanied by the following two Directives:

- 'Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption'
- 'Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quickfrozen foods intended for human consumption'

Further readings:

ScadPlus: Quick-frozen food

http://europa.eu/scadplus/leg/en/lvb/l21116.htm

Fruit Juices and similar products

'Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption' stipulates manufacturing specifications and labelling rules for four types of products intended for direct human consumption:

- fruit juice (including fruit juice reconstituted from fruit juice concentrate)
- · concentrated fruit juice

Directive 2001/112/EC

dehydrated/powdered fruit juice

fruit nectar

The Directive also lays down labelling requirements specific to these products. The labelling should clearly indicate whether the product is obtained entirely or partly from a concentrated product, whether it is a mixture of fruit juice and fruit juice from concentrate or a fruit nectar. This Directive contributes to simplifying certain vertical Directives relating to labelling of foodstuffs, which takes account of essential requirements for specified products.

Emerging issues:

- In July 2006, the Commission published a 'Proposal for a Regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC'.
- Specific requirements for non-pasteurised fruit and vegetable juices as laid down in regulation (EC) 2075/2005 may complicate international trade (see chapter 4.2.3.4 on page 76/77 – Official Food and Feed Controls).

Further readings:

ScadPlus: Fruit juices and similar products http://europa.eu/scadplus/leg/en/lvb/l21132.htm

EC: Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/I_010/I_01020020112en00580066.pdf

EC: Proposal for a Regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC

http://eur-lex.europa.eu/Result.do?RechType=RECH_celex&lang=en&ihmlang=en&code=52006PC0425

Fruit Jams, Jellies, Marmalades, Chestnut Purée

Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption sets out the essential requirements to be met by a number of products defined in Annex I thereof, including 'jam' and 'marmalade', so that these products may move freely within the internal market.

Directive 2001/113/EC

The Directive defines product specifications and reserves the names corresponding to the product specifications. Furthermore, raw materials and additives which may be used in the manufacture are defined and listed. The maximum sulphur dioxide content is fixed and precise rules for labelling defined.

Emerging issues:

In 2004, the EC submitted a 'Proposal for a Council Directive amending Directive 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption'

Further readings:

EC: Council Directive 2001/113/EC of 20 December 2001 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/l_010/l_01020020112en00670072.pdf EC: Proposal for a Council Directive amending Directive 2001/113/EC http://eur-lex.europa.eu/LexUriServ/site/en/com/2004/com2004_0151en01.pdf

Honey

Directive 2001/110/EC

The 'Council Directive 2001/110/EC of 20 December 2001 relating to honey' gives a general definition of honey and indicates the main varieties, which may be marketed in the Community. It furthermore establishes general and specific compositional characteristics and indicates the principal labelling requirements.

The names, under which the varieties are listed are recognised and protected throughout the Community and may be used only in conformity with the definitions and rules laid down in the Directive.

Third countries intending to export honey to the European Community have to prove equivalence with the Community's law or present alternative guarantees, in particular with regard to residues control (for details see further readings: DG SANCO third country residues web page).

List of third countries authorised to import honey into the EU (issued on 7 March 2006): Argentina, Australia, Belize, Bulgaria, Canada, Chile, China, Croatia, Cuba, El Salvador, Guatemala, India, Israel, Jamaica, Kenya, Kyrgyzstan, Mexico, Montenegro, New Zealand, Nicaragua, Norway, Paraguay, Pitcairn Islands, Romania, Russia, San Marino, Serbia, South Africa, Switzerland, Tanzania, Taiwan, Thailand, Turkey, Uganda, Ukraine, Uruguay, USA, Vietnam and Zambia.

Further readings:

EC: Council Directive 2001/110/EC of 20 December 2001 relating to honey http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/I_010/I_01020020112en00470052.pdf EC: DG SANCO third country residues web page http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm

Edible Oils and Fats

Directive 76/621/EEC

The 'Council Directive 76/621/EEC of 20 July 1976 relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats' stipulates that the upper limit for the erucic acid in the products for which it applies should not exceed 5%, calculated on the total level of fatty acids in the fat component.

The preventive and protective character of this rule is reinforced by the existence of a safeguard clause to which the Member States may have recourse.

Further readings:

EC: ScadPlus – Edible oils and fats http://europa.eu/scadplus/leg/en/lvb/l21121.htm

4.2.4 **Food Quality**

Responsibility for food quality stays with the Directorate-General (DG) Agriculture, which, among others, has the task of making EU policies in the fields such as sustainability of agricultural production and rural development as well as food quality within the EU's system of the so called Common Market Organisation (CMO).

4.2.4.1 Common Market Organisation (CMO) for fruit and vegetables - an introduction

Responsibility for the Common Market Organisation (CMO)⁴²⁾ stays with the **Directorate-General** Agriculture and Rural Development (DG Agriculture), which is made up of twelve Directorates dealing with all aspects of Common Agricultural Policy (CAP) including market measures, rural development policy, financial matters as well as international relations relating to agriculture. 43)

"On 26 June 2003, EU farm ministers adopted a fundamental reform of the Common Agricultural Policy (CAP). The reform will completely change the way the EU supports its farm sector. The new CAP will be geared towards consumers and taxpayers, while giving EU farmers the freedom to produce what the market wants."44) Simplification work on the CAP already dates back to 1992, but the most significant reform took place in 2003 with the introduction of a new system of direct payments, known as the Single Payment Scheme (SPS), under which aid is no longer linked to production (decoupling). This shift in the emphasis of CAP support towards direct aids to farmers, and away from price support, is accompanied by clearer obligations on farmers to manage their farms in sustainable ways. The so-called 'cross-compliance' links direct payments to farmers to their respect of good agricultural practices, animal welfare and other environmental rules⁴⁵⁾.

In line with the reform of the CAP, the Commission made the revision and simplification of the regulations governing the fresh and processed fruit and vegetable sectors a priority. The fruit and vegetables regime was already reformed in 1996 and 2001 with the intention to simplify the regime, to make it more flexible and to increase producers' responsibility. In 2002, 2003 and 2004, the Council urged the Commission to further streamline the Common Market Organisation (CMO) in the fruit and vegetables sector. The envisaged reforms for both, the CAP and the CMO, are also an attempt to meet the EU's obligations under the World Trade Organization's policy to reduce tariffs and to further liberalise and strengthen competitiveness in the global market.

The Council, the European Parliament and sector stakeholders are currently discussing a proposal for the reform of regulatory legislative provisions. The first discussions held within the Council and the European Parliament showed a broad inter-institutional consensus on the CMO in the fresh fruit and vegetables sector, as reformed in 1996. Even if objectives and the instruments of this CMO were not generally put into question, the fruit and vegetable trade disputes the CMO's impact on

⁴² also referred to as Common Organisation of Markets (COM)

see: http://ec.europa.eu/agriculture/index en.htm

Source: http://ec.europa.eu/agriculture/capreform/index en.htm

Source: http://www.euractiv.com/en/cap/cap-reforms-inevitable/article-158491

the well-functioning of the food chain, in particular with regard to market distortion effects from interventions and market imbalances between large retailers and fragmented production and wholesale trading sectors⁴⁶⁾. The CMO for the processed fruit and vegetables sector, however, requires a more fundamental reform. Export restitutions, processing subsidies as well as tariffs, quotas and the entry price system limit market access for third countries, especially for developing countries.

Against this background, the Commission decided to carry out an impact analysis of the possible alternatives to the current aid systems. The Commission will submit a proposal for a reform covering both the fresh and processed fruit and vegetables sectors at the end of 2006."⁴⁷⁾

On 18 May 2006, the Commission organised a fruit and vegetables advisory committee to discuss reform options. An impact report covering several reform options and their possible effects will be finalised in autumn 2006.

The paper presented on 18 May 2006 "Towards a Reform of the Common Market Organisation for the Fresh and Processed Fruit and Vegetable Sectors" confirms the trends, that motivated the former major reform agendas in 1996, 2000⁴⁹⁾ and 2003. Even if, "affected by new developments such as EU enlargement, the reform of the CAP and the continuing move towards greater trade liberalisation, ... pose new problems." The following problems have to be addressed by the CMO for fresh and processed fruit and vegetables⁵¹⁾:

- fall in consumption
- imbalance in the supply and distribution chain
- limited appeal of the POs (Producer Organisations)
- links with the decoupling of support
- compatibility with WTO commitments
- coherence with rural development aid
- short-term crises
- · impact on the environment
- work and employment conditions
- the question of standards

Aims of the envisaged reform⁵²⁾:

- contribute to a better distribution of the value along the chain
- strengthen the coherence between the structural measures in the CMO and those in the rural development policy
- bring the CMO's instruments closer to the approach of the reformed CAP
- help the horticultural sector overcome short-term crises

freshfel Europe voices sector's view on reform on CMO for fruit and vegetables http://www.freshfel.org/site/actueel/Freshfel%20on%20CMO%20Reform%2018.07.06.pdf

Source: http://ec.europa.eu/agriculture/capreform/fruitveg/index_en.htm

Source: http://ec.europa.eu/agriculture/consultations/fruitveg/consultationdoc_en.pdf

⁴⁹ The so-called Agenda 2000

⁵⁰ Source: ibid. (footnote 30)

⁵¹ Source: ibid.

⁵² Source: ibid.

- encourage better nutrition for better health among Europeans, by advocating the consumption of fruit and vegetables
- increase the coherence between the environmental approaches of the CMO, the reformed CAP and its second pillar, the new policy for rural development
- target the CMO's environmental approach on the main problems posed by the production and marketing of fruit and vegetables
- simplify marketing standards and direct them towards the promotion of quality and sustainable development
- promote the monitoring of relations and cooperation within the supply chain

Options studied⁵³⁾:

- contribute to a better balance within the supply chain
 - (i) producer organisations
 - (ii) support the improvement of inter-professional relations
 - (iii) encourage cooperation with third country horticulturalists
- take international commitments into account
- prevent and overcome short-term crises
- · simplify standards
- promote consumption
- · preserve the environment

Further readings:

CTA (Technical Centre for Agricultural and Rural Cooperation ACP-EU) – Agritrade:

The Fruit and Vegetable Regime

http://agritrade.cta.int/en/commodities/fruit_and_vegetable_sector/executive_brief

EC: CAP Reform

http://ec.europa.eu/agriculture/capreform/index_en.htm

EC: Commission proposes new banana regime

http://ec.europa.eu/agriculture/capreform/bananas/index_en.htm

EC: Reform of the common market organisation in fruit and vegetables

http://ec.europa.eu/agriculture/capreform/fruitveg/index_en.htm

EC: Reform of the wine sector

http://ec.europa.eu/agriculture/capreform/wine/index_en.htm

EC: Rural Development Policy 2007-2013

http://ec.europa.eu/agriculture/rurdev/index_en.htm

EC: Simplifying the CAP

http://ec.europa.eu/agriculture/simplification/index_en.htm

EC: The Common Agricultural Policy (CAP) explained

http://ec.europa.eu/agriculture/publi/capexplained/cap_en.pdf

EC (2006b): Towards a Reform of the Common Market organisation for the Fresh and Processed Fruit and Vegetable Sectors

http://ec.europa.eu/agriculture/consultations/fruitveg/consultationdoc_en.pdf

freshfel Europe voices sector's view on reform on CMO for fruit and vegetables

http://www.freshfel.org/site/actueel/Freshfel%20 on %20 CMO%20 Reform%2018.07.06.pdf

⁵³ Source: ibid.

4.2.4.2 EU Food Quality (mandatory standards)

- Marketing standards

Common Market Organisation (CMO) for fruit and vegetables

(as in force by October 2006, reforms going on, see above)

Scope

Three types of market support under the CMO for fruit and vegetables:

- support to producer organisations
- processing and marketing aids
- market interventions (withdrawals and export refunds)

"Production and processing aids are the principle support mechanisms of the CMO that are linked to production. Such aid amounted to €854m in 2005, making up 97 per cent of the expenditure on producers of fruit and vegetables for processing. These will be subject to reduction commitments on a scale to be decided at the WTO."54)

"The cornerstone of the CMO are the producer organisations, which act to regroup supply and balance the market power of the agri-food industry and the big retail chains, the Commission stated in its consultation document. The producer organisations are the main channel for CAP support to fruit and vegetable producers. The organisations are also designed to help the sector meet quality standards, and to meet the demand for variety and environmental protection."55)

Marketing Standards

Fresh Fruit & **Vegetables**

The 'Council Regulation (EC) No 2200/96 of 28 October 1996 on the Common Market Organisation in fruit and vegetables' and numerous Amendments stipulate, among others. provisions for marketing standards (articles 2 to 10).

Purposes of Regulation (EC) No 2200/96:

- facilitate trade relations based on fair competition
- · keep unsatisfactory products off the market
- guide producers to meet consumers' requirements
- · improve profitability of production

Regulation 2200/96/EC

including

Control

Conformity

The EU marketing standards for fresh fruit and vegetables are based on those of UN/ECE recommended by the Economic Commission for Europe's Working Party on perishable product standardisation and quality (see chapter 4.1.3.1). Food safety standards do not form part of the basic Regulation.

Principles:

- marketing standards are applicable at every marketing stage (dispatch, wholesale, retail, import, export)
- specific rules apply at the retail stage: tolerances (freshness and turgidity), labelling requirements (Directive 2000/13), rules for unpacked goods
- applicability without prejudice of other EU Regulations/Directives (pesticide residues, plant protection, food hygiene, contaminants, nitrate, heavy metals, mycotoxins, etc.)
- product liability stays with the holder, not the owner of the product

Exceptions:

- · chain stages within the production area before the products reach the packaging plant
- direct sales from the producer to the final consumer
- · raw products for processing
- products covered by derogation regarding traditional local consumption (e.g. small German apricots, melons in bulk in Spain and Portugal, artichokes in Italy, strawberries in Finland and Sweden)

EU marketing standards comprise:

definition of terms, minimum characteristics and classification, sizes, tolerances, presentation, labelling

Source: http://www.foodproductiondaily.com/news/ng.asp?id=67899-fruit-vegetables-cap

ibid

Marketing standards have been established for 33 fruit and vegetable products:

- fruits, namely apples and pears, apricots, avocados, bananas (green), cherries, citrus fruit, kiwis, melons, peaches and nectarines, plums, strawberries, table grapes, water melons
- · vegetables, namely artichokes, asparagus, aubergines, beans, Brussels sprouts, cabbages, carrots, cauliflowers, ribbed celery, witloof chicory, courgettes, cucumbers, garlic, leek, lettuce & endives, onions, peas, spinach, sweet peppers, tomatoes

No standards have been formulated for some products of minor importance for the EU market (especially the so-called exotic products). In order not to mislead consumers, it is prohibited to classify these goods. It is not allowed to use existing UN/ECE or Codex Alimentarius standards to label these goods for distribution within the EU. Goods that are not subject to specific marketing standards have to meet the general provisions of the food law as regards quality, freshness and labelling.

Conformity control:

Implementation guidelines for the conformity control of marketing standards for fresh fruit and vegetables are laid down in the 'Commission Regulation (EC) No 1148/2001 of 12 June 2001 on checks on conformity to the marketing standards applicable to fresh fruit and vegetables'.

Inspections:

- · sampling at all marketing stages and during transport
- checks preferably prior to dispatch from production areas (packing, loading)
- checks for compliance of exports to third countries before leaving EU customs territory
- possibility of approval of the official inspection authorities of exporting third countries
- · harmonised inspection methods

Inspection at the import stage:

- · inspection bodies check physical compliance
- inspection bodies certify compliance of each lot
- customs clearance only after certification of compliance by the inspection body
- inspection bodies can abstain from checking less risky goods (provisions to be communicated to the Commission)

Minimum Quality Standards for

Processed Fruit & Vegetables

Regulations 2201/96/EC

'Council Regulation (EC) No 2201/96 of 28 October 1996 on the Common Organisation of the Markets in processed fruit and vegetable products' regulates the production aid scheme under the CMO, the trade with non-EU countries and other dispositions. Based on article 8 of Regulation 2201/96⁵⁶⁾, the following acts regulate minimum quality requirements: - certain varieties of dried grapes

 Regulation 1666/1999 Regulation 1010/2001 Regulation 2320/89

- minimum quality requirements for mixed fruit - peaches in syrup and natural fruit juice

Regulation 2319/89

- Williams/Rocha pears in syrup and natural fruit juice

Regulation 1764/86 – products processed from tomatoes
 Recommendation 89/12/EEC – standards on tinned mushrooms

Approved third country inspection service (AIS)

Before being released for free circulation, products from third countries shall be checked for conformity with the marketing standards at the point of entry into the EU. The customs authorities will release goods only if the respective certificate is issued. Further conformity checks are carried out at each stage of the distribution chain. Conformity checks are carried out by sampling methods focusing on traders with high turnover, great variety of produce and problems during previous checks.

Regulation 1148/2001

In order to facilitate trade despite ever expanding control requirements, exporting and importing countries may conclude agreements on Approved third country Inspection Service (AIS) formally recognising that the inspection and certification system of one country is equivalent to that of the other country. Hence, national bodies are authorised to inspect and certify on behalf of the MRA-partner country authorities prior to export shipment. Thus, risks can be reduced in international trade. Costs associated with such rejections can be brought down since goods will be rejected already prior to shipment.

Regulation (EC) No 2201/96, Article 8: "Common standards may be introduced for the products listed in Article 7 (1) and those listed in Annex I, intended either for consumption in the Community or for export to third countries ... http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R2201:EN:HTML

Under certain conditions, conformity checking can be carried out by third countries' authorities in their territory. The EU approval specifies the responsible official authority and the inspection bodies in charge of the checks.

According to Commission Regulation 1148/2001, the EU has so far concluded agreements on AIS for conformity checking systems for fresh fruit and vegetables with:

Regulation: Country: India (EC) No 761/2003 (EC) No 606/2003 Israel (EC) No 431/2006 Kenya (EC) No 1791/2002 Morocco (EC) No 1557/2004 New Zealand • Republic South Africa (EC) No 2103/2002 Senegal (EC) No 430/2006 Switzerland (EC) No 2590/2001 Turkey (EC) No 1790/2006

Emerging issues • Reforming the CMO:

As explained at the beginning of this chapter, the European Commission currently reviews the CMO for fruit and vegetables. 112 public and private organisations responded to the Commission's invitation to consult on CMO reform options. For position papers of the European Commission see further readings.

· Food Quality Schemes Project:

The project provides an analysis of potential policy options for a European-wide framework for the development of quality assurance and certification schemes managed within an integrated supply chain. A study on Food Supply Chain Dynamics and Quality Certification (concluded in November 2005) and an economic analysis of the Quality Assurance and Certification Schemes value-adding process along the chain aim at providing sound scientific information on food quality assurance and certification schemes within the EU (see further readings).

Further readings

Agribusiness online: EU Common Quality Standards – Fresh Fruits and Vegetables http://www.agribusinessonline.com/regulations/grades/grades_eu_fresh.asp

Bundesanstalt fuer Landwirtschaft und Ernaehrung (BLE): Konformitaetskontrolle von frischem Obst und Gemuese

http://www.ble.de/index.cfm?E5E7D62168CF4DFBA3DF1F61F73BB77F

Commission of the European Communities (2001): Report from the Commission to the Council on the state of implementation of regulation (EC) No. 2200/96 on the common organisation of the market in fruit and vegetables

http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0036en01.pdf

Commission of the European Communities (2004): Report from the Commission to the Council and the European Parliament on the simplification of the common market organisation in fruit and vegetables

http://eur-lex.europa.eu/LexUriServ/site/en/com/2004/com2004_0549en01.pdf

EC: Commission Regulation (EC) No 1148/2001 of 12 June 2001 on checks on conformity to the marketing standards applicable to fresh fruit and vegetables

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/l 156/l 15620010613en00090022.pdf and http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32001R1148:EN:NOT

EC: Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organization of the market in fruit and vegetables

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R2200:EN:HTML
EC: Council Regulation (EC) No 2201/96 of 28 October 1996 on the common organisation of the markets in processed fruit and vegetable products

http://europa.eu/scadplus/leg/en/lvb/l11064.htm

EC: Common Organisation of the market in processed fruit and vegetables - Quality http://europa.eu/scadplus/leg/en/lvb/l11064.htm - see: Quality

EC: Directorate General Joint Research Centre - Food Quality Schemes Project http://foodqualityschemes.jrc.es/en/index.html

EUR-Lex: The Access to European Union Law - Legislation in Force - 03. Agriculture http://eur-lex.europa.eu/en/repert/index 03.htm

4.2.4.3 EU Food Quality (voluntary standards)

- Protection of geographical indications and organic farming

In contrast to non-negotiable food safety standards, certain aspects of food quality are left to the choice of producers and are therefore not mandatory. Producers may, for instance, opt for applying voluntary standards for products originating from a particular region (geographical indication) or produced with traditional methods (traditional specialities) or for products produced with methods, which pay special attention to environmental sustainability, such as organic farming. These quality standards, albeit voluntary by nature, are covered by Community legislation. The 1992 and 1999 CAP reforms emphasised agri-environmental measures and aid for extensification (including organic farming). Legislation for European quality labels was also introduced in 1992.

Protected
Geographical
Indications,
Protected
Designation
of Origin
and
Traditional
Speciality
Guaranteed

Regulations (EC) 510/2006 (EC) 509/2006 Consumers' quest for specific (high quality and safe) products generated a growing demand for foodstuffs with an identifiable geographical origin. Furthermore, the desire to protect agricultural products or foodstuffs with an identifiable geographical origin led certain Member States to introduce 'registered designations of origin'. These have proved successful with producers, who have secured higher incomes in return for a genuine effort to improve quality, and with consumers, who can purchase high quality products with guarantees owing to the method of production and origin.

These developments led to the former Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, which was replaced by two new EU regulations on 20 March 2006:

- Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs
- Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed

Types:

- PDO (Protected Designation of Origin) covering foodstuffs which are produced, processed and prepared in a given geographical area using recognised know-how
- PGI (Protected Geographical Indication) covering foodstuffs for which the geographical link must occur in at least one of the stages of production, processing or preparation
- TSG (Traditional Speciality Guaranteed) does not refer to the origin but highlights traditional character, either in the composition or means of production

Emerging issues:

- Protection of high-quality regional-specific goods:
 As discussed in chapter 4.1.1.5 (WTO TRIPS), the EU submitted two proposals to the WTO in 2002, which are still pending:
 - (i) high-quality goods that are protected in a Member State should be registered in a central databank in order to reduce costs
 - (ii) protection for names/origins of wines and spirits shall be extended to other regional-specific goods (e.g. Indian Darjeeling Tea, Spanish Jamon de Huelva)

The EU, in line with other proponents, argues that the protection of high-quality regional-specific goods will have positive effects both for developing and developed countries. Such protection would save consumers from being confused by misleading indications. Consequently, the protected goods would benefit from the increased reputation and thus gain sales potential. Members' positions on this issue polarised during WTO consultations in April 2006. While the EU, Bulgaria, India, Sri Lanka and Switzerland favour extension of the geographical indication protection for wines and spirits to other products (under art. 23), Argentina, Australia, Brazil, Canada, New Zealand and the US argue that current provisions under Article 22 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are sufficient.

Further readings:

Council Regulation (EC) No 510/2006 of 20th March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_093/l_09320060331en00120025.pdf

Council Regulation (EC) No 509/2006 of 20th March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/I_093/I_09320060331en00010011.pdf

EC Agriculture: Quality Policy – Protected Designation of Origin (PDO)/Protected Geographical Indication (PGI):

- · fruit, vegetables and cereals
 - http://ec.europa.eu/agriculture/qual/en/pgi_04en.htm
- · oils and fats, olive oils
- http://ec.europa.eu/agriculture/qual/en/pgi 11en.htm
- table olives
 - http://ec.europa.eu/agriculture/qual/en/pgi_02en.htm

Organic Farming

Regulation 2092/91/EEC (under revision)

Proposal for a revision of the current legislation on organic farming:

In a bid to reflect the increasing role of organic farming in European Agriculture and to introduce a more stringent and better harmonised legislation, the European Commission adopted a proposal for a new regulation on organic production on 21 December 2005. The new rules allow more flexibility to take account of regional differences in climate and conditions. Imports of organic products compliant with EU standards or accompanied by equivalent guarantees from the country of origin are admitted to enter the EU. The new regulation is supposed to enter into force in 2009. The new regulation will:

- · define objectives and principles of organic production
- · take into account local conditions and stages of development
- assure that the objectives and principles apply equally to all stages of the food chain
- clarify the GMO rules (GMO thresholds)
- render compulsory either the EU logo or a stylised indication 'EU-ORGANIC'
- reinforce the risk-based approach and improve controls by aligning the control system to the official EU food and feed control system applying to all foods and feeds
- improve the free circulation of organic goods by ensuring that EU rules guarantee the highest standards, reinforce the impartiality of the control system and mutual recognition
- develop permanent import rules based on direct access for fully compliant products or access based on recognition as equivalent

Provisions of the current Regulation No 2092/91/EEC:

The current legislation consists of five Regulations, namely the 'Council Regulation No 2092/91/EEC of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs' and further provisions under Regulation (EC) No 207/93 (rules for implementation), Regulation (EC) No 223/2003 (labelling requirements), Regulation (EEC) No 94/92 (imports from third countries) and Regulation (EC) 1788/2001 (certificate of inspection for imports from third countries).

Regulation 2092/92/EEC covers:

- Annex I organic farming practices (crops and livestock, including beekeeping)
- Annex IV processing organic agricultural products into foodstuffs

Emerging issues:

- · Imports from third countries:
 - Part of the import provisions of the current Regulation (EEC) No 2092/91 run out on 31 December 2006. In order not to disrupt international trade, it is considered necessary to extend the possibility for Member States to continue to grant import authorisations for individual products until the measures necessary for the functioning of the new import scheme have been put in place.
- Dispute on the reform proposal and the new inspection and certification framework: The International Federation of Organic Agriculture Movements (IFOAM) disputes the reform proposal. There is much fear that the new inspection and certification framework under regulation (EC) No 882/2004 represents a shift towards a certification system operated by authorities, in which private inspection and certification bodies will have a limited and subordinate role. A further concern is that the new decision making structure transfers power away from Member States and towards the Commission. It is feared that such centralisation of power would not be balanced by greater democratic, proper and formal stakeholder involvement. The contribution and potential to strengthen the self-responsibility of the organic sector at all levels (from local to international) is at best ignored and at worst actively diminished and discriminated against.

Further readings:

EC: Agriculture - Organic farming

http://ec.europa.eu/agriculture/qual/organic/index_en.htm

EC: Commission Regulation (EC) No 956/2006 of 28 June 2006 ... as regards the list of third countries from which certain agricultural products obtained by organic production must originate to be marketed within the Community

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/I_175/I_17520060629en00410044.pdf

EC: Organic farming – Guide to Community rules

http://ec.europa.eu/agriculture/qual/organic/brochure/abio_en.pdf

EC: Agriculture – Organic farming – Organic Farming Information system (OFIS) http://ec.europa.eu/comm/agriculture/ofis_public/

EC: Proposal for a Council regulation on organic production and labelling of organic products

http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0671en01.pdf

IFOAM: Proposed EU Regulation on Organic Agriculture Undermines Integrity and Credibility of System

http://www.ifoam.org/press/press/EU_Regulation.html

KdK (Konferenz der Kontrolstellen): Position paper of KdK on the integration of the inspection and certification system according to Regulation (EEC) No 2092/91 into Regulation (EC) No 882/2004

http://www.ifoam.org/about_ifoam/around_world/eu_group/pdfs/Position_paperKdK_Revision_EU-regulation.pdf

4.2.5 Harmonisation of EU Member States' food laws

The range of goods and services is growing. For example, more than 1,000 new products enter the German market every year. The ever expanding market offers greater choices to consumers but also makes it more difficult to judge on product quality and recognise risks for safety and health. With a view of protecting consumers, the EU laws gain priority over national laws. Harmonisation comprises legislative provisions as well as the institutional set-up for risk assessment, risk management and risk communication.

As described in chapter 4.2, all EC Regulations are directly applicable in Member States under provision of respective deadlines for implementation. Although, it should be mentioned that effective harmonisation may be delayed for many reasons both because of consultation processes with governmental, non-governmental and business stakeholders and of administrative procedures.

Regulation (EC) 178/2002 came into force on 21 February 2002. Although, certain key provisions apply only from 1 January 2005 onwards, "existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with ..." ⁵⁷⁾

- article 5 general principles of food law
- article 6 risk analysis
- article 7 precautionary principle
- article 8 protection of consumers' interests
- article 9 public consultation
- article 10 public information

Serving as examples for the systems applied in EC Member States, some very brief explanations will be given below on the institutional set-up and regulatory provisions in Germany, the United Kingdom and France. Information on institutions in other EC Member States can be obtained from the members' list of the Rapid Alert System for Food and Feed (RASFF) Network⁵⁸⁾.

Source: Regulation (EC) 178/2002, Article 4 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

Rapid Alert System for Food and Feed (RASFF) – Members of the Network http://ec.europa.eu/food/food/rapidalert/members_en.htm

4.2.5.1 Germany

With effect from 7 September 2005, the revised German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch – LFGB) established new provisions for legislation and administration in conformity with the Regulation (EC) 178/2002.

Food and Feed Code

Background

A major policy focus of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) lies in consumer interests and consumer protection both with regard to food safety and public health.

Principles

For the German food law, the same principles apply as for the EU, namely:

- comprehensive and integrated approach from farm to table
- · primary responsibility of food and feed operators for food safety
- · traceability of food and feed and their ingredients
- transparency
- · risk analysis must form the foundation on which food safety is based

General overview

In many instances, the German food and feed code provides for stricter provisions than the EC food and feed law.

Since it would go too far to elaborate on specific provisions of the German Food Law within the framework of the present reference book, interested readers are referred to the further readings listed below.

Emerging issues

- The Federal Parliament (Bundestag) decided on a new Consumer Information Law on 29 June 2006 to regulate consumers' access to federal offices' data on violations against the Food and Feed Law, on the origin and use of products, on ingredients and control measures. The law still has to be approved by the Federal Council of Germany
- The Federal Directive on Marketing Standards will be removed as from 1 January 2007 and replaced by the respective EU regulations.

Further readings

Bundesministerium fuer Ernaehrung, Landwirtschaft und Verbraucherschutz (Federal Ministry for Food, Agriculture and Consumer Protection) http://www.bmelv.de/cln_045/nn_751678/DE/02-Verbraucherschutz/Lebensmittelsicherheit/ __Lebensmittelsicherheit__node.html__nnn=true

Bundesanstalt für Landwirtschaft und Ernaehrung (BLE)

(Federal Agency for Agriculture and Food) http://www.ble.de/index.cfm/68F87C62F7844FE6B0A2FA93A266BBF4

Atlanta Labelling Wizard

(Atlanta Kennzeichnungsassistent) http://www.kennzeichnungsrecht.de/anzeige.htm Behr's - Lebensmittelrecht Online

(Food Law Online) http://www.lebensmittelrecht.com/

Institutional set-up

Background

Against the background of numerous health scandals, the government decided to reorganise the entire institutional set-up for consumer protection in Germany. With a view of strengthening the system of inspection, monitoring and risk management, two new institutions have been set up in 2002/2003.

Federal Institute for Risk Assessment (BfR)

The Bundesinstitut fuer Risikobewertung (BfR) is responsible for:

- risk assessment (expert reports and opinions on food safety and consumer health protection issues on the basis of internationally recognised scientific assessment criteria)
- · formulation of action options for risk reduction
- communication to the general public, scientists and other involved or interested parties
- · scientific advice to the Federal Ministries concerned and to the Federal Agency for Consumer Protection and Food Safety

Federal Office of Consumer Protection and Food Safety (BVL)

The Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (BVL) is responsible for:

- · harmonisation of the food control system in the Federal Republic of Germany through elaboration of general administrative directives for the implementation of laws in the field of consumer protection and food safety
- coordination of the preparation and implementation of supervisory programmes in the federal states ('Bundeslaender')
- · acting as national contact point for the rapid alert system for food/feedstuffs of the EU
- operative tasks at the national level in crisis management (including crisis prevention such as early detection and traceability)
- · communication to the general public, scientists and other involved or interested parties
- management of the national reference laboratory for residues (Commission Directive 2002/63/EC) acting as national contact point for the coordination of and support to the control institutions at the federal level (implementation of trials, elaboration of reference material. development and validation of methods, communication of results to the EU)
- collection, processing, documentation and reporting of data gained through the food monitoring system
- acting as public central point for residue control (Commission Directive 2002/63/EC) responsible for the elaboration of the annual national plan for residue control, collection, processing and communication of results
- issuing of exceptional permits in special cases for suspension of legal provisions
- registration of pesticides and national coordination of the evaluation of active substances

Further readings Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety) http://www.bvl.bund.de/cln_027/DE/00__Splash/splash__node.html__nnn=true Bundesinstitut fuer Risikobewertung

(Federal Institute for Risk Assessment)

http://www.bfr.bund.de/

4.2.5.2 United Kingdom

Institutional set-up

Agency (FSA)

Food Standards The Food Standards Agency (FSA) is known as one of the most rigorous institutions with regard to consumer protection.

Regulatory aspects

Background

From 1 January 2006 onwards, the new EU food hygiene legislation has applied throughout the UK, providing for:

- modern, consolidated and simplified EU food hygiene legislation
- · effective and proportionate controls throughout the food chain
- focused controls on what is necessary for public health protection
- primary responsibility of food business operators to produce food safely

Statutory Instruments (SI)

Requirements laid down in EC Directives are covered by national legislation, the so called Statutory Instruments (SI) in England, and equivalent legislation in Scotland, Wales and Northern Ireland, covering, among others:

- Food Hygiene (England) Regulations 2006 (SI 2006/14), which came into force on 11 January 2006
- Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15), which also came into force on 11 January 2006

The FSA has produced a vast set of guidelines to help food business operators implement the new regulations (see further readings).

Further readings **UK Food Standards Agency**

http://www.food.gov.uk/

Food Law Code of Practice and Practice Guidance for England

http://www.food.gov.uk/enforcement/foodlaw/copengland

FSA: Guidance on the requirements of food hygiene legislation

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

FSA: Guidance on the 2006 food hygiene legislation

http://www.food.gov.uk/foodindustry/guidancenotes/hygguid/fhlguidance/

FSA: Guidance for food business operators on microbiological criteria for foodstuffs

http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/microbiolreg

FSA: Summary guidance on the new food hygiene regulations for businesses

manufacturing food not of animal origin

http://www.food.gov.uk/multimedia/pdfs/summguidnonpoao060413.pdf

OPSI (Office of Public Sector Information): Legislation

http://www.opsi.gov.uk/legislation/about_legislation.htm
The University of Reading – Foodlaw^Reading

http://www.foodlaw.rdg.ac.uk/

4.2.5.3 France

Institutional set-up

Ministry of Agriculture and Fisheries The Ministère de l'agriculture et de la Pêche – Direction Générale de l'Alimentation (DGAL – Directorate General of Food) is in charge of:

quality control

food safety control

Ministry of Economy, Finances and Industry The Ministère de l'Économie, des finances et de l'industrie (DGCCRF – Directorate General for Competition, Consumption and the Repression of Fraud) is responsible for:

- elaborating legal texts (in large parts by transferring European rules)
- · defining and improving rules for food safety
- controlling all stages of the food chain (producers, importers, distributers)

French Food Safety Agency The Agence Française de la Sécurité Sanitaire des Aliments (AFSSA) is one of the three government establishments ⁵⁹⁾ created as a result of the Law of 1 July 1998 to cover the monitoring of health and the surveillance of products intended for human use. Main tasks:

- · assessing risk assessments
- · issuing risk alerts

giving advice, scientific and technical support related to food risks

Further readings

Agence Française de la Sécurité Sanitaire des Aliments (AFSSA)

http://www.afssa.fr

Ministère de l'Agriculture et de la Pêche – DGAL:

http://www.frenchfoodsafety.de

Ministère de l'Agriculture et de la Pêche - DGAL: Food Safety System Guide

http://www.frenchfoodsafety.de/sections/guide-sa-curita/ta-chargez-guide-dans

Ministère de l'Agriculture et de la Pêche – DGAL:

The hygiene package

http://www.agriculture.gouv.fr/spip/actualites.paquethygiene_a4787.html and http://www.agriculture.gouv.fr/spip/actualites.paquethygiene_a4786.html

Ministère de l'Agriculture et de la Pêche – DGAL:

Guidelines for Good Hygiene Practices

http://www.agriculture.gouv.fr/spip/actualites.paquethygiene_a5017.html

Ministère de l'Agriculture et de la Pêche - DGAL:

Regulations to be applied by operators

http://agriculture.maapar1.agriculture.gouv.fr/spip/IMG/pdf/reglementation_applicable_aux_professionnels-291205-

2.pdf

Ministère de l'Économie, des Finances et de l'Industrie - DGCCRF:

Alerts, food control, questions and answers about food safety, good practices

http://www.minefi.gouv.fr/themes/protection_conso/alimentation/index.htm

⁵⁹ The other two institutions are responsible for (i) medical products and (ii) health monitoring.

4.3 Private Industry and Trade Standards

4.3.1 Introduction

The traditionally practicised control of final products is no longer an adequate response to growing public health and consumer protection concerns. In today's highly competitive food markets, the ability to manage risks along food supply chains, to respond to ever faster changing consumer preferences, and to maintain a supplier's reputation of consistent quality and safety alongside corporate responsibility are the driving forces for the widespread use of private standards. In the course of international trade liberalisation and proceeding urbanisation, this holds increasingly true for domestic markets in newly industrialising and even in developing countries.

To effectively cope with the new challenges, liability for food safety shifted to the private sector while public interventions focus on auditing food businesses. In doing so, an ever-expanding, sometimes confusing and disparate system of regulations and standards at the multilateral, supranational and national levels evolved. Industry associations and firms, especially multiple retailers, established own standards to demonstrate their compliance with due diligence requirements. Furthermore, increasingly exact methods of detecting chemical and biological contaminants, the emergence of new foodborne pathogens as well as the retailers' interest in filling perceived gaps in legislation or forestalling more stringent laws result in ever stricter product and process standards.

After nearly two decades of ever faster consolidation in the retail market, European retailers have become the most powerful players in the food supply chain, easily capable of imposing standards on their suppliers. It is expected that in the future, about 15 huge retail conglomerates will control 80% of the fresh produce sales to an expanded European population of some 455 million consumers. Many retailers established so-called private labels/private brands intending to create strong consumer loyalty. Such trademarks serve as a marketing aid offering specific product characteristics linked to quality, performance, safety and health aspects. Once quality or safety problems arise, private label goods can be traced back to the retailer, and their reputation can easily be put at risk. In a bid to become more responsive to consumer concerns and to avoid damage to their reputation, retailers therefore become ever-more demanding as regards suppliers' commitment to and reliability in highest standards of food quality and safety.

Against this background, retailers' strategies for supply chain management are increasingly driven by the necessity of reducing risks and increasing efficiency. Even if private standards play an outstanding role in supplier screening, further criteria for supplier listing or de-listing should not be neglected, such as scale (minimum quantities), consistency, reliability and continuity of supplies.

The development of private industry and trade standards has so far mainly been driven by retailer groups (e.g. EurepGAP, BRC, IFS)⁶⁰⁾, by individual retailers (e.g. Metro), by individual processors (e.g. Nestlé, Kraft), by business associations (e.g. the Confederation of the Food and Drink

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EurepGAP – European Retailer Produce Working Group 'fruit and vegetables' Good Agricultural Practices, BRC – British Retail Consortium, IFS – International Food Standard

Industries in the EU (CIAA)⁶¹⁾, the Organisation of European Industries Transforming Fruit and Vegetables (OEITFL)⁶² or COCERAL⁶³⁾) or – in exceptional cases – by inspection bodies (e. g. EFSIS⁶⁴⁾).

While causing costs of compliance (initial investments and sometimes increased operational costs), private standards also offer a range of benefits to suppliers and their trade partners seeking excellence in quality, customer satisfaction and competitive advantages:

- trustful supplier-customer relations and improved customer satisfaction
- reduced costs in supplier screening due to reduced supplier inspections
- less product recalls
- due diligence
- compliance with food law provisions
- compliance with recognised best practices
- reduced costs through higher efficiency
- improved company reputation
- market access
- better positioning in the market (marketing aid)
- · improved working conditions

And with special regard to potential benefits for producers:

- improved knowledge and skills for increased productivity and food quality
- better on-farm infrastructure
- increased efficiency of resource usage for improved environmental sustainability
- · better marketing conditions and access to mainstream markets

These examples illustrate that despite the burden of compliance, suppliers from developing countries can as well benefit from the introduction of (voluntary as well as mandatory) standards. Jaffee (2004) comes to the conclusion that "The picture for developing countries as a whole is not necessarily problematic and certainly less pessimistic than the mainstream 'standards-as-barriers' perspective. Indeed, rising standards serve to accentuate underlying supply chain strengths and weaknesses and thus impact differently on the competitive position of individual countries and distinct market participants. Some countries and industries are even using high quality and safety standards to successfully (re-)position themselves in competitive global markets." ⁶⁵⁾

Moreover, private food standards may facilitate trade if they are understood in relation to compliance with the EU's regulatory requirements ^{66) 67)}. For food of non-animal origin, the EU

CIAA (2006): CIAA Recommendation for a Common Nutrition Labelling Scheme http://www.ciaa.be/documents/press_releases/CIAA_Nut_recommendation.pdf and Foodnews: http://www.foodproductiondaily.com/news/printNewsBis.asp?id=68830

OEITFL Publication of Code of Practices http://www.oeitfl.org/

⁶³ COCERAL – Comité du Commerce des Céréales, Aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures (European cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply trade)

⁶⁴ EFSIS – European Food Safety Inspection Service

⁶⁵ Jaffee and Henson (2004)

⁶⁶ Lee (2006); the private standards referred to in the study, are EurepGAP and BRC (see following chapters)

the following conceptual framework draws on P. Greenhalgh et al (2005)

requires "equivalence of risk-outcome" as laid out in the SPS Agreement of the WTO. As long as the final imported products pass official controls in Member States (control of the risk-outcome, for example MRLs), the EU does not control the process, in which horticultural products are produced or processed in third countries. In contrast, private standards require "equivalence of (risk-management) systems". They require tight controls over the process, in which products are produced or processed. It is claimed that these requirements are necessary to meet EU legislation on food safety and that of Member States. These specifications serve to ensure that production systems and processes result in legally-compliant products, which can pass official controls at the EU border and in EU markets.

Private standards applied in the three major EU markets United Kingdom, Germany and France have been duly analysed in the research project "The Impact of International Safety and Quality Standards on the Competitiveness of Mediterranean Fresh Produce", financed by the European Union⁶⁸: "The research focused on the standards developed by retailers in the UK, France and Germany since these markets represent the most sophisticated retail environment in international markets regarding food safety and quality standards, and they are key importers of fresh produce from Mediterranean countries. Moreover, these three countries exhibit very distinct retail structures in general, and different fresh produce procurement practices in particular, which provide an insightful comparative study on the drivers of private quality assurance schemes and their impact on international trade."

The EC's Food Quality Schemes Project realised a bibliographic review on quality assurance and labelling schemes in six EU Member States (Belgium, Germany, Italy, Latvia, United Kingdom and the Netherlands). The extensive country lists contain, among others, profiles of relevant private trade and industry standards. ⁶⁹⁾

4.3.2 Classification of private standards

According to the entity that releases the standards, two types can be distinguished:

- collective standards
 established by sub-sector networks, company networks and alike (see chapter 4.3.4 and 4.3.5)
- corporate standards
 established by individual firms (see chapter 4.3.6)

Another characteristic of private industry and trade standards relates to the scope covered:

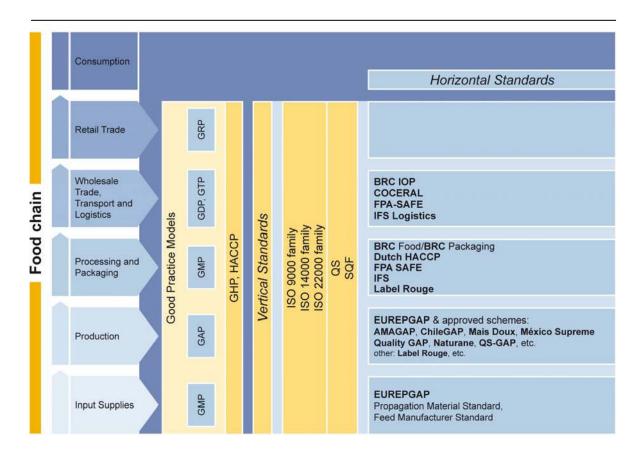
- vertical standards
 cover several/all stages of the food chain from farm to fork
- horizontal standards
 are designed for one stage of the food chain (e.g. primary production at the farm level, value-adding at the processing level, transport and logistics, marketing and storage at the distribution level)

69 Aragrande et al (2005)

⁶⁸ García (2003)

ISO (International Organization for Standardization) and ISEAL (International Social and Environmental Accreditation and Labelling) Alliance standards belong as well to the category of voluntary/private standards. As a tribute to their global importance, however, they are described in the chapter on multilateral standard setting organisations. Both types, ISO (see chapter 4.1.3.2) and ISEAL Alliance (see chapter 4.1.3.6) standards, have (partly) penetrated collective and corporate standards and codes established by the private industry or the retail trade.

The following graph illustrates the scope of selected vertical and horizontal private standards, which will be presented in the following chapters.



Graph 4: Scope of selected private industry and trade standards⁷⁰⁾

4.3.3 Initiatives to harmonise private standards

The vast number of private standards evolving in recent years has not only led to confusion among all stakeholders in the food chain (especially suppliers), but also to increasing costs and inefficiencies due to the need to undergo multiple certifications required by different customers.

for all abbreviations see chapter 4.3.3

"Most retailers would prefer to have one global standard for food safety. This would decrease certification costs for suppliers, relieving them of the need to have separate certifications for each buyer. It could also permit retailers to switch suppliers and source across the globe more easily. With global sourcing likely to increase over the medium term, harmonising of standard systems could facilitate the trade and increase efficiency in the food system. ... Harmonising process attributes such as labour standards, environment and animal welfare, having retailer minimum standard for these, may be desirable." ⁷¹⁾

From the perspective of a strongly internationally determined food market, it seems indispensable to achieve compliance, if not harmonisation, of private standards. Such cooperative approach aims at

- introducing internationally recognised standards
- facilitating independent and transparent auditing
- maintaining consumer confidence in product quality and safety
- · establishing Europe-wide supply chains meeting common or minimum standards
- making supplies interchangeable
- · reducing risks of liability
- reducing costs

4.3.3.1 Global Food Safety Initiative (GFSI)

In June 2000, CIES (The Food Business Forum), a network of leading European and US retailers, launched the Global Food Safety Initiative (GFSI). The GFSI is based on the principle that food safety is a non-competitive issue, as any potential problem arising may cause repercussions in the whole sector. It provides a framework of key principles against which existing food standards can be benchmarked.

The Global Food Safety Initiative (GFSI) is the first approach towards harmonisation in the field of private standards, ensuring food safety from farm to fork while reducing the efforts (and thus costs) for multiple certifications. GFSI has not yet proved whether it will be accepted at the global level.

Global Food Safety Initiative (GFSI)

Mission

"Continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers."

The Global Food Safety Initiative aims at creating a simple set of rules for standards, harmonisation between countries and cost efficiency for suppliers in order to:

- implement and maintain a scheme to recognise food safety standards world-wide
- facilitate better communication, cooperation and transparency between standard owners
- work towards world-wide integrity and quality in the certification of standards and the accreditation of certifying bodies

⁷¹ Source: OECD (2006), page 27

Aims

- facilitate mutual recognition between standard owners worldwide
- work towards integrity and quality in the certification of standards and the accreditation of certifying bodies
- improve cost efficiency throughout the supply chain
- · provide a unique platform for the exchange of ideas and information on food safety

Scope

The main scope of GFSI:

- private label goods and fresh produce
- · other products can be included at the discretion of retailers and manufacturers concerned

GFSI benchmarked food safety standards can be applied by stakeholders throughout the whole food supply chain. Respective agreements should be achieved with retailers and laid down in sales contracts. The application of the benchmarked standards to particular products will be at the discretion of retailers and suppliers.

GFSI is said to represent 70% of food retail revenue worldwide. 72)

Key elements for benchmarking

The GFSI Guidance Document (Fourth Edition) sets out

- Part I Requirements for food safety management schemes (introduction, scope, definitions, procedure for application etc.)
- Part II Requirements for a conforming food safety management standard (key elements: food safety management system, GAP, GMP, GDP, HACCP)
- Part III Requirements for the delivery of food safety management systems
 (auditor qualifications, minimum requirements for audit reports, guidance for the
 management of certification bodies, food certification categories, management of the
 food certification system)

GFSI explicitly focuses on food safety and leaves out product quality, environmental, social, animal welfare and sustainability issues as well as biotechnology and innovative processes.

Benefits

for retailers:

- improved production standards in factories
- · improved information on food safety schemes
- · exchange of best practices and knowledge
- simplified purchasing procedures

for manufacturers:

- · improved cost efficiency
- · reduced number of audits
- · clarity of food safety scheme requirements
- · time and resources to invest in food quality and safety levels

for certification bodies:

- information exchange
- · improved auditor competence
- · improved audit quality
- · new market opportunities

for accreditation bodies:

- · exchange of best practices
- knowledge sharing
- · opportunities to work with the food industry to improve auditing standards

for standard owners:

- exchange of information
- greater transparency in the food industry
- continuous improvement
- market opportunities

Auditing and certification

In order to harmonise the practices of auditors, it is required that certification bodies are accredited by official accreditation bodies (based on ISO Guide 65), which are themselves subject to monitoring by their peers through "Multi-Lateral Arrangements" (MLA).

⁷² SQF http://www.sqfi.com/

GFSI itself is not involved in auditing and certification but encourages third party audits against the standards recognised by GFSI.

Compliant standards as of

August 2006

- BRC Technical Standards Version 4
- Dutch HACCP CodeSQF 2000 (June 2006)
- SQF 1000 (January 2006)IFS Version 4NZ GAP (July 2006)

Emerging Issues

- GFSI Foundation created under Belgian law to provide a more streamlined approach to GFSI (July 2005)
- GFSI Guidance Document Version 4 (September 2004) includes the possibility to benchmark pre-farm gate standards
- GFSI study on Good Retail Practices compiling approaches to in-store food safety management in 9 countries (see further readings)
- Key projects 2006 2007
 - (i) greater transparency in the GFSI benchmarking process
 - (ii) clarification of ISO 22000 for the food industry
 - (iii) creation of a gold standard for auditor competence
- With the benchmarking of SQF, GFSI expects to extend the geographical reach to the Americas and Asia

Further readings

CIES (2005): Food Safety Management by Retailers: A Global Inventory of In-Store Food Safety Requirements

http://www.ciesnet.com/2-wwedo/2.2-programmes/2.2.foodsafety.goodpractices.asp

GFSI: Global Food Safety Initiative – Website

http://www.ciesnet.com/2-wwedo/2.2-programmes/2.2.foodsafety.gfsi.asp

GFSI: Global Food Safety Initiative – Mission

http://www.ciesnet.com/pfiles/programmes/foodsafety/2006_GFSI_Mission_Document.pdf

GFSI: Food Safety Management by Retailers: A global inventory of In-Store Food Safety

Requirements

 $http://www.ciesnet.com/pfiles/programmes/foodsafety/2005_Feb_GRP-GlobalInventoryofIn-StoreFoodSafety Requirements.pdf$

4.3.3.2 International Federation for Produce Standards (IFPS)

The International Federation for Produce Standards (IFPS)⁷³⁾ is composed of international fresh produce associations providing a global forum to address issues which require international harmonisation or standardisation for produce sectors. Originally brought together to address the international harmonisation of the industry-defined PLU (Price Look Up) codes⁷⁴, the body expanded its mission to the harmonisation of international standards. In so doing, IFPS enables national fresh produce associations to represent their countries' constituents.

⁷³ previously known as International Federation for Produce Coding (IFPC)

Price Look Up codes (PLU codes) or Produce Look-Up numbers (PLU numbers) are 4-digit or in special cases 5-digit numbers (here the first digit 9 indicates organic produce and the first digit 8 indicates genetically modified produce), which are affixed to produce at the retail level identifying the type of produce. "The PLU scheme for identifying produce sold in bulk/loose at retail was first introduced in North America and has spread to include use by retailers in Australia, New Zealand and countries in Europe. ... any grower/packer/shipper shipping to any country utilising the PLUs for fresh produce needs to ensure they meet the expectations of their customers. This typically means that the 4 to 5 digit number must be printed on a small sticker (or by other means depending on the produce) and adhered to the individual pieces of produce." Source: IFPS (2006), page 3

International Federation for Produce Standards (IFPS)

Objectives

- improve the supply chain efficiency of the fresh produce industry through developing, implementing and managing harmonised international standards
- act as a forum for comments and discussions on issues relating to international standards as they affect the produce industry
- make recommendations and advocate appropriate courses of action in relation to international standards that affect the produce industry
- develop, implement and manage an international standard for Price Look Up (PLU) numbers

Founding members

- Asociacion de Exportadores de Chile (Chile)
- Canadian Produce Marketing Association (Canada)
- Fresh Produce Consortium (UK)
- Horticulture Australia Ltd. (Australia)
- Norges Frukt-og Gronnsaksgrossisters Forbund (Norway)
- Produce Marketing Association (US)
- United Fresh (NZ)

Tasks

- industry technologies: product identification, application of product identification via Reduced Space Symbology (RSS), RFID, etc.
- · traceability:

harmonisation of existing guidelines and standards

- · pesticides:
 - information gathering regarding country-specific MRLs (Maximum Residue Limits), legislative changes, implications for global trade, promotion of best practices, etc.
- GAP (Good Agricultural Practices): harmonisation of existing/proposed schemes, organic standards/certification, etc.

Further readings

International Federation for Produce Standards (IFPS)

readings http://www.plucodes.com/aboutus.aspx

4.3.4 Collective standards – horizontal level

As explained above, horizontal standards are designed for a specified stage of the food chain (e.g. primary production at the farm level, value-adding at the processing level, transport and logistics, marketing and storage at the distribution level). The standards, which will be described in more detail in the present study, are either already well established in the market or are about to gain importance:

Primary production:

Global: EUREPGAP

National (UK): Assured Produce Scheme – APS

National (France): Label Rouge

Processing industry:

Global: BRC Global Standard – Food

Global: International Standard for Auditing Food Suppliers (IFS)

4.3.4.1 EUREPGAP

EurepGAP

Owner

Since March 2001, FOODPLUS GmbH has acted as global body, serves as legal owner of the normative document and hosts the Euro-Retailer Working Group (EUREP) Secretariat. FOODPLUS is a subsidiary of the EuroHandelsinstitut (EHI), a non-profit making, private research and education institute in Cologne, Germany.

GFSI status

Discussions with GFSI are ongoing to see how EurepGAP can be benchmarked. GFSI benchmarking of standards for primary production is possible since September 2004.

Background

British retailers in conjunction with supermarkets in continental Europe were the driving forces that founded EUREP in 1997 and started developing the Eurep-GAP protocol.

Objectives

Respond to consumer concerns on food safety, animal welfare, environmental protection and worker welfare by:

- encouraging adoption of commercially viable Farm Assurance Schemes and promoting the minimisation of agrochemical inputs
- developing a Good Agricultural Practice (GAP) Framework for benchmarking existing farm assurance schemes and standards including traceability
- providing guidance for continuous improvement and the development and understanding of best practice
- establishing a single recognised framework for independent verification
- communicating and consulting openly with consumers and key partners, including producers, exporters and importers

Scope

EurepGAP developed a **framework for Good Agricultural Practices** on farms for the global production of agricultural products. The scope has been expanded to other products (livestock, coffee, aquaculture etc.).

Normative documents

- Control Points and Compliance Criteria:
- defines basic production standards as major/minor musts and recommendations
- · Checklists:

tools for producers and inspectors to check compliance with Control Points and Compliance Criteria as well as with General Regulations regarding Quality Management Systems in the case of option 2

- · General Regulations:
- "Instruction booklet" of EurepGAP ruling the certification process
- Benchmarking Procedure:
- describes how other schemes can achieve recognition of equivalence by EurepGAP
- National Interpretation Guidelines: provide guidance to certification bodies how to interpret specific control points and compliance criteria in the respective country

The EurepGAP standard is subject to regular reviews to facilitate adaptation to developments in the industry and to consumer requirements.

Certification

EurepGAP is a certifiable standard for Good Agricultural Practices in conventional agriculture. Certification bodies have to be accredited according to EN 45011/ISO 65 against the EurepGAP standard with the respective scope (e.g. EurepGAP fruits and vegetables).

EurepGAP offers four options for certification:

- Individual certification to EurepGAP or a benchmarked scheme (option 1 and 3 respectively)
- Group certification to EurepGAP or a benchmarked scheme (option 2 and 4 respectively)

First issue EurepGAP standards 2001 Flowers and Vegetables 2003 Integrated Farm Assurance 2004 Integrated Aquaculture Assurance

2004 Green Coffee

2005 Feed

EurepGAP Approved

- AMAGAP Agrarmarkt Austria Marketing, Austria
- ChileGAP 2005 Fundación para el Desarrollo Frutícola (FDF). Chile

Schemes 2006 • Mais Doux - Association Générale des Producteurs de Mais (AGPM), France

• México Supreme Quality GAP - México Calidad Suprema A.C., Mexico

fruit and vegetables

- Naturane ANECOOP Spain COOP, Spain
- Natursense E. Martinavarro S.A., Spain
- New Zealand GAP Horticulture NZ, New Zealand
- QS-GAP Qualität und Sicherheit, Germany⁷⁵⁾
- UNE 155000 Asociación Española de Normalización y Certificación (AENOR), Spain

EurepGAP Applicant Schemes 2006

- Assured Produce 2005 Assured Produce, UK
- Danish GAP Fruit & Vegetables, Potatoes Danish Agricultural Advisory Service
 Integrated Production Groen Produktion I Sverige AB, Sweden
- JGAP (Japanese GAP) Agro-Information Consulting Ltd., Japan Kenya GAP – Fresh Produce Exporters Association of Kenya (FPEAK), Kenya
- SwissGAP Qualiservice, Switzerland

Emerging issues

vegetables

fruit and

• EurepGAP revision 2007:

Coming into in 2007, EurepGAP will put a new standards structure in place to facilitate a more efficient coordination between different product groups (see graph 5 below). Further issues under revision are integrated pest management, workers health, safety and welfare, residue monitoring, new scopes/modules, etc.

 Developing countries' concerns: EurepGAP represents numerous leading European food retailers (especially Belgium, Netherlands, Scandinavia, Switzerland, Spain and United Kingdom), and its market impact is growing. EurepGAP has become an important international standard that might be increasingly perceived by some as a trade barrier. In June 2005, St. Vincent and the Grenadines, Jamaica, Peru and Argentina brought the issue to the attention of the SPS Committee of the WTO. Discussion continued in a special session on private standards during the meeting of the WTO's SPS Committee in October 2006.

Benchmarking:

The benchmarking option is increasingly accepted by national governments and private trade associations as a means to have their national Good Agricultural Practice standards recognised. Applications come from industrialised countries (e.g. Switzerland. Denmark), from threshold countries (Mexico, Brazil, China) as well as from developing countries (Kenya, Ghana). UNCTAD's Consultative Task Force on Environmental and Health Requirements has undertaken some research on the pros and cons of national GAPs (see further readings).

Smallholder group certification:

The group certification option offered by EurepGAP is particularly interesting for small growers. Groups may be traditional producer organisations (e.g. farmer groups, associations, cooperatives) or contract farming schemes, organised and assisted by an exporter (e.g. outgrower scheme). A prerequisite for certification under option 2 EurepGAP is a documented Quality Management System/Internal Control System (ICS). A generic QMS has been elaborated by GTZ in close collaboration with EurepGAP and is currently being tested in the Dominican Republic, Ghana, Kenya, Macedonia and Thailand (see further readings and the case study in chapter 5.4). After conclusion of the trial phase it will be available as free public shareware.

 GRASP (Good Risk-based Agricultural Social Practices): EurepGAP in cooperation with Coop Switzerland and GTZ (Public-Private Partnership project) are currently investigating whether social requirements could be integrated into existing GAP audits, in general. More particularly, it is tested whether selected social requirements could be applied and verified within the proposed 2007 version of the EurepGAP standard.

Further readings EurepGAP Website

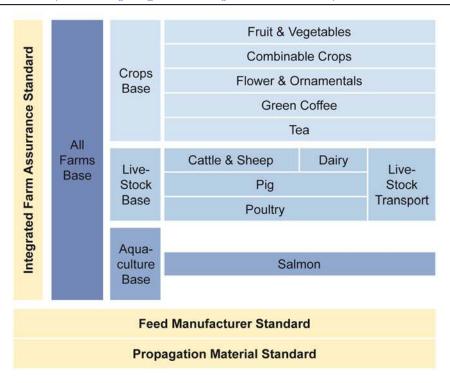
http://www.eurepgap.org/fruit/index_html

Guenther, Doris (2005): The EurepGAP Smallholder Manual – Building up an Internal Control System for Certification to EUREPGAP Option 2 in the Horticultural Sector http://www.eurep.org/documents/webdocs/E-book-Globalreport.pdf

see: http://www.eurepgap.org/Languages/English/news/299.html

UNCTAD (2006): Food Safety and Environmental Requirements, Market Access and Export Competitiveness: Turning Challenges into Opportunities for Developing Countries: The Horticultural Sector

http://r0.unctad.org/trade env/test1/meetings/ctf3/HorticultureJune30.pdf



Graph 5: EurepGAP standards structure as from 2007
Adapted from FoodPLUS GmbH, Cologne

4.3.4.2 APS

Assured Produce Scheme (APS) - UK

GFSI status Not yet benchmarked.

EUREPGAP Assured Produce 2005:

equivalence notice of intent to formally recognise equivalence (status: October 2006)

Owner Assured Produce Company Ltd, UK (non-profit company)

First protocol issued

1997

Background

The UK Government enacted the Food Safety Act in 1990, requiring due diligence. In the field of fresh produce, UK retailers introduced so called individual crop protocols. In 1996, they joined together and formed an alliance with UK growers, the UK Assured Produce Scheme. APS was the first quality assurance system in the horticultural sector worldwide.

Objectives The objective of the UK Assured Produce Scheme is

- · to produce safe food
- in an environmentally responsible manner
- with minimum use of pesticides through the adoption of ICM systems
- and to maintain consumers' confidence in the safety and integrity of the UK produce

Scope APS covers issues concerning the production of fresh fruit, salads and vegetables.

> The scheme has been accredited in 2002 by the United Kingdom Accreditation Service (UKAS) according to the EN45011/ISO Guide 65 (internationally recognised standard for the operation of product certification), which enhances its global credibility in quality

assurance issues.

Protocols In addition to setting and monitoring production standards, APS provides its members with

crop specific Best Practices Guides.

The Generic Crop Protocol and crop specific protocols are available online (see below).

Further Assured Produce Scheme (APS) http://www.assuredproduce.co.uk

readings

4.3.4.3 BRC Global Standard - Food (issue 4)

BRC Global Standard - Food (issue 4)

GFSI status The BRC Global Standard – Food is GFSI compliant as of January 2003.

Background In 1990, the UK Government enacted the Food Safety Act in response to incidences such

> as BSE (mad cow disease). For the first time, due diligence was introduced into a food law, meaning that retailers have the responsibility to ensure that their suppliers meet certain safety standards. As a result, numerous standards were elaborated, and inspections and

audits were employed without coordination.

The British Retail Consortium (BRC) is the leading UK trade association representing the Owner

retail sector (large multiples and department stores as well as small town and rural shops

as well as virtual stores).

Rationale The interest to develop the BRC Global Standard - Food was to reduce the number of

audits for own label products by retailer and third party technical representatives of food manufacturers supplying the UK retailers according to the due diligence requirements

under the UK Food Safety Act.

The objective is to specify food safety and quality criteria required by UK retailers. Objectives

Key The Standard covers all areas of product safety and legality and addresses part of the due

diligence requirements for both the supplier and the retailer. The format and the content of the Standard are designed to allow an assessment of the supplier's premises, operational systems and procedures by a competent third party so that food safety criteria and

monitoring procedures can be standardised.

The Standard requires:

• the adoption and implementation of a HACCP system

• a documented and effective quality management system (ISO based)

control of factory resource management

product and process control

Version The first issue of the BRC Global Standard – Food was published in October 1998.

Current version: BRC Global Standard - Food (Issue 4)

Emerging issues

requirements

• The completely revised issue No 4 (2005 edition) reflects revised EU legislation and best practice developments.

• The development of the new BRC on storage & distribution and packaging (see the following chapter) reflects increased stakeholder awareness of the need to assure quality across several stages of the food supply chain.

Further readings

BRC: BRC publications - Standards

http://www.brc.org.uk/brcpubs05.asp

4.3.4.4 BRC Global Standard – Storage & Distribution and Packaging

BRC Global Standards - Storage & Distribution and Packaging

BRC Global Standard

Storage and

Distribution

_

food, consumer goods and packaging. EU Regulations (No 178/2002, No 852/2004) legally oblige food operators to ensure food safety along the entire supply chain, including storage and distribution.

The standard comprises modules for storage, distribution, wholesaling and contracted specialist services such as:

The standard is equally relevant for companies storing, distributing and/or transporting

- product inspection/sorting
- contract packing (repacking, assembling)
- · quantity control inspection
- contract chilling/freezing/defrost operations

BRC Global Standard

Packaging

The BRC IOP (Institute of Packaging) standard provides safety and quality guidance for manufacturers of packaging materials and food contact materials. Legislation obliges producers to ensure the suitability of their packaging for food safety. The standard provides a common basis for the audit of companies supplying packaging for food products.

The standard came into effect on 1 March 2005.

Further readings

BRC: BRC publications - Standards

http://www.brc.org.uk/brcpubs05.asp

4.3.4.5 IFS

International Standard for Auditing Food Suppliers (IFS)

GFSI status GFSI compliant as of January 2003

Owner BDH – Bundesvereinigung Deutscher Handelsverbaende e.V. (German Union of Trade

Associations)

All tasks related to the administration and implementation of the standard has been

entrusted to HDE Trade Services GmbH.

Background

In 2002, members of the German Federation of the Retail Trade HDE (Hauptverband des Deutschen Einzelhandels) developed the IFS as a common audit standard. The IFS is supported by leading German retailers such as Metro AG, Rewe, Edeka, Aldi, Tengelmann and others. In 2003, French food retailers (and wholesalers) from the FCD (Fédération des entreprises du Commerce et de la Distribution) have joined the IFS Working Group and have contributed to the development of IFS version 4.

Scope

The standard is a tool to ensure food safety and to monitor the quality management of suppliers of retailer branded food products. The standard can be applied at all stages of food processing (post-farm gate).

The IFS standard

- is supported by German and French retailers
- · defines required quality assurance systems for suppliers of retailers
- takes international standards into consideration (GFSI)
- evaluates entire supplier performance
- makes strengths and weaknesses of suppliers transparent for customers
- · delivers a qualitative and quantitative summary report

The structure of IFS is adapted to DIN EN (ISO) 9001:2000. Certification bodies need to be accredited according to DIN EN (ISO) 45011.

Objectives

Create a consistent evaluation system for all companies supplying retailer branded food products. Facilitate uniform formulations, uniform audit procedures and mutual acceptance of audits to create a high level of transparency throughout the supply chain.

Catalogue of requirements

- management of the quality system (including HACCP requirements)
- management responsibility (including customer focus)
- resource management (including personnel issues such as hygiene)
- product realisation (including pest control, traceability)
- · measurements, analyses, improvements (including internal audit)

Quantifiable measures

Aiming at establishing a transparent system and facilitating a comparison between certified companies, IFS uses a system for quantification of audit results. To this end, the auditors distinguish between two levels plus recommendations for the higher level:

- foundation level (minimum requirements for the international food industry)
- higher level (criteria for a high standard in the food industry)
- recommendations (best practice in the industry)

A system of quantification of these levels has been introduced, which allows both the audit results of a certain company on an annual basis and the results between different companies to be compared. The results of the audits are published in the IFS-Intranet, accessible for members only.

Criteria for exclusion

If companies fail to meet one of the following criteria, they will automatically be disapproved:

- existence of a manageable number of relevant critical control points (CCP)
- implementation of a control system for all CCPs, including documentation (HACCP)
- management guarantee that the staff knows its obligations and that the management supervises the efficiency
- traceability of the way back to the processing plant and/or raw material supplier
- guarantee that corrective measures are taken in time in order to avoid repeated nonconformity

Certification

A network of IFS-accredited bodies (accreditation against EN 45011/ISO 65) avails certification services all over Europe.

Version

Current version: IFS version 4 of 18 March 2005.

The standard is complemented by the 'IFS Compendium of Doctrine,'which contains a regularly updated summary of all linguistic and content clarifications of the IFS since its first publication in January 2004. The compendium also lays down a common interpretation for certification bodies, food suppliers and other IFS users. The present compendium applies from June 2006.

Emerging issues

- The development of the new IFS Logistics standard (see the following chapter) takes the need into consideration to assure quality across several stages of the food supply chain.
- Seeking to establish the standard throughout Europe, IFS initiated discussions on the application of the IFS standard with wholesalers, retailers and their federations in Austria, Belgium, Italy, the Netherlands, Poland and the UK.

Further readings

IFS Website

http://www.food-care.info/

IFS (2006): Compendium of Doctrine

http://www.food-care.info/download.php?file_name=infos/english/IFS_Doctrine.pdf

4.3.4.6 IFS Logistics

IFS Logistics

IFS Logistics

The IFS Logistic is based on the standard EN 45011/ISO IEC 65 (process standards).

The standard is subdivided in three categories:

- basic requirements applying to all providers of logistics services (see catalogue of requirements above)
- criteria for storage and distribution (hygiene management, pest control, traceability, etc.)

 criteria for dedicated providers of transport services (specific criteria for packaging and transport)

IFS places particular emphasis on hygiene and risk management, temperature control and traceability, management responsibility and handling of corrective action.

Further readings

IFS Website

http://www.food-care.info/

4.3.4.7 Dutch HACCP Code

Dutch HACCP Code

GFSI status GFSI compliant as of January 2003

Owner The S

The SCV (Stichting Certificatie Voedselveligheid/Certification Foundation Foodsafety) was founded in 2004 by the (Dutch) National Board of Experts HACCP (NBE-HACCP) and the associated Certification Bodies to create a legal entity that could represent the NBE and its associated bodies. SCV acts as the legal owner of the 'Requirements for a HACCP based Food Safety System©' and manages the copyright with licence agreements.

Scope

Besides the management of the licence, SCV:

- promotes international compliance and adaptability of food safety standards
- develops and maintains certification and inspection systems for food safety
- · promotes the international use of food safety systems
- · provides services to support the certification of food safety systems
- · provides information on food safety issues

General information

'Requirements for a HACCP based Food Safety System' are based on Codex Alimentarius HACCP principles.

Major aspects of the standard:

- continuous participation of all parties concerned in food safety in the maintenance of the certification scheme, including governmental agencies responsible for food safety
- pragmatic elaboration of the HACCP principles and requirements based on the Codex Alimentarius norm suitable to small as well as large food businesses
- · mature and high level set of requirements for certification schemes

The Dutch HACCP Code was submitted to the International Organization for Standardization (ISO) as a basis for the preparation of the new ISO 22000 standard for food safety systems.

Version

first issue: 15 May 1996

(currently applicable: version 3 of January 2003)

Further readings

SCV (Foundation for the Certification of Food Safety Systems): Website

http://www.foodsafetymanagement.info/net-book.php

4.3.4.8 FPA-SAFE

FPA-SAFE (Supplier Audits for Food Excellence)

Owner

Food Products Association (FPA), a scientific and technical trade association representing the US food products industry.

Objective

The FPA-SAFE programme has been designed by leading food companies to meet global industry audit needs, including manufacturing of packaging material. The FPA-SAFE programme is committed to establishing excellence in food safety auditing for the food industry.

Scope FPA-SAFE is a voluntary standard for supplier auditing. FPA-SAFE provides a

comprehensive assessment of a company's entire food quality and safety system while

reducing the time and expenses associated with redundant supplier audits.

In 2005, FPA-SAFE realised 900 audits worldwide, among others, in Austria, Belgium, Denmark, France, Germany, Poland, Slovenia, Spain, Turkey and the UK. Kraft Foods

intends to use FPA-SAFE for supplier auditing.

Standards • food safety audit

primary packaging auditaseptic process auditwarehouse/distribution audit

- Wal offodoor alout battorn addit

Further readings

FPA-SAFE: SAFE Supplier Audits for Excellence – Website

http://www.fpa-safe.org

FPA-SAFE: Companies accepting the FPA-SAFE audit as one of their third party audits

http://www.fpa-safe.net/customerexcel.htm

FPA-SAFE: Masterfoods USA – Case study

http://www.fpa-safe.org/docs/SAFE_CaseStudy_MasterfoodsUSA.pdf

FPA-SAFE: Publications

http://www.fpa-food.org/upload/pdfs/Publications_A-F.pdf

4.3.4.9 COCERAL

Further horizontal standards exist in other food sub-sectors as for example the first common European Code of Good Trading Practice (GTP) launched by COCERAL. The 'Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures' (COCERAL) is the officially recognised representation of the cereals, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply trade in the EU. The main principles of the European GTP code are its voluntary nature, verification and certification by independent third parties and quality management in accordance with the HACCP principles. ⁷⁶⁾

4.3.5 Collective standards – vertical level

As defined above, vertical standards cover several/all stages of the food chain. In many countries, vertical standards have initially been developed for the meat sector, like QS (Qualitaetssicherung – Quality Assurance) in Germany (see below), I.K.B. (Integrale Ketenbeheersing – Integrated Chain Control) in the Netherlands⁷⁷⁾ or Certus Quality Label in Belgium⁷⁸⁾. None of the vertical standards are yet benchmarked against GFSI.

The following standards are either already well established in the market or are about to gain importance:

- Safe Quality Food (SQF)
- QS Qualitaet und Sicherheit (Quality and Safety)
- National Quality Labels (e.g. Label Rouge)

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COCERAL Code of Good Trading Practice http://www.coceral.com/CMS/beitrag/10010247/228174/

⁷⁷ I.K.B. (Integrale Ketenbeheersing) http://www.ikbpsb.com/

⁷⁸ CERTUS http://www.certus.be/index_fr.php

4.3.5.1 Safe Quality Food (SQF)

Safe Quality Food (SQF)

GFSI status GFSI compliant as of January 2006

Owner The SQF (Safe Quality Food) Institute is an off-spring of the Food Marketing Institute (FMI),

which represents 1,500 member companies in food retailing and wholesaling in the US and

worldwide.

Scope The SQF offers a complete programme for supplier auditing for industry or company branded products regarding food safety and quality management. SQF certification

provides an independent and external evaluation whether a product, process or service

complies with international and regulatory standards.

Focus of the SQF food safety programmes:

• assist suppliers to minimise contaminations

- · assist retailers to develop science-based control at the store level
- train employees how to safely store, handle and prepare foods
- · teach consumers basic and effective measures to safeguard products
- · notify the industry of product recalls and foodborne illness outbreaks
- · assist members in food crisis management and communication

SQF encourages chain certification without requiring individual legal entity certification.

Rationale Export markets face the increasing need to prove that

product specifications are met

- · consistency and predictability are maintained
- · regulatory compliance is fulfilled
- claims are trustworthy

Basic principles SQF standards are based on the principles of

- HACCP
- Codex Alimentarius
- ISO
- · Quality Management Systems

Benefits The SQF food safety and quality management system

- offers a management system for food safety issues
- integrates customer product quality requirements
- · meets regulatory and market requirements
- aligns with the Codex Alimentarius Commission Guidelines for the application of HACCP
- is cost effective
- · is independent

SQF thus supports

- · the protection and enhancement of brands and private labels
- · increased consumer confidence

SQF Codes SQF 1000 Code – a HACCP based supplier assurance code for the primary producer – is a third-party audit for products entering an SQF 2000 certified business. The SQF 1000 Code includes – in addition to GAP – food safety and food quality plans. SQF 1000 Code categories:

- growing and production of fresh produce
- · others such as livestock, animal feeds, grain production and storage and fish farming

SQF 2000 Code – a HACCP supplier assurance code for the food industry – is a HACCP-based food safety and quality risk management system for the manufacturing and distribution sectors, which includes – in addition to GMP – food safety and food quality plans. SQF 2000 categories:

- · fresh produce packhouse operations
- · fruit and vegetable processing
- · canning, ... and aseptic operations
- · food ingredient manufacture
- food retailing

- · fresh produce wholesaling
- · manufacture of food sector packaging materials
- · provision of crop spray services
- provision of field harvest services
- · provision of sanitation and hygiene services
- · fertilizer manufacture
- manufacture of agricultural chemicals and food processing aides etc.

In addition to food safety management, the SQF Codes are flexible to also account for (but not limited to):

- · product quality hazards
- environmental hazards
- animal welfare hazards
- · production hazards
- · occupational health and safety hazards
- regulatory hazardsethical production
- · GMO status

Editions first issue 1998

SQF 1000 5th edition – issued November 2005 SQF 2000 5th edition – issued November 2005

Further readings

SGF Institute: Website http://www.sgfi.com/

SQF Institute: SQF Program – Food Sector Categories

http://www.sqfi.com/documentation/SQF_Program_Food_Sector_Categories.pdf

SQF Institute: SQF 1000 Code

http://www.sqfi.com/documentation/SQF1000_Code.pdf

SQF Institute: SQF 2000 Code

http://www.sqfi.com/documentation/SQF2000_Code.pdf SQF Institute: SQF 2000 Guidance Documents

 $http://www.sqfi.com/guidance_documents.htm$

4.3.5.2 Qualitaet und Sicherheit – Quality and Safety (QS)

Qualitaet und Sicherheit - Quality and Safety (QS)

EurepGAP equivalence

Benchmarked with EUREPGAP certification options 1 and 3 in October 2006.

Harmonisation of group certifications is envisaged after validation of QS pilot-testing of

group certification at the beginning of 2007.

Background

Founded on 12 October 2001 as a reaction to consumer concerns.

QS represents organisations and associations from the entire food chain in Germany.

Scope

QS is an initiative of the private sector meeting the requirements of the three pillar control system (risk assessment, risk management and risk communication) as stipulated by the Federal Ministry for Food, Agriculture and Consumer Protection for organic and

conventional agriculture. QS has officially been recognised by the Ministry as control label

for conventionally produced foodstuffs.

So far, more than 70,000 companies have joined the QS system in Germany and abroad. Major retailers such as Metro, Edeka, Rewe, Kaiser's, Tengelmann, Aldi, Coop, Globus, Kaufland and Marktkauf participate in QS. According to QS, 72% of vegetables and 60% of

fruit commercialised by German producer organisations are QS-certified. 79

Principles

The QS standard is based on:

- legal provisions of the EU and German food laws
- HACCP
- guidelines of the private industry and trade (more stringent than the legal provisions)

Presseinformation October 2006 http://www.q-s.info/uploads/media/PM_061010_Der_Handel_setzt_auf_QS.pdf

Obligations

Obligations:

- self-control throughout the food chain (including observance of product and process guidelines and complete documentation)
- · third party control of quality at every stage of the food chain
- · accreditation of control bodies

QS Manuals

The quality assurance system integrates the entire food chain. Criteria have been formulated for each stage of the food chain in so called 'Lastenheften', which give guidelines for systematic quality assurance across all stages of the supply chain:

- production, including feed, meat, fruit, vegetables and potatoes, crop production
- retail food trade
- consumers

Emerging issues

On 9 April 2003, the decision has been taken to integrate **fruit and vegetables** into the QS system. Whereas the meat market in Germany is dominated by local products, the fruit and vegetable market highly depends on imports. It will thus be a major challenge for the fruit and vegetable working group to develop a QS system capable of integrating backward linkages with third countries including the respective necessary control mechanisms.

Further readings

QS Website http://www.q-s.info/ QS: Manuals

http://www.q-s.info/Manuals.88+M52087573ab0.0.html

4.3.5.3 Label Rouge

Label Rouge - France

GFSI status not yet benchmarked

EurepGAP equivalence

not yet benchmarked

Owner

CERQUA (Centre de développement des certifications des qualités agricoles alimentaires), an association uniting large professional organisations representing the French agriculture and food industries.

Objectives

Development and promotion of the quality of agricultural and food products (Label Rouge, Label Régional and IGP (Indication Géographique Protégée – Protected Geographical Indication).

Scope

The Label Rouge certifies that foodstuffs or agricultural products comply to pre-established high quality characteristics. The quality criteria are laid down in the guidelines, covering the entire supply chain. The Label Rouge approach integrates all operators along the entire food supply chain:

- · production (including planting material, field and crop management)
- processing
- · distribution and marketing

Organised in so-called "quality groups", operators jointly ensure process and product quality and traceability at the same time along the supply chain.

Apart from fresh and processed fruit and vegetables, the Label Rouge also covers dairy and meat products as well as fish, prepared meals, agricultural non-food products, etc.

Further readings

CERQUA (Centre de développement des certifications des qualités agricoles alimentaires) http://www.label-rouge.org/index.html

The Label Rouge

http://foodqualityschemes.jrc.es/en/documents/4-LabelRouge_en.pdf

4.3.6 **Corporate standards**

Importers and retailers are usually seeking long-term partnerships with their suppliers, which are built upon mutual trust and reliability in terms of food quality and safety as well as respect of agreed quantities and dates of delivery. As a basis for establishing such long-term customer-supplier relations, many retailers and quite some importers require their suppliers to meet corporate standards. Retailers and importers in the UK are the most advanced with respect to establishing corporate standards. France and Germany meanwhile catch up, both because of the growing interrelation of markets and increasing consumer concerns and administrative pressure (especially in Germany).

As a reaction to BSE and foot and mouth disease, for example, two thirds of German trade companies implemented measures to examine the quality of meat products, 80% introduced more stringent product controls at entry, and all require more stringent product standards of suppliers. Among German processors, 60% dictated quality requirements, 70% changed recipes following incidents (e.g. excluding beef), and 50% improved control at factory entry to test hormones and antibiotics (i.e. improved additional tests that are not related to BSE or foot and mouth disease). 80)

Despite the growing tendency to apply joint standards as described in chapter 4.3.4 and 4.3.5 (institutional standards), retailers as well as some importers and processors still require suppliers to respect their corporate standards. For fresh fruit and vegetables, the first ones have meanwhile been benchmarked against EUREPGAP (see chapter 4.3.4.1).

Corporate level - Private standards

Objectives To keep existing and gain new market shares in a highly competitive environment by

offering safe, high quality and innovative products.

Principles In a bid to achieve these objectives, companies define company policies around principles such as:

> · food safety · food quality

· environmental responsibility (GAP)

· origin of products

· increasingly also: traceability, social and ethical responsibility

Foundation The standards are for example based on:

• ISO 9000:2001 ff or ISO 14001

• EN 45001/GLP for laboratory controls

HACCP principles

traceability concept according ISO 9002 or EAN

• social responsibility according to SA 8000

Only few firms have adopted ISO 14001 and SA 8000 so far (e.g. Dole Food Company).

Activity levels

Food safety and quality throughout the production and distribution chain:

• GAP – cultivation and post-harvest management

• GDP - transport, logistics and marketing

quality assessment (grading, point of departure and point of entry)

· HACCP throughout the chain

Source: Lebensmittelzeitung 12.10.2001

Organisational set-up

Most European multiple retailers established systems for quality assurance by

- · establishing departments for quality assurance
- ensuing controls along the process chain (primary produce, manufacturing, product, logistics)
- implementing procedures for product recall

Emerging issues

- Retailers and manufacturers expect "standards to become more stringent with more
 precisely identified processes and control mechanisms. ... standards would extend more
 to non-food areas such as social and labour conditions, environment and even health."
 81)
- In a bid to build a reputation of an environmentally friendly retailer, Wal-Mart, for example, announced a 'green rating system' for the packaging used by their private label suppliers in November 2006. The so-called 'sustainability scorecard' will oblige up to 60,000 suppliers worldwide to reduce packaging material in general, use more renewable materials and establish energy-saving processes.

Further readings

Edeka - Quality management

http://www.edeka.de/EDEKA/Content/DE/ForYou/EDEKAMarken/Qualitaetsmanagement/index.jsp

Marks & Spencer – Our responsibilities – Suppliers

http://www2.marksandspencer.com/thecompany/ourcommitmenttosociety/suppliers/index.shtml

Metro Group - Quality assurance

http://www.metrogroup.de/servlet/PB/menu/1002731_12/index.html Tesco – Our policies – Supply chain standards

http://www.tescocorporate.com/ourpolicies.htm

Further to these food safety and quality management standards, environmental and ethical standards, suppliers have to meet the product specifications of their customers. In times of rising interest of food supply chain operators to avoid food safety risks and – at the same time – to gain a competitive edge, customers (trade, further processing) oblige suppliers to adhere to special requirements (specifications).

Whereas not all importers, wholesalers and processors have established written specifications, most retail groups and many smaller retailers have developed formal and detailed quality specifications. Consignments not meeting the specifications are rejected. In case of failure to meet specifications, a joint solution might be discussed when the relationship is built upon long-lasting and trustful customer-supplier relations. New suppliers though, risk not to be listed when not meeting the specifications with the first consignments. Specifications are not covered by joint standards such as BRC, IFS, SQF, APS or EUREPGAP, etc.

Corporate level - Product Specifications

Objectives

Specifications accompany each order and give detailed information on product-specific requirements to be met by the supplier.

Types of specifications

According to the processes along the food chain, different specifications are to be distinguished:

- · procurement specification
- · intermediate good specification
- end-product specification

Specifying requirements for product characteristics (sometimes also process characteristics) from input procurement, through to production and processing, up to distribution, these specifications have to be aligned with one another in order to ensure that the final product meets the customer's requirements.

⁸¹ Source: OECD (2006), page 26

Contents

Specifications give detailed instructions for example for:

- raw material:
 - (e.g. varieties, grading, category, colour, degree of ripeness, sugar content, nutritional content, degree of defects allowed)
- instructions on manufacturing procedures (recipes)
- control parameters
 - (sensorial characteristics, chemical-physical requirements, micro-biological requirements)
- product presentation
 - (labelling of the lot, keeping quality, packaging)
- storage and transport conditions
- (e. g. temperatures)conformity with the German and EU food law (company requirements usually more stringent than legal provisions)
- additional obligations for the supplier (e.g. prohibition/permission of GMO use, irradiation)
- content of potential allergens