We have seen the general legislative framework by which the EU aims to ensure food hygiene from farm to consumer.

The Hygiene Package

- the hygiene of foodstuffs (Regulation EC/852/2004)
- specific hygiene rules for food of animal origin (Regulation EU/853/2004)
- official controls on products of animal origin intended for human consumption (Regulation EU/2017/625.

The package assigns **responsibility** for food hygiene directly to the various **Food Business Operators** in the food chain through a system of self-regulation, using the method of **Hazard Analysis and Critical Control Points** (HACCP), monitored by official controls.

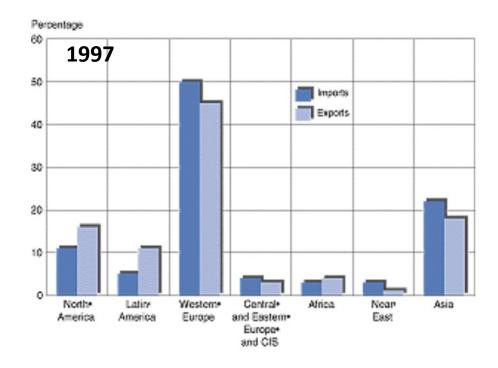
Regulation EC/178/2002 on the general principles of EU food law introduced **traceability** rules, whereby if a food represents a **risk** to health, FBO must immediately **withdraw** it from the market, inform **consumers** and notify the **competent authority**.

Governments recognize that a strong national food industry is an important supplier of food to the population and a significant contributor to **food security**.

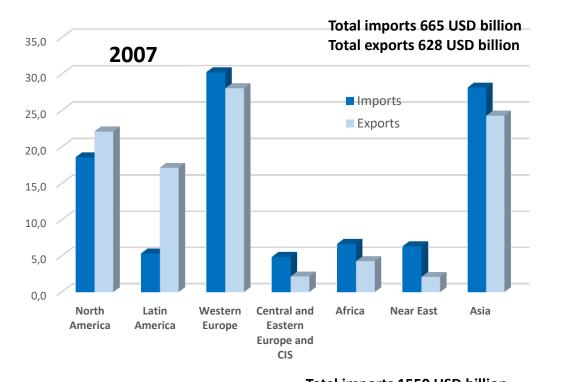
They also view food exports as an important source of foreign exchange.

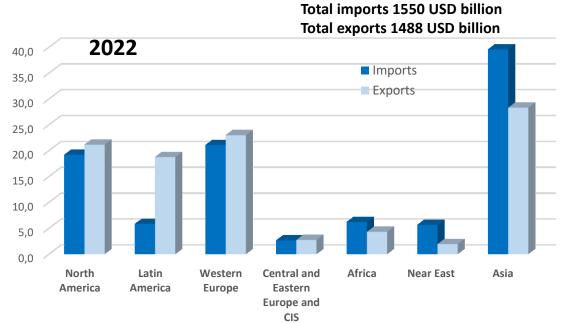
The expansion and diversification of the food trade can be attributed to many factors.

- **First**, the disciplines of food microbiology, food chemistry and food technology are continuously providing a broader range of foods by developing new and more sophisticated preservation, processing and packaging techniques which make foods safer, less perishable and more attractive to the consumer.
- **Second**, rapid transport and improved handling methods have reduced the length of time and difficulties associated with moving food long distances, thus allowing traders access to new and faraway markets.
- **Third**, consumers' tastes and food habits have become more varied and their incomes and purchasing power have risen, stimulating the demand for traditional and new foods from other regions.

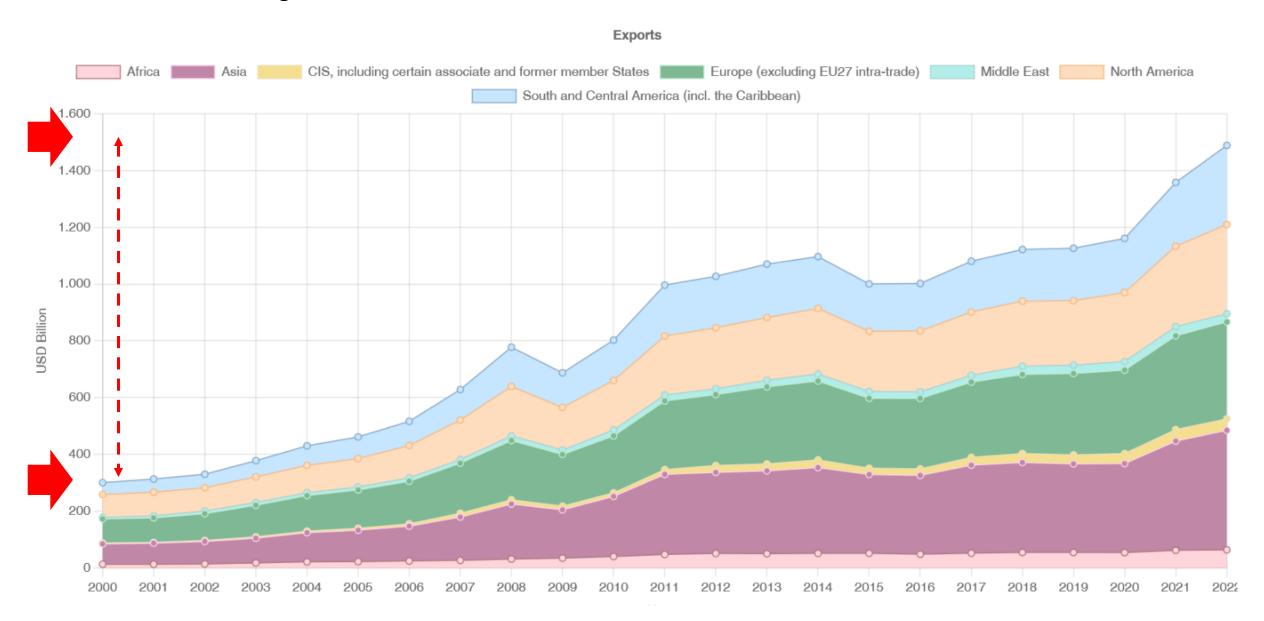


INTERNATIONAL FOOD TRADE World trade of food products by region





World trade of agricultural products, by geographical regions and broad categories of products (Billion US dollars) Source: www.wto.org



Whether a country is a net food importer or exporter may be determined by factors such as local conditions for agricultural production and food manufacturing, costs and demands for domestic or foreign food products and economic activities which provide other sources of income.

An increasing number of countries are becoming both significant importers and exporters of food.

It is customary for countries that are self-sufficient in food or have an excess of food to also **import** some food products.

At the same time, countries that are not self-sufficient in food may **export** some of their products, especially when these foods are much sought after elsewhere and bring premium prices.

REGULATORY CONTROL

International trading in food formerly took place with little, if any, government intervention, and it was accepted that the food producers set their own standards and determined the quality of food products offered to consumers.

Many traders were reputable and responsible and took great care to protect the health of consumers. However, some dishonest food traders found that the unregulated markets gave them an excellent opportunity to exploit consumers through unfair trade practices associated with pricing, misrepresentation of products and misleading labelling.

Such abuses led to government involvement and, over time, the enactment of food laws and regulations and the establishment of food control agencies to ensure that all **domestically** produced food, **imported** food and **exported** food complied with the appropriate laws.

These laws, regulations and agencies comprise the food control system which today provides essential support to the food industry and exporters.

With the increasing volume of trade among countries, difficulties arising from the independent establishment of laws and standards in different countries are becoming evident.

Uruguay Round trade agreements

The Uruguay Round trade negotiations were concluded in 1994 and led to the establishment of the World Trade Organization (WTO) in 1995.

WTO and the associated agreements provide a basis of facilitating international trade and intergovernmental trade arrangements.

During the Uruguay Round, agriculture was included in trade talks in a significant way for the first time. These trade talks led to two binding agreements relevant to food regulations:

- the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
- the Agreement on Technical Barriers to Trade (TBT Agreement).

The **SPS** and **TBT** agreements set important parameters governing the adoption and implementation of <u>food quality</u> and <u>safety measures</u>.

They are designed to minimize the discriminatory and adverse effects of food regulations.

1. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

Purpose: to regulate measures intended to protect human, animal, or plant life or health from diseases, pests, or contaminants.

2. Agreement on Technical Barriers to Trade (TBT Agreement)

Purpose: to ensure that technical regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to trade

World Trade Organization (WTO)

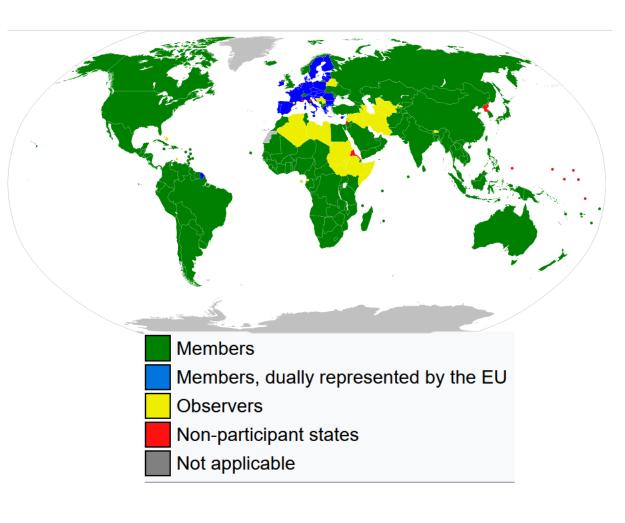
The **World Trade Organization (WTO)** is an intergovernmental organization whose headquarter is in Geneva Switzerland, that regulates and facilitates international trade.

Governments use the organization to establish, revise, and enforce the rules that govern international trade in cooperation with the United Nations System.

The WTO is the world's largest international economic organization, with 166 members representing over 98% of global trade.

The WTO facilitates trade in goods, services and intellectual property among participating countries by providing a framework for negotiating trade agreements which usually aim to reduce or eliminate tariffs, quotas and restrictions in general.

It also administers independent dispute resolution for enforcing participants' adherence to trade agreements and resolving trade-related disputes.



The **Agreement on the Application of Sanitary and Phytosanitary Measures**, also known as the **SPS Agreement** or just **SPS**, is an international treaty of the WTO.

It was negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and entered into force with the establishment of the WTO at the beginning of 1995.

The SPS measures covered by the agreement are those aimed at the protection of **human**, **animal** and **plant** life or health from certain risks.

Under the SPS agreement, the WTO sets constraints on member-states' policies relating to food safety (bacterial contaminants, pesticides, inspection and labelling) as well as animal and plant health (phytosanitation) with respect to imported pests and diseases.

There are 3 organizations who set standards that WTO members should base their SPS methodologies on:

- Codex Alimentarius Commission(Codex),
- World Organization for Animal Health (OIE),
- The Secretariat of the International Plant Protection Convention (IPPC).

Sanitary and Phytosanitary Measures

All countries maintain measures to ensure that food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants.

These sanitary and phytosanitary measures can take many forms, such as:

- requiring products to come from a disease-free area,
- inspection of products,
- specific treatment or processing of products,
- setting of allowable maximum levels of pesticide residues
- permitted use of only certain additives in food.

Sanitary (human and animal health) and phytosanitary (plant health) measures apply to domestically produced food or local animal and plant diseases, as well as to products coming from other countries.

The most important facilitation tools for the international food trade should be identified on:

- Harmonisation
- Equivalence
- Mutual recognition

different Members

Harmonisation is one of the key principles of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), defined as: the establishment, recognition and application of common sanitary and phytosanitary measures by

The SPS Agreement encourages WTO Members to base their SPS measures on international standards, guidelines or recommendations, developed by the three international standard-setting bodies recognised by the WTO for this purpose:

- the Codex Alimentarius Commission (Codex) for food safety,
- the Secretariat of the International Plant Protection Convention (IPPC) for plant health,
- the World Organisation for Animal Health (OIE) for animal health and zoonoses

The SPS Committee is tasked with monitoring the process of harmonisation and the use of international standards

The main instrument to assist countries in the harmonization of food standards is the **Codex Alimentarius**, a collection of internationally adopted food **standards**, maximum residue limits for pesticides and residues of veterinary drugs and codes of practice.

The Codex Alimentarius Commission is cited as the reference point for **standards** relevant to food quality and safety in the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

The objectives of the Codex programme are to protect the health of consumers, to ensure fair practices in the food trade and to promote the coordination of all food **standards** work undertaken by national governments.

According to the ISO (2004), a **standard** is:

a document established by consensus and approved by a recognized body, that provides for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievements of the optimum degree of order in a given context.

It also notes that: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

In contrast, a **technical regulation** is defined as:

a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory

Standards set by public authorities, usually referred to as technical regulations, are typically mandatory.

Private standards by definition are **voluntary** they may in practice become de facto mandatory where compliance is required for entry into certain markets.

Private standards and certification schemes have emerged for a number of reasons.

In the food safety area, private certification schemes emerged to verify compliance with government-mandated requirements for firms to introduce Hazard Analysis and Critical Control Point (HACCP) food safety management systems.

Food safety standards are a set of rules and regulations established by governments, international organizations, and industry bodies to ensure the safety and quality of the food supply chain.

The standards aim to reduce the risk of contamination, reduce the chances of foodborne illnesses, and protect the workers and customers who come into contact with the product.

Typically, food safety standards cover all aspects of food production, from gathering ingredients and materials and processing to packing and distribution. That way, customers and workers have comprehensive protections and controls in place to prevent the risks that come with preparing and manufacturing food products.

Food safety standards vary worldwide. The standards differ depending on the geographical location.

Five significant food standards all over the world:

Food Safety Modernization Act (USA)

The Food Safety Modernization Act (FSMA) is an act that shifted the USA's entire approach to food safety. Enacted by the Food and Drug Authority (FDA), the FSMA is a comprehensive document that contains standards on agriculture, water, food traceability, sanitation, preventive controls.

European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) is the EU's main governing body for food safety standards in EU states. The authority provides scientific data and advice on food-related risks to protect consumers from food-related health and safety risks.

Food Standards Agency (UK)

The Food Safety Standard Agency is responsible for food safety in the UK. The agency works with local authorities to ensure that UK organizations in the food industry adhere to safety standards to lower the risk of foodborne illnesses and safety hazards.

Australian Food Safety Standards

Australia has a long list of food safety standards that apply to all food businesses. It consists of standards for safety programs, food handling tools, and general safety practices and recommendations for those in the food industry.

Food Standards Australia New Zealand (FSANZ) revised these specifications for a particular industry, which must be complied with starting December 2023. According to the updated **Standard 3.2.2A**, businesses in food services, caterers, and retailers must adhere to two or three additional requirements depending on their category.

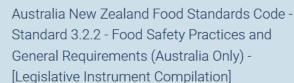
WHO Food Safety Standards (SSA)

The World Health Organization (WHO) has a set of Standards and Scientific Advice on Food and Nutrition (SSA). These international standards set a global benchmark for all food organizations to follow to ensure that consumers face the lowest level of risk possible.

In addition, the WHO has collaborated with the Food and Agriculture Organization (FAO) in developing the Codex Alimentarius, a food safety and quality standard for producers, processors, and distributors of food products around the world.

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STANDARD 3.2.2

FOOD SAFETY PRACTICES AND GENERAL REQUIREMENTS

(Australia only)

Purpose

This Standard sets out specific requirements for food businesses and food handlers that, if complied with, will ensure food does not become unsafe or unsuitable.

This Standard specifies process control requirements to be satisfied at each step of the food handling process. Some requirements relate to the receipt, storage, processing, display, packaging, distribution disposal and recall of food. Other requirements relate to the skills and knowledge of food handlers and their supervisors, the health and hygiene of food handlers, and the cleaning, sanitising, and maintenance of premises and equipment.

Contents

Division 1 - Interpretation and application

Interpretation

2 Application of this Standard

Division 2 - General requirements

3 Food handling – skills and knowledge

4 Notification

Division 3 - Food handling controls

5 Food receipt

Food storage

7 Food processing

8 Food display

9 Food packaging

10 Food transportation

11 Food disposal

12 Food recall

Division 4 – Health and hygiene requirements Subdivision 1 –Requirements for food handlers

General requirement

4 Health of food handlers

15 Hygiene of food handlers

Subdivision 2 - Requirements for food businesses

16 Health of persons who handle food – duties of food businesses

17 Hygiene of food handlers – duties of food businesses

18 General duties of food businesses

Division 5 - Cleaning, sanitising and maintenance

19 Cleanline

20 Cleaning and sanitising of specific equipment

21 Maintenance

Division 6 - Miscellaneous

22 Temperature measuring devices

3 Single use items 4 Animals and pests

25 Alternative methods of compliance

Clauses

Division 1 - Interpretation and application

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Australia New Zealand Food Standards Code -Standard 3.2.3 - Food Premises and Equipment - [Legislative Instrument Compilation]

STANDARD 3.2.3

FOOD PREMISES AND EQUIPMENT

(Australia only)

Purpose

This Standard sets out requirements for food premises and equipment that, if complied with, will facilitate compliance by food businesses with the food safety requirements of Standard 3.2.2 - Food Safety Practices and General Requirements.

The objective of this Standard is to ensure that, where possible, the layout of the premises minimises opportunities for food contamination. Food businesses are required to ensure that their food premises, fixtures, fittings, equipment and transport vehicles are designed and constructed to be cleaned and, where necessary, sanitised. Businesses must ensure that the premises are provided with the necessary services of water, waste disposal, light, ventilation, cleaning and personal hygiene facilities, storage space and access to toilets.

Contents

Division 1 – Interpretation and application

- Interpretation
- Application of this Standard

Division 2 – Design and construction of food premises

- General requirements
- Water supply
- Sewage and waste water disposal
- Storage of garbage and recyclable matter
- Ventilation
- Liahtina

Division 3 - Floors, walls and ceilings

- Application
- 10 Floors
- 11 Walls and ceilings

Division 4 - Fixtures, fittings and equipment

- 12 General requirements
- 13 Connections for specific fixtures, fittings and equipment
- 14 Hand washing facilities

Division 5 - Miscellaneous

- 15 Storage facilities
- 16 Toilet facilities
- 17 Food transport vehicles

GENERAL REQUIREMENTS FOR FOOD PREMISES

(Chapter I, Annex II, Reg. EU/852/2004)



Temperature control

The layout, design, construction, siting and size of food premises are to:

- where necessary, it must be provided suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at **appropriate temperatures** and designed to allow those temperatures to be **monitored** and, where necessary, **recorded**.

Codex Alimentarius

- Impacted quality and safety of world food supply
- Upgraded standards for manufacturing, processing, safety and quality throughout world
- Increased international trade 800% since 1962
- Contributes to lowering of trade barriers and protectionism

Codex Alimentarius

- Ensures that products complying with Codex standards can be bought and sold on the international market without compromising health or interests of consumers
- Codex standards ensure product is safe internationally
- Review of member laws based in internationally accepted scientific and technological standards

Codex Alimentarius

- Codex standards cover all the main foods, whether processed, semi-processed or raw that are intended for sale for the consumer or for immediate processing.
- Codex provisions concern the hygienic and nutritional quality of food, including microbiological norms, contaminants, food additives, pesticide and veterinary drug residues, labelling and presentation, and methods of sampling and risk analysis.

Structure of Codex Commission

- Inter-governmental body
- Open to all UN member nations
- Currently 165 members (98% of world)
- Executive Committee oversees Commission activities
- Secretariat oversees Executive Committee (located at FAO in Rome)

Subsidiary Bodies in the Codex

The structure of the Codex Alimentarius Commission (CAC) consists of the Commission, the Executive Committee and the **subsidiary bodies**.

Two kinds of **subsidiary bodies** can be established and these are classified as general subject committees and commodity committees.

- **General Subject Committees** are so called because their work has relevance for all Commodity Committees
- **Commodity Committees** have the responsibility for developing standards for specific foods or classes of food

Subsidiary Bodies in the Codex

General Subject Committees

- Food Additives (China)
- Food Hygiene (USA)
- Food Labelling (Canada)
- Methods of Analysis and Sampling (Hungary)
- Pesticide Residues (China)
- Residues of Veterinary Drugs (USA)
- Food Import and Export Inspection and Certification
 Systems (Australia)
- Contaminants in Foods (Netherlands)
- Nutrition and Foods for Special Dietary Use (Germany)

Commodity Committees

- Milk and Milk Products (New Zealand)
- Processed Fruit and Vegetables (USA)
- Meat Hygiene (New Zealand)
- Fish and Fishery Products (Norway)
- Fresh Fruit and Vegetables (Mexico)
- Fats and Oils (Malaysia)
- Sugars (United Kingdom)
- Cereals, Pulses and Legumes (USA)
- Vegetable Processes (Canada)
- Natural Mineral Waters (Switzerland)
- Cocoa Products and Chocolate (Switzerland)

Acceptance

Member nation must formally accept Codex standard

Types of acceptance:

- Full Acceptance
 — Product distributed freely under standard name if complies with Codex standard
- Acceptance with specified variations
 Product distributed freely only if complies with standard and variation

Variations in the procedures of national food control systems involving monitoring and sampling, detection and analytical methods, application of standards and food safety requirements can give rise to trade restrictions.

On some occasions countries have developed standards that were not based on science and in effect were nothing more than **non-tariff barriers to trade**.

It has become obvious that there is a need to harmonize food requirements globally and there is a growing need for international guidelines and rules.

The Uruguay Round trade agreements – that established World Trade Organization (WTO) - take the approach of adopting **international standards** and codes of practice; this approach can be expected to decrease the variation in requirements imposed in the past by different countries.

Standards and certification schemes operating in fisheries and aquaculture

 1 S = standard, C = Code, G = guidelines, L = label, CS = certification scheme. Source: Adapted from FAO (2009a).

			Market access issues addressed				
	Type ¹	Main market orientation	Food safety	Animal health	Environment	Social/ ethical	Food quality
Codex Alimentarius	S, C, G	Global	$\sqrt{}$	-	_	_	$\sqrt{}$
World Organisation for Animal Health (OIE)	S, C, G	Global	$\sqrt{}$	$\sqrt{}$	_	_	_
GLOBALG.A.P	S, CS	Europe	√	√	√	_	√
Global Aquaculture Alliance (GAA)/ Aquaculture Certification Council (ACC)	CS, L	United States	V	_	V	√	-
Naturland	CS, L	Europe	√	_	V	√	√
Friend of the Sea	C, S	Global	_	_	\checkmark	_	_
Seafood Watch	C, L	United States	_	_	\checkmark	_	_
Alter-Trade Japan (ATJ)	C, L	Japan	_	_	$\sqrt{}$	V	?
Federation of European Aquaculture Producers (FEAP) code of conduct	С	Europe	V	$\sqrt{}$	V	V	V
Safe Quality Food (SQF)	S, L, CS	Global	V	_	_	_	√
British Retail Consortium (BRC)	S, L, SC	Global	\checkmark	_	_	_	\checkmark
Quality Certification Services (QCS)	CS, L	Global	\checkmark	-	_	_	$\sqrt{}$
Fairtrade	L	Global	_	_	_	\checkmark	_
ISO 22000	S	Global	\checkmark	_	\checkmark	_	\checkmark
ISO 9001/14001	S	Global	_	_	\checkmark	_	$\sqrt{}$
Marine Stewardship Council (MSC)	C, S, L	Global	_	_	\checkmark	_	_
Fair-Fish	S, L	Switzerland	_	$\sqrt{}$	\checkmark	\checkmark	_
International Social and Environmental Accreditation and Labelling Alliance (ISEAL)	S, C, L	Global	-	_	V	\checkmark	_
Scottish Salmon Producers' Organization (SSPO), Code of Good Practice (COGP)	C, L	Global	V	V	V	-	V

		Main market orientation	Market access issues addressed					
	Type ¹		Food safety	Animal health	Environment	Social/ ethical	Food quality	
Pêche responsable Carrefour, France	C, L	Global	-	-	\checkmark	-	_	
SIGES Salmon Chile	CS, L	Europe, United States	\checkmark	\checkmark	\checkmark	-	\checkmark	
Shrimp quality guarantee ABCC, Brazil	CS, C, L	United Kingdom, Europe	V	√	V	V	√	
Thai quality shrimp, GAP, Thailand	S, L	Europe, United States	V	_	-	-	√	
COC-certified Thai shrimp, Thailand	S, L	Europe, United States	√	√	V	√	-	
International Federation of Organic Agriculture Movements (IFOAM)	S, L	United Kingdom, Europe	√	√	√ Organic	V	√	
Soil Association	S, L	United Kingdom	√	√	√ Organic	√	√	
Agriculture Biologique	S, L	Europe	√	√	√ Organic	_	_	
Bioland, Germany	CS, L	Europe	√	√	√ Organic	_	_	
Bio Gro, New Zealand	S, L	Global	√	V	√ Organic	_	_	
Debio, Norway	CS, L	United Kingdom, Europe	√	√	√ Organic	-	-	
KRAV, Sweden	C, L	Europe	V	√	√ Organic	-	_	
BioSuisse	C, L	Switzerland	√	√	√ Organic	-	_	
National Association for Sustainable Agriculture, Australia (NASAA)	C, L	Global	√	√	√ Organic	-	-	
Irish Quality salmon and trout	C, L	Europe	$\sqrt{}$	$\sqrt{}$	√ Organic	-	√	
Label Rouge, France	C, L	France, European Union	\checkmark	_	-	-	√	
La truite charte qualité	C, L	France, European Union	\checkmark	_	_	-	\checkmark	
Norway Royal Salmon	S, L	Europe	$\sqrt{}$	$\sqrt{}$	-	-	√	
Norge Seafood, Norway	S, L	Europe	_	_	√	_	-	
Qualité aquaculture de France	S, L	France, European Union	-	_	\checkmark	-	√	
Shrimp Seal of Quality, Bangladesh	S, L	Global	√	_	√	√	√	
China GAP	C, CS	Global	√	√	_	_	√	
Fishmeal and fish oil Code of Responsible Practice (CORP)	C, CS	Global	V	_	√ Sustaina- bility	-	V	
The Responsible Fishing Scheme	C, CS	United Kingdom	-	-	√ Responsible fishing	√ Safety of fishers	-	

 1 S = standard, C = Code, G = guidelines, L = label, CS = certification scheme. Source: Adapted from FAO (2009a).

Standards and certification schemes operating in fisheries and aquaculture

Practice (COGP)

¹ S = standard, C = Code, G = guidelines, L = label, CS = certification scheme. *Source:* Adapted from FAO (2009a).

		Main market orientation	Market access issues addressed					
	Type ¹		Food safety	Animal health	Environment	Social/ ethical	Food quality	
Codex Alimentarius	S, C, G	Global	$\sqrt{}$	-	_	_	$\sqrt{}$	
World Organisation for Animal Health (OIE)	S, C, G	Global	\checkmark	\checkmark	_	_	_	
GLOBALG.A.P	S, CS	Europe	√	√	V	_	√	
Global Aquaculture Alliance (GAA)/ Aquaculture Certification Council (ACC)	CS, L	United States	V	_	V	√	-	
Naturland	CS, L	Europe	√	_	V	√	V	
Friend of the Sea	C, S	Global	_	_	\checkmark	_	_	
Seafood Watch	C, L	United States	_	_	$\sqrt{}$	_	_	
Alter-Trade Japan (ATJ)	C, L	Japan	_	_	\checkmark	V	?	
Federation of European Aquaculture Producers (FEAP) code of conduct	С	Europe	V	V	V	V	$\sqrt{}$	
Safe Quality Food (SQF)	S, L, CS	Global	√	_	_	_	V	
British Retail Consortium (BRC)	S, L, SC	Global	V	_	_	_	V	
Quality Certification Services (QCS)	CS, L	Global	V	_	_	_	V	
Fairtrade	L	Global			_	√		
ISO 22000	S	Global	V	_	√	_	V	
ISO 9001/14001	S	Global	_	-	$\sqrt{}$	_	V	
Marine Stewardship Council (MSC)	C, S, L	Global	_	_	\checkmark	_	_	
Fair-Fish	S, L	Switzerland	_	$\sqrt{}$	\checkmark	\checkmark	_	
International Social and Environmental Accreditation and Labelling Alliance (ISEAL)	S, C, L	Global	-	-	V	V	-	
Scottish Salmon Producers' Organization (SSPO), Code of Good	C, L	Global	V	V	√	_	V	

UNI EN ISO 22000

Food safety management systems

Requirements for any organization in the food chain

UNI EN ISO 22000

Voluntary

It is an internationally recognized voluntary certification standard

Focus

It defines the requirements for a Food Safety Management System (FSMS)

Content

It includes interactive communication, prerequisite programs (PRPs), and the principles of hazard analysis and critical control points (HACCP)

Objective

To provide a systemic framework for controlling food safety risks, improving business performance, and demonstrating compliance with legal requirements.

EC Regulation 852/2004 (Hygiene Package)

Mandatory

This European law is binding on all food businesses

Focus

It defines general hygiene requirements, conditions for controlling hazards, and ensuring food safety, including HACCP principles

Content

It specifies requirements for premises, means of transport, equipment, personal hygiene, and employee training

Objective

To ensure that food is wholesome and fit for human consumption by establishing a self-monitoring system based on the HACCP system.

ISO 22000 is based on Codex Alimentarius fundamentals with special regards for HACCP programme

Relationship between ISO 22000 and Reg. EU/852/2004

Complementarity

The ISO 22000 standard builds on and goes **beyond** the requirements established by Regulation 852/2004

Continuous improvement

Adopting ISO 22000 helps companies implement a more structured and comprehensive food safety management system, which also includes the mandatory elements required by the European regulation.

ISO 22000 is applicable to **all companies** operating **directly or indirectly** along the **agri-food supply chain**, including producers

processors

dealers and users of packaging and materials and objects intended to come into contact with food (FCM)

detergent manufacturers cleaning companies pest control companies industrial laundries

ISO 22000 clarify key concepts that have caused confusion, such as critical control points (CCPs), operational prerequisite programs (OPRPs), and prerequisite programs (PRPs).

PRPs are necessary, but not sufficient, programs for implementing a Food Safety Management System.

The annex II of Reg./EC/852/2004 lists some **general hygiene requirements** applicable to all food business operators.

These generally concern:

Facilities intended for food handling

Places in which food products are prepared, handled, or transformed

Transport

Equipment

Waste

Personal hygiene

Packaging

Heat treatment

Training

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.

This approach, based on the European Community's 1985 "new approach" to standardization, is contained in Article 2.7 of the TBT Agreement.

EQUIVALENCE

For example..... country A, wishing to avoid the growth of *Clostridium botulinum* in meat products uses the approach of nitrate/nitrite addition.

In country B, the same objective is achieved through the approach of activity water control (decrease the aw level up to 0.95 within 3 days from that of start of processing). Since health concerns are identical in the two countries — to avoid the growth of *C. botulinum* - A and B can agree that their technical regulations are essentially equivalent.

Thus, if meat products manufacturers in country A want to export to B, they will not be obliged to satisfy country B's requirement to fit activity water control and vice versa.

This will eliminate the costs of adjusting production facilities to fulfil foreign regulations.

EQUIVALENCE

The concept of equivalence requires countries to develop confidence in their trading partners' health and safety standards without compromising their own health objectives.

Bilateral consultations and the sharing of information are essential to the successful negotiation of equivalence agreements.

For example, if Country A is concerned with foot-and-mouth disease in Country B, the latter must cooperate by letting experts from Country A visit its farm operations and inspect its meat processing facilities.

Mutual Recognition Agreements (MRAs)

Compliance with technical regulations may impede international trade.

In particular, if products are to be exported to multiple markets, multiple testing may be required. Manufacturers can have difficulties in securing approval for their products on foreign markets, for instance because testing experts disagree on optimal testing procedures, from bureaucratic inertia, or even from manipulation of the testing process by protectionist groups.

One of the main difficulties exporters face is costly multiple testing or certification of products. These costs would be drastically reduced if a product could be **tested once and the testing results be accepted in all markets**.

In practice, countries would agree to accept the results of one another's conformity assessment procedures, although these procedures might be different.

Mutual Recognition Agreements (MRAs)

Article 6.3 of the TBT Agreement strongly encourages WTO Members to enter into negotiations with other Members for the mutual acceptance of conformity assessment results. The presence of a high degree of confidence in testing and certification bodies is, in fact, a prerequisite for the good functioning of an MRA.

Article 6.1 of the TBT Agreement recognizes that prior consultations may be necessary to arrive at a mutually satisfactory understanding regarding the competence of the conformity assessment bodies.

It also points out that compliance by conformity assessment bodies with relevant guides or recommendations issued by international standardizing bodies can be regarded as an indication of adequate technical competence.

REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Article 1

Subject matter and scope

1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities.

Article 2

Definitions

10.	•••	•••	•••	•••	 • • •	• •	•••	 	 	 •
11										

12. *conformity assessment* shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

In other words.....

Mutual Recognition Agreements on Conformity Assessment provide for mutual recognition between trading partners of mandatory test results and certificates for certain manufactured products.

This makes trade quicker, easier, and cheaper, while maintaining a high level of safety.

MRAs lay down the conditions under which country A will accept conformity assessment results performed by designated conformity assessment bodies of country B to show compliance with the requirements of country A, and vice-versa.

MRAs include specific sectors and relevant lists of designated laboratories, inspection bodies and conformity assessment bodies in both the EU and the partner country.



EA, the **European co-operation for Accreditation**, is a not-for-profit association, registered in the Netherlands. It is formally appointed by the European Commission in Regulation (EC) No 765/2008 to develop and maintain a multilateral agreement of mutual recognition, the EA MLA, based on a harmonized accreditation infrastructure.

The EA MLA exists to facilitate **fair trade**, **ensure product and service quality** and **reduce technical barriers to trade**.

EA currently has 49 Members. The EA Members are National Accreditation Bodies (NAB) that are officially recognized by their national governments to assess and verify – against international standards – organizations that carry out conformity assessment activities such as **certification**, **verification**, **inspection**, **testing** and **calibration**.







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Natura del Campione / Vs. identificazione: Vino / MANZONI BIANCO DOC VENEZIA OTTOCENTO

Data di Presentazione: 29/06/2022 Lotto: L.UNIPD001

Ricevimento: a mano, prelevato e consegnato dal cliente

Data inizio prove 01/07/2022 Data fine prove: 21/07/2022

I dati sopraindicati che identificano il campione sono forniti dal cliente che se ne assume la responsabilità in merito alla veridicità degli stessi. Il Campionamento è stato eseguito dal cliente.

Determinazione	Valore	U.M.	Incertezza +/-	Metodo
Titolo alcolometrico volumico	13.60	% vol	0.13	OIV-MA-AS312-01 Met B R2021
Densità relativa a 20 °C	0.99103	d 20/20	0.00018	OIV-MA-AS2-01 Met B R2021
Massa volumica a 20 °C	0.98925	g/mL	0.00018	OIV-MA-AS2-01 Met B R2021
Glucosio + Fruttosio	3.1	g/L	0.3	OIV-MA-AS311-10 R2018
Glucosio + Fruttosio + Saccarosio espressi in Glucosio	3.1	g/L	0.3	POP 282 rev3 2022
Acidità volatile	0.25	g/L in ac	cido acentoso	OIV-MA-AS313-02 R2015
Estratto secco totale	22.6	g/L	0.6	OIV-MA-AS2-03B R2012
Estratto senza zuccheri (da calcolo)	19.5	g/L	0.7	DIV-MA-AS2-03B R2012 + OIV-MA-AS311-02 R2009
Anidride solforosa totale	100	mg/L	11	OIV-MA-AS323-04A2 R2021

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

Members must establish SPS measures on the basis of an evaluation of the actual risks involved.

The parameters used in such risk analyses commonly include substantial safety margins as a precautionary measure.

For example, if a country is concerned about the **residues** from a **pesticide** on **imported fruit**, it has two alternatives:

- use an existing international standard to justify its decision,
- conduct its own risk assessment in order to evaluate the food-borne risks and their possible consequences.

Quantitative risk assessment in particular can be a costly process requiring expertise, and an adequate sanitary infrastructure, and this may not always be within the reach of countries with budget constraints and scarce resources. This implies that there are significant advantages in adopting established international standards.

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

An acceptable level of risk can often be ensured in alternative ways.

Once the government has determined its appropriate level of sanitary and phytosanitary protection, it should not choose a measure that is more stringent and trade-restrictive than necessary.

A complete ban on imports of wheat for example may be one way to limit pesticide residue levels causing certain health risks to consumers.

Random **testing** for **maximum residue levels** at the port of entry may be a less trade-restrictive measure than a complete ban of wheat imports, and wheat complying with the relevant residue requirements could safely be distributed on the domestic market.

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

The SPS Agreement allows Members to take precautionary measures in cases of emergency and when sufficient scientific evidence does not yet exist to support definitive measures.

For example, following the BSE scare in 1996, and in the absence of sufficient scientific evidence, several **emergency bans** were immediately introduced. However, these emergency measures should only be provisional. Within a reasonable period of time, governments must seek the additional information needed to carry out a more objective assessment of the risks involved, and review their measures accordingly.

Beef Hormone Dispute

A prominent SPS case is the hormone-treated beef case.

In 1996, the United States and Canada challenged before the WTO Dispute Settlement Body (DSB) a number of EU directives prohibiting the importation and sale of meat and meat products treated with certain growth hormones.

The complainants alleged that the EU directives violated, among other things, several provisions of the SPS Agreement.

The EU contended that the presence of the banned hormones in food may present a risk to consumers' health and that, as a consequence, the directives were justified under several WTO provisions authorizing the adoption of trade-restrictive measures that are necessary to protect human health.

In 1997 and 1998, the WTO adjudicating bodies admitted USA and Canada claims and invited the EU to bring the directives into conformity with WTO law before the end of May 1999.

Hormone-treated beef

(2)

Beef Hormone Dispute

EU did not comply and the DSB authorized the US and Canada to take countermeasures against the EU. The countermeasures took the form of increased custom duties applied by the US and Canada on certain EU products, including the notorious Roquefort cheese.

In 2004, while the ban on hormone-treated meat was still in place, the EU initiated before the DSB new proceedings seeking the lifting of the countermeasures applied by the US and Canada.

EU alleged that it had collected new scientific data evidencing that the banned hormones may cause harm to consumers.

According to the EU, the new scientific data provides sufficient ground for the ban on hormones, which may no more be sanctioned by the countermeasures imposed by the US and Canada.

Hormone-treated beef (3)

Beef Hormone Dispute

Discussions between the United States and the EU resulted in the conclusion of a Memorandum of Understanding ("Beef MOU") on May 13, 2009.

The Beef MOU provides for increased, duty-free access to the EU market for beef produced without certain growth promoting hormones and maintains increased duties on a reduced list of EU products. Under the terms of the Beef MOU, after three years, duty-free access to the EU market for beef produced without certain growth promoting hormones may increase and the application of all remaining increased duties imposed on EU products may be suspended.

The Beef MOU also suspends further litigation in the EU

The disputes

When a dispute occurs between two countries, WTO encourages them to find a mutually acceptable solution.

If this is not possible there are several optional dispute procedures, including good offices, conciliation, mediation and arbitration.

Alternatively, an impartial panel of experts may be convened to hear all sides of the dispute and make recommendations.

If the panel concludes that a country is violating its obligations under either of the Uruguay Round agreements, it will normally recommend that the country take such action as necessary to bring its offending measures into conformity with its obligations under the agreement.

The Agreement on Technical Barriers to Trade (the TBT Agreement) is a multilateral agreement administered by the World Trade Organization.

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**. The TBT covers all types of standards 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.

Testing or certification procedures are examples of technical barriers to trade.

For instance, a Canadian entrepreneur may have a product certified by the Canadian Standards Association (CSA), but that certification may not be valid in other countries. This forces the company to recertify the product in the country where they wish to sell it, a potentially costly and time-consuming procedure.

The World Trade Organization's Technical Barriers to Trade Agreement aims to reduce these barriers to trade. The goal is to create a more open and competitive marketplace.

While allowing all WTO members to maintain their right to adopt regulations to pursue legitimate objectives – such as the protection of public health, consumers and the environment – the TBT Agreement aims to:

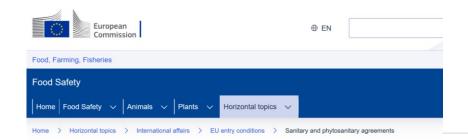
- Prevent the creation of unnecessary technical barriers to international trade;
- Prevent the adoption of protectionist measures;
- Encourage global harmonisation of technical requirements and mutual recognition of test results and certificates,
- Enhance transparency.

The European Union's participation in the TBT Agreement helps businesses in EU Member States access markets in countries outside the EU.

Under the TBT Agreement, WTO members must notify their draft technical regulations and conformity assessment procedures to fellow WTO members.

This gives all WTO members and economic operators advance knowledge of the measures envisaged, to assess their potential impact on exports and to identify any provisions breaching the TBT Agreement.

Companies can use the notification procedure as a source of information on product requirements in non-EU countries. They can make appropriate preparations to make sure their products comply with these requirements.



Sanitary and phytosanitary agreements

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EU-New Zealand agreement

EU-San Marino veterinary agreement

EU-Switzerland agreement

EU-USA agreement

EU-Central America

Council Decision of 25 June 2012 on the signing, on behalf of the European Union, of the
Agreement establishing an Association between the European Union and its Member States, on the
one hand, and Central America on the other, and the provisional application of Part IV thereof
concerning trade matters

EU-Chile agreement

- Decision no 1/2006 ⊕ of the joint management committee of 9 november 2006 amending appendices ic, iiia, iiib and xi to annex iv to the agreement
- Agreement establishing an association between the European Community and the EU countries, of the one part, and the Republic of Chile, of the other part. (Annex IV Agreement on Sanitary and Phytosanitary measures applicable to trade in animals and animal products, plants, plant products and other goods and animal welfare)
- Council Decision

 of 18 November 2002 on the signature and provisional application of certain provisions of an Agreement establishing an association between the European Community and the EU countries, of the one part, and the Republic of Chile, of the other part
- Decision 1/2003 of the Joint Management Committee of 24 October 2003 concerning the rules of procedure

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