Box 3.1 Standards

The WTO TBT Agreement clearly distinguishes standards from "technical regulations" (a type of legislation) in its Annex 1 definitions: standards are voluntary in application, whereas technical regulations are mandatory. This essential difference is also recognized by the EU. For example, the first recital of Regulation 1025/2012 states: 'The primary objective of standardization is the definition of voluntary technical or quality specifications'. The key characteristics of standards as distinct from legislation include:

Legislation	**Standards**
Mandatory	Voluntary
Created by legislator	Developed by interested parties through private standardization organizations' processes
Consultation depending on public authorities' policies[110]	Full open and transparent public consultation
Decided by legislator	Based on consensus of interested parties
Revised when legislator decides[111]	Considered for revision at least every 5 years
For the New Approach / New Legislative Framework	
Sets high-level essential requirements	Offer technical means of meeting essential requirements of legislation

Source: CEN-CENELEC Guide 30: European Guide on Standards and Regulation - Better regulation through the use of voluntary standards - Guidance for policy makers, Edition 1, 2015-06. Viewed at: ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/30_CENCLCGuide30.pdf.

3.113. The European standardization system was reviewed in 2011 and 2012 and was covered in previous TPR reports. The resulting standards regulation[112], adopted in October 2012, clarifies the relationship between regulations and standards, and confirms the role of the three European standards bodies in developing harmonized standards. The emphasis is also on cooperation between European standardization organizations and international standardization bodies. According to the Commission, the adoption of the Regulation on European standardization has created a framework for a more transparent and efficient European standardization system for industry sectors. This Regulation also deals with the rapid evolution of technology and the way in which new products and services, such as 'smart' or connected devices (referred to as the 'Internet of Things') or the Cloud, transform markets. The process outlined in Articles 13 and 14 seeks to ensure that innovative state-of-the-art global information, communication and technology (ICT) specifications can be used in Europe as enablers for innovation and growth.[113]

[110] According to Article 11 of the Treaty on the European Union, 'the European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent'. Consultation is a continuous process and formal stakeholder consultations complement the Commission's broader interaction with stakeholders (e.g. meetings or exchanges or through existing permanent platforms for dialogue). In the process of the evaluation or the preparation of a legislative or policy initiative or the implementation of an existing intervention, "stakeholder consultation" should be carried out. Stakeholder consultation is governed by four principles: participation, openness, effectiveness and coherence. See: http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm.

[111] The Commission is committed to evaluating, in a proportionate way, all EU spending and non-spending activities intended to have an impact on society or the economy. A commitment to evaluation is included in Article 318 of the TFEU. More specific requirements are often written into individual legal acts. Furthermore, the Commission examines all suggestions from stakeholders, and submits those relevant - on how to make EU laws more effective and efficient - to the REFIT Platform for advice. In general, EU product regulations are evaluated at least every five years. See: http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm.

[112] Regulation (EU) No. 1025/2012 of the European Parliament and the Council of 25 October 2012 on European standardization, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council, and repealing Council Decision 87/95/EEC and Decision No. 1673/2006/EC of the European Parliament and of the Council, OJ L 316/12 of 14 November 2012.

[113] European Commission (2016), *ICT Standardisation Priorities for the Digital Single Market*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2016) 176 final, 19 April 2016.

3.114. In a 2016 Communication[114], the Commission elaborated a comprehensive approach to standardization for priority ICT technologies that play an essential role in the completion of the Digital Single Market.

3.115. To reinforce the partnership between the European institutions and the European standardization community, the Commission announced in its Single Market Strategy its intention to launch a Joint Initiative on Standardization, bringing together public and private institutions and organizations in a collaborative dialogue process. The shared objective is to establish common standardization values, to promote European and international standardization, to develop standards in a timely, open, transparent and inclusive manner, to support and promote innovation for all and to increase competitiveness of European companies by increasing global value chains. This will be done by implementing 15 specific actions by 2019 in order to strengthen not only the European standardization system but also the public-private-partnership at the basis of it.

3.116. On 1 June 2016, the Commission adopted a Standardization Package on *European Standards for the 21st Century*, containing four elements: (i) a Communication on *European Standards for the 21st Century*[115]; (ii) a staff working document on *Tapping the potential of European service standards to help Europe's consumers and businesses*[116]; (iii) a report from the Commission to the European Parliament and Council on the implementation of the Standards Regulation (EU) 1025/2012[117]; and (iv) the annual Union work programme for European standardization for 2017.[118] This was followed on 13 June 2016 by the signature of the Joint Initiative on Standardisation.

3.3.1.1 Institutional framework

3.3.1.1.1 ESOs

3.117. There are three European standardization organizations (ESOs): the European Committee for Standardization (CEN); the European Committee for Electrotechnical Standardization (CENELEC); and the European Telecommunications Standards Institute (ETSI). The members of CENELEC and CEN include the national standards bodies (NSBs) of 33 European countries, including all the member States of the EU, EFTA countries, and those countries candidates for EU membership that fulfil the membership criteria. It is a condition of membership of both CEN and CENELEC that at least 80% of European standards are adopted identically by each member.[119]

3.118. Specific CEN activities cover: accessibility, air and space, bio-based products, chemistry, construction, consumer products, energy and utilities, food, health and safety, healthcare, heating, ventilation and air conditioning, ICTs, innovation, machinery safety, materials, measurement, nanotechnologies, pressure equipment, security and defence, services, transport and packaging.

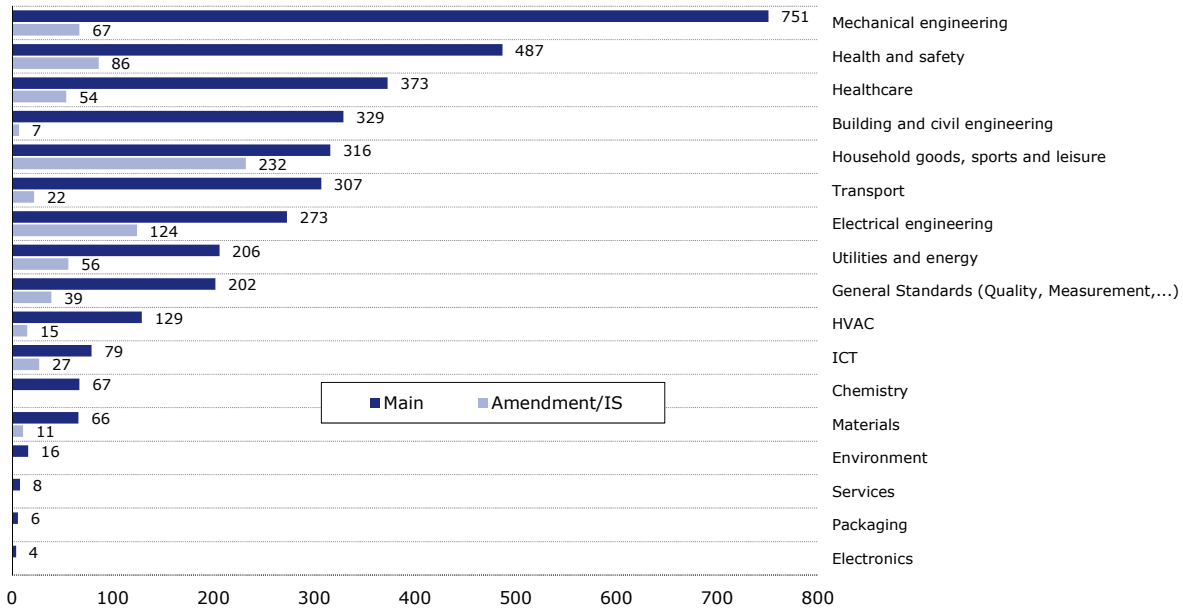
3.119. Specific CENELEC activities cover electro-technical standardization in sectors including: electric vehicles, smart grids and smart metering, household appliances, electrical engineering, fibre optic communications, fuel cells, medical equipment, railways, and solar electricity systems. An increasing number of sectors are being addressed together by CEN, CENELEC and ETSI regarding, for example, innovative technologies, smart grids and eco-design.

3.120. ETSI specializes in telecommunications, broadcasting and services standards, and uses a different participation model to CEN and CENELEC. ETSI's membership includes global industry players as well as NSBs and others. ETSI allows direct participation in its technical committees from businesses including non-EU companies that have interests in Europe, and its standards are freely available on its website. As with CEN and CENELEC, ETSI is subject to EU Regulation 1025/2012 in relation to its activities as an ESO.

[114] Communication from the Commission: *ICT Standardisation Priorities for the Digital Single Market*. Brussels, 19 April 2016 in COM(2016) 176 final.
[115] Document COM(2016)) 358 final.
[116] Available at: http://ec.europa.eu/DocsRoom/documents/16823.
[117] Document COM/2016/0212 final.
[118] Document SWD (2016) 185 final.
[119] European Commission online information. Viewed at: https://ec.europa.eu/growth/single-market/european-standards/key-players_en [November 2016].

3.121. ESOs are the only organizations authorized to create European standards (EN). As of September 2016, 19,854 European standards (ENs and HDs) have been created by CEN and CENELEC for products and services, of which around 20% are defined as harmonized standards.[120] In addition, there are around 40,000 standardization deliverables by ETSI.[121] In 2015, CEN and CENELEC approved and published some 473 harmonized standards which were intended for citation in the EU *Official Journal*, in support of specific directives and regulations.[122] CEN and CENELEC also accepted 14 new standardization requests from the European Commission, relating, *inter alia*, to eco-design and energy labelling of energy related products. An overview of harmonized standards by business domain in 2016 is given in Chart 3.7.

Chart 3.7 CEN-CENELEC Portfolio of Harmonized Standards per business domain



Source: CENELEC. CEN-CENELEC Quarterly Statistical Pack 2016 Q4. Viewed at: ftp://ftp.cencenelec.eu/EN/AboutUs/InFigures/CEN-CENELEC_StatPack2016-Q4.pdf [February 2017].

3.122. Standards are created or modified by experts in technical committees or working groups. The members of CEN and CENELEC are the national standards bodies of the member States, which monitor and delegate experts to participate in ongoing European standardization. European standards, always CEN/CENELEC/ETSI ones, are implemented as national standards by each of the 33 members of CEN/CENELEC/ETSI and "conflicting national standards shall be withdrawn"[123], which results in a single standard for accessing the EU single market. CEN and CENELEC rules require that, when work is started on a European standard, a 'standstill' procedure applies, and members cannot start or continue national work on the same subject. National standards' development has to be reported at least annually by each NSB under EU Regulation (EU) No. 1025/2012 to provide transparency on national work programmes. In the case of harmonized standards, standstill and withdrawal are compulsory.

3.123. CEN and CENELEC standards are significantly aligned with ISO and IEC standards. According to the latest statistics available, 72% of all the standards in the CENELEC catalogue are identical to IEC standards, while 32% of standards in the CEN catalogue are identical to ISO publications.[124] Participation in international standards development is arranged by the NSB of each country via their membership of the International Organization for Standardization (ISO) and

[120] CEN-CENELEC Guide 30, p. 5. Viewed at: ftp://ftp.cencenelec.eu/EC/EuropeanStandardization/Guides/30_CENCLCGuide30.pdf.
[121] On the ETSI website, the figure is 40,517 standards in the database including all versions of the standards.
[122] Annual Report 2015, p. 2.
[123] CEN-CENELEC Guide 30, p. 8.
[124] CEN-CENELEC Quarterly Statistical Pack, Q4 2016, p. 13. Viewed at: ftp://ftp.cencenelec.eu/EN/AboutUs/InFigures/CEN-CENELEC_StatPack2016-Q4.pdf.

the International Electrotechnical Commission (IEC) or their European counterparts, CEN and CENELEC.

3.3.1.1.2 European Commission

3.124. In addition to the three ESOs, the European Commission plays a role in standardization by funding participation in the standardization process by small and medium-sized companies and non-governmental organizations, such as environmental and consumer groups and trade unions. The Commission issues standardization requests for harmonized standards in support of EU policy and legislation, and supports financially the work of the ESOs, but is not involved in the process of standard-setting, which is carried out by the ESOs. EU-funded research and innovation projects also make their results available to the standardization work of the standards-setting organizations (Table 3.12).

Table 3.12 Roles of main actors in setting and executing EU standardization policy (Commission-requested standardization)

Main actors	Tasks and/or roles
The legislator (the Council, including member States, and the European Parliament)	- sets the legal framework and boundaries for standardization policy; - decides how to use standards or other technical specifications in Union legislation; - may challenge harmonized standards providing, or intended to provide, a legal effect (formal objection); - in some cases, a member State may regulate how standards requested by the Commission can be used to comply with national conditions.
Commission	- implements Union standardization policy and sets priorities; - proposes new legislation where application is supported by standards; - manages other specific standardization-related tasks assigned to it in Union legislation (e.g. adoption of standardization requests, assessment of compliance of documents drafted by ESOs with its initial requests, publication of the references of harmonized standards in the *Official Journal*, adoption of decisions to remove publication of the references of harmonized standards from the *Official Journal*, management of Union financing on European standardization); - manages relations between the Union and the ESOs.
ESOs (together with their members and stakeholders)	- execute the technical work requested in standardization requests; - coordinate the technical work to develop and adopt state-of-the-art technical specifications in cooperation with their members on the basis of consensus between those participating in the standardization work; - ensure that the transparency and inclusiveness requirements in the regulation are respected and appropriately reported; - offer the references of the requested technical specifications to the Commission, which then assesses the compliance of technical specifications with the requirements of the relevant Union legislation.
European stakeholder organizations meeting the criteria in Annex III and financed by the Union (Annex III organizations)	- have a specific status under the regulation to make the Commission-requested standardization process more inclusive; - ensure that SMEs', consumers', workers' and environmental interests are made known to the Commission before the Union work programme (UWP) or new standardization requests are adopted; - have direct access to policy development and technical work within the ESOs on the basis of the regulation.

Source: European Commission Staff Working Document: Vademecum on European standardisation in support of Union legislation and policies. Part I: Role of the Commission's standardization requests to the European standardisation organisations, p. 11. Document SWD(2015) 205 final, Brussels, 27.10.2015. Viewed at: http://ec.europa.eu/DocsRoom/documents/13507/attachments/1/translations.

3.125. According to CEN-CENELEC, 19% of European standards in 2016 were developed following a request from the European Commission.[125] The majority of these standards specifically respond to harmonized regulatory requirements across the single market. Other European standards that are not developed to meet European Commission requests meet other market needs. These include test methods, specifications for products and services, business process standards and guidance on good practice.

3.3.1.2 New Legislative Framework

3.126. Existing legislation has been reviewed to bring it in line with NLF concepts, see Box 3.2. The date of applicability depends on the product category.[126] Where products are not regulated by specific EU technical legislation, they are always subject to the EU's General Product Safety Directive[127] as well as to possible additional national requirements.

3.127. An explanation of the different elements of the NLF and how it works is contained in the new version of the Blue Guide on the implementation of EU product rules 2016.[128]

Box 3.2 New Legislative Framework

The NLF aims to: (i) improve market surveillance rules to better protect both consumers and professionals from unsafe products, including those imported from outside the EU. In particular, this applies to procedures for products which can pose danger to health or the environment; (ii) set clear and transparent rules for the accreditation of conformity assessment bodies; (iii) improve confidence in the conformity assessment of products through stronger and clearer rules on the requirements for the notification of conformity assessment bodies; (iv) clarify the meaning of CE marking and enhance its credibility; and (v) establish a common legal framework for industrial products in the form of a toolbox of measures for use in future legislation. This includes definitions of terms commonly used in product legislation, and procedures to allow future sectorial legislation to become more consistent and easier to implement.

The NLF consists of three regulatory elements: (i) **Regulation (EC) 765/2008** setting out the requirements for accreditation and the market surveillance of products; (ii) **Decision 768/2008** on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonization legislation; and (iii) **Regulation (EC) 764/2008** laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country.

Alignment of product legislation: A main objective of the Commission is to bring product harmonization legislation in line with the reference provisions of Decision 768/2008/EC. The following directives and regulations were aligned with these reference provisions:

1. Toy safety - Directive 2009/48/EU
2. Transportable pressure equipment - Directive 2010/35/EU
3. Restriction of hazardous substances in electrical and electronic equipment - Directive 2011/65/EU
4. Construction products - Regulation (EU) No. 305/2011
5. Pyrotechnic articles - Directive 2013/29/EU
6. Recreational craft and personal watercraft - Directive 2013/53/EU
7. Civil explosives - Directive 2014/28/EU
8. Simple pressure vessels - Directive 2014/29/EU
9. Electromagnetic compatibility - Directive 2014/30/EU
10. Non-automatic weighing instruments - Directive 2014/31/EU
11. Measuring instruments - Directive 2014/32/EU
12. Lifts - Directive 2014/33/EU
13. Equipment for explosive atmospheres (ATEX) - Directive 2014/34/EU
14. Radio equipment - Directive 2014/53/EU

[125] Calculation based on the CEN-CENELEC portfolio of harmonized standards cited or to be cited in the OJEU, p. 19 of the CEN-CENELEC Quarterly Statistical Pack, 2016, Q4. Viewed at: ftp://ftp.cencenelec.eu/EN/AboutUs/InFigures/CEN-CENELEC_StatPack2016-Q4.pdf.

[126] For example, the new Electromagnetic Compatibility Directive (2014/30/EU) replaced the existing directive and became applicable on 20 April 2016.

[127] The General Product Safety Directive (GPSD 2001/95/EC) requires that all consumer products on the EU market are safe. The Directive recognizes that national legislation may set legal requirements as to the safety of consumer products that go beyond this general safety requirement. Hence, the harmonization is considered to set a minimum level of safety that must be met in all cases. Generally, the GPSD does not apply to products where there is harmonization legislation in place.

[128] Commission Notice of 5 April 2016; The Blue Guide on the implementation of EU product rules 2016. Brussels, 5 April 2016 C(2016) 1958 final. Viewed at: http://ec.europa.eu/DocsRoom/documents/18027/.

15. Low voltage - Directive 2014/35/EU
16. Pressure equipment - Directive 2014/68/EU
17. Marine equipment - Directive 2014/90/EU
18. Cableway installations - Regulation (EU) 2016/424
19. Personal protective equipment - Regulation (EU) 2016/425
20. Gas appliances - Regulation (EU) 2016/426

Further aligning proposals are pending on medical devices and in vitro diagnostic (IVD) medical devices.

Source: European Commission. Viewed at: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_de.

3.128. An NLF directive requires member States to implement the legislation at national level within a set timeframe. This gives more flexibility to the member States, as they can reflect the principles of the legislation within their own legal and administrative frameworks.

3.3.1.3 Conformity assessment

3.129. The conformity assessment procedure is carried out before the product is placed on the EU market. It is a mandatory step for the manufacturer in the process of assessing and ensuring compliance with specific EU legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages, from design to production, and to allow acceptance of the final product. Conformity assessment procedures in the EU product legislation range from a self-certification examination and production quality control system, to a full quality assurance system, depending on the impact of the product on the protection of public interest (health, safety, environment, etc.). Several pieces of EU legislation require the involvement of a notified body in the conformity assessment process.

3.130. Conformity assessment bodies that have been notified by the national authorities in the member State of their establishment to provide conformity assessment prescribed by EU harmonized legislation are listed in the New Approach Notification and Designated Organizations (NANDO) information system.

3.3.1.3.1 Product marking

3.131. To sell products in the EU market of 28 member States as well as in Norway, Liechtenstein and Iceland, foreign suppliers are required to apply CE marking whenever their product is covered by specific product legislation that provides for this. The CE marking is the manufacturer's declaration that a product meets the requirements of the applicable EC directives. It is the responsibility of manufacturers both within and outside the EU to ensure that their products, where applicable, comply with the relevant directives before affixing the CE marking and placing them on the market in Europe.

3.132. Only the products that fall within the scope of at least one of the 20 or more directives require the CE marking. These include, for example: the Low Voltage Directive (2014/35/EU); the Machinery Directive (2006/42/EC); the Medical Device Directive (93/42/EEC); the Radio Equipment Directive (2014/53/EU); the Restriction of Hazardous Substances Directive (2011/65/EU); and the Electromagnetic Compatibility (EMC) Directive (2014/30/EU).

3.133. The CE marking addresses itself primarily to the national control authorities of the member States, and its use simplifies the task of essential market surveillance of regulated products. As market surveillance was found lacking, the EU adopted the NLF, which entered into force in 2010 (Box 3.2). As mentioned before, this Framework is like a blueprint for all CE marking legislation, harmonizing definitions, responsibilities of economic operators, European accreditation and market surveillance. The CE marking is not intended to include detailed technical information on the product[129], but there must be enough information to enable the inspector to trace the product back to the manufacturer or the local contact established in the EU.

[129] This detailed information should not appear next to the CE marking, but rather on the declaration of conformity (which the manufacturer or authorized representative must be able to provide at any time, together with the product's technical file), or the documents accompanying the product.

3.3.1.4 Accreditation

3.134. Accreditation is the last level of public control in the EU conformity assessment system and is designed to ensure that conformity assessment bodies have the technical competence to carry out their duties. The European Cooperation for Accreditation (http://www.european-accreditation.org) is the organization representing the national accreditation bodies. Membership is open to the national accreditation bodies in countries in the European geographical area that can demonstrate that they operate an accreditation system compatible with appropriate ISO/IEC standards and EU legal requirements.

3.3.1.5 Transparency

3.135. To help prevent the creation of technical barriers to trade, the Commission manages two notification procedures: one for the internal market of the EU and one at WTO level.

3.136. According to Directive (EU) 2015/1535, EU member States must communicate to the Commission any draft technical regulation before its adoption. Starting from the date of notification, a three-month standstill period comes into place, during which the EU member State must refrain from adopting the technical regulation in question. This procedure enables the Commission and other EU member States to examine the proposed text and react to it. The Commission and other EU member States may submit a detailed opinion or comments to the draft if they deem that the notified text may create barriers to the EU internal market. The notified drafts and their translations in all EU languages are available in the Technical Regulations Information Systems database (TRIS).

3.137. At the WTO level, under the TBT notification procedure, between 1 January 2015 and 31 December 2016, the EU submitted 176 notifications under Article 10.6 to the TBT Committee, and individual member States submitted another 52. In the same time-period, WTO Members used the TBT Committee to raise specific trade concerns relating to notifications made by the EU, and the EU raised its own concerns with measures proposed or implemented by other Members.

3.138. The *Official Journal*, as the official publication of the EU, publishes all EU harmonized technical rules, and lists the standards reference numbers linked to legislation (http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm).

3.3.2 Sanitary and phytosanitary measures

3.139. As noted in the last report, to a large extent SPS measures in the EU have been harmonized, and most measures are taken by the EU, although member States may, and sometimes do, take specific measures in specific circumstances.[130]

3.140. EU member States are members of the Codex Alimentarius Commission, the World Organization for Animal Health (OIE), and contracting parties to the International Plant Protection Convention (IPPC). The EU itself is a member of Codex and a contracting party to the IPPC.

3.141. Since the last Review in 2015, a new regulation on transmissible animal diseases (Animal Health Law)[131] and a new law on plant pests (Plant Health Law)[132] were adopted (Table 3.13). In addition, the European Commission noted that a new regulation on official controls is close to

[130] WTO document WT/TPR/S/317/Rev.1, 21 October 2015, para. 3.98.

[131] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law').

[132] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No. 228/2013, (EU) No. 652/2014 and (EU) No. 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC.

adoption. The new regulation will replace Regulation (EC) No. 882/2004[133] and repeal Regulation (EC) No. 854/2004.[134]

3.142. The Animal Health Law is to become applicable on 21 April 2021 and the Plant Health Law on 14 December 2019, except for the provisions relating to a phytosanitary certificate for exports (from 1 January 2021), and a change to the obligation to information the authorities of suspected pests (from 1 January 2017). In the meantime, several implementing measures are to be adopted by the Commission to complement the new rules.

3.143. The new legislation on animal health, plant pests, and official controls are part of the Animal and Plant Health Package which was adopted by the Commission in May 2013. The Package aims to simplify and modernize the existing legislation covering the food chain. It condenses nearly 70 different legislative acts to four, covering: official controls; animal health; plant health; and related financing measures.

Table 3.13 Principal SPS legislation in the EU in 2017

Legislation	Last amended	Note
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	2014	The General Food Law. Regulates the safety of food and feed produced or consumed in the internal market; established a framework for controlling and monitoring the risks and their prevention and management, and created the European Food Safety Authority (EFSA) for the control and evaluation of food and feed.
Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs	2009	On the hygiene of foodstuffs. General rules for food business operators on the hygiene of foodstuffs, putting primary responsibility on the operators, implementation of procedures based on the HACCP principles and good hygiene practice, and ensuring that imported foods are at least the same, or equivalent, hygiene standard as food produced in the EU
Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin	2016	Supplementing Regulation (EC) No. 852/2004. Setting out specific rules on hygiene for food of animal origin for food business operators and applying to unprocessed and processed products of animal origin.
Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption	2015	Setting out specific rules on the organization of official controls on products of animal origin intended for human consumption. The Regulation applies in addition to Regulation (EC) No. 882/2004.
Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules	2014[a]	On official controls for verification of compliance with feed and food law, animal health, and animal welfare rules. The Regulation sets out general rules for the performance of official controls to verify compliance with rules aiming, in particular, at: (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and (b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.
Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption[b]	2013	Setting out rules for the production, processing, distribution, and introduction of products of animal origin for human consumption. The Directive lays down the general animal health rules governing all stages of the production, processing and distribution within the EU and the introduction from third countries of products of animal origin and products obtained therefrom intended for human consumption.

[133] Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

[134] Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

Legislation	Last amended	Note
Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')		Animal Health Law Repeal of Council Directive 64/432/EEC, Council Directive 77/391/EEC, Council Directive 78/52/EEC, Council Directive 80/1095/EEC, Council Directive 82/894/EEC, Council Directive 88/407/EEC, Council Directive 89/556/EEC, Council Directive 90/429/EEC, Directive 91/68/EEC, Council Decision 91/666/EEC, Council Directive 92/35/EEC, Council Directive 92/65/EEC, Council Directive 92/66/EEC, Council Directive 92/118/EEC, Council Directive 92/119/EEC, Council Decision 95/410/EC, Council Directive 2000/75/EC, Council Decision 2000/258/EC, Council Directive 2001/89/EC, Council Directive 2002/60/EC, Council Directive 2002/99/EC, Council Directive 2003/85/EC, Council Regulation (EC) No. 21/2004, Council Directive 2004/68/EC, Council Directive 2005/94/EC Council Directive 2006/88/EC, Council Directive 2008/71/EC, Council Directive 2009/156/EC, Council Directive 2009/158/EC and Regulation (EU) No. 576/2013 of the European Parliament and of the Council. *Inter alia*, the Law consolidates animal health legislation and aims to simplify and clarify the rules relating to prevention and eradication of diseases.
Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No. 228/2013, (EU) No. 652/2014 and (EU) No. 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC		Repeal of Directive 2000/29/EC Protective measures against the introduction of organisms which are harmful to plants or plant products.

a Currently under review (see para 3.141.).
b In addition to Directive 2002/99/EC, there are many other legislative acts in the EU relating to animal health (see the directives repealed by Regulation (EU) 2016/429).

Source: European Commission and Eurlex http://eur-lex.europa.eu/homepage.html.

3.144. The European Commission is responsible for developing draft proposals for legislation and, where the legislation delegates the authority, delegated acts.[135] The Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) is the principal regulatory body responsible for delivering opinions on draft implementing measures. The PAFF Committee is made up of 14 different sections, each responsible for different aspects related to SPS measures.[136] In addition, there are five committees that are also responsible for specific SPS-related issues:

- Regulatory Committee under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms;
- Regulatory Committee under Directive 2009/41/EC on the contained use of genetically modified microorganisms;
- Standing Committee on Plant Variety Rights;
- Standing Committee on Zootechnics; and
- Biocidal Products Committee.

3.145. The EFSA, established under the General Food Law of 2002, is an independent agency responsible for risk assessment for food and feed safety, nutrition, animal health and welfare, plant protection, and plant health, as well as, through environmental risk assessments, the

[135] A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of a legislative act (Article 290 of the Treaty on the Functioning of the European Union). Legal acts adopted by the Commission in this way are referred to as 'delegated acts'.

[136] General Food Law, Biological Safety of the Food Chain, Toxicological Safety of the Food Chain, Controls and Import Conditions, Animal Nutrition, Animal Health and Animal Welfare, Genetically Modified Food and Feed and Environmental Risk, Phytopharmaceuticals, Plant Health, Propagating Material of Ornamental Plants, Propagating Material and Plants of Fruit Genera and Species, Seeds and Propagating Material for Agriculture and Horticulture, Forest Reproductive Material, and Vine.

possible impact of the food chain on biodiversity.[137] The Health and Food Audits and Analysis Directorate (formerly known as the Food and Veterinary Office (FVO)) of the Commission is responsible for audits, inspections, and related activities to assess compliance with EU food safety and quality, animal health and welfare, and plant health legislation within the EU, and compliance with EU import requirements in third countries exporting to the EU.

3.146. The Commission's TRAde Control and Expert System (TRACES) is an online system which manages official controls and route planning for imports of animals, semen and embryos, food, feed and plants which must be accompanied by health certificates and/or trade documents. All harmonized certificates for exporting to the EU are available on TRACES which is used to notify the relevant authorities in the importing member State of the arrival of a consignment.[138]

3.147. According to the Commission, SPS measures taken in the EU are normally based on international standards or, in other cases - including the absence of an international measure - based on the scientific opinion of the EFSA.[139]

3.3.2.1 Plants and plant products

3.148. The new Regulation (EU) 2016/2031 on protective measures against plant pests extends the definition of pests to include non-parasitic plants that could have a severe economic, social, or environmental impact within the EU. It also lists pests as being in the category of quarantine pests or quality pests. Quarantine pests are those that pose the greatest danger for the EU and are to be eradicated and/or protected zones created to prevent their spreading outside areas where they are endemic.

3.149. The new Regulation also includes measures to tackle pests from outside the EU under which the Commission will be able to implement precautionary measures for emerging risks from plants coming from certain non-EU countries. A category of "high risk" plants, plant products or other objects has been created for plants, plant products or other objects which present, on the basis of a preliminary assessment, a pest risk of an unacceptable level for the EU. Therefore their introduction into the EU from a third country will be prohibited, pending the completion of a full risk assessment.

3.150. The new rules also propose to extend, simplify and harmonize the existing plant passport scheme. This means that an extended range of plants, plant products or other objects will need:

- a phytosanitary certificate before being imported into the EU (attesting conformity with Union legislation); and
- a plant passport for movement within the EU.

3.151. Plant passports will also be needed for all movements between professional operators, but not for sales to final non-professional users. The new rules would also require relevant professional operators to be registered in a single register.[140]

3.152. Under the currently applicable legislation on trade in plants and plant products (Directive 2000/29/EC)[141], a phytosanitary certificate from the competent authorities in the exporting country is required for plants for planting, some fruits, vegetables, seeds and cut flowers. Once in the EU, a plant passport may replace the phytosanitary certificate. Imports into the EU of most plants and plant products from most countries do not require prior approval or notification, although they are subject to rules on food safety and customs procedures and inspection. The competent authorities in the member States must be notified of imports of some food and feed products of non-animal origin from specified third countries which must enter the EU through

[137] EFSA online information. Viewed at: http://www.efsa.europa.eu/ [December 2016].
[138] Directorate-General for Health and Food Safety (DG SANTE) online information. Viewed at: http://ec.europa.eu/food/animals/traces_en [December 2016].
[139] WTO document WT/TPR/S/317/Rev.1, 21 October 2015, para. 3.104.
[140] European Council online information. Viewed at: http://www.consilium.europa.eu/en/policies/animal-plant-health-package/plant-health/ [December 2016].
[141] 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.

designated points of entry where they are subject to additional controls.[142] The list of products and exporting countries is reviewed quarterly.

3.153. The procedure for approving genetically modified organisms (GMOs) has not changed. An application for approval for use of a GMO for food, feed, cultivation, or release on the market for other purposes (e.g. cut flowers) must be made to the competent authority in a member State. The EFSA, in collaboration with the member States' scientific bodies, conducts a risk assessment and delivers an opinion. On the basis of the opinion, the Commission prepares draft legislation to grant or refuse authorization. Directive (EU) 2015/412[143] gives the member States more flexibility to restrict or prohibit cultivation of a GMO in their territory either during the authorization procedure, by demanding to exclude their territory from the geographical scope of the application, or, after authorization has been granted, by adopting measures that prohibit or restrict cultivation of specific GMOs. The Commission has also proposed a review of the decision-making process on GMOs.[144]

3.154. As at end-2016, one GMO is approved for cultivation (with ongoing procedures for renewal of authorization) and 72 for food and feed uses. In addition, 3 applications for cultivation and 47 for food and feed uses were pending. There are also 5 GMO flowers approved for sale in the EU.

3.3.2.2 Live animals and animal products

3.155. The new Animal Health Law does not make significant changes to the existing system for the entry into the EU of animals and animal products.

3.156. Under the currently applicable legislation, to export live animals and animal products, products of animal origin for human consumption, animal by-products and derived products to the EU, the competent authority of the exporting country must be recognized as being able to "ensure credible inspection and controls throughout the production chain, which cover all relevant aspects of hygiene, animal health and public health"[145] and provide adequate guarantees.[146] In addition, the country of origin must: be authorized for the specific species of animals or animal products; and, where appropriate, have an approved residue plan for the relevant animal species, a salmonella control programme for poultry and poultry products, and meet other requirements depending on the animal and/or product.

3.157. At the request of the supplying country, the EU normally audits the country to ensure that all the criteria provided for in the EU legislation are met. Based on the results of the audit, the country may then be added to the list of countries authorized to export to the EU. In some cases, and depending on the animal health situation within a country, part of a country may be authorized to export to the EU, or different parts of a country may face different requirements. Additions to the list of approved third countries, territories, zones, or compartments are made through amendments to the relevant legislation following approval of a Commission proposal by the PAFF Committee.[147]

3.158. In addition, an establishment in a third country that would like to export to the EU needs to be added to the list of eligible exporters. It must inform its national authorities, which may then make a request to the Health and Food Audits and Analysis Directorate in the EU, after they have

[142] Commission Regulation (EC) No. 669/2009 of 24 July 2009 implementing Regulation (EC) No. 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.

[143] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the member States to restrict or prohibit the cultivation of GMOs in their territory.

[144] Commission Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 1829/2003 as regards the possibility for the member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM(2015) 177 Final, 22 April 2015.

[145] Commission (2007), *EU import conditions for fresh meat and meat products*, Directorate-General for Health and Consumers.

[146] Commission (2010), *General guidance on EU import and transit rules for live animals and animal products from third countries*, SANCO/7166/2010.

[147] For example, Commission Regulation (EU) No. 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorized for the introduction into the EU of certain animals and fresh meat, and the veterinary certification requirements.

verified that production in the establishment is compliant with, or equivalent to, the requirements laid down in the EU legislation.[148]

3.159. Imports of live animals and animal products must be accompanied by a health certificate issued by the competent authorities of the exporting country, stating that the animals or products meet EU import requirements. Before their arrival on EU territory, the approved Border Inspection Post (BIP)[149] of arrival must be notified through TRACES (at least 24 hours before arrival for live animals) using the Common Veterinary Entry Document (CVED). At the BIP, the consignment must undergo official controls, including documentary, identity, and physical checks, which may include laboratory tests. Depending on the risks associated with the animal product concerned, physical checks may be reduced.[150]

3.160. Where a recurrent problem has been identified with a specific animal product from a third country, special import conditions may be applied, such as reinforced testing or pre-export testing in the country of origin.[151]

3.3.2.3 Rapid Alert System for Food and Feed

3.161. The Rapid Alert System for Food and Feed (RASFF) allows food and feed authorities of the member States and the Commission to exchange information about measures taken in response to direct and indirect risks to human health from food, and human and animal health and the environment from feed.[152] Member States notify risks detected in products already on the market (market notifications) and when products are refused entry into the EU (border rejections).

Table 3.14 RASFF notifications, 2012-15

Year	Alert[a]	Border rejection[b]	Information for attention[c]	Information for follow-up[d]
Original notification				
2012	523	1,712	679	507
2013	584	1,438	679	429
2014	725	1,357	605	402
2015	750	1,380	476	378
Follow-up notification				
2012	2,312	906	664	1,325
2013	2,376	525	763	1,493
2014	3,280	571	670	1,377
2015	4,030	417	538	1,219

a Alert notifications are sent when a food or feed presenting a serious health risk is on the market and when rapid action is required.
b Border rejections concern food and feed consignments that have been tested and rejected at the external borders of the EU (and the EEA) when a health risk has been found.
c Information notifications for attention are related to a product that is present only in the notifying member country, or has not been placed on the market, or is no longer on the market.
d Information notifications for follow-up are related to a product that is, or may be, placed on the market on another member country.

Source: Commission (2016), *RASFF - The Rapid Alert System for Food and Feed - 2015 Annual Report*, Publications Office of the EU, p. 30.

[148] The lists of establishments are available from DG SANTE on: https://ec.europa.eu/food/safety/international_affairs/trade/third_en [December 2016].
[149] Commission Decision of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in TRACES (notified under document C(2009) 7030).
[150] Commission Decision 94/360/EC of 20 May 1994 on the reduced frequency of physical checks of consignments of certain products to be implemented from third countries, under Council Directive 90/675/EEC.
[151] DG SANTE online information. Viewed at: http://ec.europa.eu/food/animals/vet-border-control/special-import-conditions_en [December 2016].
[152] Regulation (EC) No. 178/2002 (General Food Law), Article 50.

3.3.2.4 SPS Committee in the WTO

3.162. The EU and each member State have notified enquiry points under the SPS Agreement.[153] The Directorate-General for Health and Food Safety (DG SANTE) of the European Commission is the EU notification authority.[154]

3.163. In 2015 and 2016, the EU made a total of 107 notifications to the Committee on Sanitary and Phytosanitary Measures in the WTO, of which: 47 were addenda; 8 were emergency notifications; 1 was a supplementary notification; and the remainder were regular notifications. In addition: Germany made 1 emergency notification and 1 regular notification; France made 2 regular notifications, 2 emergency notifications, and 1 addendum; and Slovenia made 1 emergency notification.

3.164. During this period, WTO Members used the SPS Committee to raise two new specific trade concerns about measures taken in the EU or a member State[155] and referred to eight concerns that had been raised earlier.[156] The EU has also used the Committee to raise its concerns in nine cases.

3.3.3 Subsidies and other government assistance

3.165. Subsidies in the EU are granted both out of the EU budget and by member States in the form of state aid. The most recent information and statistical data concerning subsidies granted during the years 2013 and 2014 is contained in the EU's subsidies notification to the WTO and member States' addenda submitted in August 2015.[157]

3.3.3.1 EU level subsidies

3.166. The two largest areas of expenditure out of the EU budget in 2013 and 2014 were agriculture and structural operations, comprising the European Agriculture Guarantee Fund, the European Agricultural Fund for Rural Development, and the Cohesion Fund. Another notable area of expenditure is research. The structural funds comprise the European Regional Development Fund (ERDF) and the European Social Fund (ESF). ERDF resources focus on the co-financing of productive investment leading to job creation and maintenance and investment in infrastructure. The ESF supports programmes in education and job market improvement, and the Cohesion Fund covers member States whose gross national income per inhabitant is less than 90% of the EU average, and, *inter alia*, funds projects in the field of transport and environmental infrastructure.

3.167. The overall goal of the Cohesion policy, the EU's key investment policy, is to support job creation, business competitiveness, economic growth and sustainable development in all regions. The policy is put in place for a seven-year period, currently 2014-2020. The EU's intervention regarding the Cohesion policy is being carried out via the ERDF, the ESF and the Cohesion Fund. The budget for the current 2014-2020 period[158] is estimated to amount to €346 billion, or one third of the EU budget, according to the latest notification. Additional funding from the member States will bring the total amount spent to €477 billion. Outlays under the ERDF, the Cohesion Fund and the ESF amounted to €56.8 billion in 2013 and €52.8 billion in 2014.

[153] WTO document G/SPS/ENQ/16, 21 December 2016.
[154] WTO document G/SPS/NNA/8, 21 December 2016.
[155] EU proposal to amend Regulation (EC) No. 1829/2003 to allow EU member States to restrict or prohibit the use of genetically modified food and feed (ID 396), EU restrictions on exports of pork from the State of Santa Catarina (ID 407).
[156] Agricultural biotechnology approval process (ID 110), France's ban on Bisphenol A (BPA) (ID 346), EU phytosanitary measures on citrus black spot (ID 356), EU ban on mangoes and certain vegetables from India (ID 374), EU withdrawal of equivalence for processed organic products (ID 378), EU revised proposal for categorization of compounds as endocrine disruptors (ID 382), EU proposal to amend regulation (EC) No. 1829/2003 to allow EU member States to restrict or prohibit the use of genetically modified food and feed (ID 396), and EU restrictions on exports of pork from the State of Santa Catarina (ID 407).
[157] WTO document G/SCM/N/284/EU of 7 August 2015; subsidies granted by individual member States are contained in addenda to this notification.
[158] For the programming period 2014–20, the legal basis, according to the EU notification, comprises: Commission Delegated Regulation (EU) No.480/2014 of 3 March 2014 supplementing Regulation EU No. 1303/2013.