3.128. FINEP finances Brazilian research institutions and companies active at every phase and dimension of the scientific and technological development cycle (e.g. basic research, applied research and technological innovation). It also provides financial support for the organization of conferences, seminars and fairs approved by the National Council for Scientific and Technological Development (CNPq).

3.129. FINEP support may take the form of repayable financing, non-repayable financing to non-profit institutions, grants (*subvenção econômica*) to enterprises, and investments in projects and companies.[170] Repayable financing may be provided from both FNDCT and FINEP's own resources. FINEP accepts and analyses such applications continuously, whereas applications for non-repayable financing must be submitted in response to a public call for proposals. Non-repayable financing is funded from the FNDCT budget. It is made available to public universities, research centres, and non-profit institutions in programmes and areas determined by the FNDCT's steering committees.

3.130. FNDCT disbursements totalled R$7.9 billion over the 2013-16 period. Significant shares of this amount were attributable to the CT-INFRA, CT-SAÚDE and CT-PETRO funds. Details on types of support provided and on the beneficiary projects/activities were not available.

3.3.2 Standards and other technical requirements

3.131. Brazil's legal and institutional framework related to the implementation and administration of the TBT Agreement remained broadly unchanged during 2013-2016; no notifications pursuant to Article 15.2 of the TBT Agreement were received at the WTO during this period.[171]

3.132. The National Council of Metrology, Standardization and Industrial Quality (CONMETRO) continues to oversee the National System of Metrology, Standardization and Industrial Quality (SINMETRO), which regroups public and private entities active in metrology, standardization, quality management, and certification at the federal and sub-federal levels. The National Institute of Metrology, Quality and Technology (INMETRO) continues serving as: CONMETRO's Executive Secretariat; the coordinator of the Brazilian Network of Legal Metrology and Quality (RBMLQ-I); the regulatory and supervising authority for legal metrology and compulsory conformity assessment in the areas of security, environmental and health protection, and prevention of deceptive trade practices[172]; and the national enquiry point and notification authority under the TBT Agreement.

3.133. The Brazilian Association for Technical Standardization (ABNT) remains in charge of developing (voluntary) standards. Besides CONMETRO and INMETRO, some 31 federal agencies are responsible for issuing technical regulations and determining conformity assessment systems in their respective areas of competence. Any of these competent agencies may request that INMETRO coordinate conformity assessment activities for a particular technical regulation.

3.134. Brazil's approach to granting equivalence remains based on the acceptance of test results, without explicit recognition of foreign technical regulations. During the review period, Brazil notified to the WTO four plurilateral agreements on TBT matters concluded with other Members, including three new mutual recognition agreements (MRAs) on accreditation.[173] Through INMETRO, Brazil is a party to some 120 TBT-related technical cooperation instruments, of which 89 (including 19 in the field of accreditation) are currently in force. INMETRO also represents Brazil at the Inter-American Accreditation Cooperation, the International Accreditation Forum, the International Laboratory Accreditation Cooperation, the International Bureau of Weights and Measures, the International Organization of Legal Metrology, and in relevant initiatives within MERCOSUR, LAIA, and the Organization of American States.

3.135. As a member of MERCOSUR, Brazil participates in the elaboration, adoption and revision of common technical regulations; the relevant MERCOSUR procedures remained unchanged

[170] Investments may be made either directly or by way of venture capital and seed money funds.
[171] WTO document WT/TPR/S/283/Rev.1, 26 July 2013.
[172] Provisional measure No. 541 of 2 August 2011, converted into Law No. 12,545 of 14 December 2011.
[173] WTO documents G/TBT/10.7/N/129 and 130 (30 June 2016), and G/TBT/10.7/N/131 and 132 (1 July 2016).

during 2013-2017.[174] At the national level, CONMETRO's non-binding Guide on Good Regulatory Practices continues to frame, in principle, the elaboration, dissemination, periodic review, and elimination of technical regulations and conformity assessment procedures.[175] Technical regulations may be established through laws, decrees, ordinances, normative instructions or resolutions, and should be published in the *Official Journal*. A period of six months is typically allowed between the publication of a measure and its entry into force. Ministries and agencies with authority to elaborate and issue technical regulations may do so *ex officio* or at the request of a third party; the holding of public consultations is generally required, except in exceptional cases. In principle, if a proposed technical regulation is considered to have trade effects, INMETRO would forward a draft to the WTO for Members' comments. After all comments and suggestions are taken into consideration, the competent ministry or agency decides whether to adopt the technical regulation, with or without modifications. According to the authorities, most technical regulations enacted in Brazil are based on international standards or MERCOSUR regional standards; when this is not the case, they are based on performance criteria. The recommended period for review and revision of technical regulations is five years.

3.136. Generally, the process for adopting conformity assessment procedures is similar to the one for technical regulations. Conformity assessment may involve certification, performance verification, sampling, labelling, inspection, and a conformity declaration by the supplier; certain activities (e.g., certification) may be delegated to accredited third parties. The supplier's declaration of conformity is an admissible instrument only for products or services of low to medium risk to human health and safety. In general, labelling requirements relate to the products' quality, quantity, composition, guarantee, shelf life, origin, and risks to consumer health and safety. All labels must bear this information in Portuguese and indicate the brand or name of the manufacturer.

3.137. As at 31 December 2016, INMETRO applied the following 148 compulsory conformity assessment procedures: certification (114 products and 10 services); conformity declaration by the supplier (16 products and 10 services); and inspection (6 products and 4 services). Additional compulsory conformity assessment procedures are administered by other competent entities, such as the Brazilian Health Regulatory Agency (ANVISA), the National Telecommunications Agency ANATEL, and MAPA. SISCOMEX (Section 3.1.1.), accessible only to registered users, contains the most up-to-date information on conformity assessment measures affecting imports.[176]

3.138. The marketing of products and services, which are both under INMETRO's authority (directly or through delegation) and subject to compulsory conformity assessment, is conditional on inscription in its Register of items.[177] In addition, importers of products regulated by INMETRO must apply for an import licence through SISCOMEX and request its analysis for approval at INMETRO.[178] Other regulatory agencies, such as ANVISA, MAPA and ANATEL, may also require inscription in their respective registers.

3.139. INMETRO maintains a computerized system (Orquestra) for the management of its Register of items and its non-automatic import licensing activities.[179] As at March 2016, INMETRO's Register contained 32,736 items, up from 13,002 in 2013. The total number of requests for analysis of an import licence rose from 197,326 in 2013 to 754,270 in 2016.

3.140. INMETRO's General Coordination of Accreditation (CGCRE) is Brazil's national accreditation body in the field of conformity assessment.[180] It accredits entities engaging in certification, inspection, calibration, and testing. The accreditation process is managed online through Orquestra and comprises the submission of a formal request, a review of supporting documentation, and an *in situ* assessment. Accredited entities are evaluated periodically. According to the authorities,

[174] WTO document WT/TPR/S/283/Rev.1, 26 July 2013.
[175] CONMETRO (2007), *The Brazilian Guide on Good Regulatory Practices*. Viewed at: http://www.inmetro.gov.br/qualidade/guiaRegulamentacao.asp [06 November 2016].
[176] An indicative list of compulsory conformity assessment procedures can be viewed at: http://www.inmetro.gov.br/qualidade/rtepac/compulsorios.asp
[177] This requirement does not apply to products and services under the regulatory competence of other federal agencies. Items subject to pattern approval by INMETRO are exempted.
[178] INMETRO Ordinance No. 18 of 14 January 2016.
[179] The following fees apply: R$60.01 for analysis of licensing requests; and R$60.01 and R$1,516.46 for the inscription/renewal of products and services, respectively, in INMETRO's Register of items.
[180] Decree No. 7938 of 19 February 2013.

entities seeking accreditation to carry out compulsory conformity assessment activities are generally not required to have a permanent office in Brazil, but a few technical regulations stipulate it as a prerequisite.

3.141. As at January 2017, 382 calibration laboratories and 1,046 testing laboratories were accredited in Brazil. There were also 879 entities with active accreditations to perform conformity assessments (certification, inspection, performance verification). Among the Brazilian-accredited entities, 10 laboratories and 4 certification bodies were located overseas.

3.142. The ABNT coordinates the consensus-based development of Brazilian standards, and represents Brazil in the ISO/IEC and in regional normalization forums. It signed the WTO/TBT Code of Good Practice in 1995 and follows its Annex 3.[181] Standards are elaborated by technical committees and sectoral standardization bodies; all interested parties are allowed to submit requests for new standards and to participate in the standardization work. At present, there are 150 active technical committees. Draft standards are open to national consultation for 60 days. Once a consensus is reached among all interested parties, the standard is published by the ABNT. Standards older than five years are reviewed to ensure that they remain up to date; the review process also includes 60 days of public enquiry. Standards adopted by the ABNT may be used as references in the adoption of technical regulations by INMETRO, especially in the absence of international and regional ones.

3.143. As at March 2017, there were 7,815 standards in force in Brazil. Between January 2013 and January 2017, Brazil adopted 2,557 new standards, some 33% of which were adoptions of international (ISO/IEC) standards. Similar statistics on technical regulations were not made available. Between January 2013 and April 2017, Brazil made 193 regular notifications to the WTO Committee on Technical Barriers to Trade, for the most part under Article 2.9 of the TBT Agreement. In only 12 of the notified cases (6.2% of the total), the timeliness of the submission allowed for a comment period of 60 days or more, whereas in 21.7% of all cases the comment period was less than 45 days.

3.144. Between January 2013 and January 2017, Brazil was asked to respond to four newly raised specific trade concerns at the Committee on Technical Barriers to Trade.[182] During that period, Brazil also joined various delegations in raising 19 specific trade concerns.

3.3.3 Sanitary and phytosanitary requirements

3.145. Brazil's institutional framework for sanitary and phytosanitary (SPS) protection has been altered somewhat since its last Review. In April 2015, the Ministry of Fisheries and Aquaculture (MPA) was abolished and its competences were transferred to MAPA.[183] Consequently, the responsibility for the protection of animal and plant health was consolidated at MAPA, with most relevant SPS controls of domestic production and international trade being carried out by its Secretariat of Animal and Plant Health and Inspection (SDA). ANVISA, an autonomous body, retains regulation and surveillance responsibilities for the protection of human health, including the setting of maximum residue levels of pesticides.[184] ANVISA and MAPA share regulatory and surveillance competences over certain vegetable products. Pre-marketing regulation and surveillance of *in natura* food are the remit of MAPA.

3.146. The National Technical Commission on Biosafety (CTNBio), a multidisciplinary advisory body to the Federal Government, remains Brazil's authority for all activities involving genetically modified organisms (GMOs). Besides assisting in GMO policy formulation and elaborating relevant technical advice, CTNBio acts as the national certifying body for quality systems in biosafety and is the sole issuer of research authorizations and of commercial approvals for GMOs. Entities wishing to engage in any activity involving GMOs must obtain a certificate of quality in biosafety and a prior authorization from CTNBio.

[181] WTO document G/TBT/CS/2/Rev.14, 20 February 2008.

[182] WTO documents G/TBT/M/63, 19 September 2014; G/TBT/M/64,10 February 2015; G/TBT/M/66, 17 September 2015; and G/TBT/M/67, 3 February 2016.

[183] Law 13,266 of 5 April 2016.

[184] Besides coordinating the National Sanitary Surveillance System and sanitary controls at Brazil's borders, ANVISA regulates health services, public health laboratories, and health-related products (including their advertising). It also monitors the prices of pharmaceuticals. ANVISA is connected to the Ministry of Health through a management contract, which is renewed periodically.

3.147. Following the MPA's abolition, Brazil's enquiry points comprise MAPA's Secretariat for International Relations of Agribusiness and ANVISA's Office of International Affairs. The Ministry of Foreign Affairs remains the national notification authority for SPS matters. Brazil submitted 515 notifications, including 1 emergency and 472 regular ones, to the WTO between January 2013 and April 2017. Approximately one fifth of the measures announced in regular notifications were based on international standards. As at the time of its previous Review, the majority of Brazil's notifications allowed for comment periods of less than 60 days and few envisaged a six-month period between publication and entry into force. According to the authorities, comments from interested parties have generally been taken into consideration even after the stipulated deadlines.

3.148. Between January 2013 and January 2017, Brazil raised six new specific trade concerns related to various restrictions on its exports of beef and poultry at the Committee on Sanitary and Phytosanitary Measures.[185] Brazil was also asked to respond to one specific trade concern by China regarding its implementation of a standardized international certificate for fish and fishery products exported to Brazil.[186]

3.149. In May 2015, the SDA elaborated its first Agricultural Defence Plan (*Plano de Defesa Agropecuária*) for the period 2015-2020.[187] The Plan envisages a number of actions, structured along five axes: cutting red tape; updating the legal framework; strengthening strategic support (investigation, risk assessment and risk management); ensuring cost efficiency; and meeting various qualitative objectives. During the review period, the main SPS-related legislative developments and procedural changes concerned: labelling requirements for animal products; overseas inspection procedures for recognition of equivalence (animal products); and trade facilitation improvements in the Brazilian Agricultural Surveillance System. As from January 2016, all communications between MAPA and CTNBio are carried out through an Electronic Information System (SEI), which has accelerated approval procedures. Plans are also under way to involve the SDA and ANVISA in Brazil's AEO scheme (Section 3.1.1).

3.150. Competence for the adoption of SPS measures remains vested in ANVISA and MAPA. According to the authorities, both entities follow similar procedures for the adoption of SPS measures, which generally comply with guidelines issued by relevant international organizations. Under Brazil's SPS system, the conclusions of pest risk analyses are notified, as a draft for comments, to the pertinent SPS authority of the country of origin and to the WTO. After consideration of the comments received, phytosanitary import requirements are publicized in Brazil's *Official Journal* and notified to the country of origin and the WTO; there is no statutory time-frame for the assessment process.[188] Risk assessments for plant pests comply with International Plant Protection Convention (IPPC) standards; in general these assessments are required when there is no record of prior importation of the plant or plant product concerned from a given country. Risk assessments for imports of animals and animal products follow World Organisation for Animal Health (OIE) standards. Sanitary requirements are adopted after public consultations, which are publicized in the *Official Journal* and notified to the WTO.

3.151. Brazil maintains a non-automatic licensing system for imports subject to SPS controls. In addition, the importation of some of these products may require prior authorization, certification (for unrestricted commercialization or quality), and/or inscription in a register. Indicative lists of the goods controlled by the SDA and ANVISA upon importation are available online.[189] Exports of most of these goods from Brazil are also subject to registration and/or authorization requirements. In principle, ANVISA and the SDA issue import and export licences and/or authorizations in their respective areas of competence directly through SISCOMEX. In order to obtain a licence through SISCOMEX, importers of animal products must also request authorization from the SDA department (the Federal Inspection Service) in the Brazilian state where they are based,

[185] WTO documents G/SPS/R/73, 15 January 2014; G/SPS/R/79, 4 September 2015; and G/SPS/R/82, 7 June 2016.

[186] WTO document G/SPS/R/75, 18 September 2014.

[187] MAPA online information. Viewed at: http://www.agricultura.gov.br/arq_editor/PDA2015_2020.pdf [17 October 2016].

[188] Generally, the cost of the risk analysis is borne by the Brazilian Government; however, interested parties may choose to contract, at their own expense, an accredited analyst (university or laboratory).

[189] The products subject to SDA controls upon importation are listed by tariff line (NCM) in the Annex to Normative instruction No. 51 (7 November 2011), viewed at: http://www.agricultura.gov.br/animal/importacao [12 October 2016]. A similar (NCM) list of products controlled by ANVISA is available at: http://portal.anvisa.gov.br/registros-e-autorizacoes/produtos/importacao [12 October 2016].

indicating, *inter alia*, the shipment's point of entry and destination.[190] Authorizations for live animals and reproductive material are issued by SDA representations at the state level, as part of the overall import licensing and authorization formalities.[191] Importers of controlled foodstuffs, cosmetics, and pharmaceutical products must obtain an authorization from ANVISA and a licence from a state or municipal sanitary authority; the licence serves as an authorization from the National Sanitary Surveillance System and is valid throughout Brazil. Some of these products can only be imported after inscription in ANVISA's sanitary register.[192] Pharmaceutical raw materials can only be imported by companies holding an authorization to operate in Brazil, issued by ANVISA.

3.152. Imports of plants and plant products are subject to documentary and inspection requirements that vary according to the product's intended use and its classification in one of five risk categories. Plant products commercialized in Brazil, including imports, must comply with quality-related characteristics (e.g. size, purity, and maturity) laid out in the Brazilian classification system, whenever a specific standard to that effect is in place; the classification of imported plant products is done by MAPA.[193] The importation of seeds for commercial purposes is strictly limited to the species and varieties contained in the National Register of Plant Varieties (RNC) maintained by MAPA.[194] The conformity of imports is verified at the border, either by the SDA or by accredited private companies.[195]

3.153. The prerequisites for the importation of products of animal (including aquatic animal) origin into Brazil include: recognition of the exporting country's sanitary inspection systems as equivalent to Brazil's; accreditation of the exporting establishments; and approval of each establishment's products and labels.[196] Each shipment to Brazil must be accompanied by a sanitary certificate issued by the exporting country's competent authorities, and carry approved labels or stamps. All imports of animal products and their sub-products are physically inspected at the port of entry, with samples taken for laboratory testing whenever necessary.[197]

3.154. Brazil maintains an Importation Alert Regime (RAI) targeting foreign establishments whose shipments of animal products have been found to be non-compliant with Brazilian SPS requirements. Whenever an irregularity is detected and an exporter is placed under the RAI, the SDA carries out 100% physical inspections and laboratory testing of the 10 consecutive shipments (of all products) originating from that establishment.[198] Should another irregularity be detected in the course of the 10 inspections, the establishment's licence to export to Brazil is suspended.[199] If no sufficient evidence of corrective measures taken is received 30 days after notification of the exporting country's competent authorities, the SDA may revoke the establishment's accreditation. In case of recurrent serious irregularities, or if non-compliant shipments are detected from at least three establishments within 30 days, the SDA may suspend the accreditation of all similar establishments from that country or of the country as a whole.[200]

[190] SDA Ordinance No. 183 of 9 October 1998.

[191] MAPA online information. Viewed at: http://www.agricultura.gov.br/animal/importacao [13 October 2016].

[192] Products that require registration are listed in ANVISA Resolution RDC No. 278 of 22 September 2005 (foodstuffs); ANVISA Resolution RDC No. 211 of 14 July 2005 (cosmetics); and ANVISA Resolution RDC No. 132 of 29 May 2003, as amended (pharmaceuticals).

[193] Law No. 9,972 of 25 May 2000 and Decree No. 6,268 of 22 November 2007.

[194] New plant varieties may be included in the register after specific trials designed to verify their adaptation to Brazilian conditions (Normative Instruction No. 50 of 15 December 1998).

[195] The rules and guidelines that regulate inspections of imported plants and their products are laid out in Normative Instruction MAPA No. 36 of 10 November 2006 (WTO document G/SPS/N/BRA/144/Add.1, 28 November 2006 and addenda).

[196] The SDA carries out on-site inspections and sends questionnaires to the SPS authorities of the exporting country to evaluate the procedures followed by its counterparts; on-site inspections of the exporters' establishments are undertaken at the cost of the interested party.

[197] In general, testing is carried out at MAPA laboratories; when necessary, laboratories officially accredited by MAPA may also be used. Testing costs are paid by the owner of the products.

[198] The 10 subsequent shipments must arrive at Brazilian points of entry that have adequate facilities for thorough inspection. Information on the establishments placed under the RAI and the possible points of entry for their shipments is published on MAPA's website: http://www.agricultura.gov.br/animal/importacao/regime-de-alerta-importacao [14 October 2016].

[199] To have the licence reinstated, the competent certifying authorities in the exporting country must provide detailed information on the measures taken to address the problem, and another 10 consecutive shipments from that establishment must successfully undergo thorough inspection and testing.

[200] SDA Ordinance No. 183 of 9 October 1998 and SDA Internal Norm No. 01 of 02 August 2016.

3.155. Exporters of products of animal origin from Brazil must obtain accreditation (*habilitação*) for their target market, conditional on a favourable official opinion (*parecer official*) by the SDA as to the applicant's documentary conformity and capacity to comply with any market-specific SPS requirements. A sanitary certificate must also be obtained from the SDA for each export shipment.[201]

3.156. Establishments that produce, import, or export fertilizers, as well as the products themselves, must be registered with MAPA. The Ministry also maintains a register of pesticides (AGROFIT), which incorporates relevant information from the Ministries of Health and Environment.

3.157. Brazil prohibits the commercialization, including imports and exports, of hormonal substances with anabolic characteristics, unless intended for therapeutic or research use.[202] The use of substances with anabolic hormonal properties for the purpose of promoting growth and weight in bovines and poultry destined for slaughter is banned; imports of hormone-treated meat are also prohibited.[203]

3.3.4 Competition policy and price controls

3.3.4.1 Competition policy

3.158. Since the overhaul of Brazil's competition regime[204] in 2012, there have been no major changes during 2013-16. The Administrative Council for Economic Defence (CADE) remains in charge of competition policy enforcement, including *ex-ante* merger control, investigation of anti-competitive conduct, and administrative adjudication. Consumer protection remains the remit of the National Secretariat for Consumers (SENACON), whereas the Special Secretariat of Economic Monitoring (SEAE) is primarily responsible for competition advocacy, including issuing advisory opinions on competition-related matters (e.g. in regulation, trade, and industrial policies), and sector-wide studies.[205]

3.159. CADE may initiate investigations *ex officio* or on the basis of complaints from any person.[206] Independently of CADE administrative proceedings, which are not to be suspended by virtue of filing a lawsuit, injured parties may seek cessation of anti-competitive practices (and compensation for damages) in civil courts. According to the authorities, court judges may decide to await and take into consideration the outcome of CADE proceedings. Likewise, independent and parallel appeals to CADE decisions may be made before the competition authority itself and a civil court; however, the judicial system has the final say. Due to the peculiarities of Brazil's judicial system and the number of distinct instances for appeal, appeals of CADE decisions may take several years to reach final settlement in a court of law. Since 2007, court injunctions that suspend the enforcement of CADE decisions involving the imposition of a fine require the deposit of the same amount in an account under judicial administration.

3.160. In 2013, CADE implemented a new settlement policy requiring the signatory of a cease-and-desist agreement to collaborate with the investigation, in addition to admitting and ending its anti-competitive conduct. The settlement policy foresees a reduction of the relevant fine according to the contribution provided during the investigation, which has resulted in increasing numbers of completed settlements and leniency agreements (Table 3.17). In 2016, CADE strengthened merger notification criteria with the establishment of notification requirements for associative contracts.[207] During 2013-16, CADE also published guidelines on: its antitrust leniency

[201] Memorandum No. 15/2013/GAB/DIPOA of 06 February 2013. Viewed at: http://www.agricultura.gov.br/arq_editor/file/Aniamal/dipoa/DE_%20HAB_MEMON%C2%BA15%202013_BOVINOS_AVES_SUINOS_MANUALDEPROCEDIMENTOS.pdf [13 October 2016].

[202] MAPA Normative Instruction No. 55 of 1 December 2011.

[203] MAPA Normative Instruction No. 17 of 18 June 2004.

[204] WTO Document WT/TPR/S/283/Rev.1, 26 July 2013.

[205] As part of its mandate, the SEAE also provides advisory opinions to CAMEX on AD measures, monitors markets and prices (including, since 2011, regulated prices), and undertakes *ad hoc* studies upon request. The SEAE's advisory opinions and recommendations are non-binding.

[206] Pursuant to Brazil's competition legislation, CADE may undertake *ex officio* market-wide studies, which are consultative and non-binding. There are no prescribed time-frames for the conclusion of such studies.

[207] Resolution No. 17 of 18 October 2016.