October 27, 2023

Checklists on technical regulations and conformity assessment procedures

The **Good Regulatory Practices (GRP) Checklists on technical regulations (TR) and conformity assessment procedures (CAP)** provide useful information for those countries interested in (i) complying with international law; and (ii) reducing the uncertainty regarding the development or update of regulations in accordance with good regulatory practices. It was developed by the Medical Device Regulatory Convergence Project (MDRC), jointly with MDRC government partners.

The checklist creates an orderly framework for decision making that sets out key concepts to guide administrators through the complexities of the design and implementation of an effective and high-quality regulatory development and implementation. Compliance with this kind of proposed structure by national regulators enables an easier flow of trade; a cost-efficient analysis and increases availability of products throughout the countries.

The **Checklist on TR** is comprised of three sections, with desk-based questions regulators should answer when a TR or a CAP is being planned, drafted and after it is in force. Questions were formulated based on international agreements and international standards.

The **first section** is directed to regulators prior to the start of the regulatory process and during the planning process of the TR. This is the longest part of the checklist and aims to provide a solid preparation of the TR, according to the World Trade Organization rules, international standards and references. The **second section** have questions related to transparency, public participation, impact assessment analysis, elaboration, and publication of the TR to control compliance during the regulatory process. Finally, the **third section** assess the review process of the TR and procedures related the TR's implementation after it is in force. Specifically, there are questions regarding the significant effects on trade of the TR and the creation of procedures for its' revision.

The **Checklist on CAP** has five main directions related to observance of national treatment rules, explanation and information provided on CAP, subcontracts by conformity assessment bodies, conditions for acceptance of accreditation and selection of schemes for CAP.

National regulators are encouraged to operationalize the checklist so that it becomes part of its internal management procedure to support a transparent and compliant creation of rules. For this, there should be a mechanism formalizing compliance with the checklist within the national regulators' bodies, which allows for evidence of compliance and external auditing.

More Executive Operating Procedures can be implemented by the national regulators to meet the elements of the checklist. The MDRC is working with countries to implement such SOP, under the Quality Management System of the National Regulatory Authorities, to operationalize the checklist in an **efficient manner**, taking into consideration regulators' resources.

GOOD REGULATORY PRACTICES CHECKLIST TECHNICAL REGULATIONS Section I. Prior to the start of the regulatory process/ During the planning process					
DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
1. Technical Regulations - National Treatment	1.1 Does the proposed technical regulation establish the characteristics of a product or the processes and production methods related to them, including the applicable administrative provisions?	Annex 1, paragraph 1			
	1.2 Does the proposed technical regulation establish terminology, symbols, packaging, marking or labeling requirements applicable to a product, process, or production method, or does it deal exclusively with them?	Annex 1, paragraph 1			
	1.3 Is the instrument referred to in questions 1.1 or 1.2 mandatory?	Annex 1, paragraph 1			
	1.4 Did the regulatory authority ensure that the technical regulation provides imported products from any of Country's trading partners no less favorable treatment than that accorded to similar products of national origin?	2.1			
	1.5 In the technical regulations that have as scope the prescription of the products, did the regulatory authority define such products based on the properties of use and application of the products?	2.8			
	1.6 In the technical regulations that have as scope the prescription of products, did the regulatory authority avoid defining products based on their design or descriptive characteristics?	2.8			
2 **Technical Regulations - Preparation**	2.1 Did the regulatory authority carry out an adequate assessment of the technical regulation, including a regulatory impact analysis of the potential impacts of the technical regulation?	N/A			
	2.2 Did the regulatory authority carry out an evaluation of alternative measures that could be applied instead of the technical regulation?	2.2			
	2.3 Did the regulatory authority evaluate the voluntary actions, such as alternative measures to the technical	N/A			

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		TBT Agreement	**Yes**	**No**	**N/A**
	regulation, which were made known to it in a timely manner?				
	2.4 Did the regulatory authority ensure that its proposed technical regulations adequately inform interested persons and the governments of Country's trading partners about how their commercial interests could be affected?	N/A			
3. Technical Regulations - Use of International Standards	3.1 Did the regulatory authority identify in the technical regulation the relevant international standards, guidelines, or recommendations with which the project is complying?	2.4			
	3.2 Specifically, did the regulatory authority identify all international standards that could be effective and appropriate to meet the legitimate objectives of the proposed technical regulation?	2.4			
	3.3 Did the regulatory authority use as a basis for the technical regulation each of the relevant international standards identified based on question 3.2?	2.4			
	3.4 To determine whether an international standard exists, did the regulatory authority rely on the principles of transparency, openness, impartiality, consensus, effectiveness, relevance, and coherence contained in the TBT Committee's Decision on International Standards?	13.2; 13.3			
	3.5 Did the regulatory authority ensure not to consider or use international standards that were developed through processes that are incompatible with the TBT Committee's Decision on International Standards?	13.2; 13.3			
	3.6 To recognize a standard as international, did the regulatory authority ensure not to apply additional principles or criteria to those already established in the TBT Committee Decision on International Standards?	13.2; 13.3			
	3.7 To determine whether a standard is an international standard, did the regulatory authority ensure not to use the domicile of the standardization body that issued the standard as a criterion for its determination?	N/A			

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	3.8 To determine whether a standard is an international standard, did the regulatory authority ensure not to use as a criterion the fact that the standardization body that issued the standard is a non-governmental or intergovernmental body?	N/A			
	3.9 To determine whether a standard is an international standard, did the regulatory authority ensure not to use as a criterion whether the standardization body that issued the standard limits delegations' participation?	N/A			
	3.10 Where an international standard is adopted as a technical regulation, did the regulatory authority cooperate with the governments of its trading partners[1], in appropriate circumstances, to ensure that the international standard that became a technical regulation would not create unnecessary barriers to trade?	2.2			
	3.11 Did the regulatory authority ensure that no preference is given to the consideration or use of international standards that are developed through processes that treat natural or legal persons in the territory of any of its trading partners less favorably than persons whose residence is the same as one of the standardization bodies that issued the relevant international standard?	2.1			
	3.12 If an international standard was rejected and brought to the attention of the regulatory authority, did the regulatory authority issue a written explanation containing the reasons for the decision?	N/A			
	3.13 Was this explanation provided directly to the proponent of the international standard or was it published in a document at the same time the corresponding technical regulation was published?	N/A			

[1] Country's "trading partners" are defined as the member countries of the World Trade Organization (WTO).

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	3.14 In the case of technical regulations that are consistent with the technical content of international standards, guidelines, or recommendations, and if these could have a significant effect on trade, was the notification of the draft or modification to the proposed technical regulation requested to the regulatory authority?	2.4, 2.9			
	3.15 Regarding question 3.14, was the regulatory authority requested to identify relevant international standards, guidelines, or recommendations with which the project is in compliance?	2.4			
	3.16 In cases where there is no relevant international standard or where the content of the technical regulation is not in compliance with the technical content of such relevant international standard, and provided that the regulation may have a significant effect on trade, did the regulatory authority request the competent authority to notify the draft or amendment to the proposed technical regulation?	2.9; 2.9.1			
	3.17 Was the notification referred to in question 3.16 of this section made at an early stage?	2.9.1			
	3.18 Does the regulatory authority provide means to facilitate, upon request, details on the technical regulation, the text of the technical regulation and to point out those parts of the technical regulation that differ in substance from the relevant international standards?	2.9.3			
	3.19 Did the regulatory authority promote greater alignment of technical regulations with relevant international standards, except in cases where it was inappropriate or ineffective?	2.4			
4. Technical Regulations - Use of international standards	4.1 In the absence of an international standard that meets the legitimate objectives of the proposed technical regulation, did the regulatory authority consider standards developed by a standardization body established in the	N/A			

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	territory of the Country's trading partners that would meet the legitimate objectives of the technical regulation?				
	4.2 Did the regulatory authority consider the use of international standards, referred to in question 4.1, during the planning phase or when the proposed technical regulation was published for comments?	N/A			
	4.3 Regarding question 4.1, did the regulatory authority accept any of these standards?	N/A			
	4.4 If a standard developed by a standardization body established in the territory of one of the Country's trading partners that has been brought to the attention of the regulatory authority was rejected, did the regulatory authority issue a written explanation containing the reasons for its rejection?	N/A			
	4.5 Regarding question 4.4, was this explanation provided directly to the proponent of the given international standard or was it published in a document at the same time the corresponding technical regulation was published?	N/A			
5. Technical Regulations - Information Exchange with the government of Country's trading partners.	5.1 Did the regulatory authority issue an explanation to the government of any of Country's trading partners regarding the absence of a relevant international standard as the basis for a technical regulation or deviated substantially from it?	10.1.1			
	5.2 In the explanation referred to in question 5.1, was it explained why the rule has been judged inappropriate or ineffective for the legitimate objective pursued?	N/A			
	5.3 In the explanation referred to in question 5.1, was there scientific or technical evidence on which the assessment was based for not considering an international standard as a basis for the technical regulation or for substantially deviating from it identified?	N/A			
	5.4 At the time of receiving the request referred to in question 5.1, did the regulatory authority register whether	N/A			

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		TBT Agreement	**Yes**	**No**	**N/A**
	the international standard was communicated to it when it was developing the technical regulation?				
	5.5 At the time of receiving the request referred to in question 5.1, did the regulatory authority review that the applicant had identified the relevant international standard that the technical regulation supposedly did not use as a basis?	N/A			
	5.6 At the time of receiving the request referred to in question 5.1, did the regulatory authority review that the request described how the technical regulation was restricting or had the potential to restrict exports?	N/A			
6. Technical Regulations - Equivalence	6.1 Did the regulatory authority favorably consider accepting as equivalent technical regulations adopted by other trading partners that adequately meet the legitimate objectives, even if they differ from the technical regulations developed by it?	2.7			
	6.2 Specifically, did the regulatory authority promote the acceptance of technical regulations from the government of any of its trading partners as equivalent?	2.7			
	6.3 Where a request from the government of any of its trading partners for the recognition of equivalence of a technical regulation was denied by regulatory authority, were reasons given to justify the denial?	2.7; 10.1			
	6.4 Did the regulatory authority provide the response referred to in question 6.3 within a reasonable period of time?	N/A			
7. Technical Regulations - Labeling	7.1 In case of a technical regulation on labeling, did the regulatory authority ensure that it grants no less favorable treatment to goods imported from the territories of the country's trading partners than that granted to similar goods of national origin?	2.1			
	7.2 In case of a technical regulation on labeling, did the regulatory authority ensure that it does not create	2.2			

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		TBT Agreement	**Yes**	**No**	**N/A**
	unnecessary barriers to trade between the country and its trading partners?				
8. Technical Regulations - Notification and publication of regulatory proposal	8.1 Was the proposed[2] technical regulation or proposed modification of the technical regulation published on the official website of the regulatory authority?	10.3.1			
	8.2 If the answer to question 8.1 is no, was it published in other media?	N/A			
	8.3 Does the standardization authority provide procedures to notify through the regulatory authority draft regional technical regulations that may have a significant effect on trade, and which are in conformity with the technical content of relevant international standards, guidelines, or recommendations?	N/A			
	8.4 Was the notification of the proposed technical regulation transmitted to the regulatory authority at a convenient early stage where the regulatory authority could make amendments and take into account any comments provided?	2.9.2			
	8.4.1 Does the notification includes a description of the objective(s) and purpose of the proposed technical regulation?	2.9.2			
	8.4.2 Does the notification include an explanation of how the proposed technical regulation meets the objectives identified in the measure?	N/A			
	8.4.3 Does the notification include an indication of the legal grounds on which the measure was based?	N/A			
	8.4.4 Does the notification include the products covered by the proposed technical regulation?	2.9.2			
	8.5 Did the regulatory authority ensure that it was included in the notification a copy of the proposed technical regulation or an online address where a request can be	N/A			

[2] The term proposed may refer to a proposal prepared by the federal or local government.

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	made to the regulatory authority to access the proposed measure?				
	8.6 Did the regulatory authority ensure that the notification was transmitted electronically to its trading partners through its information services that respond to all reasonable requests for information?	10.1			
	8.7 Did the regulatory authority ensure that the technical regulation to the WTO TBT Committee was notifies?	2.11; 10.6			
	8.8 In the notification referred to in question 8.7, was the text of the technical regulation and/or an online address where the text of the measure can be consulted transmitted electronically?	N/A			
	8.9 In the case of first-time notifications, did the regulatory authority notify the proposed technical regulation to the TBT Committee as a periodic notification?	N/A			
	8.10 Regarding question 8.9, did the regulatory authority ensure that the objective of the proposed technical regulation was identified in the notification, as well as the reference to the specific Harmonized System heading, subheading or tariff code for the products that are affected by the proposal?	N/A			
	8.11 For purposes of the notification, did the regulatory authority ensure that it followed the recommendation of the TBT Committee G/TBT/35, related to the Coherent Use of Formats/Notification Templates?	N/A			
	8.12 In case of a notification related to a previously notified measure, did the regulatory authority ensure that it was provided the notification signature to the WTO for the previously notified measure?	N/A			
	8.13 Does the regulatory authority-directly or indirectly-maintain a single, free, publicly accessible website containing all information related to the development of a technical regulation?	10.1.5; 10.3.1			

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	8.14 In case of more than one website, did the regulatory authority verify that the information can be accessed, and that comment submissions can be made from a single web portal linked to the other related websites?	10.1.5; 10.3.1			
9. Technical regulations - Participation of interested parties in the development of technical regulations	9.1 Were natural or legal persons located in the territory of Country's trading partners allowed to participate in the elaboration of the technical regulation under conditions no less favorable than those granted to nationals?	2.1			
	9.2 Were the proposed technical regulations published online and freely accessible? [3]	N/A			
10. Technical Regulations - Emergency Notifications	10.1 In those cases where urgent safety, health, environmental protection, or national security issues arose or threatened to arise, did the regulatory authority immediately notifies the technical regulation?	2.10			
	10.2 In the case that a technical regulation was notified under the terms of question 10.1 of this section, did the regulatory authority verify that the notification was made to the Secretariat of the WTO and the Committees of the bilateral or regional free trade agreements of which the Country is a party?	2.10.1			
	10.3 Did the regulatory authority ensure that the notification referred to in questions 10.1 and 10.2 of this section includes the products, the objective, the rationale of the technical regulation and the nature of the urgent problems?	2.10.1			
	10.4 Did the regulatory authority ensure that it provides the means to facilitate a copy of the emergency technical regulation to Country's trading partners?	2.10.2			
	10.5 Did the regulatory authority ensure that Country's trading partners were given the opportunity to provide written comments on the emergency technical regulation?	2.10.3			

[3] Unless they are technical regulations developed by non-governmental organizations or have been incorporated by reference into a technical regulation.

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		TBT Agreement	**Yes**	**No**	**N/A**
	10.6 Did the regulatory authority, directly or through the Secretariat of Economy, held discussions with the governments of Country's trading partners regarding their comments on the emergency technical regulation?	2.10.3			
	10.7 Did the regulatory authority consider the written comments and discussions hold with Country's trading partners?	2.10.3			
11. Technical Regulations - Trade Cooperation and Facilitation	11.1 Did the regulatory authority carry out any of the following mechanisms to promote dialogue and cooperation to support a greater regulatory alignment:	N/A			
	11.1.1 Exchange information on regulatory practices and approaches.	N/A			
	11.1.2 Promote the use of good regulatory practices to improve the efficiency and effectiveness of technical regulations or standards.	N/A			
	11.1.3 Provide technical advice and assistance on mutually agreed terms and conditions, to improve practices related to the development, implementation and revision of technical regulations or standards.	N/A			
	11.1.4 Provide technical assistance and cooperation, on mutually agreed terms and conditions, to build capacity and support the implementation of the Technical Barriers to Trade Chapter of the trade agreements of which the Country is part of?	N/A			
	11.2 Did the regulatory authority promote the facilitation of greater use of relevant international standards, guidelines, and recommendations as a basis for technical regulation?	N/A			
	11.3 Did the regulatory authority exchange information on the use of standards related to the technical regulation?	N/A			
	11.4 If requested by the governments of Country's trading partners, did the regulatory authority ensure that the standards indicatively referred to in the draft technical regulation were provided?	N/A			

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		TBT Agreement	**Yes**	**No**	**N/A**
12. Technical Regulations - Contact Points	12.1 Was a point of contact for Good Regulatory Practices designated and notified?	N/A			
13. Technical Regulations - Internal Consultation, Coordination and Review	13.1 Do the processes or mechanisms adopted within the regulatory authority to facilitate inter-institutional coordination, promote and facilitate regulatory coherence and facilitate trade and investment?	N/A			
	13.2 Regarding question 13.1 of this section, was adherence to good regulatory practices promoted within the regulatory authority?	N/A			
	13.3 Regarding question 13.1 of this section, were improvements in the regulatory processes within the regulatory authority identified and developed?	N/A			
	13.4 Regarding question 13.1 of this section, did the regulatory authority identify potential overlaps or duplications between proposed and existing regulations, as well as prevent the creation of incompatible requirements with other authorities?	N/A			
	13.5 Regarding question 13.1 of this section, did the regulatory authority support compliance with international trade and investment obligations, including, as appropriate, consideration of international standards, guidelines, and recommendations?	N/A			
	13.6 Regarding question 13.1 of this section, was it promoted to address regulatory impacts, including burdens on SMEs in the collection and implementation of information?	N/A			
	13.7 Regarding question 13.1 of this section, were regulatory approaches that avoid unnecessary restrictions to competition in the market promoted?	N/A			
	13.8 Did the regulatory authority review the proposed technical regulations to determine the degree in which the development of these measures adheres to good regulatory practices established in free trade agreements	N/A			

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	to which the Country is a party, and did it issue recommendations based on that review?				
	13.9 Did the regulatory authority make recommendations for systematic regulatory improvements?	N/A			
	13.10 Did the regulatory authority publicly inform about the revised regulatory measures, any proposals for systematic regulatory improvement, and any updates on changes to the above processes and mechanisms?	N/A			
	13.11 Was a description of the above processes or mechanisms made publicly available?	N/A			
14. Technical Regulations - Quality of information	14.1 Did the regulatory authority verify that the information on which the regulation was based is indeed reliable and of high quality?	N/A			
	14.2 Did the regulatory authority adopt or keep publicly available guidelines or mechanisms that encouraged it to seek the best information reasonably obtainable, including scientific, technical, economic, or other information relevant to the regulation being developed?	N/A			
	14.3 Did the regulatory authority adopt or keep publicly available guidelines or mechanisms that encouraged it to rely on information that is appropriate to the context in which it is used?	N/A			
	14.4 Did the regulatory authority adopt or keep publicly available guidelines or mechanisms that encouraged it to identify sources of information in a transparent manner, as well as any significant assumptions and limitations?	N/A			
	14.5 In case of systematically collecting information from members of the public, through identical survey questions to be used in the development of the regulation, did the regulatory authority use solid statistical methodologies before making generalized conclusions regarding the impact of the regulation on the population affected by the technical regulation?	N/A			

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		TBT Agreement	**Yes**	**No**	**N/A**
	14. In case of systematically collecting information from members of the public, through identical survey questions to be used in the development of the regulation, did the regulatory authority avoid unnecessary duplication and minimized unnecessary burdens on respondents?	N/A			
15. Technical Regulations - Advanced Planning	15.1 Did the regulatory authority publish a list of regulations that it reasonably expected to adopt or propose within the next 12 months, including the technical regulation in question?	N/A			
	15.2 Was the technical regulation identified in the list accompanied by a brief description of the planned regulation?	N/A			
	15.3 Was the technical regulation identified in the list accompanied by a contact point for a knowledgeable individual in the regulatory authority responsible for the regulation?	N/A			
	15.4 Was the technical regulation identified in the list accompanied by an indication, if known, of the sectors to be affected and whether any significant effect on international trade or investment is expected?	N/A			
	15.5 Was the technical regulation identified in the list accompanied by timetables for subsequent actions, including those providing opportunities for public comment?	N/A			
16. Technical Regulations - Use of simple language.	16.1 Did the regulatory authority draft the technical regulation and its final version using plain language?	N/A			
	16.2 Is the proposed technical regulation and its final version clear, concise, well organized, and easy for the public to understand?	N/A			
17. Technical Regulations - Suggestions for improvement	17.1 Did the regulatory authority provide the opportunity for any interested person to submit written suggestions for the issuance, modification, or repeal of a technical regulation?	N/A			

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
18. Technical Regulations - Regulatory Process Information	18.1 Was a description of the processes and mechanisms used by the regulatory authority to prepare, evaluate, or revise the technical regulation published online?	N/A			
	18.2 Does the description referred to in question 18.1 identifies the applicable guidelines, rules, or processes, including those related to opportunities for the public to provide comments?	N/A			
	18.3 Was a description of the functions and organization of the regulatory authority published, including the appropriate offices through which individuals may obtain information, make submissions or requests, or obtain decisions? If so, where?	N/A			
	18.4 Were any procedural requirements or promulgated forms used by the regulatory authority published? If so, where?	N/A			
	18.5 Did the regulatory authority publish the legal authority for verification, inspection, and enforcement activities of the regulatory authority? If so, where?	N/A			
	18.6 Did the regulatory authority publish information regarding the judicial or administrative processes available to challenge the technical regulation? If so, where?	N/A			
	18.7 Was any fee charged by the regulatory authority to a person in the territory of any of Country's trading partners for services rendered in connection with the implementation of the technical regulation, including licenses, inspections, audits, and other administrative actions required to import, export, sell, market or use a good, published? If so, where?	N/A			
19. Technical Regulations - Promoting Regulatory Compatibility and Cooperation	19.1 Did the regulatory authority participate in mutually beneficial regulatory cooperation activities with the relevant counterparts of Country's trading partners in appropriate circumstances to promote regulatory compatibility and regulatory cooperation?	N/A			

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	19.2 Did the regulatory authority participate in bilateral and trilateral cooperation forums to achieve greater regulatory compatibility on a mutually beneficial basis?	N/A			
	19.3 Did the regulatory authority consider relevant events that took place in international or regional forums for the preparation and revision of its technical regulations?	N/A			
	19.4 To help minimize unnecessary regulatory differences and facilitate trade or investment, did the regulatory authority implement any of the following mechanisms?	N/A			
	(a) an initial phase of formal or informal exchange of technical or scientific information or data, including coordination of research agendas, to reduce duplication of research; and information provided by foreign SMEs;	N/A			
	(b) exploration of possible common approaches to the assessment and mitigation of risks or hazards, including those potentially associated with the use of emerging technologies;	N/A			
	(c) where appropriate, regulation through the specification of performance requirements rather than design characteristics, to promote innovation and facilitate trade;	N/A			
	(d) collaboration in relevant international forums;	N/A			
	(e) exchange information, of a technical or practical nature, on regulations that Country's trading partners are developing to maximize the opportunity for common approaches;	N/A			
	(f) co-finance research to support regulations and implementation tools of joint interest;	N/A			
	(g) facilitate a greater use of relevant international standards, guidelines, and recommendations as a basis for regulations, testing and approval processes;	N/A			
	(h) when developing or implementing regulations, consideration of relevant scientific or technical guidance	N/A			

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DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	documents developed through international collaborative initiatives;				
	(i) consideration of common approaches to the display of product or consumer information;	N/A			
	(j) consideration of developing compatible platforms or formats for industry submission of product information for regulatory review;	N/A			
	(k) coordination of the implementation of regulations and share compliance information, including, as appropriate, signing confidentiality agreements;	N/A			
	(l) a periodically exchange information, as appropriate, regarding any planned or ongoing post-implementation reviews or evaluations of existing or planned regulations affecting trade or investment;	N/A			
	(m) training programs, seminars, and other relevant assistance;	N/A			
	(n) strengthening cooperation and other relevant activities among regulatory authorities.	N/A			
20. Technical Regulations - Participation of Interested Parties	20.1 Were continuous opportunities offered to interested persons from Country's trading partners to provide input on issues relevant to improving regulatory coherence of technical regulations?	N/A			
21. Technical Regulations - Good Regulatory Practices	21.1 Is the regulatory authority part of the Good Regulatory Practices/Regulatory Coherence/Regulatory Improvement Committee of the trade agreements of which the Country is part of?	N/A			
	21.2 Does the regulatory authority attend or attended the annual meeting required by the trade agreements of which the Country is part of?	N/A			
22. Technical Regulations - Competent authorities for medical devices	22.1 Did the regulatory authority publish online a description, including specific responsibilities, of each authority that has the responsibility to implement and enforce measures regulating medical devices?	N/A			

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		TBT Agreement	**Yes**	**No**	**N/A**
	22.2 Did the regulatory authority publish online a contact point within each authority responsible for implementing and enforcing measures regulating medical devices?	N/A			
	22.3 Were the other Parties promptly notified of any material changes to the above information?	N/A			
	22.4 Is the information kept up to date online?	N/A			
	22.5 Did the regulatory authority avoid adopting or maintaining unnecessary duplicate regulatory requirements with respect to medical devices?	N/A			
23. Technical Regulations - Improving Regulatory Compatibility for Medical Devices	23.1 Was the term medical devices defined in a manner consistent with the meaning of the term "medical device" provided in the Definition of the Terms "Medical Device" and "In Vitro Diagnostic Medical Device (IVDMDD)" adopted by the Global Harmonization Working Group on May 16, 2012?	N/A			
	23.2 Did the regulatory authority publish online a description, including specific responsibilities, of each authority that has the responsibility to implement and enforce measures regulating medical devices?	N/A			
	23.2 Did the regulatory authority sought to collaborate to improve the alignment of regulations and regulatory activities for medical devices by working on relevant international initiatives?	N/A			
	23.3 Did the regulatory authority look for collaboration to improve the alignment of regulations and regulatory activities for medical devices by working on regional initiatives that support those relevant international initiatives?	N/A			
	23.4 To improve cooperation in inspections of medical device manufacturers' quality management systems, are audits of medical device manufacturers' quality management systems that are in accordance with the requirements established by the Medical Device Single	N/A			

GOOD REGULATORY PRACTICES CHECKLIST TECHNICAL REGULATIONS Section I. Prior to the start of the regulatory process/ During the planning process					
DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	Audit Program, and conducted by audit organizations authorized by the regulatory authorities participating in the Program, recognized?				
	23.5 In case of the development or implementation of regulations for the commercial authorization of medical devices, did the regulatory authority consider relevant scientific or technical guidance documents developed through international collaborative effort?	N/A			
	23.6 In the case of the development or implementation of regulations for the commercial authorization of medical devices, did the regulatory authority consider regionally developed scientific or technical guidance documents that are aligned with international efforts?	N/A			
24. Technical Regulations - Regulatory Controls Application	24.1 In the case of a measure applied to guarantee the safety, effectiveness, or quality of medical devices, Did the regulatory authority ensure that products imported from the territory of the government of any of Country's trading partners are not granted treatment no less favorable than that granted to similar products of national origin and to similar products originating in any other country, in a comparable situation?	N/A			
	24.2 For the classification of medical devices according to risk, did the regulatory authority consider the relevant scientific factors (i.e., contact with the body, degree of invasion, local effect and systemic effect)?	N/A			
	24.3 Where regulatory requirements on medical devices were imposed to ensure the safety and effectiveness of the device, did the regulatory authority base the requirements on a risk assessment of the medical device?	N/A			
25. Technical Regulations - Commercial Authorizations	25.1 Did the regulatory authority base its determination to grant a marketing authorization for a medical device on clinical data and information, if appropriate, on safety and effectiveness?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST TECHNICAL REGULATIONS Section I. Prior to the start of the regulatory process/ During the planning process					
DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	25.2 Was the determination to grant a marketing authorization for a medical device based on information about the performance, design, and quality of the device?	N/A			
	25.3 Was the determination to grant a marketing authorization for a medical device based on labeling information related to the safety, effectiveness, quality, and use of the device?	N/A			
	25.4 Does the regulatory authority manage any commercial authorization process it maintains for medical devices in a timely manner?	N/A			
	25.5 Does the regulatory authority reasonably administrate any commercial authorization process it maintains for medical devices by avoiding duplicate applications or requests for unnecessary information from the applicant, promptly communicating any deficiencies in the application and the reasons for them, and providing a determination within a reasonable time?	N/A			
	25.6 Does the regulatory authority objectively manage any commercial authorization process it maintains for medical devices through the application of published criteria?	N/A			
	25.7 Does the regulatory authority impartially manage any commercial authorization process it maintains for medical devices, including adopting or maintaining procedures to manage any conflicts of interest?	N/A			
	25.8 Does the regulatory authority transparently manage any commercial authorization process it maintains for medical devices, including the publication of a checklist or other guidance regarding the information that must be provided in any application?	N/A			
26. Technical Regulations - Trade Effects/Technical Barriers to Trade	26.1 When determining whether a draft technical regulation may have a significant effect on trade, did the regulatory authority consider the relevant guidance in the Decisions and Recommendations adopted by the WTO	2.5; 13.2 ; 13.3			

GOOD REGULATORY PRACTICES CHECKLIST TECHNICAL REGULATIONS Section I. Prior to the start of the regulatory process/ During the planning process					
DISCIPLINE TYPE	**OBLIGATION**	**Legal Ground**	**Was it fulfilled?**		
		TBT Agreement	**Yes**	**No**	**N/A**
	Committee on Technical Barriers to Trade since January 1st, 1995 (G/TBT/1/Rev. 13)?				
	26.2 Did the regulatory authority ensure not to develop a technical regulation that restricts trade more than necessary to achieve a legitimate objective, considering the risks that would be created by not achieving it?	2.2			
	26.3 In assessing the risks, did the regulatory authority take into consideration the available technical and scientific information, the related processing technology or the end uses for which the products are intended?	2.2			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	**WAS IT FULFILLED?**		
DISCIPLINE TYPE	**OBRIGATION**	**TBT Agreement**	**YES**	**NO**	**N/A**
1. Technical Regulations - Transparency	1.1 During the working groups and/or technical discussions, did the regulatory authority allow the participation of individuals or legal entities from the territory of any of Country's trading partners under conditions no less favorable than those granted to nationals?	2.1			
	1.3 Did the regulatory authority publish the comments referred to in question 1.2 of this section?	N/A			
	1.4 Was the time allowed for the submission of the comments noted in question 1.2 of this section enough for	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	the regulatory authority to review them and, if appropriate, revise the measure to take them into consideration?				
	1.5 Did the regulatory authority consider the written comments of a natural or legal person located in the territory of one of Country's trading partners in terms no less favorable than those submitted by nationals?	2.1			
	1.6 If feasible, did the regulatory authority accept the request from the governments of Country's trading partners to discuss the written comments they submitted?	10.1			
	1.7 If the answer to question 1.6 of this section is affirmative, did the regulatory authority ensure the participation of individual officials from the competent administrative units in these discussions?	N/A			
	1.8 Did the regulatory authority allow the Country's trading partners to exchange relevant information regarding the process under conditions no less favorable than those granted to nationals?	N/A			
	1.9 In the event that the regulatory authority requested a standardization or normalization body registered in Country to develop a national standard or norm to be used as a technical regulation, was said body required to allow the participation of individuals or legal entities from the territory of any of Country's trading partners in the groups or committees created by the body that developed the technical regulation?	N/A			
	1.10 Regarding question 1.9 of this section, was the body required to allow the submission of comments from individuals or legal entities from the territory of any of Country's trading partners during the public consultation period?	N/A			
	1.11 Was the participation of individuals or legal entities from the territory of any of Country's trading partners in the processes described in questions 1.9 and 1.10 granted on terms no less favorable than those granted to nationals?	2.1			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	1.12 Did the regulatory authority publish online and with unrestricted access the final technical regulation?[4]	2.11			
	1.13 Were efforts made to make comments received during the public consultation promptly publicly available?	N/A			
	1.14 Were the comments posted on a single specific website for the technical regulation or on the regulatory authority website?	N/A			
	1.15 Did the regulatory authority use available means to protect confidential information from comments received during the public consultation and withhold personally identifiable information or inappropriate content?	N/A			
	1.16 In the final version of the technical regulation, did the regulatory authority publish an explanation of how the substantive issues raised in the comments submitted were addressed?	N/A			
	1.17 Did the regulatory authority participate in the procedure to explain how the comments submitted were considered?	N/A			
	1.18 Was the information regarding the draft technical regulation published on an official centralized website?	10.1.1; 10.3.1			
2. Technical Regulations - Notifications	2.1 Was an attempt made to submit to the regulatory authority a revision of a notification if the content of the notified measure has substantially changed prior to its entry into force?	N/A			
	2.2 In the event that the content or objective of a notified measure is totally or partially modified, was an effort made to allow a new or extended deadline for interested persons to submit their comments to the authority?	N/A			
	2.3 Was an attempt made to notify the final text of the technical regulation at the time the text was adopted or published as an addendum to the proposal's original notification?	N/A			

[4] Unless they are technical regulations developed by non-governmental organizations or have been incorporated by reference into a technical regulation.

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	2.4 Do the procedures and/or criteria for submitting an addendum to the TBT Committee through the regulatory authority contemplate any of the following circumstances:	N/A			
	(a) the deadline for submitting comments on the proposed measures has changed;	N/A			
	(b) the notified measure has been adopted or otherwise has entered into force;	N/A			
	(c) compliance with the dates of the final measure has changed;	N/A			
	(d) the notified measure has been withdrawn, revoked, or replaced;	N/A			
	(e) the content or objective of the notified measure is totally or partially modified;	N/A			
	(f) any interpretative guidance on a notified measure that has been issued, or	N/A			
	(g) the final text of the notified measure is published or adopted or otherwise enters into force.	N/A			
3. Technical Regulations - Transparency	3.1 Did the regulatory authority provide a reasonable period for Country's trading partners to provide written comments and for discussions to be held regarding those comments?	N/A			
	3.2 Was enough time provided between the end of the comment period and the adoption of the notified technical regulation to ensure that the regulatory authority could fully consider the comments submitted and Country's trading partners could issue their responses to the comments?	N/A			
	3.3 Was a period of at least 60 days from the date the draft was transmitted given for Country's trading partners or other interested persons in those countries to provide written comments on the proposal?	N/A			
	3.4 Are procedures foreseen to consider a reasonable request from the governments of Country's trading partners or interested persons from such countries to extend the comment period?	10.1			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	3.5 Did the regulatory authority formally respond to the comments received during the public consultation period no later than the date on which the final version of the technical regulation was published?	N/A			
	3.6 Did the regulatory authority ensure that there are reasonable means for Country's trading partners or its nationals to make reasonable requests for information?	10.3			
4. Technical Regulation – Transparent Elaboration of Regulations	4.1 During the process of developing the technical regulation until before the end of the process, did the regulatory authority ensure to publish the text of the technical regulation together with its regulatory impact assessment?	N/A			
	4.2 During the process of developing the technical regulation until before the end of the process, did the regulatory authority ensure to publish an explanation of the technical regulation, including its objectives, how it was intended to achieve those objectives, the rationale for the material features of the regulation and any major alternatives considered?	N/A			
	4.3 During the process of developing the technical regulation until before the end of the process, did the regulatory authority ensure to publish an explanation of the data, other information, and analysis on which the regulatory authority relied to support the regulation?	N/A			
	4.4 During the process of developing the technical regulation until before the end of the process, did the regulatory authority ensure to publish the name and contact information of an official from the regulatory authority, who may be contacted to answer questions related to the regulation?	N/A			
	4.5 Until before the end of the process, did the regulatory authority ensure to publish, by the data, other information, and the scientific and technical analyses on which the regulatory authority relied to support the technical regulation, including any risk assessment?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	4.6 Were the above elements published before the regulatory authority finalized its work on the technical regulation and at a time that allowed it to consider the comments received and, as appropriate, review the text of the technical regulation?	N/A			
	4.7 Did the regulatory authority ensure that any interested person, regardless of domicile, had the opportunity, on terms no less favorable than those granted to nationals, to submit written comments on the published items?	2.1			
	4.8 Were interested persons allowed to submit comments and observations electronically?	N/A			
	4.9 Were written communications allowed to be submitted by mail to a published address or through other technology?	N/A			
	4.10 In the event that the technical regulation was expected to have a significant impact on trade, the regulatory authority, provided a period of not less than 60 days from the date of publication of the above elements to submit written comments and other information?	N/A			
	4.11 Due to the nature and complexity of the technical regulation that has a significant impact on trade, was a longer timeframe provided for interested persons to have the opportunity to understand how the technical regulation would affect their interests and develop informed responses?	N/A			
	4.12 If the technical regulation was not expected to have a significant impact on trade, and due to its nature was not required to provide a period of no more than 60 days to submit comments, was a period for submitting written comments and other input on the published information provided for no less than four weeks from the date of publication of the information?	N/A			
	4.13 Were reasonable requests to extend the deadline for submitting written comments or other observations considered?	10.1			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	4.14 Were efforts made to make promptly available to the public any written comments received, either through the website dedicated to such publications or through the regulatory authority website?	10.1.5			
	4.15 Before the technical regulation was finalized, did the regulatory authority evaluated any information provided in the written comments received during the comment period?	N/A			
	4.16 Once the work on the technical regulation was completed, did the regulatory authority promptly published the text of the technical regulation, any final impact assessment, as well as other elements such as those referred to in section 7 of this section?	N/A			
	4.17 Were the documents and information published in a format that could be read and processed digitally through word searches and data extraction by a computer or other technology?	N/A			
5. Technical Regulations - Expert Advisory Groups	5.1 If required during the elaboration or implementation of regulations by groups or bodies that include non-governmental persons, did the regulatory authority look for advice and recommendations from experts?	N/A			
	5.2 Did the regulatory authority ensure that expert advice or recommendations served as a complement to, rather than a substitute for, the procedures for seeking public comment?	N/A			
	5.3 Did the regulatory authority ensure that the membership of any expert group or body included a range and diversity of views and interests?	N/A			
	5.4 Was public notice regarding the name of any expert group or body created or used, and the names of the members of the group or body and their affiliations provided?	N/A			
	5.5 Was public notice regarding the mandate and functions of the expert group or body provided?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	5.6 Was public notice regarding meetings of the expert group or body provided?	N/A			
	5.7 Was public notice regarding the summary of the outcome of any meeting of an expert group or body provided?	N/A			
	5.8 Were efforts made to make publicly accessible any documentation made available to or prepared for or by the expert group or body?	N/A			
	5.9 Did the regulatory authority ensure to provide a means for interested persons to provide comments to the expert groups or bodies?	N/A			
6. Technical Regulation - Regulatory Impact Assessment	6.1 Did the regulatory authority include in the proposed regulation a regulatory impact assessment when costs or economic impacts are anticipated?	N/A			
	6.2 Did the regulatory authority include in the regulatory impact assessment the need for the proposed regulation, including a description of the nature and importance of the problem that the regulation was intended to address?	N/A			
	6.3 Did the regulatory authority include in the regulatory impact assessment feasible and appropriate regulatory and non-regulatory alternatives that could address the need for the regulation, including the alternative of not regulating?	N/A			
	6.4 Did the regulatory authority include in the regulatory impact assessment the benefits and costs of the selected alternative and other feasible alternatives, including relevant impacts (such as economic, social, environmental, public health and safety effects) as well as the risks and distributional effects over time, recognizing that some costs and benefits are difficult to quantify or monetize?	N/A			
	6.5 Did the regulatory authority include in the regulatory impact assessment the reasons why the regulatory authority concluded that the selected alternative is preferable, including a reference to the costs and benefits, and the possibilities of managing risks?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	6.6 Did the regulatory authority base the regulatory impact assessment on the best available information that can reasonably be obtained including relevant scientific, technical, economic, or other information, within the limits of its boundaries, mandates, and resources?	N/A			
	6.7 Did the regulatory authority consider the adverse economic impact that the proposed technical regulation could have on SMEs?	N/A			
	6.8 In case of an adverse economic impact according to question 6.7, did the regulatory authority consider possible measures to minimize them without implying the failure to comply with the objectives of the technical regulation?	N/A			
7. Technical Regulations - Final publication	7.1 Once the work on the regulation was finalized, was the date by which compliance is required promptly published in a final regulatory impact assessment or other document?	N/A			
	7.2 Once the work on the regulation was finalized, was it promptly published, in a final regulatory impact assessment or other document, an explanation of how the regulation achieves the regulatory authority's objectives, the rationale for the material features of the regulation, and the nature of and reasons for any significant revisions made since the regulation was made available for public comment?	N/A			
	7.3 2 Once the work on the regulation was finalized, were the regulatory authority's views on any substantive issues raised in the comments submitted promptly published in a final regulatory impact assessment or other document?	N/A			
	7.4 2 Once the work on the regulation was finalized, were the main alternatives, if any, that the regulatory authority considered in developing the regulation and the reasons supporting the alternative it selected, promptly published in a final regulatory impact assessment or other document?	N/A			
	7.5 2 Once the work on the regulation was finalized, was the relationship between the regulation and the key evidence, data, and other information that the regulatory authority considered in finalizing its work on the regulation promptly	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section II. During the regulatory process					
		LEGAL GROUND	WAS IT FULFILLED?		
DISCIPLINE TYPE	OBRIGATION	TBT Agreement	YES	NO	N/A
	published in a final regulatory impact assessment or other document?				
	7.6 Was the regulation that finally came into force published on a free and publicly available official website?	10.1.1; 10.3.1			
8. Technical Regulations - Compliance Deadline	8.1 Did the technical regulation provide for a period of not less than six months between its publication and its entry into force?	2.12			
	8.2 Was providing a period longer than six months between the publication of the technical regulation and its entry into force considered?	2.12			
	8.3 In determining the reasonable interval, did the regulatory authority seek to take into consideration the resources available to suppliers to be able to demonstrate the conformity of their products with the relevant requirements of the technical regulation before its entry into force?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section III. After the regulatory process					
DISCIPLINE TYPE	**OBLIGATION**	**LEGAL GROUND**	**WAS IT FULLFILLED?**		
		TBT Agreement	**YES**	**NO**	**N/A**
1. Technical Regulations - Revision	1.1 Does the regulatory authority contemplate a periodic review process of the technical regulations to determine whether it is appropriate to modify, simplify, expand or cancel them?	N/A			
	1.2 Did the regulatory authority analyze whether the technical regulation had already been previously submitted for review?	N/A			
	1.3 During the review process of the technical regulation, did the regulatory authority consider the criteria established in the its domestic legal framework regarding the periodic/retrospective reviews of existing instruments?	N/A			
	1.4 During the review process of the technical regulation, did the regulatory authority assess the persistence of the circumstances that gave rise to divergences with respect to a relevant international standard that was not considered in the development of the technical regulation?	N/A			
	1.5 During the review process of the technical regulation, did the regulatory authority review the international standards developed after the entry into force of the technical regulation subject to periodic/retrospective review?	N/A			
	1.6 During the review process of the technical regulation, did the regulatory authority carry out a re-evaluation process to consider the existence of less trade restrictive approaches?	N/A			
	1.7 During the review process of the technical regulation, did the regulatory authority consider the revision requests made by any individual or legal entity, national or foreign?	10.1			
	1.8 If the answer to question 1.7 is affirmative, did this process assign a high value to the arguments related to the evaluation of the changed circumstances that led to the development of a technical regulation and/or the existence of a less trade restrictive method to meet the objective of the technical regulation?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section III. After the regulatory process					
DISCIPLINE TYPE	**OBLIGATION**	**LEGAL GROUND**	**WAS IT FULLFILLED?**		
		TBT Agreement	**YES**	**NO**	**N/A**
	1.9 When reviewing the regulation, did the regulatory authority assess whether the circumstances or objectives that led to the adoption of the regulation still exist?	2.3			
	1.10 If the answer to question 1.9 of this section is affirmative, did the regulatory authority assess whether the technical regulation can be addressed with a less restrictive measure?	2.3			
	1.11 Are there any processes or mechanisms available for the regulatory authority to conduct retrospective reviews of the technical regulation to determine whether modification or repeal is appropriate?	N/A			
	1.12 Is the initiation of a retrospective review permitted in response to a suggestion submitted by an interested party?	N/A			
	1.13 When conducting a retrospective review of the technical regulation, did the regulatory authority consider the effectiveness of the regulation in meeting its initial stated objectives, for example, by assessing its current social or economic impacts?	77			
	1.14 When conducting a retrospective review of the technical regulation, did the regulatory authority consider any circumstances that have changed since the development of the regulation, including the availability of new information?	N/A			
	1.15 When conducting a retrospective review of the technical regulation, did the regulatory authority consider new opportunities to eliminate unnecessary regulatory burdens?	N/A			
	1.16 When conducting a retrospective review of the technical regulation, did the regulatory authority consider ways to address unnecessary regulatory differences that may adversely affect trade among its trading partners?	N/A			
	1.17 When conducting a retrospective review of the technical regulation, did the regulatory authority consider any relevant views expressed by members of the public?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section III. After the regulatory process					
DISCIPLINE TYPE	**OBLIGATION**	**LEGAL GROUND**	**WAS IT FULLFILLED?**		
		TBT Agreement	**YES**	**NO**	**N/A**
	1.18 Were provisions addressing impacts on SMEs included in the processes or mechanisms for retrospective reviews of the technical regulation?	N/A			
	1.19 To the extent available, were the official plans and results of retrospective revisions to the technical regulations published?	N/A			
2. Technical Regulations - Request for Documents	2.1 Did the regulatory authority ensure that copies of the technical regulations or other related document are available upon request by a business partner or interested person?	10.4			
3. Technical Regulations - Annual Report	3.1 Did the regulatory authority prepare an annual report that establishes, to the extent feasible, an estimate of the annual costs and benefits of significant economic regulations issued within a 12-month period, on an aggregate or individual basis?	N/A			
	3.2 Was a report setting out any changes or proposals to make changes to the regulatory system prepared and made freely available online?	N/A			
	3.3 Was an annual public notice given of any covered regulatory measures that the regulatory authority contemplated issuing during the following 12 months where the regulation in question was included?	N/A			
4. Technical Regulations - Revisions Notification	4.1 In case of a notification related to a revision, amendment, or replacement of a previously notified measure, is the WTO notification symbol provided for the previously notified measure?	N/A			
	4.2 In case the regulatory authority submitted a revision of a previously notified measure, was an effort made to allow a new or extended deadline for interested persons to submit their comments to the authority?	N/A			
5. Technical Regulations - Significant Effects on Trade	5.1 In cases where a technical regulation has been adopted that may have a significant effect on trade, was an explanation of how the technical regulation achieves the parties' objectives promptly posted online?	2.5			
	5.2 Regarding question 5.1 of this section, was a publication included describing the alternative approaches, if any, that	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Section III. After the regulatory process					
DISCIPLINE TYPE	**OBLIGATION**	**LEGAL GROUND**	**WAS IT FULLFILLED?**		
		TBT Agreement	**YES**	**NO**	**N/A**
	the regulatory authority considered in the development of the adopted technical regulation and an explanation of why it chose one approach over the others it considered?				
	5.3 Was the description mentioned in question 5.2 provided within 60 days of receiving a request from any of Country's trading partners?	10.1			
	5.4 Regarding question 5.1 of this section, were the regulatory authority's views on any substantive issues raised in comments received on the technical regulation promptly posted online?				
	5.5 Regarding question 5.1 of this section, was a description of significant revisions made to the proposed technical regulation, including those made in response to comments, provided as soon as possible, but no later than 60 days after receiving a request from any of Country's trading partners?	10.1			
	5.6 Regarding question 5.1 of this section, was any impact assessment conducted by the regulatory authority promptly published online?	N/A			
	5.7 Regarding questions 5.1 and 5.6, if not addressed by an impact assessment, was an explanation of the relationship between the regulation or the key evidence, data, and other information that the authority considered in finalizing its work on the regulation promptly published online?	N/A			
	5.8 Regarding question 5.6 of this section, was the date by which compliance would be required promptly posted online?	N/A			

GOOD REGULATORY PRACTICES CHECKLIST Conformity Assessment						
		LEGAL GROUND		WAS IT FULLFILLED?		
DISCIPLINE TYPE	OBLIGATION	TBT Agreement	AfCFTA	YES	NO	N/A
1. Conformity Assessment Procedure - National Treatment	1.1 Does the regulatory authority contemplate the participation of conformity assessment bodies located in the territories of country's trading partners in national conformity assessment procedures under conditions no less favorable than those granted to bodies located in the country or in other countries? In the answer consider: procedures, criteria, fees, and other conditions related to accreditation, approval, authorization or otherwise, recognition of conformity assessment bodies.	5.1.1 and 6.4	Articles 1, 3 and 8.			
	1.2 When requesting conformity assessment results from conformity assessment bodies located in the territories of country's trading partners, does the regulatory authority accept the results regardless of whether such body is not located and/or does not operate an office in the Country?	6.1	Articles 1, 3 and 8.			
	1.3 If requested by a conformity assessment body located in the territory of one of country's trading partners, does the regulatory authority determines that such body complies with the procedures, criteria and other conditions required to be considered competent? Or does the regulatory authority approves the body to evaluate or certify the product or to perform an inspection?	6.1 and 6.4	Articles 1, 3 and 9.			
	1.4 Did the regulatory authority authorize the participation of conformity assessment bodies located in the territory of any of country's trading partners in its conformity assessment procedures under conditions no less favorable than those granted to bodies located in the country or in any other country?	6.4	Articles 1, 3 and 8.			
2. Conformity Assessment Procedure - Explanations and Information	2.1 If the regulatory authority conducts a conformity assessment procedure directly or through any other government agency or entity, is it able to explain, upon request, the sequence in which a conformity assessment procedure is conducted and concluded?	5.2.3	Articles 1, 3 and 8.			
	2.2 If the regulatory authority conducts a conformity assessment procedure directly or through any other government agency or entity, is it able to explain, upon request, the sequence in which a conformity assessment procedure is conducted and concluded?	N/A				
	2.3 Regarding question 2.2, did the regulatory authority, upon request, publish the normal processing period for a conformity assessment procedure?	5.2.2	Articles 8 and 11.			
	2.4 Regarding question 2.2, can the regulatory authority ensure that a conformity assessment procedure is initiated and completed as quickly as possible and, in an order no less favorable for products originating from country's trading partners than for domestic products?	5.2.1	Articles 1, 3 and 8.			
	2.5 If the regulatory authority carries out a conformity assessment procedure directly or through any other government agency or entity, is it able to explain, upon request, how it ensures that confidential business information is protected?	5.2.4	Articles 1, 3 and 8.			

GOOD REGULATORY PRACTICES CHECKLIST Conformity Assessment						
		LEGAL GROUND		WAS IT FULLFILLED?		
DISCIPLINE TYPE	OBLIGATION	TBT Agreement	AfCFTA	YES	NO	N/A
	2.6 Regarding question 2.5, does the regulatory authority protects confidential information regarding products originating from country's trading partners in the same way as it does for domestic products?	5.2.4	Articles 1, 3 and 8.			
	2.7 If the regulatory authority conducts a conformity assessment procedure directly or through any other government agency or entity, is it able to explain, upon request, the procedure for reviewing complaints regarding the operation of the conformity assessment procedure and for taking corrective action when a complaint is justified?	5.2.8	Articles 8 and 11.			
	2.8 the regulatory authority provides procedures for explaining the reasons for declining: i. accredit, approve, license or otherwise recognize a conformity assessment body; ii. recognize the results of a conformity assessment body that is a signatory to a mutual recognition arrangement; iii. accept the results of a conformity assessment procedure carried out in the territory of country's trading partners; or iv. continue with negotiations for a mutual recognition agreement.	N/A				
	2.9 Does the regulatory authority publish, preferably by electronic means, any procedures, criteria, and other conditions that it may use as a basis for determining whether conformity assessment bodies are competent to receive accreditation, approval, authorization, or other recognition granted pursuant to a mutual recognition agreement?	N/A				
3. Conformity Assessment Procedure - Subcontracting	3.1 In cases where conformity assessment is required, does the regulatory authority, when required, allow conformity assessment bodies to use subcontractors and accepts the results of conformity assessments that use subcontractors to perform tests or inspections related to conformity assessment, including subcontractors located in the territory of country's trading partners that have been accredited and approved in its territory?	N/A				
4. Conformity Assessment Procedure - Accreditation	4.1 When requesting conformity assessment results from conformity assessment bodies located in the territories of country's trading partners, does the regulatory authority accept the results regardless of whether such a body has been accredited by a body that: i. operates in the territory of any of country's trading partners where there is more than one accreditation body; ii. is a non-governmental body; iii. is domiciled in the territory of one of the country's trading partners that does not maintain a procedure for the recognition of accreditation bodies, provided that the body is internationally recognized; iv. does not operate an office in the country, or v. is a for-profit entity?	6.1				
	4.2 the regulatory authority maintains measures to:	6.1				

GOOD REGULATORY PRACTICES CHECKLIST Conformity Assessment						
		LEGAL GROUND		WAS IT FULLFILLED?		
DISCIPLINE TYPE	OBLIGATION	TBT Agreement	AfCFTA	YES	NO	N/A
	i. facilitates and build confidence in mutual or multilateral recognition arrangements for accrediting, approving, licensing or otherwise recognizing a conformity assessment body; and ii. approve or recognize accredited conformity assessment bodies for its technical regulations or standards, by an accreditation body that is a signatory to a recognition or multilateral arrangement.					
5. Conformity Assessment Procedure - Conformity Assessment Selection	5.1 In case of a conformity assessment procedure, did the regulatory authority carry out an assessment of the risks involved in the selection of the schemes included in such procedure?	5.2.2				
	5.2 Regarding question 5.1, did the regulatory authority carry out an assessment of the need to adopt procedures to address the risks involved?	N/A				
	5.3 Regarding question 5.1, did the regulatory authority justify the selection of such procedure based on relevant scientific and technical information?	5.2.2				
	5.4 Regarding question 5.1, did the regulatory authority carry out an evaluation of the incidence of non-compliant products?	5.1.2				
	5.5 Regarding question 5.1, did the regulatory authority include an assessment of possible alternative approaches to establish that the technical regulation has been met?	N/A				
	5.6 In case the regulatory authority requests that conformity assessment procedures regarding certain products be carried out by itself or by specific government authorities, does the regulatory authority limit any fees imposed for conformity assessment procedures on products from other Parties to the costs of the services it provides?	N/A				
	5.7 Does the regulatory authority not impose fees on an applicant from a trading partner of the country to provide conformity assessment services, except to recover costs incurred for services rendered?	N/A				
	5.8 Does the regulatory authority make available to the public the amounts of the fees for conformity assessment procedures?	N/A				
	5.9 Does the regulatory authority not apply a new or modified fee for conformity assessment procedures until the fee and the method to assess the fee are published and, if possible, until it has provided an opportunity for interested persons to comment on the proposed introduction or modification of a conformity assessment fee?	N/A				
	5.10 Upon request from the governments of any of country's trading partners or from any individual or legal entity applicant from those countries, can the regulatory authority explain how any fees it imposes for such conformity assessment are not higher than the cost of the service provided and, likewise, how any information it requires is necessary to calculate such fees?	N/A				

GOOD REGULATORY PRACTICES CHECKLIST Conformity Assessment						
		LEGAL GROUND		WAS IT FULLFILLED?		
DISCIPLINE TYPE	OBLIGATION	TBT Agreement	AfCFTA	YES	NO	N/A
	5.11 Upon request from the governments of any of country's trading partners or from any individual or legal entity requesting such information, can the regulatory authority explain how the fees for its conformity assessment procedures are calculated?	N/A				
	5.12 In case the regulatory authority takes actions to verify the results of a conformity assessment procedure, including requesting information from the conformity assessment or accreditation body, did it ensure that such actions will not subject a product to duplicative conformity assessment procedures?	N/A				