

THE NATIONAL TECHNICAL REGULATION BILL, 2017

MEMORANDUM

The objects of this Bill are to —

- (a) provide for the principles of, and a framework for, technical regulation that are compliant with best practice and regional and international obligations to which Zambia is a party;
- (b) establish the Department of Technical Regulation in the Ministry responsible for trade;
- (c) provide for the development and implementation of technical regulation for public safety and health, consumer protection and environmental protection;
- (d) provide technical guidance to regulatory agencies on the development, implementation, administration and review of technical regulations;
- (e) domesticate the International and Regional Trade Agreements on Technical Barriers to Trade in order to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade but implement legitimate policy objectives and measures; and
- (d) provide for matters connected with, or incidental, to the foregoing.

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Attorney-General

N.A.B. 5, 2017
28th January, 2017

**THE NATIONAL TECHNICAL REGULATION BILL,
2017**

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ENTITLED

An Act to provide for the principles of, and a framework for, technical regulation that are compliant with best practice and regional and international obligations to which Zambia is a party; establish the Department of Technical Regulation in the Ministry responsible for trade; provide for the development and implementation of technical regulation for public safety and health, consumer protection and environmental protection; provide technical guidance to regulatory agencies on the development, implementation, administration and review of technical regulations; domesticate the International and Regional Agreements on Technical Barriers to Trade in order to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade but implement legitimate policy objectives and measures; and provide for matters connected with, or incidental, to the foregoing.

ENACTED by the Parliament of Zambia

Enactment

PART I

PRELIMINARY PROVISIONS

1. This Act may be cited as the National Technical Regulation Act, 2017, and shall come into operation on a date that the Minister appoints by statutory instrument.

Short title and commencement

N.A.B. 5, 2017

Interpretation	2. In this Act, unless the context otherwise requires — “accreditation” means third party attestation for a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks;	5
Act No. 12 of 2011	“adverse” has the meaning assigned to it in the Environmental Management Act, 2011;	
Act No. of 2017	A Bureau” means the Zambia Bureau of Standards established under the Standards Act, 2017;	
Act No. of 2017	“certification” means the formal substantiation that a product, process, service, organisation or individual meets the requirements of a standard;	10
Act No. of 2017	“commodity” has the meaning assigned to it in the Standards Act, 2017;	
Act No. of 2017	“compulsory standard” means a compulsory standard declared under the Compulsory Standards Act, 2017;	15
	“conformity assessment” means the demonstration that a product, process, system, person or body meets the specified requirement;	
	“conformity assessment procedure” means a procedure used, directly or indirectly, to determine that relevant requirements of a technical regulation or standard are met, and includes a procedure for sampling, testing, inspection, evaluation, verification, assurance of conformity, registration, accreditation and approval or a combination of these procedures;	20 25
	“conformity assessment scheme” means the rules, procedures and management for carrying out a conformity assessment;	
	“Department” means the Department of Technical Regulation established under section 5;	30
	“designate” in relation to conformity assessment service providers, means the governmental authorisation of a conformity assessment body to perform specified conformity assessment activities with a public domain responsibility;	35

- “ Director ” means the Director of Technical Regulation appointed under section 7;
- “ environment ” has the meaning assigned to it in the Environmental Management Act, 2011; Act No. 12 of 2011
- 5 “ inspection ” means the examination of a product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements;
- “ ISO ” means the International Organisation for Standardisation;
- 10 “ legal metrology ” has the meaning assigned to it in the Metrology Act, 2017; Act No. of 2017
- “ market ” in relation to any goods or services, includes a market for those goods or services and other goods or services that are substitutable for, or otherwise competitive with, the goods or services;
- 15 “ market surveillance ” means random checks and audits of, or taking samples and gathering of information with regard to, products and services available on the market and in warehouses;
- 20 “ metrology ” has the meaning assigned to it in the Metrology Act, 2017; Act No. of 2017
- “ national quality infrastructure ” means the totality of the institutional framework, whether public or private, the output of which includes metrology, standards, inspection, testing, certification and accreditation;
- 25 “ process ” means a method of operation, manufacturing, production, storage, transportation, disposal or combination of these processes;
- 30 “ product ” has the meaning assigned to it in the Standards Act, 2017; Act No. of 2017
- “ production method ” means the mechanical or chemical steps used to create an object, usually repeated to create multiple units of the same item and generally involves the use of raw materials, machinery and human resource to create a product;
- 35 “ regulatory agency ” means a Ministry, department or agency with authority and power to develop or oversee the implementation of a technical regulation;

- “relevant Minister ” means the Minister under whose portfolio a regulatory agency falls;
- “service ” means any work or doing work for remuneration and at the request of a recipient of the service, and includes the process used for delivering the service; 5
- “service provider ” means a person who supplies a service to which a technical regulation applies;
- “standard ” means a document, approved by a recognised body, which provides for common and repeated use of the rules, guidelines or characteristics for products and their 10 related processes or production methods, with which compliance is not mandatory, and includes terminology, symbols, packaging, marking or labelling requirements as they apply to a product or process;
- “supplier ” means the manufacturer, merchant, distributor, 15 importer or agent who places a product, process or service onto the market;
- “SADC ” means the Southern African Development Community;
- “technical regulation ” means a document which lays down 20 commodity or service characteristics or their related processes and production methods, including administrative provisions, with which compliance is mandatory, and includes terminology, symbols, packaging, marking or labelling requirements as they apply to a commodity or 25 service or their related processes;
- “technical regulation framework ” means the manner in which technical requirements, the conformity assessment system, regulatory authority mandates and sanctions are applied in the development and implementation of technical regulation; 30
- “trade ” means the buying, selling or exchange of goods and services;
- “WTO TBT Agreement ” means the World Trade Organisation Agreement on Technical Barriers to Trade; and 35
- “Zambian National Standard ” means a standard approved by the Bureau under the Standards Act, 2017 .

Act No. of
2017

Act No. of
2017

3. (1) Despite any other written law, and subject to subsections (2) and (3), a technical regulation that is developed, implemented or maintained by a regulatory agency shall comply with the requirements of this Act.

Application of Act

5 (2) The provisions of this Act do not apply to a law, standard or technical regulation relating to national security the disclosure of which is prejudicial to the interests of the State.

(3) The mandatory requirements for a commodity or service, and the method and scheme for assessing its conformity, which is 10 contained in a technical regulation are exhaustive, have direct effect throughout the Republic and shall be amended by the introduction of an amendment or supplement to the technical regulation.

4. A technical regulation shall be developed, implemented and maintained in accordance with the following principles:

Principles of technical regulation

15 (a) a technical regulation shall not be prepared, adopted or applied in order to create an unnecessary obstacle to international trade, but to facilitate the trade;

20 (b) a technical regulation shall be developed and implemented where it is necessary for the protection of human health or safety, animal or plant life or health, the prevention of deceptive practices and environmental protection;

(c) technical regulation shall comply with the requirements of international and regional agreements to which Zambia is a party;

25 (d) technical regulation shall comply with the national technical regulation framework, the functions of regulatory agencies and conformity assessment systems and sanctions;

30 (e) technical regulation shall take into account the national economic interest, related processing technology or intended end-uses of products and the level of scientific and technical development;

35 (f) the requirements of any technical regulations shall not create barriers to entrepreneurial activities to a greater degree than is minimally necessary for achieving its purposes;

(g) technical regulation shall be applied in a non-discriminatory and uniform manner to imported and locally produced commodities and services;

- (h) conformity assessment systems and technical regulation shall not serve as disguised protection against imported commodities and services;
- (i) conformity assessment systems governing imported products and services shall not be less favourable than those accorded to domestic products and services;
- (j) international, regional and national standards and norms, where available and applicable, shall be used as the basis for technical regulation;
- (k) the national quality infrastructure shall be used and suppliers shall choose their conformity assessment service providers who are technically competent and acceptable to, or so designated by, regulatory agencies;
- (l) regulatory agencies shall not, as far as is practicable and consistent with international practice, provide or participate in providing conformity assessment for commodities or services that they are mandated to inspect and control;
- (m) accreditation, certification and inspection bodies shall be independent from suppliers; and
- (n) technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the circumstances or objectives can be addressed in a less trade-restrictive manner.

PART II

ADMINISTRATION

Establishment
of
Department
of
Technical
Regulation

5. (1) There is established the Department of Technical Regulation in the Ministry responsible for trade to implement the national technical regulation framework and ensure transparency and consistency in the development, implementation and maintenance of technical regulations in accordance with the requirements of this Act.

(2) The Minister may, by statutory instrument, appoint a Government department to perform the functions of the Department or agency on such terms and conditions as the Minister may determine.

Functions of
Department

6. (1) The functions of the Department are to—

- (a) oversee the review of technical regulations to ensure compliance with the provisions of this Act and international standards;

- (b) audit technical regulations proposed by regulatory agencies to ensure that they comply with the national technical regulation framework;
- (c) coordinate the development of technical regulations by—
- 5 (i) facilitating consensus among the regulatory agencies for purposes of this Act; and
- (ii) minimising overlaps in technical regulation for commodities and services among the regulatory agencies; and
- 10 (d) review the compliance of the relevant authorities with the obligations under international and regional agreements relating to technical regulation that Zambia has ratified;
- (2) The Department shall, in implementing its functions under 15 subsection (1) —
- (a) act as the notification point for Zambia with regard to technical regulation;
- (b) manage the regional and international trade agreement notification points;
- 20 (c) facilitate Zambia=s participation in the WTO TBT Agreement and relevant regional committees;
- (d) promote good regulatory practices;
- (f) conduct training for officers responsible for technical regulation in regulatory agencies;
- 25 (g) provide information related services on technical regulations; and
- (h) disseminate information to assist local companies and entrepreneurs to overcome technical barriers to trade.
- (3) The Department may —
- 30 (a) develop and implement technical regulations;
- (b) provide conformity assessment services; and
- (c) accredit and designate conformity assessment service providers.
- (4) Except as provided for in subsection (1), the Department 35 shall not exercise any authority over decisions made by a regulatory agency, metrology institution, accreditation body or standard setting body.

Director and
other
staff

7. The Public Service Commission shall appoint, as public officers, the Director for Technical Regulation and such other staff as are necessary for the proper administration of this Act.

International
cooperation
on
technical
regulation

8. (1) A regulatory agency may cooperate with foreign and international regulatory agencies in the development and implementation of technical regulations. 5

(2) International cooperation on technical regulation under subsection (1) may include—

- (a) information sharing;
- (b) enforcement of standards; 10
- (c) reciprocal recognition of standards; or
- (d) any other matter in respect of which cooperation may be granted under this Act.

(3) A request for international cooperation by a foreign or international regulatory agency shall be made to the relevant regulatory agency in the prescribed manner and form. 15

PART III

TECHNICAL REGULATION

Structure and
content of
technical
regulation

9. The structure and content of a technical regulation that is developed by a regulatory agency shall comply with the requirements specified in this Act. 20

Scope of
technical
regulation

10. (1) A technical regulation shall —

- (a) define the range of the commodities and services that are covered by the technical regulation;
- (b) clarify the nature of the hazards that it is intended to prevent; 25
- (c) avoid a proliferation of technical regulations for the same commodities or services related to similar hazards;
- (d) indicate the sequence and details of pre-market testing and certification, product approval and post-market surveillance, as relevant; 30
- (e) indicate the arrangement of information on the designated conformity assessment service providers; and

(f) identify the regulatory agency and its powers and responsibilities regarding pre-market approvals and post-market surveillance.

(3) A technical regulation shall state that the supplier is responsible for providing proof that the commodity or service failing within the scope of a technical regulation meets its requirements.

(4) A technical regulation shall provide for a process of appeal by suppliers who are aggrieved with, or are adversely affected by, a decision of the regulatory agency concerned.

10 11. (1) Technical regulations shall, taking into account the degree of risk to causing harm, contain the minimum safety requirements for commodities and services, but shall not specify or predict the technical solutions for doing so.

Essential
safety
requirements

(2) The safety requirements for commodities and services shall be precisely worded in order to —

(a) create legally binding and enforceable obligations;

(b) facilitate the development and reference of the appropriate standards; and

20 (c) enable the assessment of conformity of commodities or services.

12. (1) A technical regulation may, in order to facilitate compliance with the requirements for a commodity or service where a standard exists or has been established for the commodity or service to which the technical regulation relates, reference the standard or list of standards or specify the official publication listing of the standards for purposes of conformity.

Referencing
of
standards

(2) The reference of the standards shall include, as a minimum, the number, title, scope and publisher of the standards.

30 (3) The standards referred to in this section may be a National Standard published by the Bureau, a regional standard published by regional bodies or an international standard published by international standards bodies.

(4) Compliance with a referenced standard confers a presumption of conformity of the commodity or service with the requirements of the technical regulation.

35 13. (1) The obligations of the State and the supplier in financing the surveillance functions of the regulatory agency shall be clearly detailed in the technical regulation.

Financing
of
surveillance
by
regulatory
agency

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- (2) The supplier shall be responsible for financing the conformity assessment services provided by the designated or acceptable conformity assessment service providers.
- Placement on market of commodities and services
- 14.** A commodity and service falling under a technical regulation shall be placed on the market if the commodity and service — 5
- (a) does not endanger public safety or health or plant or animal life or health;
- (b) does not give rise to consumer exploitation;
- (c) does not have adverse effects on the environment when undertaken, installed and maintained; and 10
- (d) is used for the purpose for which they were intended. Proof of compliance with technical requirements
- Proof of compliance with technical requirements
- 15.** (1) A supplier shall provide proof of compliance with a conformity assessment scheme as provided under Part IV.
- (2) A supplier shall, in all cases, be required to compile and 15 retain the required technical documentation including the declaration of conformity.
- Responsibility for compliance with technical regulation
- 16.** (1) Subject to subsection (2), a supplier or service provider of a commodity or service, or a representative of the supplier or service provider, shall ensure that the commodity or service complies 20 with the requirements of a technical regulation.
- (2) A regulatory agency shall, in conducting market surveillance, hold the supplier, seller or marketer responsible for compliance of the commodity or service with the technical regulation applicable to the commodity or service. 25
- Guidelines for developing and implementing technical regulations
- 17.** (1) A regulatory agency shall —
- (a) before developing a technical regulation, ensure that the technical regulation is justified based on evidence and the nature of the problem; and
- (b) in developing a technical regulation, ensure conformity 30 with relevant laws and guidelines for developing regulations that impact on business.
- (2) A regulatory agency shall, when consulting stakeholders during the development of the technical regulations, provide the following information: 35
- (a) a full description of the commodity or service which will be the subject of the technical regulation;

- (b) the justification or the necessity of its development and implementation;
- (c) information on the adoption of international, regional or national standards as the basis for the technical regulation, including reasons for non-adoption, if any; and
- (d) the envisaged conformity assessment systems.

(3) A regulatory agency shall submit the technical regulation to the Department for review for compliance with the national technical regulation framework and with international and regional obligations.

(4) A regulatory agency shall, after clearance by the Department, submit the draft technical regulation, including the outcome of the review by the Department to the relevant Ministry for consideration and publication.

(5) The Department shall notify the secretariat of the international and regional organisations as required by the relevant international and regional agreements regarding the technical regulation.

20 **18.** (1) The Department shall, not later than five years from the date that a technical regulation became effective, cause the relevant regulatory agency to review whether the technical regulation still complies with the principles stated in section 4 and with current international or regional standards, norms and rules.

Review of technical regulation

25 (2) Where the circumstances or purposes that caused the development and implementation of the technical regulation change or cease to exist, the Department shall cause the relevant regulatory agency to initiate the appropriate procedures for revision or withdrawal of the technical regulation.

30 **19.** (1) The relevant Minister may, where there is a threat to the environment or human and animal life and health, in consultation with Cabinet, by statutory instrument, adopt and publish a technical regulation intended to deal with the threat, without following the procedure specified in section 17.

Procedure for developing and implementing technical regulation for emergency situation

(2) The statutory instrument referred to in subsection (1) shall state the justification for the technical regulation.

(3) A technical regulation promulgated under this section shall not remain in force for a period exceeding one year from the date of its publication. 5

(4) The relevant regulatory agency shall, while implementing a technical regulation for purposes of this section, develop an appropriate technical regulation in the manner prescribed in section 17.

(5) A technical regulation passed under this section shall cease to have effect on the promulgation of the appropriate technical regulation. 10

(6) The Department shall notify the secretariat of the international and regional organisations as required by the relevant international and regional agreements regarding the technical regulation. 15

PART IV

CONFORMITY ASSESSMENT SCHEMES

Conformity
assessment
schemes

20. (1) Where a formal assurance of conformity with a technical regulation is required, a regulatory agency shall, where practicable — 20

(a) formulate and adopt conformity assessment schemes based on international best practice; and

(c) ensure that the conformity assessment services are provided in the most cost effective way.

(2) A regulatory agency shall maintain a database of designated conformity assessment service providers. 25

(3) Zambia shall recognise the accreditation body or bodies providing accreditation services in the technical regulation domain as part of the international mutual recognition mechanisms.

Principal
guidelines

21. (1) A conformity assessment scheme shall enable the regulatory agency to ensure that commodities and services placed on the market conform to the requirements of the relevant technical regulation. 30

(2) A regulatory agency shall, in selecting the appropriate conformity assessment scheme, take into consideration the —

- (a) appropriateness of the scheme for the type of commodity or service;
- 5 (b) nature of the risks involved;
- (c) economic infrastructure of the sector;
- (d) type and importance of local production or importation mechanisms;
- (e) level of State surveillance;
- 10 (f) technical capability of the national quality infrastructure; and
- (g) other requirements as prescribed by statutory instrument.

(3) A regulatory agency shall not impose a conformity assessment scheme that is or is likely to be onerous relative to the objectives 15 of the relevant technical regulation.

22. A foreign test report and certification for imported or local commodities may be accepted by the regulatory agency if —

Foreign test reports and certification

- (a) an agreement of mutual recognition has been negotiated between the regulatory agency and the conformity assessment provider in the foreign country; or
- 20 (b) the regulatory agency is of the opinion that the foreign conformity assessment service provider's technical competency has been adequately demonstrated through accreditation and that the risk of accepting the test reports and certification unilaterally is acceptable.

23. (1) A regulatory agency shall monitor the commodities and services placed on the market to ensure that they comply with the relevant technical regulation.

Market surveillance

(2) Pre-market approval of a commodity or service by a 30 regulatory agency shall only be considered if the risk of failure and the consequential damage of the failure is so high that market surveillance alone is inadequate.

PART V

GENERAL PROVISION

Regulations 24. The Minister may, by statutory instrument, make regulations for the better carrying out of the provisions of this Act.