



**भारतीय आयुर्विज्ञान अनुसंधान परिषद**  
**INDIAN COUNCIL OF MEDICAL RESEARCH**  
स्वास्थ्य अनुसंधान विभाग ( स्वास्थ्य एवं परिवार कल्याण मंत्रालय )  
DEPARTMENT OF HEALTH RESEARCH ( MINISTRY OF HEALTH & FAMILY WELFARE)

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V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX-4911, NEW DELHI-110029

No.18/2/2015-Admn-II

Dated: 29/12/2015.

To,

The Directors/Directors-in-Charge of all  
Permanent Institutes/Centres of the Council

Sir/Madam,

Please find enclosed herewith a copy of D.O. No. 3/14/2015-NPC-QCI dated 14<sup>th</sup> December, 2015 received from Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce & Industry, Udyog Bhawan, New Delhi regarding action for amendment in requisite standard and regulations for exports for information and taking further necessary action at your end.

Yours faithfully,

(Bharat Bhushan)  
Administrative Officer  
for Director General

Encl: as above

Copy to:-

- 1 PS to DG/Sr. DDG (A)/FA
- 2 All Divisional Heads.
- 3 Asstt. Director-General (Admn.) (AX)/(JP)
- ✓ 4 Dr. S.K. Dey Biswas, Scientist (G) with the request to place above circulars on ICMR website.



सत्यमेव जयते

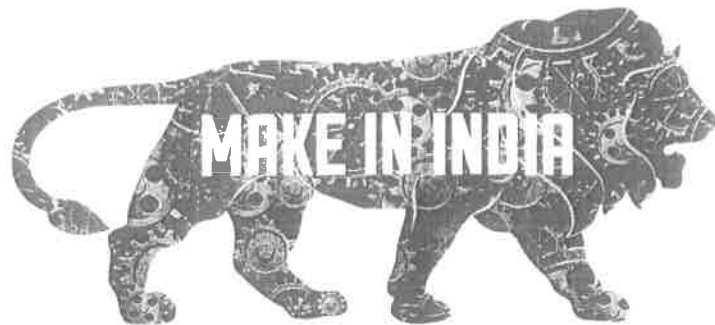
अमिताभ कान्त

सचिव

AMITABH KANT

Secretary

Ho (Admin)  
Circulate to  
Chief & Directors  
22/12



GOVERNMENT OFFICE

Diary No. 4803

Date 23/12/2015

14<sup>th</sup> December, 2015  
makeinindia.com

Dear Shri Soumya Swaminathan

Indian exporters routinely face non-tariff measures in the global markets, especially in developed countries, in the shape of mandatory technical regulations imposed by importing countries. On the other hand, most standards in India continue to be voluntary in nature, as the concerned products have not been brought under technical regulations.

Most developed countries, under the provisions of WTO Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) Agreements that govern international trade in goods, have based their technical regulations on international standards for **(1) products, and (2) conformity assessment procedures (testing, inspection and certification)**. As the products in India, barring a few sectors like food and drugs, do not have mandatory technical regulations, and even the standards prescribed are at times out-dated or not at par with international standards, the quality of domestic production falls short of the requisite standards and regulations for exports.

It is thus crucial that we raise our voluntary standards to internationally acceptable standards, at the same time, products that are amenable to mandatory technical regulations need to be identified and accordingly their technical regulations formulated to international standards.

In this regard, it is imperative that each department undertake action on the following points:

**A. Review Old and Prepare new Voluntary standards to internationally acceptable levels.**

Identify internationally acceptable voluntary standards and adopt them as Indian standards for the concerned products to the extent possible, if these are to be adopted under BIS Act, then co-ordinate with BIS for the same.

**B. Review old and prepare new technical regulations that are based on international standards.**

The existing regulations be reviewed and aligned to international standards. If it is not possible to align with international standards right away, prepare a specific time frame preferably not exceeding three years, in which sectoral industry would be facilitated and required to meet respective international standards. Also, identify and bring new products, depending upon domestic needs, under new technical regulations.

भारत सरकार

Contd...2/-

औद्योगिक नीति और संवर्धन विभाग, वाणिज्य एवं उद्योग मंत्रालय, उद्योग भवन, नई दिल्ली – 110011

Government of India

Department of Industrial Policy and Promotion, Ministry of Commerce &amp; Industry, Udyog Bhawan, New Delhi-110011

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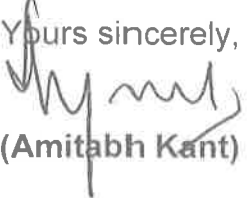
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**C. Upgrading conformity assessment procedures to international level**

Take steps for accreditation of conformity assessment bodies as permissible under the applicable law; adopt procedures at par with international practices. This would also greatly aid in the ease of doing business by cutting costs and simplifying procedures.

A brief on standards and technical regulations as also an indicative step by step process for bringing a product under technical regulation are enclosed herewith. May I request you to initiate action on the above cited points.

With regards

Yours sincerely,  
  
(Amitabh Kant)

Encl: As above.

**Shri Soumya Swaminathan**  
**Secretary**  
**Department of Health Research**  
**Indian Council of Medical Research, V. Ramalingaswami Bhawan, Ansari**  
**Nagar , New Delhi - 110029**

## Standards and technical regulations

Standards are of two types: voluntary and mandatory. The mandatory standards are called technical regulations which are becoming important for international trade because:

- a) There is synergetic relation of standards (basically mandatory standards called as technical regulations) and trade. Standards are trade enhancing because standards reduce information asymmetries, signal quality to consumers and create a common language for potential trading partners, thus reducing overall transaction cost. However at the same time the concerns over the impact of standards as non-tariff barriers (NTBs) in global trade are also well-documented.
- b) Internationally the tariffs has been going down and overall global average import weighted tariff on industrial goods has gone down to just around 4%. With FTAs being negotiated among large number of countries, average global tariff rates will go down further, reducing the role of tariff in market access.
- c) At the same time the use of technical regulations (mandatory standards) has grown worldwide along with growth of variety of conformity assessment procedures which is having a vital impact on market access and global trade.
- d) Mandating standards on products and putting in place a proper eco-system related to standards, metrology, testing and quality would help preventing flooding of domestic market with unsafe/sub-standard imports, which adversely affect consumers as well as domestic industry.
- e) In the globalized marketplace following the creation of the World Trade Organization, a key challenge facing developing countries is a lack of national capacity to overcome technical barriers to trade and to comply with the requirements of agreements on sanitary and phytosanitary conditions, which are now basic prerequisites for market access embedded in the global trading system. The World Trade Organization has adopted two important agreements in these areas: the Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary Measures.
- f) Complying with these technical requirements would help domestic industry in increasing the exports by measuring up to standards and conformity assessment procedures both in quantitative terms and also getting higher value of exports.

## INDICATIVE STEP BY STEP PROCESS OF BRINGING A PRODUCT UNDER TECHNICAL REGULATION

1. Identification of the **product** for bringing under technical regulations for legitimate objectives (amongst others National security requirements, Prevent deceptive practices, Protect human health and safety, Protect animal and plant health, Protect the environment)
2. Identify the **appropriate legislation** which has provision for enforcing regulation of products (e.g. FSSAI Act, Drugs & Cosmetics Act, Explosives Act, The Petroleum and Natural Gas Regulatory Board Act, 2006 etc). If such a legislation is not available with the ministry then BIS Act can be used as it is the only option in that scenario.
3. In case BIS Act is being used at present there is a limitation as per section 14 of BIS Act that the product should be of any 'scheduled industry' mentioned in the schedule of The Industries (Development & Regulation) Act 1951. There is however an amendment of the BIS Act in process which seeks to remove this limitation.
4. Identification of the **relevant Standard**. As far as possible international standards should be used for regulation.
5. In case BIS Act is being used, then identification of relevant Indian Standard (IS) in BIS.
  - a. If it exist, whether it is suitable and it can be checked with BIS if it is harmonized with relevant international standard.
  - b. If it doesn't exists or not suitable, matter needs to be taken up with BIS to make one.
  - c. In case BIS standard doesnot exist and an international standard exist, which has been found suitable, matter needs to be taken up with BIS for its adoption.
6. Identify the relevant **conformity assessment procedure**. In case of instrument other than BIS Act being used examine the possibility of using third