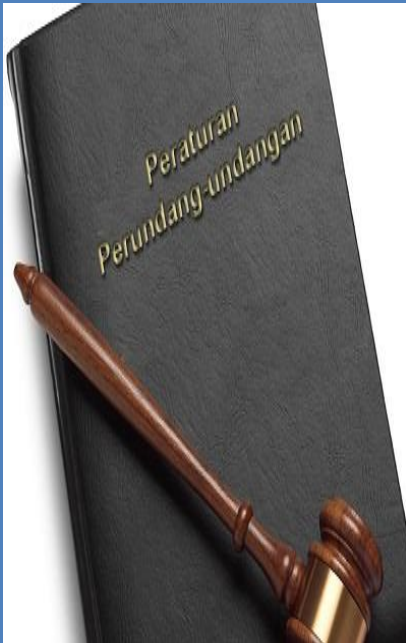


THE ROLE OF BSN IN THE IMPLEMENTATION OF GOOD REGULATORY PRACTICES, STANDARDIZATION AND CONFORMITY ASSESSMENT SYSTEM

**Direktorat Sistem Penerapan Standar dan Penilaian Kesesuaian
Jakarta, 15 Juni 2022**



Law No. 20 of 2014, Standardization and Conformity Assessment

Government Regulation 34 of 2018, System for Standardization and Conformity Assessment

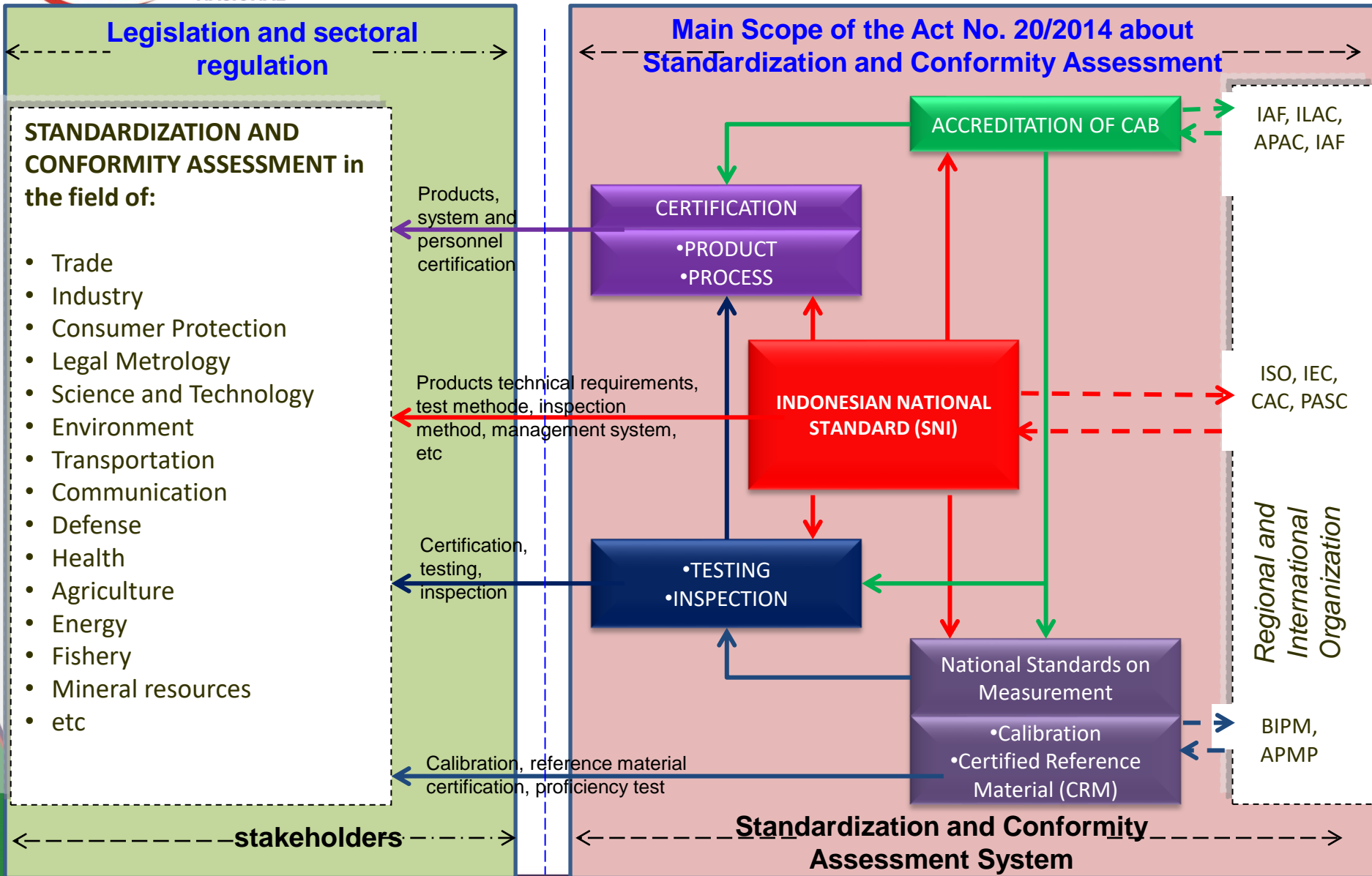
PBSN No. 2 of 2017, Procedures for SNI Marks and SNI-Based Conformity Marks

PBSN No. 7 of 2020, Procedures for Mandatory Enforcement of Standard Nasional Indonesia (SNI)

PBSN No. 8 of 2020, Procedures for Regulatory Impact Analysis and Compliance to International Obligations



National Standardization System



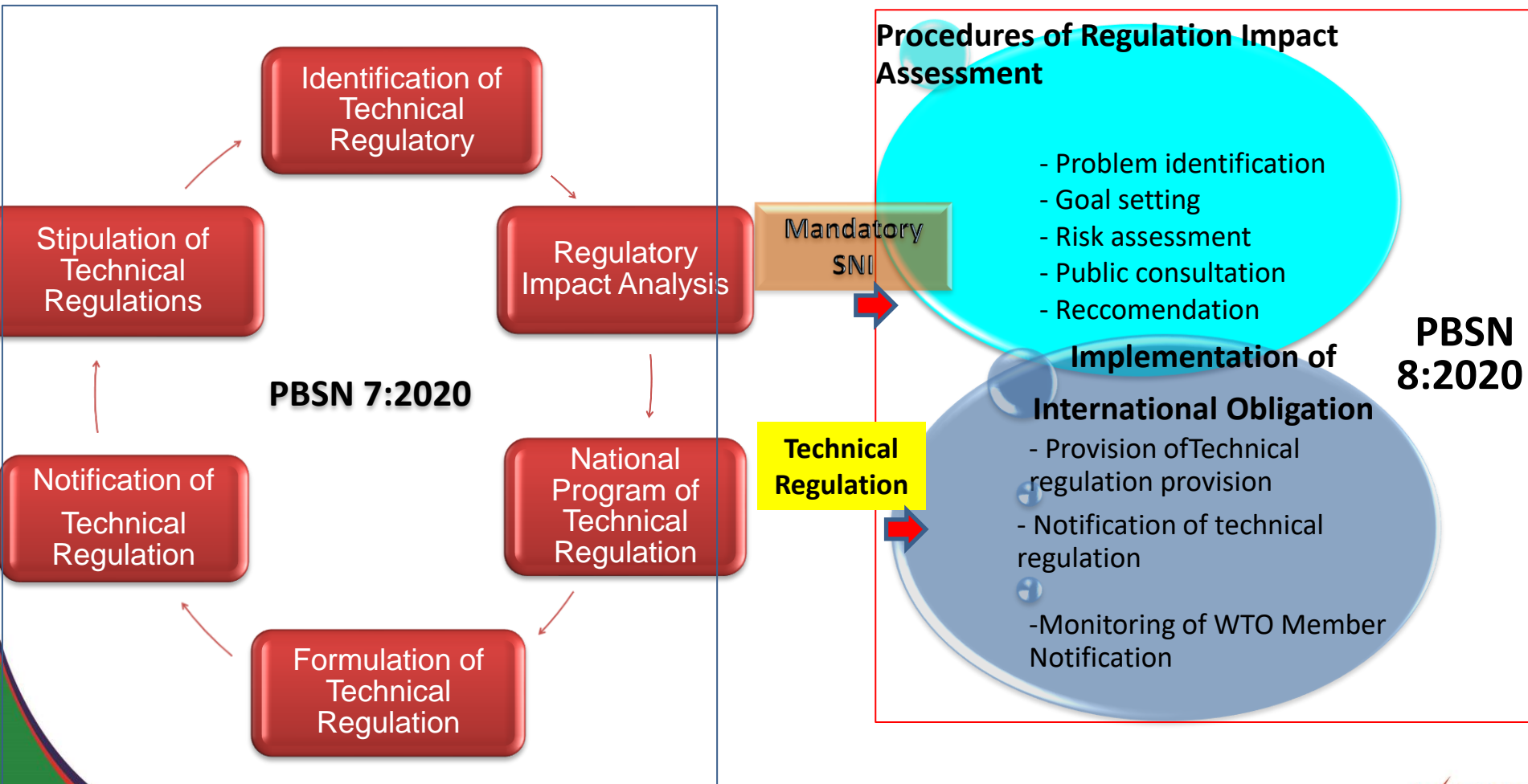
INDONESIA'S PARTICIPATION IN ISO/IEC COMMITTEE

	ISO	IEC
P-member	97 TC/SC	25 TC/SC
O-member	161 TC/SC	43 TC/SC

BSN O member in ISO TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

BSN P member in ISO TC 84 Devices for administration of medicinal products and catheters

PBSN 7/2020 and PBSN 8/2020 GRP



NO	MINISTRY OR AGENCY	NUMBER OF SNI THAT HAVE BEEN REGULATED	NUMBER OF SNI NOTIFIED TO WTO	INFORMATION (TYPE OF ENFORCEMENT)
1	Ministry of Industry	124	120	Obligation of SPPT SNI, Method of Numbering NIK (Motor Vehicle Identification Number)
2	Ministry of Energy and Mineral Resources	86	29	Obligations of SPPT SNI, test result certificate, reference in technical rules
3	Ministry of Agriculture	7	7	Obligations of SPPT SNI, test result certificate
4	Ministry Of Marine Affairs and Fisheries	2	2	Obligations of SPPT SNI
5	Ministry of Transportation	9	0	Reference/Procedures for the implementation of activities
6	Ministry of Public Works	44	0	Reference/Procedures for the implementation of activities
7	Ministry of Trade	24	0	Obligation of SPPT SNI for export, Certificate/test report
8	Ministry of Communication and Informatics	4	0	Technical requirements for device certification
9	National Cyber and Crypto Agency	1	0	Information Security Management System (SMPI) Certificate Requirements for electronic system operators
Total		301	158	

As of May 2022

<https://bsn.go.id/main/berita/detail/11826/regulasi-teknis-sni-yang-diwajibkan>

Notification Body:

To notify the draft of technical regulation to WTO Secretariat within the framework of implementing the WTO TBT Agreement after the coordination mechanism among regulators and other stakeholder

Enquiry Point

Response the inquiries from other WTO members regarding the technical regulation that have the potential to create trade barriers

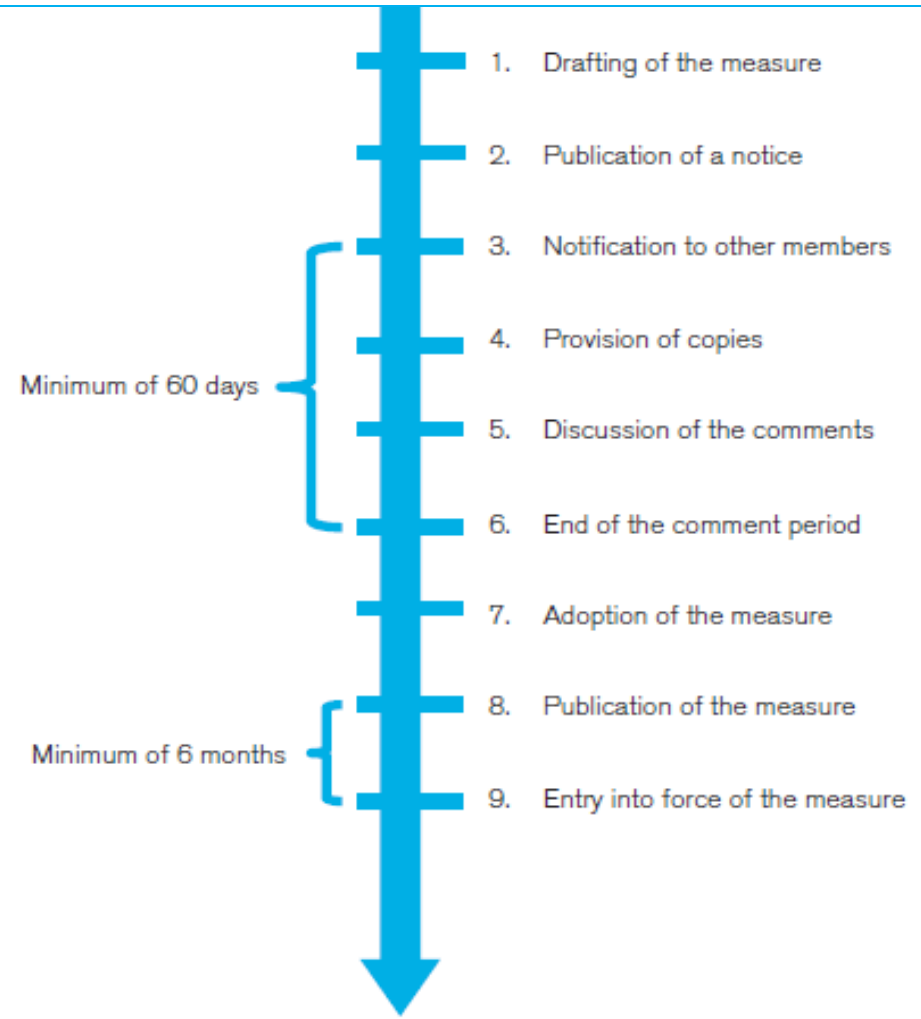


Notification Process

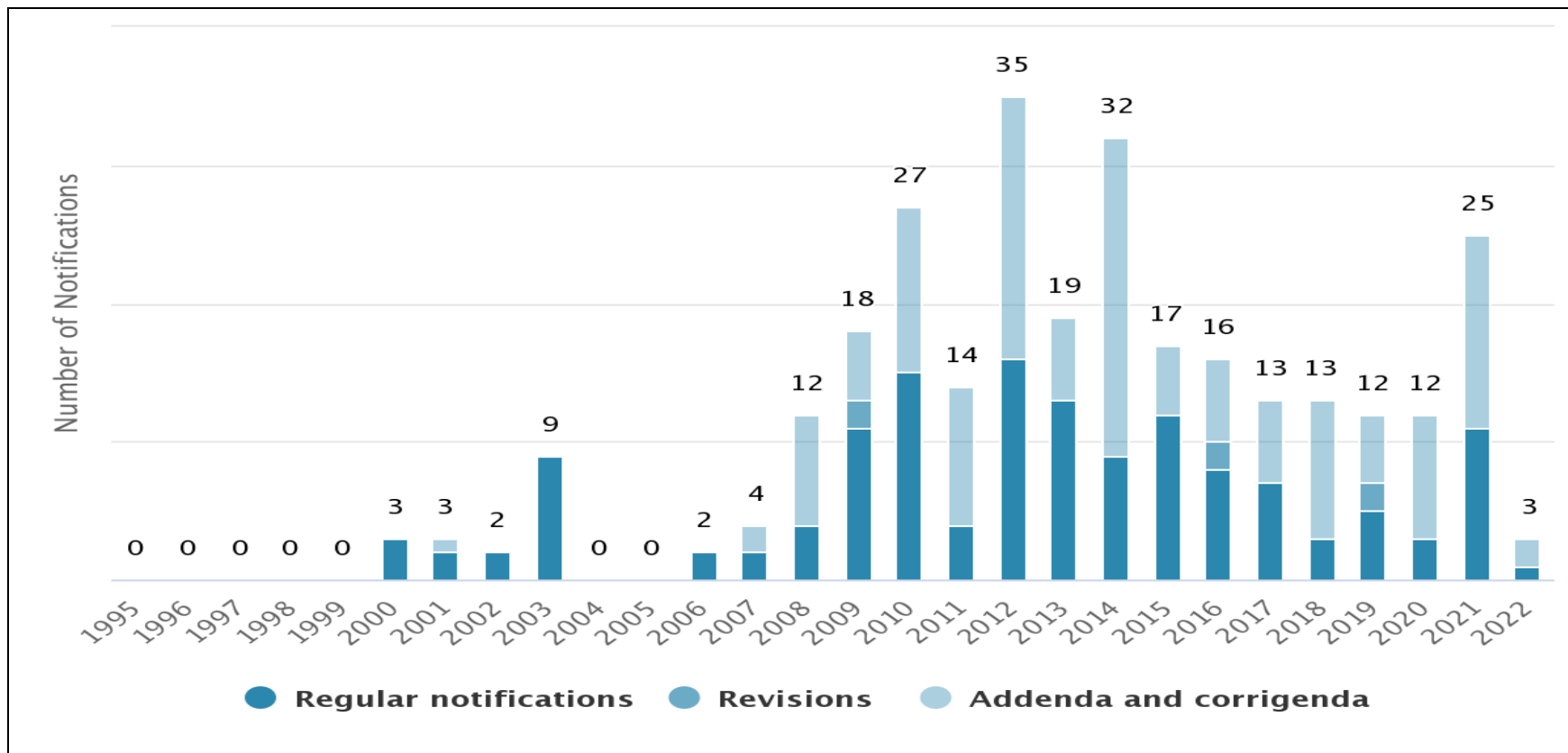
Subject being notified to TBT Secretariat

1. **Technical Regulation (Article 2.9.2)**
2. **Technical Regulation – Urgent (Article 2.10.1)**
3. **Conformity Assessment Procedure (Article 5.6.2)**
4. **Conformity Assessment Procedure - Urgent (Article 5.7.1)**
5. **Technical Regulation - Local Government (Article 3.2)**
6. **Conformity Assessment Procedure - Local Government (Article 7.2)**

**Minimum 60 days Comment Period
(90 days, if necessary)**



Indonesia Notification to the TBT Committee



Total Notifications : 291
(Regular and addendum notification)

Source: epingalert.org

Regulation on Fat sugar and salt labelling on food product: Indonesia
Ministry of health

Medical Device Regulations in Indonesia

Law Number 8 of 1999 concerning Consumer Protection

Law Number 11 of 2008 concerning Information and Electronic Transactions

Law Number 36 Year 2009 concerning Health

GR Number 72 of 1998 concerning Security of Pharmaceutical Preparations and Medical Devices

GR No. 35 of 2015 concerning the Ministry of Health

MoH Reg No. 1189/Menkes/Per/VIII/2010 concerning Production of Medical Devices and Household Health Supplies

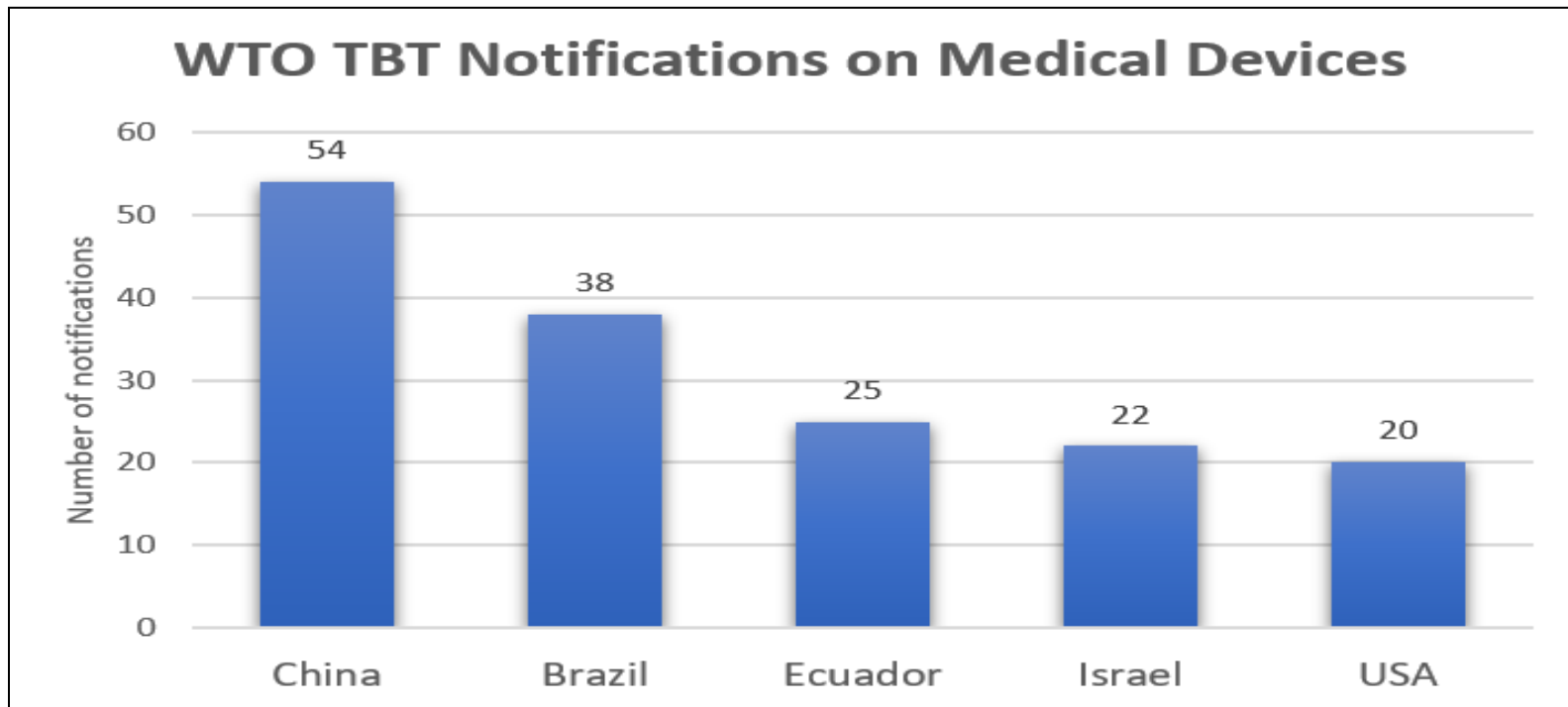
MoH Reg No 1191/Menkes/Per/VIII/2010 on Distribution of Medical Devices;

MoH Reg No 76 Tahun 2013 regarding Medical Devices and Household Health Supplies (PKRT) Advertisements

MoH Reg No 62 tahun 2017 regarding Circulation Permits of Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Supplies

MoH Reg No 63 tahun 2017 concerning Good Clinical Test Methods for Medical Devices

Medical Devices TBT Notifications from WTO Members



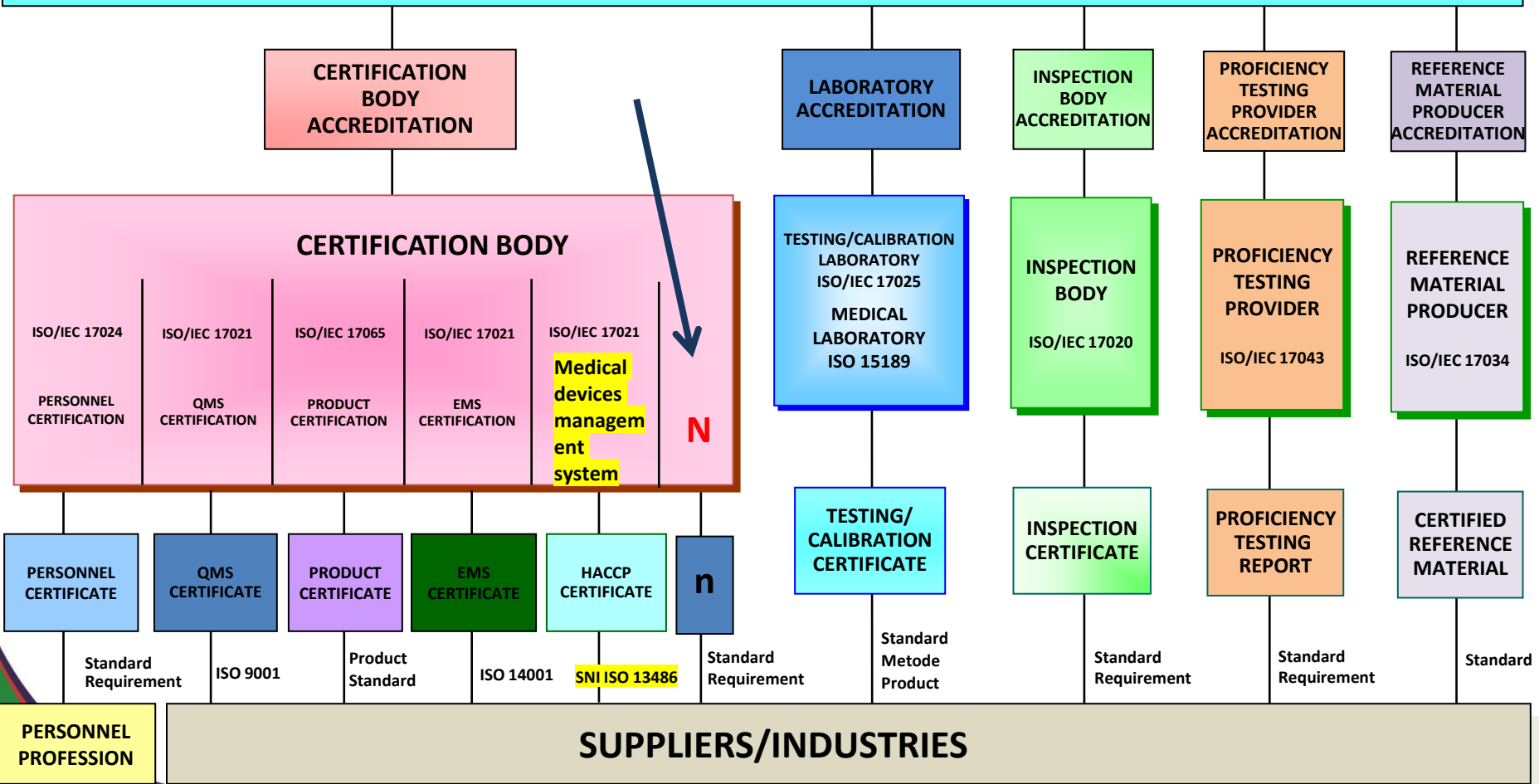
Examples of notified Medical Devices regulations:

1. Category and reference standards for medical devices
2. Enforcement of national standards
3. Medical device product registration, inspection and certification procedures
4. Company supervision procedures and circulating medical supplies
5. Import control regulations

Source : epingalert.org
HS 9018, 621010, 621143, 630790

KAN - ACCREDITATION AND CONFORMITY ASSESSMENT SYSTEM

KOMITE AKREDITASI NASIONAL (KAN) (ISO/IEC 17011)



Regional and International Recognition

MRA

APAC



1. Test Laboratory
2. Calibration Laboratory
3. Inspection Body
4. Medical Laboratory

MLA on QMS CB (PAC, 2000), (IAF, 2002)

2001 : MRA on Testing Laboratory

2003 : MRA on Calibration Laboratory

2004 : MRA on Inspection Body

MLA on EMS CB (PAC, 2004), (IAF, 2007)

2009 : MLA on Products CB (PAC & IAF)

2013 : MRA on Medical Laboratory

MLA on FSMS CB (PAC, 2013), (IAF, 2015)

Etc.



MLA

APAC



1. Certification Body of MS
2. Certification Body of EMS
3. Products Certification Body
4. Food Safety Certification Body
5. Personal Certification Body

TERIMA KASIH THANK YOU



member of

member of



Bureau
International des
Poids et
Mesures



APAC

www.bsn.go.id

www.kan.or.id



Badan Standardisasi Nasional



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