

25 - 26.10.2023 | DAY 2

Chemical Regulations and
Sustainability Symposium 2023



Chemical
Business
Association

REACHLAW
COMPLIANCE. SUSTAINABILITY.

India Chemical Regulations

Welcome

Speaker:



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India Chemical Regulations

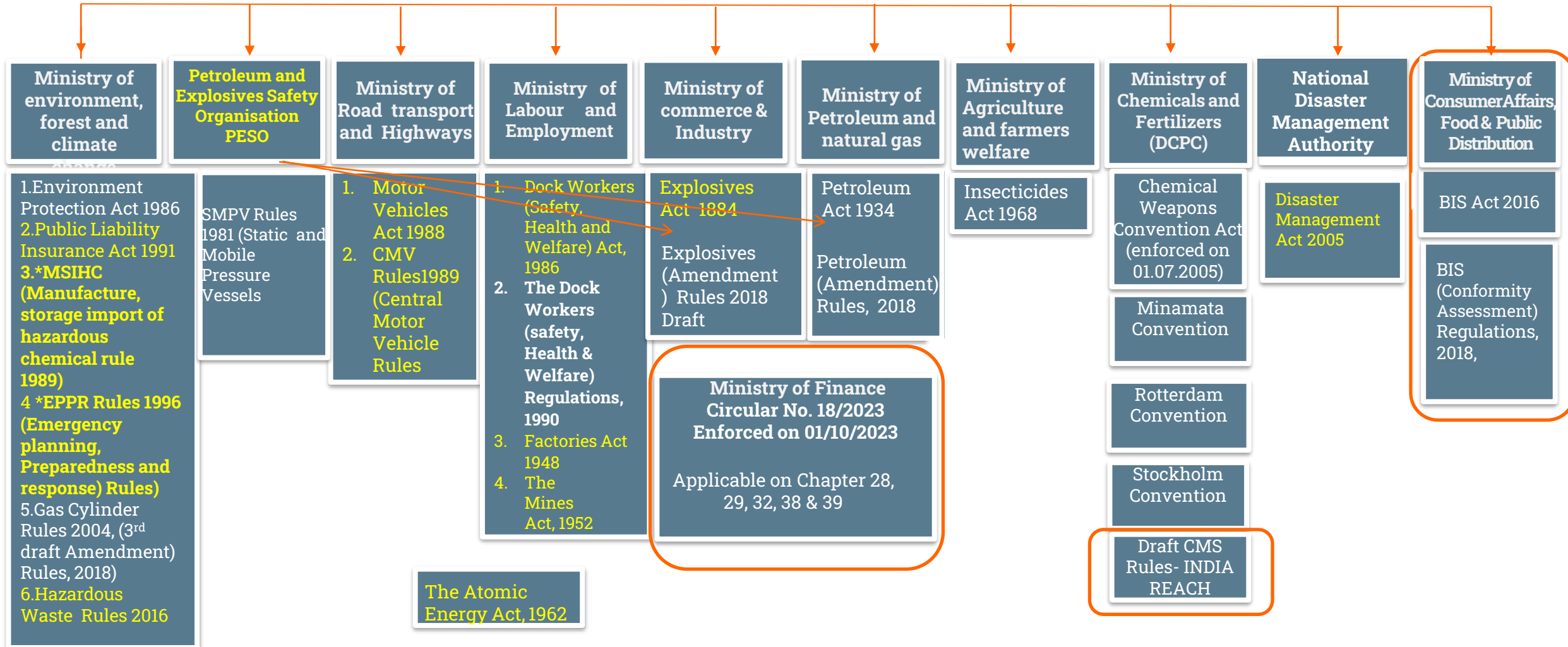
Topics

- Chemical Regulatory Landscape in India
- Impact of Business – Foreign Manufacturers
- Best Practice for Compliance
- Conclusion
- Contact

- 1. Chemical Regulatory Landscape in India**
- 2. Impact of Business – Foreign Manufacturers**
- 3. Best Practice for Compliance**
- 4. Conclusion**
- 5. Contact**

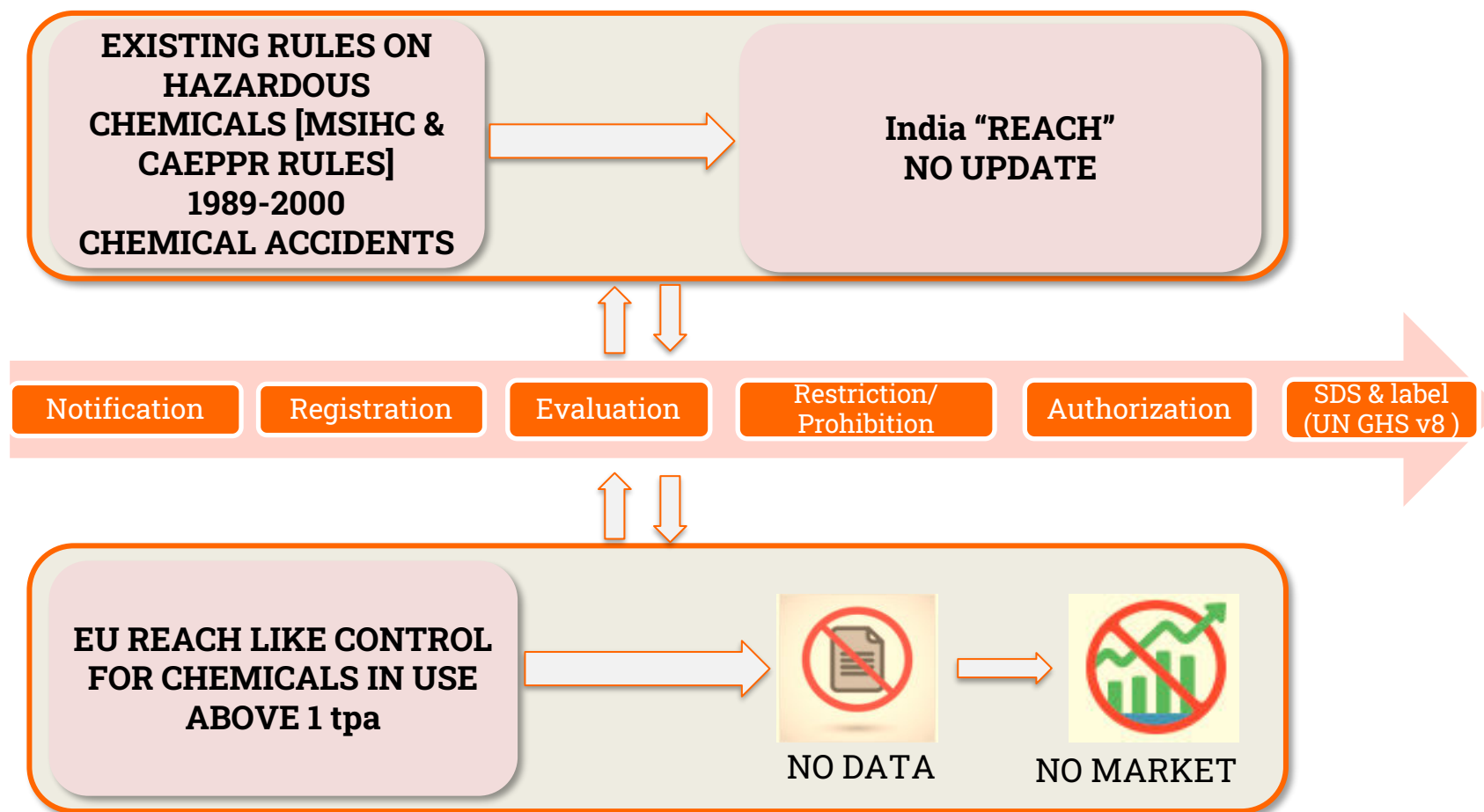
Chemical Regulatory Landscape in India

Chemical Regulatory Environment & Authorities



Chemical Regulatory Landscape in India

Draft - Chemical (Management and Safety) Rule, 20xx – aka India REACH



Draft Chemicals (Management and Safety) Rules, 20xx

In exercise of the powers conferred by Sections 3, 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989 and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996, except things done or omitted to be done before such supersession, the Central Government hereby makes the following Rules relating to the management and safety of chemicals, namely:

1. Short Title and Commencement

(1) These Rules may be called the Chemicals (Management and Safety) Rules, 20xx.

(2) These Rules shall come into force on the date of their publication in the Official Gazette.

Chapter I
Definitions, Objectives and Scope

2. Definitions

(1) In these Rules, unless the context otherwise requires

(a) "Act" means the Environment (Protection) Act, 1986 (29 of 1986) as amended from time to time;

(b) "Article" means any object whose function is determined by its shape, surface or design to a greater degree than its chemical composition;

(c) "Authorised Representative" means a natural or juristic person in India who is authorised by a foreign Manufacturer under Rule 6(2);

(d) "Chemical Accident" means an accident involving a sudden or unintended occurrence while handling any Hazardous Chemical, resulting in exposure (continuous, intermittent or repeated) to the Hazardous Chemical causing death or injury to any person or damage to any property, but does not include an accident by reason only of war or radioactivity;

(e) "Competent Person" means a person recognized by the Chief Controller to be a competent person, or a person who holds a certificate of competency for the job in respect of which competency is required from an institution recognized by the Chief Controller in this behalf;

(f) "Concerned Authority" means an authority specified in column 2 of Schedule III;

(g) "Division" means the Chemical Regulatory Division of the Petroleum and Explosives Safety Organisation, whose functions are set out under Rule 5;

(h) "Downstream User" means any natural or juristic person in India, other than a Manufacturer or an Importer, who Uses a Substance in the course of his industrial or professional activities;

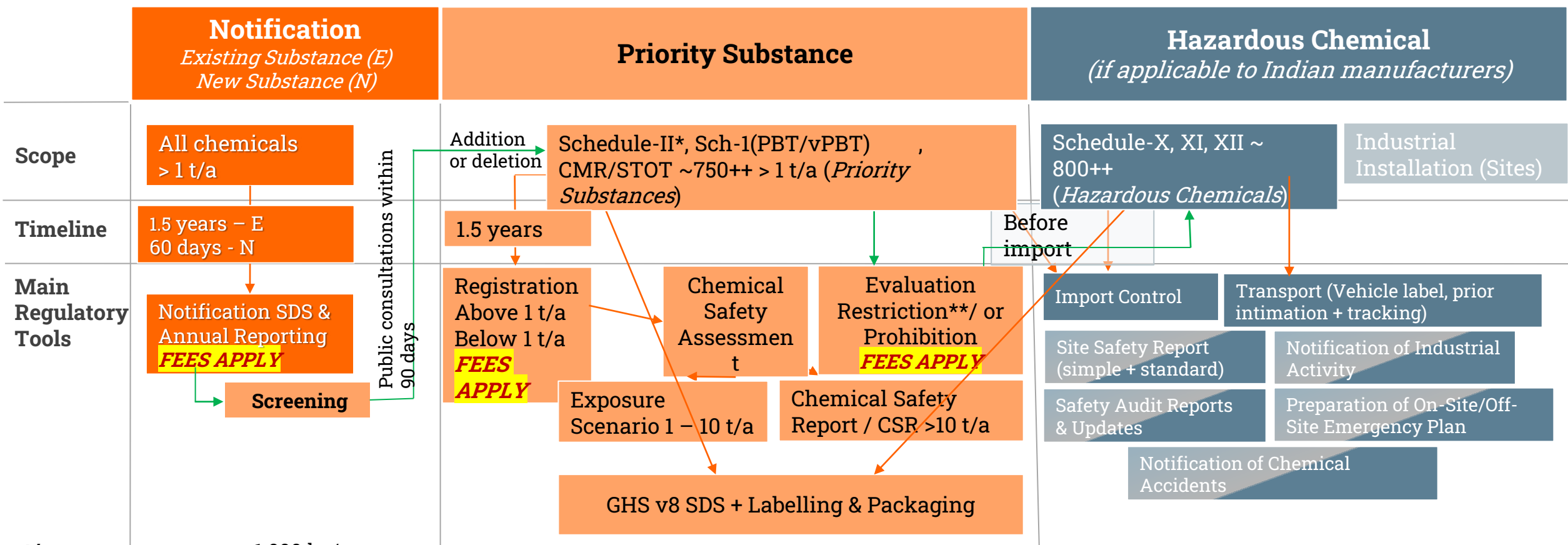
Explanatory Note: Downstream User does not include end-use consumer.

(i) "Existing Industrial Activity" means an Industrial Activity which is not a New Industrial Activity;

New Draft OCR 24 Aug 2020 Page 1/98

Chemical Regulatory Landscape in India

India REACH - Scope Detail



t/a = tonnes per annum, 1 000 kg/year
SDS = Safety Data Sheet
GHS = United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 8)

Chemical Regulatory Landscape in India

Circular: Overview & Requirements

Voluntary Declaration published on 17/12/2020

Circular No. 55/2020

Objective:

Complete description of imported goods during Bill of Entry

- Generic Description
- Specific Description
- Model and Brand Name
- Supplier & Manufacturer detail
- **Item qualifiers**
- Previous bill of entry

Ministry of Finance
Department of Revenue
Central Board of Indirect Taxes & Customs



Chapter 28

Inorganic chemicals, organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes



Chapter 29

Organic chemicals



Chapter 32

Tanning or dyeing extracts; tannins and their derivatives; dyes, pigments, and other colouring matter; paints and varnishes; putty and other mastics; ink.



Chapter 3808

Miscellaneous chemical products



Chapter 39

Plastics and articles thereof

Mandatory Declaration enforced from 01/10/2023

Circular No. 15/2023 → Circular No. 23/2023

Date of enforcement extended
from 01/07/2023 to 15/10/2023

Objective:

To prepare inventory for imports of Chemicals
Monitoring of Imports under "Others" category

Obligation: Importers

Requirement: Additional qualifiers- IUPAC names & CAS Number in bill of entry

Applicable on:

Chapter 28, 29, 32, 38 (3808) & 39

Ministry of Finance
Department of Revenue
Central Board of Indirect Taxes & Customs

Circular No. 18/2023-Customs

F.No. 528/36(2016-STOCTU)
Government of India
Ministry of Finance
Department of Revenue
Central Board of Indirect Taxes & Customs

North Block, New Delhi
Dated: 30.06.2023

To:-
All Principal Chief Commissioners/ Chief Commissioners of Customs/ Customs (Preventive),
All Principal Chief Commissioners/ Chief Commissioners of Customs and Central Tax
All Principal Commissioners/ Commissioners of Customs/ Customs (Preventive)
All Principal Directors General/ Directors General, under CBIC.

Madam/ Sir,

Subject: Mandatory additional qualifiers in import/export declarations in respect of certain products w.e.f. 01.07.2023 – reg.

Reference is drawn to the Circular No. 15/2023-Customs dated 07.06.2023 wherein mandatory additional qualifiers were added for purposes of import or export declarations under specified chapters. These additional qualifiers were made mandatory for imports/ exports for all Bills of entry/ Shipping bills filed on or after 01.07.2023.

2. Representations have been received from several trade associations requesting for extension of the due date which is 01.07.2023 for mandatory declaration of additional qualifiers in import declarations as prescribed in above Circular. Further, Department of Chemicals and Petrochemicals has also requested to defer implementation of above Circular for a further period of 3 months. Additionally, during testing certain mismatches have been observed in qualifier information for export products.

3. In view of above, due date for mandatory declaration of additional qualifiers in import/export declaration is extended from 01.07.2023 to 01.10.2023.

4. Suitable Public Notice etc. may kindly be issued for guidance. Any difficulties faced or doubts arising in the implementation of this Circular may please be brought to the notice of Board.

5. The Hindi version follows.

Jitender Singh
Jitender Singh
OSD-Tariff Unit
email: tariffunit-rev@nic.in
Tel: 23095557

Format for declaration of chemicals

ANNEXURE-1 (IMPORTS)

All CTHs of CHAPTER-28, 29, 32, 38, 39

Field Description in Bill of Entry	Constituent element name	Constituent element code
	IUPAC name of the chemical	CAS Number
Constituent 1		
Constituent 2		
Constituent 3		
Constituent 4		

Chemical Regulatory Landscape in India

Circular Requirements: Foreign manufacturer/Importer

Additional requirements for the manufacturers of following:

- **Bulk and basic chemicals:** CAS number and IUPAC name is mandatory.
- **Proprietary Components, R&D or others:** CAS number **or** IUPAC name of Main/Active ingredients (at least one) is mandatory.
- **Formulations and Mixtures:** CAS number **and** IUPAC name of Main/Active ingredients (at least one) is mandatory.

Self undertaking in case of non availability of information for even one ingredient

The details (CAS number and IUPAC) of chemicals **will be masked** in bill of entry.

Recent updates

- New dedicated HS Codes at 8 digit level for monitoring of imports under 'Others' category.
- Neither purity nor 100% constituent required in the bills of entry.
- Relaxed regime for 3 months and review after 1 year
- Data to be shared only with Ministry of Chemical & Fertilizer, Department of Chemicals & Petro Chemicals

Chemical Regulatory Landscape in India

BIS: Overview

Source: BIS Annual_Report_2020-21

Source: www.bis.gov.in



Bureau of Indian Standards
The National Standards Body of India

- National Standard Body of India under **Ministry of Consumer Affairs, Food and Public Distribution**, Govt. of India
- **Founded in** 1986
- **Headquartered:** New Delhi, India
- **Indian Standard published:** 22644
- Member of ISO* & IEC**
- BIS has been operating Foreign Manufacturers' Certification Scheme (FMCS) since 2000
- 1341 operating license*** under **FMCS**

*International Organization for Standardization

**International Electro-technical Commission

***http://203.153.41.213:8098/fmcs/All_fmcs.aspx



STATUTORY FRAMEWORK

BIS Act 2016

Rules and Regulations framed there under e.g., Bureau of Indian Standards (Conformity Assessment) Regulations, 2018



BIS MANDATE

to satisfy the customer needs for quality

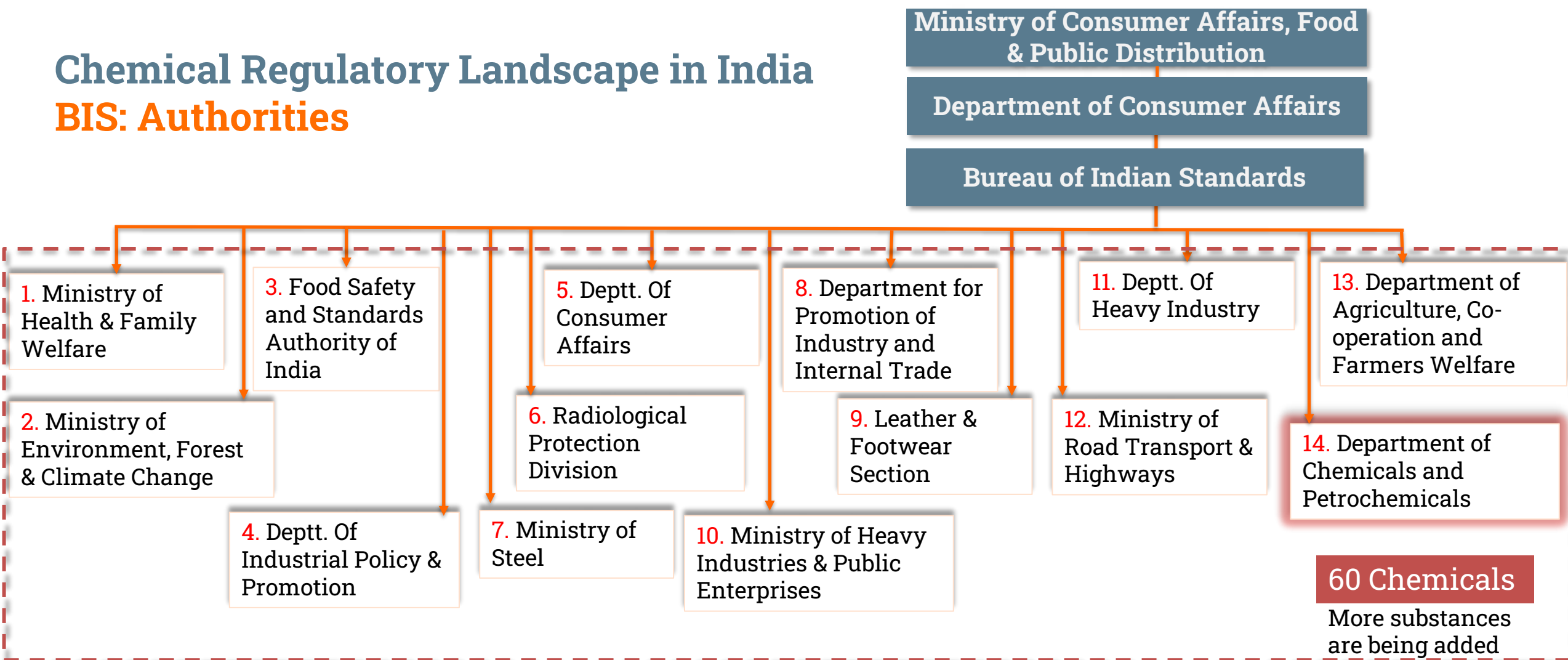


OBJECTIVES OF BIS

Harmonious standardization with ISO/IEC
Conformity Assessment
Quality Assurance
standardization and quality control for growth and development of industry & consumer needs.

Chemical Regulatory Landscape in India

BIS: Authorities



14 regulators (Line ministries) under central govt. are responsible for development of Quality Control Order (QCO) including their amendments/ extensions

1. Chemical Regulatory Landscape in India

2. Impact of Business – Foreign Manufacturers

3. Best Practice for Compliance

4. Conclusion

5. Contact

Impact of Business – Foreign Manufacturers

Scope

Scheme I (ISI Mark Scheme)



Cover **412 items** under 42 categories

1. Cement (any variety of cement manufactured or sold in India)
2. Household Electrical goods
3. Batteries
4. Food & Related Products
5. Oil Pressure Stoves
6. Automobile Accessories
7. Cylinder, Valves and Regulator
8. Medical Equipment
9. Steel and Iron Products
10. Electrical Transformers
11. Electrical Motors
12. Capacitors
- 13. Chemicals, Fertilizers, Polymers & Textiles (60 Chemicals)**
14. Kitchen Appliances
15. Domestic Water Heaters for use with LPG

16. Air Conditioner and its related Parts, Hermetic Compressor and Temperature Sensing Controls
17. Plugs and Socket-Outlets and Alternating Current Direct Connected Static Prepayment Meters for Active Energy
18. Domestic Gas Stoves for use with Liquefied Petroleum Gases
19. Transparent Float Glass
20. Domestic Pressure Cooker
21. Cables
22. Rubber Hose for Liquefied Petroleum Gas (LPG)
23. Aluminium Foil
24. Non Electric Toys
25. Electric Toys
26. Flat Transparent Sheet Glass
27. Safety Glass
28. Woven sacks

29. Butterfly Valves
30. Reflectors for Bicycles
31. Paper
32. Cattle Feeds
33. Automobile Wheel Rim Component
34. Foot Wear
35. Press Tool-Punches
36. Helmet for riders of Two Wheeler Motor Vehicles
37. Refrigerating Appliances
38. Centrifugally cast (Spun) iron pipes
39. Flux Cored (Tubular) Electrodes
40. Sewing Machine
41. Water Treatment System
42. Jute bag

Impact of Business – Foreign Manufacturers

Scope: Existing Chemicals (60)

- | | | |
|--|--|---|
| 1. Caustic Soda | 21. Sodium Formaldehyde Sulphoxylate | 41. Synthetic Micro-Fibres for use in Cement Based Matrix |
| 2. Boric Acid | 22. Sodium Tripolyphosphate | 42. Linear Alkyl Benzene |
| 3. Poly Aluminium Chloride | 23. n- Butyl Acrylate | 43. Ethylene Vinyl Acetate (EVA) Copolymers |
| 4. Acetic Acid | 24. Ether | 44. 3(N, N-DiEthyl) Aminophenol |
| 5. Aniline | 25. Ethylene Glycol | 45. Methylene Chloride (Dichloromethane) |
| 6. Methanol | 26. Toluene | 46. Red Phosphorus |
| 7. Phthalic Anhydride | 27. Terephthalic Acid | 47. Acrylonitrile Butadiene Styrene (ABS) |
| 8. Pyridine | 28. Methyl Acrylate | 48. Ethylene Dichloride |
| 9. Gamma Picoline | 29. Ethyl Acrylate | 49. p-Xylene |
| 10. Beta Picoline | 30. Vinyl Acetate Monomer | 50. Polycarbonate |
| 11. Morpholine | 31. Styrene (Vinyl Benzene) | 51. Polyurethanes |
| 12. Sodium Sulphide | 32. Maleic Anhydride | 52. Vinyl Chloride Monomer |
| 13. Potassium Carbonate | 33. Acrylonitrile | 53. 1,3 Phenylenediamine |
| 14. Acetone | 34. Polyester Spun Grey and White Yarn (PSY) | 54. Lauric Acid |
| 15. Phosphorous Trichloride | 35. Polyester Continuous Filament Fully Drawn Yarn (FDY) | 55. Acid Oil |
| 16. Phosphorous Pentachloride | 36. Polyester Industrial Yarn (IDY) | 56. Palm Fatty Acids |
| 17. Phosphorous Oxychloride | 37. Polyester Partially Oriented Yarn (POY) | 57. Rice Bran Fatty Acids |
| 18. Stabilized Hydrogen Peroxide | 38. Polyester Staple Fibres (PSF) | 58. Coconut Fatty Acids |
| 19. Precipitated Barium Carbonate | 39. LDPE, LLDPE & HDPE | 59. Rubberseed Fatty Acids |
| 20. Precipitated Barium for Ceramic and Glass Industry | 40. Styrene-Butadiene Rubber Latex | 60. Hydrogenated Rice Bran Fatty Acids |

Impact of Business – Foreign Manufacturers

Scope: New Chemicals Expected in Nov'23 (16)

Chemicals Notified at WTO in 2023			
S.No	Title	Distribution date	Final date for comments
1	Textiles –Polypropylene (PP)/High Density Polyethylene (HDPE) Laminated Woven Sacks for Mail Sorting, Storage, Transport and Distribution (Quality Control) Order, 2023	13-09-2023	12-11-2023
2	Anhydrous Ammonia (Quality Control) Order, 2023	13-09-2023	12-11-2023
3	Ethylene Oxide (Quality Control) Order, 2023	13-09-2023	12-11-2023
4	Industrial Grade Urea (Quality Control) Order, 2023	13-09-2023	12-11-2023
5	Textiles – High Density Polyethylene (HDPE) Polypropylene (PP) Woven sacks for Packaging of 25 kg Polymer Materials (Quality Control) Order, 2023	13-09-2023	12-11-2023
6	Textiles – High Density Polyethylene (HDPE)/ Polypropylene (PP) Woven Sacks for Packaging Fertilizers (Quality Control) Order, 2023	13-09-2023	12-11-2023
7	Monocrotophos (Quality Control) Order, 2023	13-09-2023	12-11-2023
8	Toluene Diisocyanate (Quality Control) Order, 2023	13-09-2023	12-11-2023
9	Diesel Engines – NOx Reduction Agent AUS 32 (Quality Control) Order, 2023	13-09-2023	12-11-2023
10	Alumina Calcined (Quality Control) Order, 2023	13-09-2023	12-11-2023
11	Textiles - Polypropylene (PP) Woven, Laminated, Block Bottom Valve Sacks for Packaging of 50 kg Cement (Quality Control) Order, 2023	13-09-2023	12-11-2023
12	Textiles - High Density Polyethylene (HDPE)/ Polypropylene (PP) Woven Sacks for Packaging of 50 kg Cement (Quality Control) Order, 2023	13-09-2023	12-11-2023
13	Captafol (Quality Control) Order, 2023	13-09-2023	12-11-2023
14	Sodium Cyanide (Quality Control) Order, 2023	13-09-2023	12-11-2023
15	Polypropylene (PP) Materials for Moulding and Extrusion (Quality Control) Order, 2023	15-08-2023	14-10-2023
16	Poly Vinyl Chloride (PVC) Homopolymers (Quality Control) Order, 2023	11-08-2023	10-10-2023

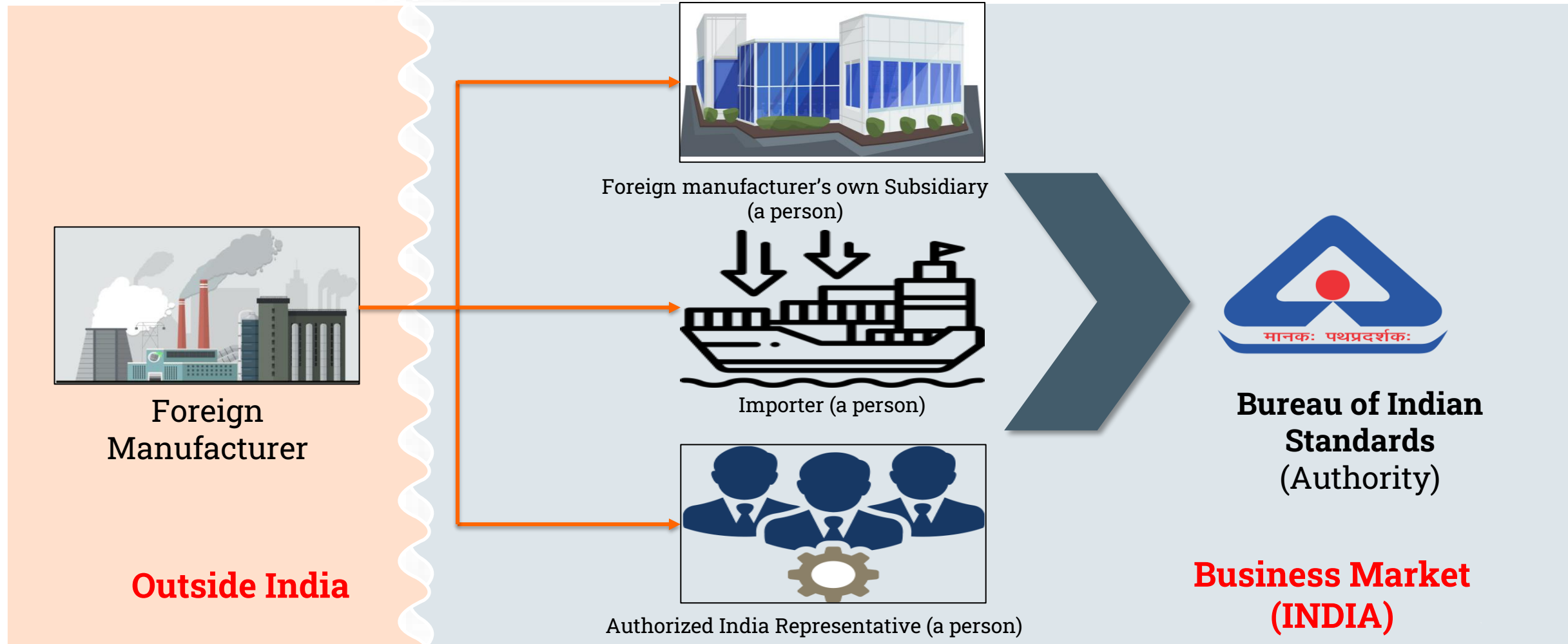
Impact of Business – Foreign Manufacturers

Scope: Proposed Chemicals (76)

1	Carbofuran	20	Cadmium Oxide	39	Ethyl Acetate	58	Nitric Acid	
2	Short Chain Chlorinated Paraffins (SCCP)	21	Calcium Carbide	40	Ethylene Oxide	59	Nitrobenzene	
3	Phorate	22	Captan	41	Formaldehyde	60	Nitrogen	
4	Dicofol	23	Carbon tetrachloride	42	Formic Acid	61	Oleum	
5	Acetaldehyde	24	Carbon disulphide	43	Hexane	62	P-Nitrophenol	
6	Acetic Anhydride	25	Cellulose Nitrate	44	Hydrogen	63	Perchloroethylene	
7	Acetylene	26	Chlorine	45	Hydrogen Fluoride	64	Potassium Chlorate	
8	Aluminium (Powder)	27	Chloroaniline-2	46	Isopropyl Alcohol	65	Potassium Cyanide	
9	Aluminium Chloride	28	Chloroaniline-4	47	Magnesium Powder or Ribbon	66	Potassium Silver Cyanide	
10	Aluminium phosphide	29	Chlorobenzene	48	Malathion	67	Propylene Glycol, Allylether	
11	Ammonia	30	Chloroform	49	Methyl Bromide	68	Sodium Cyanide	
12	Ammonium Nitrate	31	Copper and Compounds	(Bromomethane)	50	Methyl Chloride	69	Sodium Hydroxide
13	Anthraquinone	32	Crotonaldehyde	51	Methyl Chloroform	70	Sodium Pentachloro- Phenate	
14	Barium Nitrate	33	Cyclohexanone	52	Methyl Isobutyl Ketone	71	Sulphur dioxide	
15	Benzene	34	Diethylene Glycol	53	Monocrotophos	72	Sulphur trioxide	
16	Benzotrichloride	35	Dimethoate	54	N-Butyl Acetate	73	Sulphuric Acid	
17	Benzoyl Chloride	36	Dimethylamine	55	N-Butyl Alcohol	74	Trichloroethylene	
18	Benzyl Chloride	37	Dimethylaniline	56	N-Hexane	75	Zinc Phosphide	
19	Bromine	38	Dinitrotoluene	57	Naphthalene	76	Zirconium & Compounds	

Impact of Business – Foreign Manufacturers

Foreign Manufacturers: How to Comply



Impact of Business – Foreign Manufacturers

Role of Authorized Indian Representative (AIR)

- 1 Shall be an **Indian resident**
- 2 Preferably at least **graduate by qualification**
- 3 Shall declare his **consent to be responsible for compliance** to the provisions of the BIS Act, Rules, Regulations and Terms & Conditions laid down in BIS Licence, Agreement, Undertaking etc. executed by or on behalf of the foreign manufacturer in connection with grant and operation of the licence.
- 4 Shall **represent one manufacturing firm only**
- 5 In case of foreign manufacturers belonging to one group of companies and importers, **one AIR can be nominated.**
- 6 No conflict of interest with respect to their role as AIR with testing of sample(s) in third party laboratories.
- 7 **Submit and make available records** without delay upon request to any competent authority
- 8 Has a **written AIR Nomination letter/agreement** in place
- 9 **Communicate proactively** with BIS Authority, handling queries (if any) with client
- 10 **Monitoring of the legislation and ministry guidance** to ensure compliance with BIS License (FMCS)

**AGREEMENT FOR THE GRANT OF BIS LICENCE
(FOR USE BY THE FOREIGN MANUFACTURER)**
(On Rs. 100=00 non judicial stamp paper, to be attested by Notary Public)

The Agreement made at New Delhi on this -----day of -----month ----- year, between Bureau of Indian Standards, a body corporate established under the Bureau of Indian Standards Act, 2016 having its Head Office at Manak Bhavan, 9, Bahadur Shah Zafar Marg, New Delhi-110 002 (hereinafter referred to as "BIS", which expression shall include its administrators, assigns, agents and or representatives) of the one part,

AND

M/s... a foreign manufacturer having its office atand a Liaison/Branch Office/Office of its legally appointed Agent, namely, ~~Mr/Ms~~ located in India at..... (hereinafter referred to as the 'manufacturer' which expression shall include its heirs, and or assigns) through Mr./Mrs..... (its Managing Director/proprietor/partner or authorised signatory, as the case may be):

Whereas BIS has been established by the BIS Act, 2016 for harmonious development of activities of ~~Standardisation, Quality Certification and Marking of goods and for matters connected therewith or incidental thereto~~;

And whereas in furtherance of its functions as provided in the BIS Act, 2016 and in particular to provide service to foreign manufacturers, BIS is empowered to grant certification mark ~~licence~~ for foreign manufacturers of articles and ~~processes~~;

And whereas under BIS Act, 2016 BIS is ~~authorised~~ to grant BIS ~~licence~~ for use of the BIS Standard Mark by the foreign manufacturer on its such products, which conform to the relevant Indian Standards, and the grant of such ~~licence~~ is subject to the manufacturer complying with the norms laid down by BIS from time to time;

And whereas the foreign manufacturer has applied to Bureau of Indian Standards for grant of Bureau of Indian Standards ~~licence~~ under BIS Act, 2016 and BIS after satisfying itself about the capability of the manufacturer and that it satisfies the requirement as laid down in BIS Act, rules and regulations framed thereunder, and the terms and conditions of the ~~licence~~, has decided to grant to the manufacturer BIS ~~licence~~ on the terms and condition hereinafter mentioned.

Now the parties hereto agree as under:

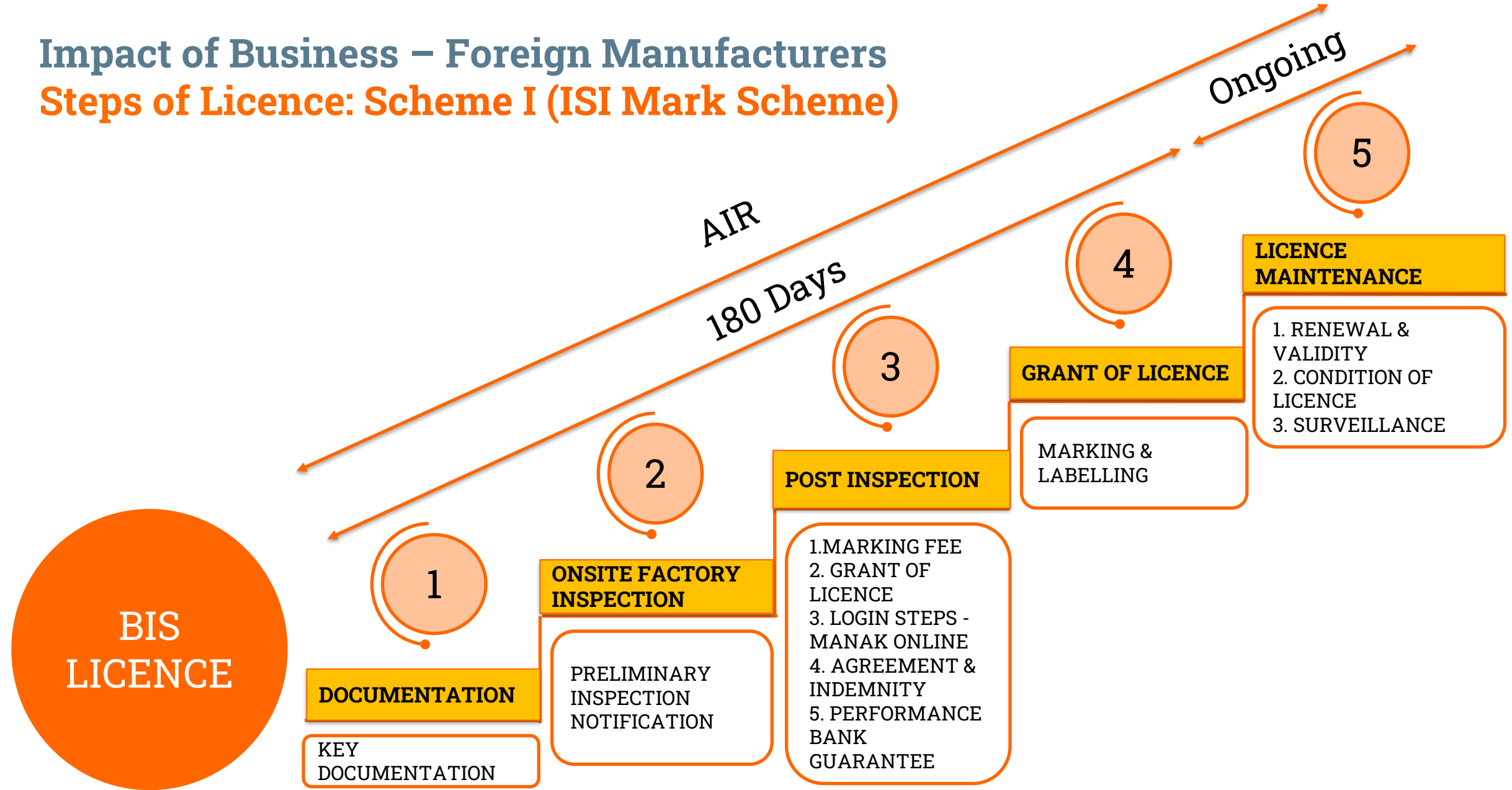
1. Definitions:

In this Agreement, unless the context otherwise requires,

- 1.1 "BIS ~~licence~~" means a ~~licence~~ granted under section 13 of the BIS Act, 2016 to use the Standard Mark in relation to any article or process, which conforms to the Indian Standard.

Impact of Business – Foreign Manufacturers

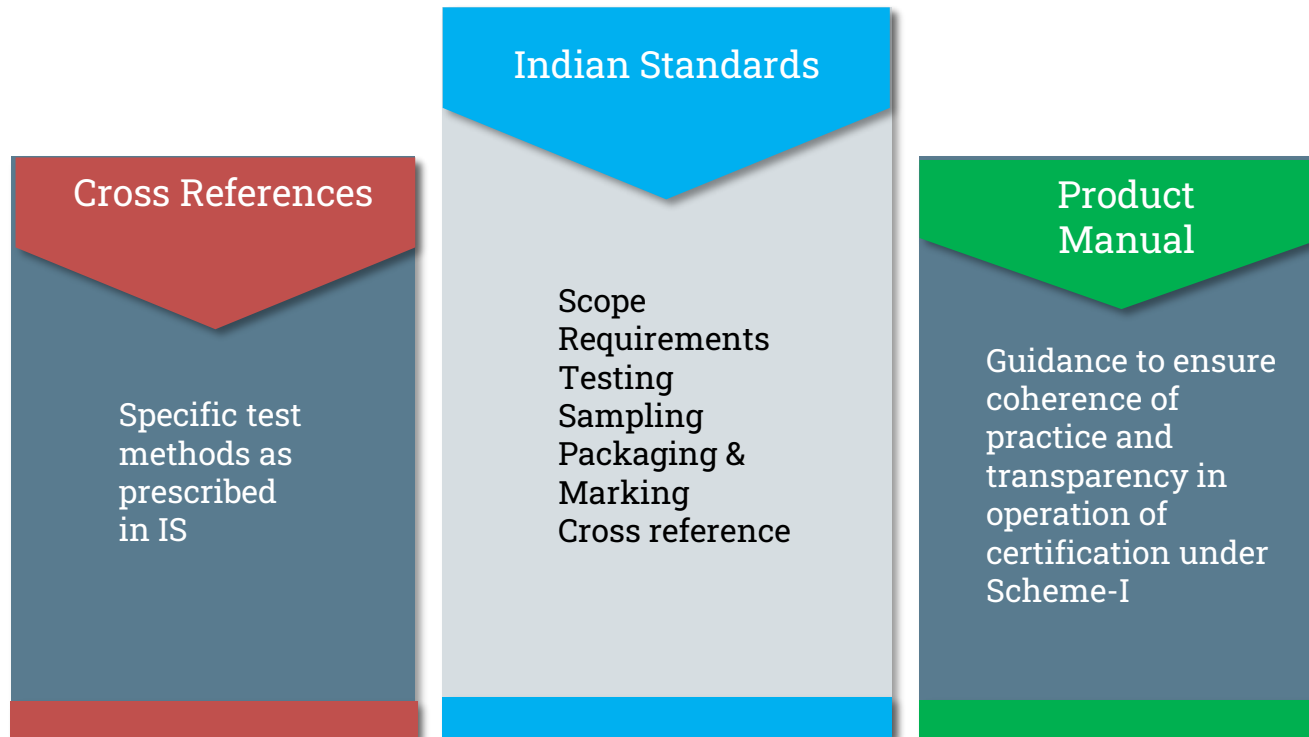
Steps of Licence: Scheme I (ISI Mark Scheme)




Impact of Business – Foreign Manufacturers

Steps of Licence

1 Documentation - Key Documents



 www.bis.gov.in	
उत्पाद मानुषल SPECIFICATION FOR POLYETHYLENE MATERIAL FOR MOULDING AND EXTRUSION IS 7328:2020 के अनुसार	
PRODUCT MANUAL FOR SPECIFICATION FOR POLYETHYLENE MATERIAL FOR MOULDING AND EXTRUSION ACCORDING TO IS 7328:2020	
<p>भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन (विनियम की स्कीम-I के तहत यह उत्पाद मानुषल प्रमाणीकरण के प्रचलन में रीति और पारदर्शिता के सुसंगत सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों एवं लाइसेंस धारियों द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस लाइसेंस/प्रमाण पत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है।</p> <p>This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.</p>	
1. उत्पाद Product:	: IS 7328:2020
शीर्षक Title	: SPECIFICATION FOR POLYETHYLENE MATERIAL FOR MOULDING AND EXTRUSION
संशोधन संख्या No. of Amendments	: 01
2. नमूनाकरण दिशा निर्देश Sampling Guidelines:	
a) कच्चा माल Raw material	: Not Applicable
b) समूहिकरण दिशा निर्देश Grouping guidelines	: Please refer ANNEX – A
c) नमूने का परिमाण Sample Size	For factory sample: Approximately 1 kg (or higher quantity required for testing) of sample collected from 3 or more sealed bag/package to be taken and sealed in a clean plastic bag to have approx. 3 kg composite sample. (See Cl 8.2.1 of IS 7328) For market sample: Minimum 3 kg
3. परीक्षण उपकरणों की सूची निरीक्षण व परीक्षण स्कीम List of Test Equipment	: Please refer ANNEX – B

संकचन और बहिर्वेधन के लिए पोलीइथाइलीन
सामग्री की विशिष्टि


(तीसरा पुनरीक्षण)

Specification for Polyethylene
Material for Moulding and Extrusion

(Third Revision)

ICS 83.080.20

© BIS 2020


भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फ़र मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

September 2020

Price Group 7

Impact of Business – Foreign Manufacturers

Documentation – Application & Supporting Documents

Application Form V	1	8	Format of Test report, Form IV
Nomination of Authorized Indian Representative (AIR) - Form VI	2	9	Layout of plant premises
Manufacturing machinery list, Form I & Process Flow Chart with descriptive summary of process	3	10	Manufacturing Location Plan
List of Test Equipment, Form II	4	11	Method of disposal of substandard product (After manufacturing)
Valid calibration certificates of testing equipment	5	12	Organizational Chart of Factory
Appointment Letter, Qualification and Experience details of Lab Supervisor	6	13	Agreement, Indemnity Bond
Proposed Levels of Controls for Inspection and Testing, Form III	7	14	Bank Performance Guarantee

Impact of Business – Foreign Manufacturers

Steps of Licence

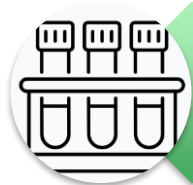
2 Onsite Factory Inspection/Unit -2 Days



Introduction to Plant Premise



Plant tour & Testing (batch 1 sample)



Sampling (batch 2 sample)



Final Documentation and Signatures



Impact of Business – Foreign Manufacturers

Steps of Licence

3

Post Inspection

1

Receipt of sample in India

2

Testing in Indian lab and report submission at BIS portal

3

Inspection report submission by Inspector

4

Marking fee & annual payment

5

Grant of Licence

6

Account Creation at Manak online

7

Agreement & Indemnity Bond Signing by AIR

8

Performance Bank Guarantee

Impact of Business – Foreign Manufacturers

Steps of Licence

4 Marking & Labelling

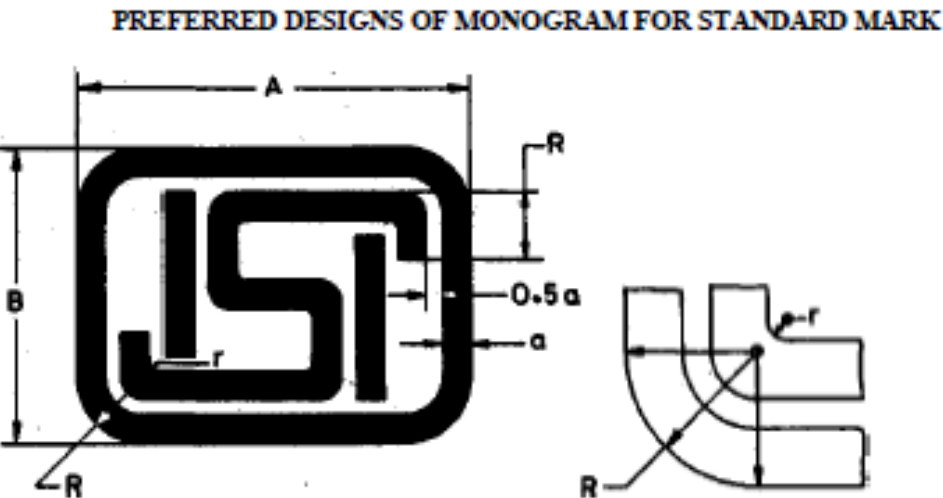


FIG. 1 MONOGRAM FOR STANDARD MARK

The monogram of the Standard Mark consists of the pictorial representation, drawn in the exact style as indicated in Fig. 1 and in relative proportions as given in Table 1.

Table 1 Preferred Dimensions of Monogram
All dimensions in millimeters

A	B	a	R	r	SIZE OF LETTERS
2.5	1.9	0.2	0.4	-	1.0 mm
5	3.8	0.4	0.8	0.1	1.0 mm
10	7.5	0.7	1.7	0.2	2.0 mm
20	15	1.5	3.3	0.5	3.0 mm
40	30	2.9	6.7	1.0	4.0 mm
80	60	5.9	13.4	1.9	6.0 mm
160	120	11.7	26.7	3.8	10.0 mm
320	240	23.4	53.4	7.6	16.0 mm

Impact of Business – Foreign Manufacturers

Steps of Licence

4

Marking & Labelling

1



2 LABEL

1. Name of the material
2. Designation/Grade
3. Net Mass
4. Batch No./Lot No.
5. Month/Year of Manuf.
6. Name of Manuf.



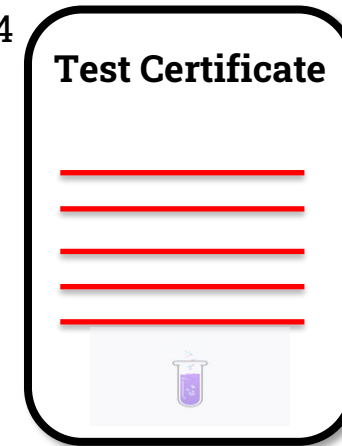
Product details, as per the requirement of the standard, shall be marked on either the product or the packaging or contained in a label attached to the product

3

<https://www.bis.gov.in/>

Reference to the website to verify the authenticity

4



If ISI mark cannot be applied on the product or the packaging physically, to be given on the test certificate as mentioned in IS/PM

5



As specified by Bureau

Dimension:

Free to choose any proposed dimension in the matrix.

Marking:

On Immediate packing

- ✓ Print
- ✓ Emboss

Licence number:

Should be below ISI marks

Impact of Business – Foreign Manufacturers

Steps of Licence

4

Marking & Labelling Example

1. The material shall be legibly marked with the following information:

- a) Name of the material;
- b) Indication of source of manufacture
- c) Batch number, in code or otherwise to enable the lot of manufacture to be traced back from records
- d) Net mass of the material.

2. In addition, the following shall be incorporated on each container

- (i) BIS Licence No. (CM/L.....)
- (ii) BIS website details i.e. –For details of BIS certification please visit www.bis.gov.in ‘.

3. BIS Certification Marking (ISI standard Mark)



Impact of Business – Foreign Manufacturers

Steps of Licence

5

Validity, Renewal & Suspension



ADHARALAPTE POST

Our Ref: FIC/01-XXXXXXX (IN: DD-ME-YYYY)

Subject: Grant of BIS Certification Mark License No. CM/XXXXXXX as per IS 17077 (Part 1): 2022

M/s. _____

Dear Sir,

With reference to your application (A/XXXXXXX), we are pleased to inform you that the Certification Mark License has been granted to you to use the Standard Mark in respect of the following:

Grant of License For The Product "Pharmaceuticals: Sterile Emulsion (ARS) Marking and Extension Materials - Part 1 (Designation System)"

Name of the product	Product - Pharmaceutical Emulsion (ARS) Marking and Extension Materials
Vaccine	

Additional requirements: Not suitable for product used in contact with foodstuff, pharmaceutical and drinking water.

IS 17077 (Part 1): 2022

The license is granted on the explicit condition that you will mark unmanufactured production which conforms to the Indian Standards.



Initially: validity upto 2yrs
Renewed: validity upto 5yrs



Form –XII
Apply 3 month before
the expiration of
license



Closure for >6months without intimation



Deviation in the implementation of scheme of inspection and testing



Test reports indicating non- conformity



Unavailability of testing personnel



Use of Standard Mark on the non-conforming products



Major deviation in manufacturing process



Relocation of manufacturing unit

Impact of Business – Foreign Manufacturers

BIS Licence Cost/Product/Site

BIS Fee (A+B+C)

10 components

(paid in equivalent US \$)

Consultant Fee

Variable A (One-Time)

1. Inspection Fee
2. BIS inspector visit charges
3. BIS Lab Testing Fee

Fixed B (Annual)

4. Marking Fee (*Import Quantities, Fee rate varies product to product*)
5. Renewal Fee (*as per date of expiry*)

Fixed C (One-time)

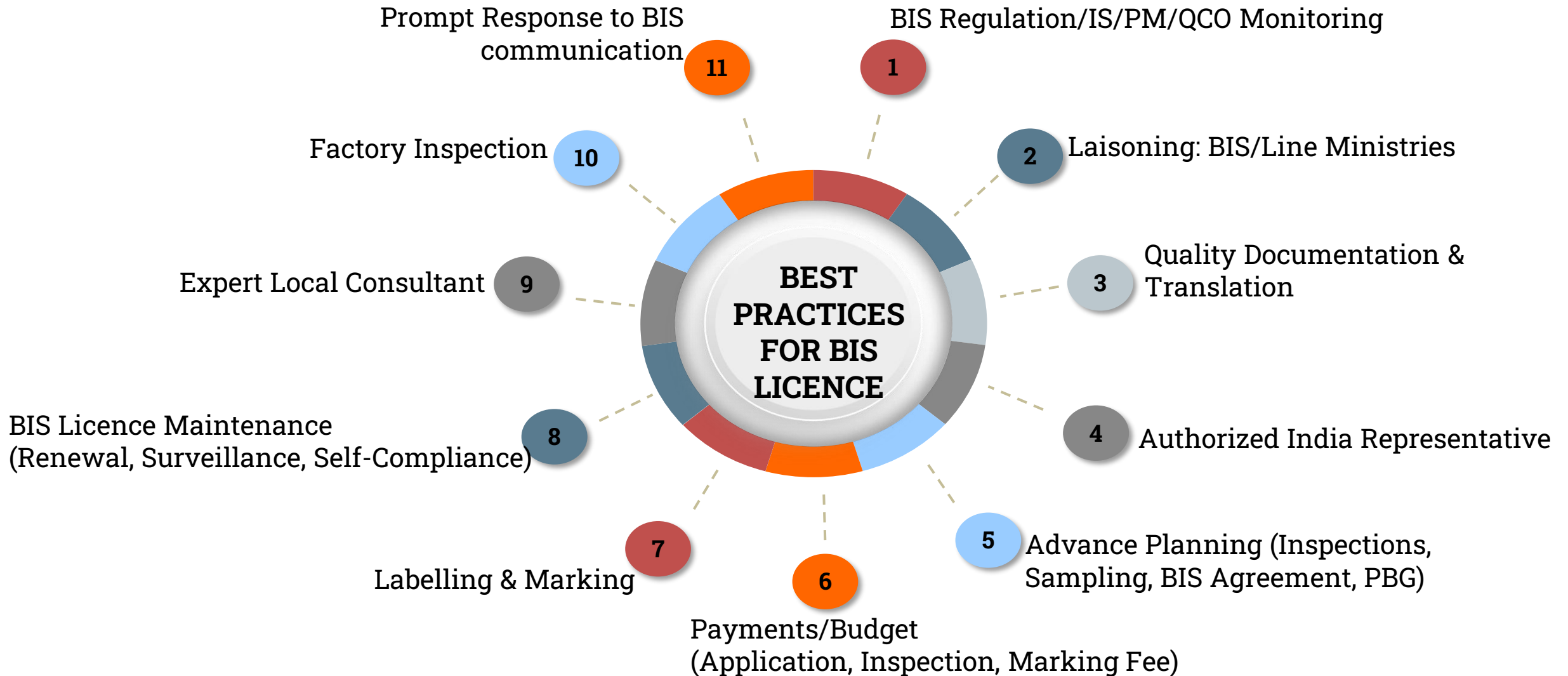
6. Annual License Fee
7. Application Fee
8. Processing & Approval Charges
9. Indemnity bond
10. Bank Guarantee (US \$ 10 000)

<https://www.bis.gov.in/wp-content/uploads/2021/06/LIST-OF-FEE-3.pdf>

<https://www.manakonline.in/MANAK/ApplicationLicenceRelatedrpt> (Marking Fee)

1. **Chemical Regulatory Landscape in India**
2. **Impact of Business – Foreign Manufacturers**
3. **Best Practice for Compliance**
4. **Conclusion**
5. **Contact**

Best Practice for Compliance



- 1. Chemical Regulatory Landscape in India**
- 2. Impact of Business – Foreign Manufacturers**
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Conclusion

BIS Licence

- ✓ FMCS Portal: The integrated web portal is being enhanced to cater to the foreign manufacturer certification activity of BIS. Module has been upgraded to further include the information of consignment details and surveillance.
- ✓ Mandatory (QCO) proposed for 76 Chemicals
- ✓ 9000 Indian Standards for Chemicals to be developed
- ✓ Appoint AIR carefully
- ✓ Study IS & PM for BIS certificate eligibility before application
- ✓ Plan QCO deadline Extension (3-6 months)
- ✓ Stay upto date

Circular: Mandatory Qualifiers for Import

- ✓ Mandatory declaration of IUPAC & CAS number for foreign manufacturers to be enforced from 15/10/2023
- ✓ The details (CAS number and IUPAC) of chemicals will be masked in bill of entry.
- ✓ Relaxed regime for 3 months

Notification: Collection of statistics of Chemical

- ✓ Collection of statistics relating to production, installed capacity, import, export, sales of chemical.
- ✓ Mandatory data collection through online portal.
- ✓ Compilation of monthly index of industrial production, use for policy and supervision purposes.
- ✓ Monitor for further updates.

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REACH→LAW

***We Specialize in Chemical
Regulatory Compliance and Sustainability***