

# Risk Management in Pre-Market Inspection

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# Outline

- ❖ Inspection System of the BSMI
- ❖ The Role of Risk Assessment in Inspection System
- ❖ Decision-Making on Pre-market Inspection Controls
- ❖ Observations

# Inspection System of the BSMI

- ⊕ Basic law: The Commodity Inspection Act
- ⊕ Scope:
  - ◆ consumer products      ◆ mechanical products
  - ◆ electrical products      ◆ electronic products
- ⊕ Pre-market inspection: third-party testing/certification
  - Conformity assessment procedures
    - ◆ Batch-by-Batch Inspection (BBI)
    - ◆ Monitoring Inspection (MI)
    - ◆ Registration of Product Certification (RPC)
    - ◆ Declaration of Conformity (DoC)
- ⊕ Border and Customs Checks
- ⊕ Market Surveillance

# Conformity Assessment Procedures

High Risk

Low Risk

Inspection Scheme	Characteristics	Regulated Products
Batch-by-Batch Inspection (BBI)	<ul style="list-style-type: none"> <li>Applicable to <b>high-risk</b> commodities</li> <li>Suitable for manufactured or imported customized products of SMEs</li> <li>Per batch per certificate</li> </ul>	Valves for high pressure gas cylinder, Baby walkers, Household pressure cooking pots, etc.
Type Approval Batch Inspection (TABI)	<ul style="list-style-type: none"> <li>Simplified BBI</li> <li>Applicable to <b>medium-risk</b> commodities</li> <li>With simplified procedures compared to BBI</li> <li>Per batch per certificate</li> <li>Some double-track with RPC</li> </ul>	Household appliances, Handheld electric tools, Portable stoves, Fire-retardant paints, etc.
Monitoring Inspection (MI)	<ul style="list-style-type: none"> <li>Applicable to <b>medium-risk</b> commodities</li> <li>With simplified procedures compared to BBI</li> <li>Per batch per certificate</li> <li>Some double-track with RPC</li> </ul>	Toys, Cement, Gasoline, Diesel fuel, Butane, Tires, etc.
Registration of Product Certification (RPC)	<ul style="list-style-type: none"> <li>Applicable to <b>medium-risk</b> commodities</li> <li>With type testing, quality management, or factory inspection requirements</li> <li>Certificate is valid for 3 years, renewable</li> </ul>	Household appliances, Loudspeakers, Laptops, Computers, Tablets, etc.
Declaration of Conformity (DoC)	<ul style="list-style-type: none"> <li>Applicable to <b>low-risk</b> commodities</li> <li>Testing by designated laboratories is required, no needs for acquiring approval</li> </ul>	Cash registers, USB drive, Hard-disks, CD-players, etc.



# The Role of Risk Assessment in Inspection System

標準 · 檢驗 · 度量衡 · 驗證  
Standards · Inspection · Metrology · Certification

## Risk Assessment at Different Stages of Product Safety Framework\*

- Stage One – Legislating, Regulating and Setting Standards\*\*
- Stage Two – Pre-market Controls
- Stage Three – Border and Customs Checks
- Stage Four – Market Surveillance\*\*
- Stage Five – Enforcement\*\*

\* Reference: *Report on International Consumer Product Safety Risk Assessment Practices*, DSTI/CP/CPS(2015)13/FINAL, 20 September 2016, OECD

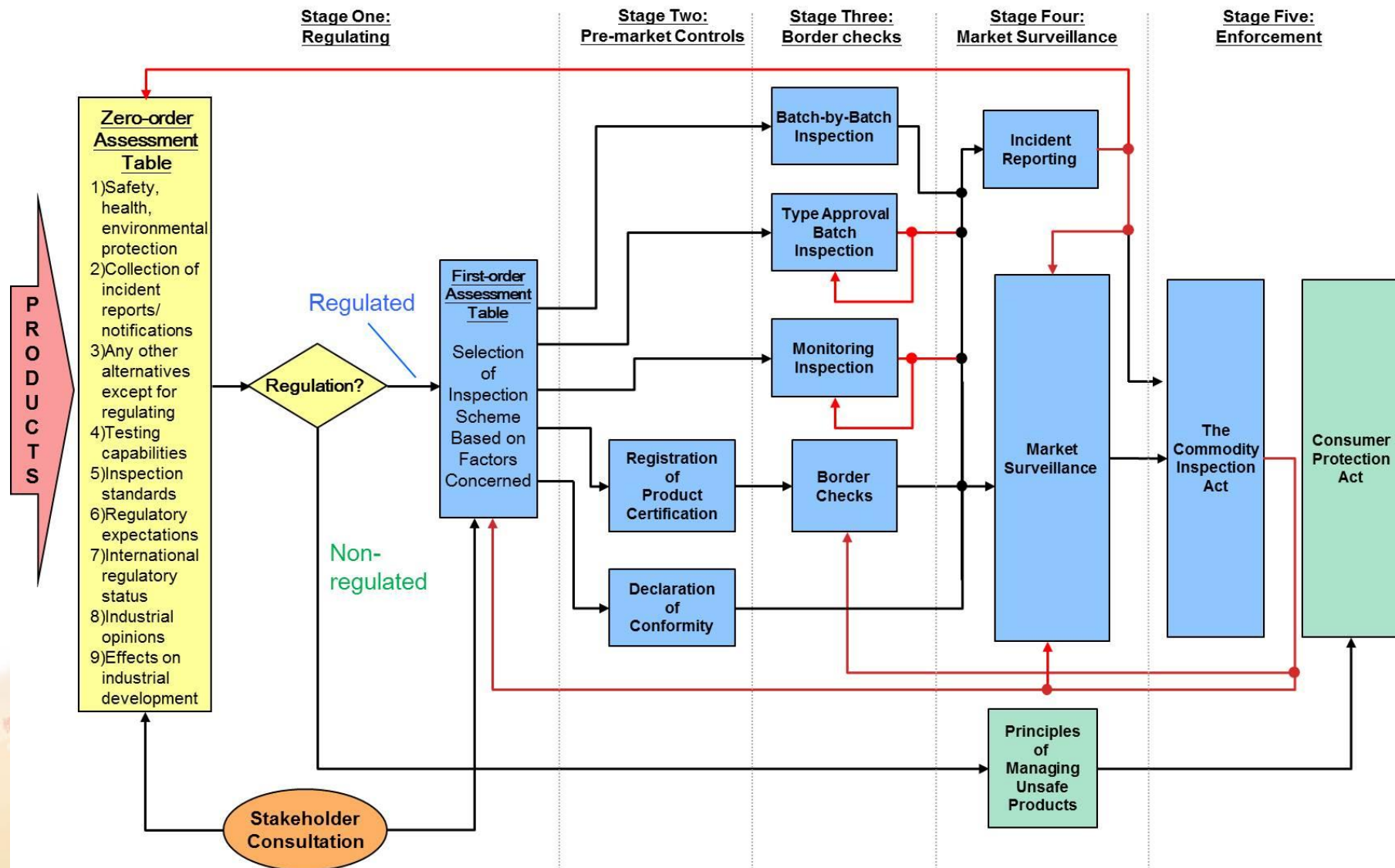
\*\* Setting Standards, Stages Four and Five are not covered in this presentation

標準 · 檢驗 · 度量衡 · 驗證  
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# Risk Assessment in BSMI Product Safety Framework





# Decision-Making on BSMI Pre-market Inspection Control

## Stage One: Legislating, Regulating and Setting standards

- ⊕ The criteria for identification of risks of hazard ... the assessment procedure, analysis and application, as well as guidelines for other matters shall be prescribed by the competent authority. (Article 6 of the Commodity Inspection Act)
- ⊕ Procedures of Implementing and Rescinding of Technical Regulations (Internal procedure)
  - ◆ Zero-order Assessment Table
    - To assist us in making decisions on whether a new product should be regulated
  - ◆ First-order Assessment Table
    - To assist us in making decision on what conformity assessment procedure should be selected for a regulated product
  - ◆ Case study: electric scooter chargers (pages 10-13)

# Stage One: Legislating, Regulating and Setting standards



## Zero-order Assessment Table

- ◆ Potential risk factors were identified by consultation with a group of experts from the BSMI.
- ◆ **Analytic Hierarchy Process (AHP)** was used to give the weight of each risk factor(\*) by conducting a comparative survey.
- ◆ An additional survey was conducted to use the weighted Zero-order Assessment Table on non-regulated products to find out the distribution of scores and the threshold value for making decisions on whether a regulation is needed.
  - Threshold value = 44 (95% confidence interval)
    - Score > 44 : regulation is required
    - Score < 44 : regulation is not required

\*The sum of weights on all risk factors is 100; the greater the risk, the greater the weight.





# Stage One: Legislating, Regulating and Setting standards



## First-order Assessment Table

- ◆ Potential risk factors were identified by consultation with a group of experts from the BSMI.
- ◆ A questionnaire was established based on the risk factors with weights, determined by using qualitative analysis in accordance with AS/NZS 4360.
- ◆ A survey was performed based on the questionnaire to establish discriminant function, by using Discriminant Analysis, for each conformity assessment procedure. Benchmarks were drawn from a number of regulated products from different categories.

# Stage One: Legislating, Regulating and Setting standards



## Case study: electric scooter chargers



### Background

- Statistics show that there are more than 13.6 millions of scooters (motorbikes) registered in 2016, that is 91.5 scooters for every 100 people holding licenses.
- Sound development of electric scooter industry is identified as prioritized environmental policy, which promotes the production and use of eco-friendly scooters.



### Assessment of risks

- Zero-order and First-order assessment tables were used, as a reference, in the process of determining whether regulating electric scooter chargers is necessary and the appropriate conformity assessment procedure.
- Electric scooter chargers were regulated in 2013, and the conformity assessment procedure is RPC.

# Stage One: Legislating, Regulating and Setting standards

## Zero-order Assessment Table: electric scooter chargers

Item	Factor	Option	Descriptions of Factor / Weight on each Option		Selection of Option	Score
1	Concerns of safety, health, environmental protection	1	Seriously detrimental to safety, health, environmental protection	32.4	2	9.7
		2	Potential detrimental to safety and health	9.7		
		3	Potential detrimental to environmental protection	5.3		
		4	None	2.2		
2	Incident(s) happened in domestic/foreign market	1	Multiple incidents have been happening	18.9	2	5.1
		2	Incidents happened but as single events	5.1		
		3	None	2.3		
3	Any other measures except for regulation	1	None	9.9	1	9.9
		2	Existing voluntary certification, but it's been doubted	8.3		
		3	Existing safety liability insurance	2.3		
		4	Existing trusted voluntary certification	0		
4	Inspection capabilities of public or private units	1	Sufficient inspection capabilities of public and private units	9.5	1	9.5
		2	Only public units have inspection capabilities	5.1		
		3	Only private units have inspection capabilities	4.3		
		4	Insufficient inspection capabilities, but domestic witness test is adoptable	2.4		
		5	Insufficient inspection capabilities, but foreign witness test is adoptable	1.8		
		6	Insufficient inspection capabilities but could be developed	1.7		
		7	Insufficient inspection capabilities and couldn't be developed	0.7		



Item	Factor	Option	Descriptions of Factor and Weight on each Option		Selection of Option	Score
5	Availabilities of inspection standards	1	Existing national standards	9.3	1	9.3
		2	Existing inspection specifications developed by other domestic authorities	7.5		
		3	Existing international or regional standards (e.g., IEC, ISO, ITU, CODEX, EN)	6.3		
		4	Existing foreign national standards (e.g., BS, DIN, JIS)	3.7		
		5	Existing inspection specifications developed by foreign authorities	3.1		
		6	Existing standards developed by foreign standard setting bodies (e.g., UL, ASTM)	2.3		
		7	Existing local/foreign industrial specifications or tentative standards	2.0		
		8	None	0.8		
6	Regulatory expectations	1	Suggestion by consumers’ protection organizations	7.2	3	6.6
		2	Public suggestions	6.9		
		3	Suggestion by the other authorities	6.6		
		4	Suggestion by representatives of public opinion	6.5		
		5	Suggestion by the media	4.5		
		6	None	2.1		
7	International regulatory status	1	Existing technical regulations	5.6	1	5.6
		2	Existing voluntary measures	2.1		
		3	None	0.8		
8	Industrial opinions	1	Few or no objections received	3.6	1	3.6
		2	Many objections received	1.2		
9	Effects on industrial development	1	Minor or no impacts	3.6	1	3.6
		2	Major impacts	0.7		
				Total score:	62.9	

**Total score :**  
**62.9**  
**>**  
**Threshold: 44**  
**↓**  
**Regulated**



# Stage One: Legislating, Regulating and Setting standards

## First-order Assessment Table: electric scooter chargers

Item	Factor	Option	Descriptions of Factor	Selection of Option
1	Concerns of safety, health, environmental protection	1	With no concerns to safety, health, environmental protection	3
		2	Potential detrimental to health and environmental protection	
		3	Potential detrimental to safety and health	
		4	Seriously detrimental to safety and health	
2	Incident(s) happened in domestic/foreign market	1	None	2
		2	Incidents happened but as single events	
		3	Multiple incidents have been happening	
3	Duration of testing	1	Over 10 days	2
		2	5-10 days	
		3	Less than 5 days	
4	Sales volume of single product type	1	Many sales	2
		2	Few sales	
5	Reliability of product technology	1	High reliability	1
		2	Low reliability	

### Result of Assessment:

- Batch-by-Batch inspection: 48.5 %
- **Registration of Product Certification: 51.1 %**
- Declaration of Conformity: 0.4 %



# Stage Two: Pre-market Controls

## The Relationship between Risks and CAPs

June 2017

	Inspection Scheme	Regulated products subject to each Inspection Scheme			
		Consumer products	Mechanical products	Electrical products	Electronic products
<div>High Risk</div> <div>Low Risk</div>	BBI	4% (33/843)	22% (20/92)	0% (0/189)	4% (5/121)
	TABI*	27% (231/843)	55% (51/92)	98% (186/189)	63% (76/121)
	MI*	45% (377/843)	0% (0/92)	0% (0/189)	0% (0/121)
	RPC*	50% (425/843)	89% (82/92)	100% (189/189)	64% (78/121)
	DoC	1% (11/843)	0% (0/92)	0% (0/189)	31% (38/121)

\*Both MI/TABI and RPC are often made available to a single regulated product and the applicant may choose either one based on its needs.





# Stage Three: Border and Customs Checks

## Border Checks and Sampling Frequencies

<div>High Risk</div> <div>Low Risk</div>	Inspection scheme	Sampling frequency per batch of products	Inspection measures on the border
	BBI	1	<ul style="list-style-type: none"> <li>Sampling inspection</li> </ul>
	TABI	0.33, 0.2, 0.1, or 0.05	<ul style="list-style-type: none"> <li>Sampling inspection on reduced frequencies(*); or</li> <li>Random check and verification of conformity to type; or</li> <li>Document examination</li> </ul>
	MI	0.5, 0.2, or 0.1	<ul style="list-style-type: none"> <li>Sampling inspection on reduced frequencies(*), or</li> <li>Document examination</li> </ul>
	RPC	<ul style="list-style-type: none"> <li>Randomly-selected batch verification: <b>0.003-0.005</b></li> <li>Enhanced randomly-selected batch verification: <b>0.03-0.05</b></li> <li>Batch-by-batch verification: <b>1</b></li> </ul>	<ul style="list-style-type: none"> <li>Sampling on random frequencies(**) to check the conformity to the appearance, type/model, marking and labelling</li> </ul>
	DoC	0	<ul style="list-style-type: none"> <li>None</li> </ul>

\*Sampling frequency may be adjusted depending on inspection results.

\*\*Sampling frequency may be adjusted depending on results of examination, market surveillance, incident reports, or non-compliant records, etc.



# Observations

- ✚ The evolution of the inspection system is a slow progress which dynamically seeks for a stable state that meets the expectations of different societies. Thus, different approaches of risk management are taken in different societies.
- ✚ The role of risk assessment in regulatory decision-making processes might be reduced due to pressures from the media, consumer groups, or legislators when incidents occur. However, risk assessment could play an important role to achieve regulatory objectives proactively to mitigate potential risks of hazard of a non-regulated product.
- ✚ Results of risk assessment may change overtime due to different perceptions of risk factors when different social issues evolve. It is crucial to identify and scrutinize the key factors that contribute to the risks, and to incorporate those factors into the assessment.



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