

Substance Control Directives – Not for the Faint of Heart!

Arlene Farrar
Director, EHS Medical Device Div.
Fenwal, A Fresenius Kabi Company
Lake Zurich, II 60047
847-550-2340
Arlene.Farrar@fenwalinc.com





Substance Control Directives



- **EU** Packaging Directive
- **WEEE/ Batteries**
- **EU RoHS Directive**
- **EU REACH Regulation**
- China and India as time permits

China RoHS



Broader Regulatory Control, Narrower Scope

- The regulation was passed February 28, 2006
 - The regulation covers the RoHS 6 Substances, and
 - Other substances deemed toxic and harmful by the state
- The regulation is reliant upon the "China RoHS Catalogue"
 - Classifies individual types of products regulated e.g. actual breakdo of what goods are in scope, rather than broad categories of EU RoH
 - Packaging Materials must identify presence of substances
 - Chinese approved lab testing a requirement
- Key Issue...
 - The catalogue is being redrafted
 - The first catalogue was never fully implemented







Compliance is as Easy as Tic-Tac-Toe,

产品中有毒有害物质或元素的名称	乃今县
一广加里往垂往春初网络兀盔凹着树	/火呂里

DD 14-02-54-		有毒有害物质或元素						
部件名称	铅(Pb)	汞(Hg)	镉(Cd)	六价铬(Cr(VI))	多溴联苯(PBB)	多溴二苯醚(PBDE)		
DSP TMA320C	X	X	X	X	X	X		
8-Bit µP 相容 A/D 轉換器	0	0	0	0	0	0		
DA 轉換器 1220E	0	0	0	0	0	0		
RF TX	0	0	0	0	0	0		
ASIC Z80 MPROC	0	0	0	0	0	0		
鋰電池	0	0	0	0	0	0		
電容 641 (D)	0	0	0	0	0	0		
電阻 208	0	0	0	0	0	0		
電阻 946	0	0	0	0	0	0		
過濾器	0	0	0	0	0	0		
RF總成	X	0	0	0	0	0		
Power Lead	0	0	0	0	0	0		
電阻 556	X	X	X	X	X	X		
S250 美式充電器	X	0	0	0	0	0		
表面接著鋁電容	0	0	0	0	0	0		
TRANS, POWER MOSFET, P-CH, 5.9A, SO8	X	X	X	X	X	X		
表面組裝技術 RES.	X	X	X	X	X	X		
綠色LED	0	0	0	0	0	0		
雙紅/綠LED	0	0	0	0	0	0		
電容 522	0	0	0	0	0	0		
電容 522 / 98	X	X	X	X	X	X		

O:表示该有毒有害物质在该部件所有均质材料中的含量均在 SJ/T 11363-2006 标准规定的限量要求以下。

X:表示该有毒有害物质至少在该部件的某一均质材料中的含量超出 SJ/T 11363-2006 标准规定的限量要求。



China REACH

The Ministry of Environmental Protection Department Order No. 7, Environmental Management of New Chemical Substances, (October 15, 2010)

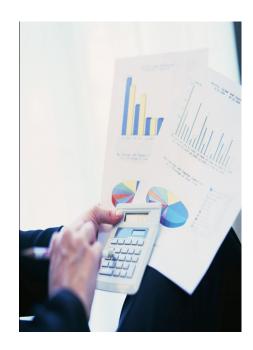
- Establishes a risk classification system for new chemical substances which are intentionally released.
 - New chemicals are those that are not on the list of existing chemical substances in China.
 - These are subject to registration and reporting requirements.
- The regulation came into effect October 15, 2010.
 - The consultation period is closed.
 - Guidance documents are expected summer 2011.







- Threshold calculation is 1 tonne of the chemical per year:
 - <1 tonne, then submit a simplified filing form and an ecotoxicology test performed by an approved Chinese facility
 - >1 tonne, then submit classification and labelling information, risk assessment reports, toxicology and ecotoxicology reports.
 - Eco-toxicology reports must be conducted in China.
- Must report annually with increasing requirements dependent upon the quantity of import.
- The principal enforcement mechanism will be fines for non-compliance.
- You must use Chinese approved laboratories to test your products.







- March 11, 2011: The China State Council, publishes the revised version of Regulations on Safe Management of Hazardous Chemicals in China. (China REACH).
 - The regulation governs the production, storage, use, sales and transporting of hazardous chemicals.
 - It comes into force beginning December 1, 2011.
- The law provides an enforcement mechanism for the China GHS national standards.
 - Penalties for failure to to classify, label and package hazardous chemicals include:
 - Fines up to 50,000 yuan and/or
 - a ban on production or import.
- The regulation requires registration of existing hazardous chemicals with the Chemical Registration Centre (CRC).

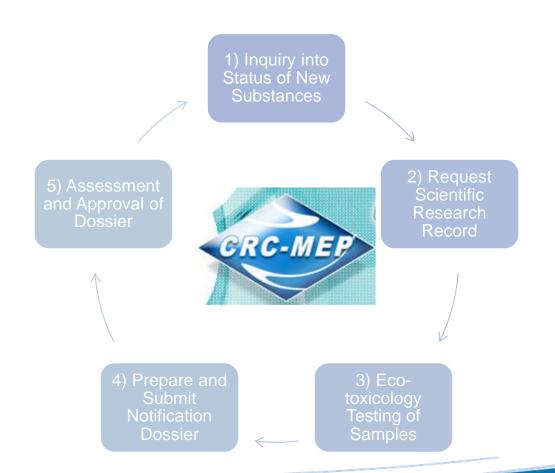




Process for Simplified Testing and Compliance



Controlled by the Chinese Chemical Registration Centre (CRC)



Highlighting India RoHS





The E-Waste (Management and Handling) Rules, 2011, S.O No. 1035 E.

- Rules became effective May 1, 2012. There will be a 2-year phase in period, so India RoHS will be in force starting May 1 2014.
- India RoHS rules shall apply to every producer, consumer or bulk consumer involved in the manufacture, sale, purchase and processing of electrical and electronic equipment or component s as specified in Schedule-I
- Collection centre, dismantler and recycler of e-waste and shall not apply to batteries, as covered under the Batteries (Management and Handling) Rules; Micro and small enterprises; and radio-active wastes

India RoHS: Schedule I Categories



Schedule I:

Categories of electrical and electronic equipment

Information technology and telecommunications equipment

- 1. Centralized data processing
- 2. Mainframes, minicomputers
- 3. Personal computing (Central processing unit with input and output devices)
- 4. Personal computers (Central processing unit with input and output devices)
- Laptop computers
- 6. Notebook computers
- 7. Notepad computers
- 8. Printers including cartridges
- 9. Copying equipment
- 10. Electrical and electronic typewriters
- 11. User terminals and systems
- 12. Facsimile
- 13. Telex
- 14. Telephones
- 15. Pay telephones
- 16. Cordless telephones
- Cellular telephones
- 18. Answering systems

Consumer electrical and electronics

- 1. Television sets(including sets based on liquid crystal display and light emitting diode technology
- 2. Refrigerators
- 3. Washing machine
- 4. Air conditioners excluding centralized air conditional plants



	· · ·				
	India	EU			
Legislation	Joint for WEEE and RoHS	Separate for WEEE and RoHS			
Legal Responsibility :	Producers Consumers Collection centres Dismantlers Recyclers	Producers Distributors Business end users Treatment facilities for WEEE Exporters of WEEE			
Business size affected (de minimus)	Does not apply to Micro & Small Enterprises as defined under the Micro, Small & Medium Enterprises Development Act, 2006	All sizes in the categories above			
In Scope	(i) IT & Telecommunications Equipment All from EU RoHS Cat 3 'IT & Telecomms Equipment', except: Calculators Printer cartridges Product for collection, storage, processing presentation or communicating information electronically Other equipment for transmitting sound images or other info by telecommunications. (ii) Consumer electrical & electronics from EU RoHS Cat 1 'Large Household Appliances': Refrigerators Washing machines Air-con (not centralised air-con plant) from EU RoHS Cat 4 'Consumer Equipment': Television sets (all types) Note: These are inclusive lists, there is no 'anything else' comment.	1. Large household appliances 2. Small household appliances 3. IT and telecommunications equipment 4. Consumer equipment 5. Lighting equipment, (including electric light bulbs and household luminaires) 6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools) 7. Toys, leisure and sports equipment 10. Automatic dispensers Following the pending recast: 8. Medical devices (with the exception of all implanted and infected products) 9. Monitoring and control instruments 11. Anything else not covered in categories 1 - 10			

Summary



- India RoHS is similar to EU RoHS.
- However, the regulation combines WEEE and RoHS, which complicates the requirements for recycling and e-waste disposal.
- The Scope of the regulation incorporates more specific category definitions than EU RoHS and is less broad in application to smaller organizations.
- Recycling requirements will be mandated by the State Pollution Control Board.



Please contact:

Arlene Farrar
Director, EHS
630-870-9829 (cell)
847-550-2340 (office)

Arlene.Farrar@fresenius-kabi.com