

A Global Regulatory Regime For a Globalised Industry?



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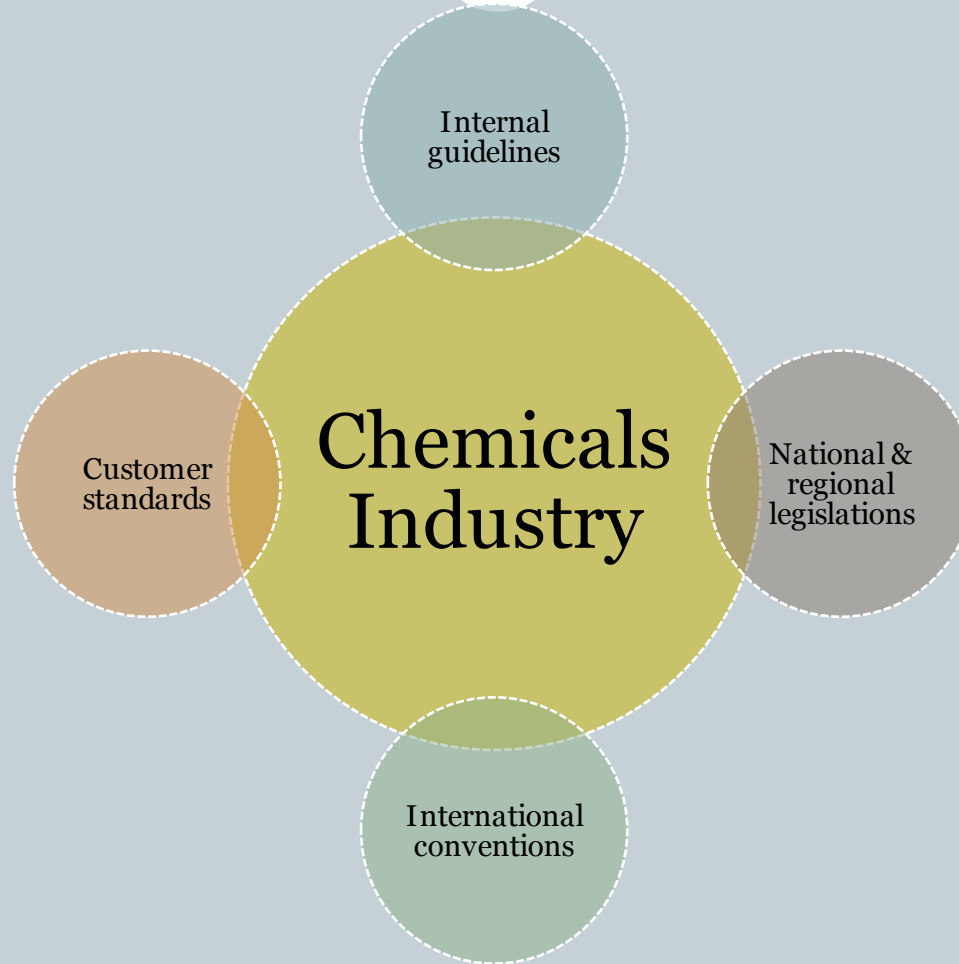
Contents

2

1. The global chemical industry
2. Risks from chemicals
3. Current global/regional regulatory system
 - REACH
 - Global Harmonised System [GHS]
4. Emerging scenario
 - REACH as model for other countries?
 - Industry efforts: Global Product Strategy
5. India's response so far
 - What India must do

The challenging environment

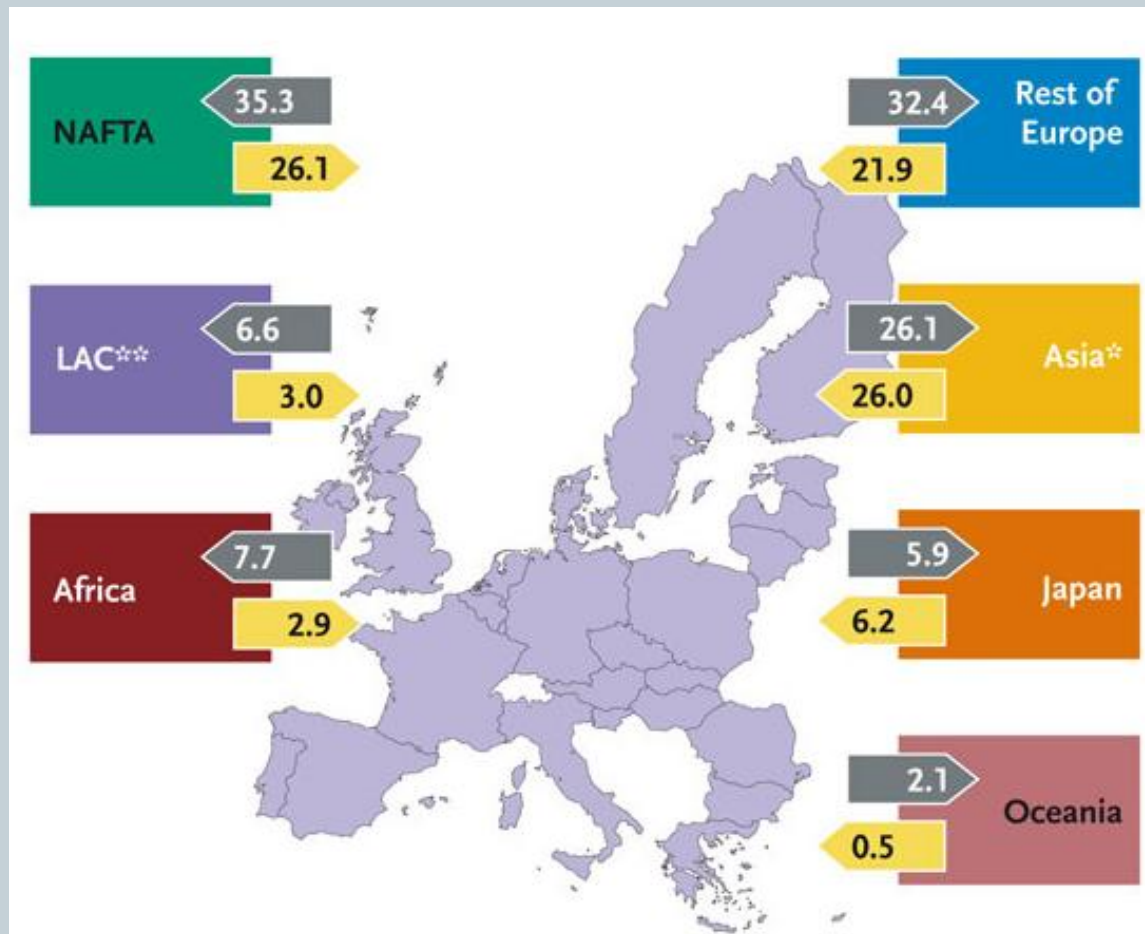
3



Regional regulations have global impact

4

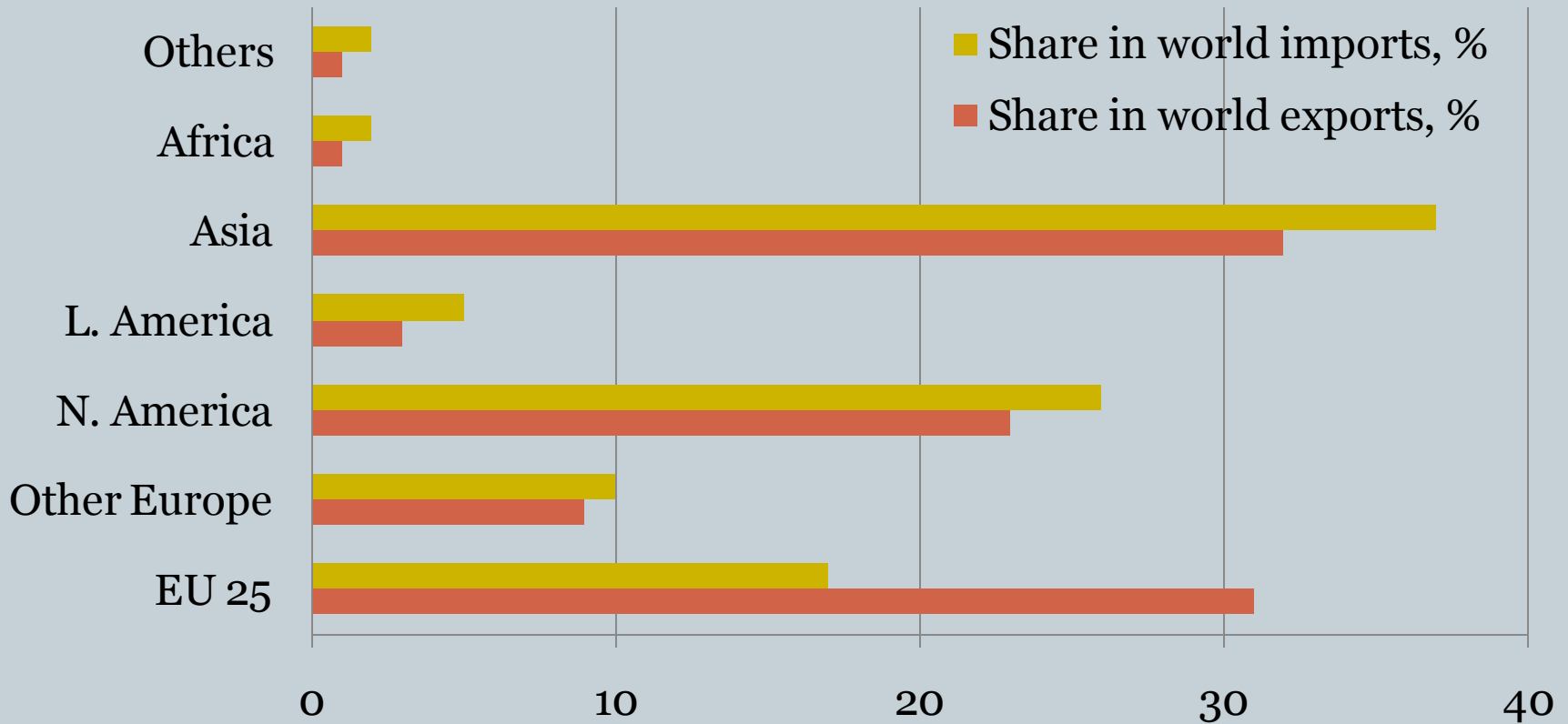
Extra-EU Chemical trade flows, billion €, 2007



Regional regulations have global impact

5

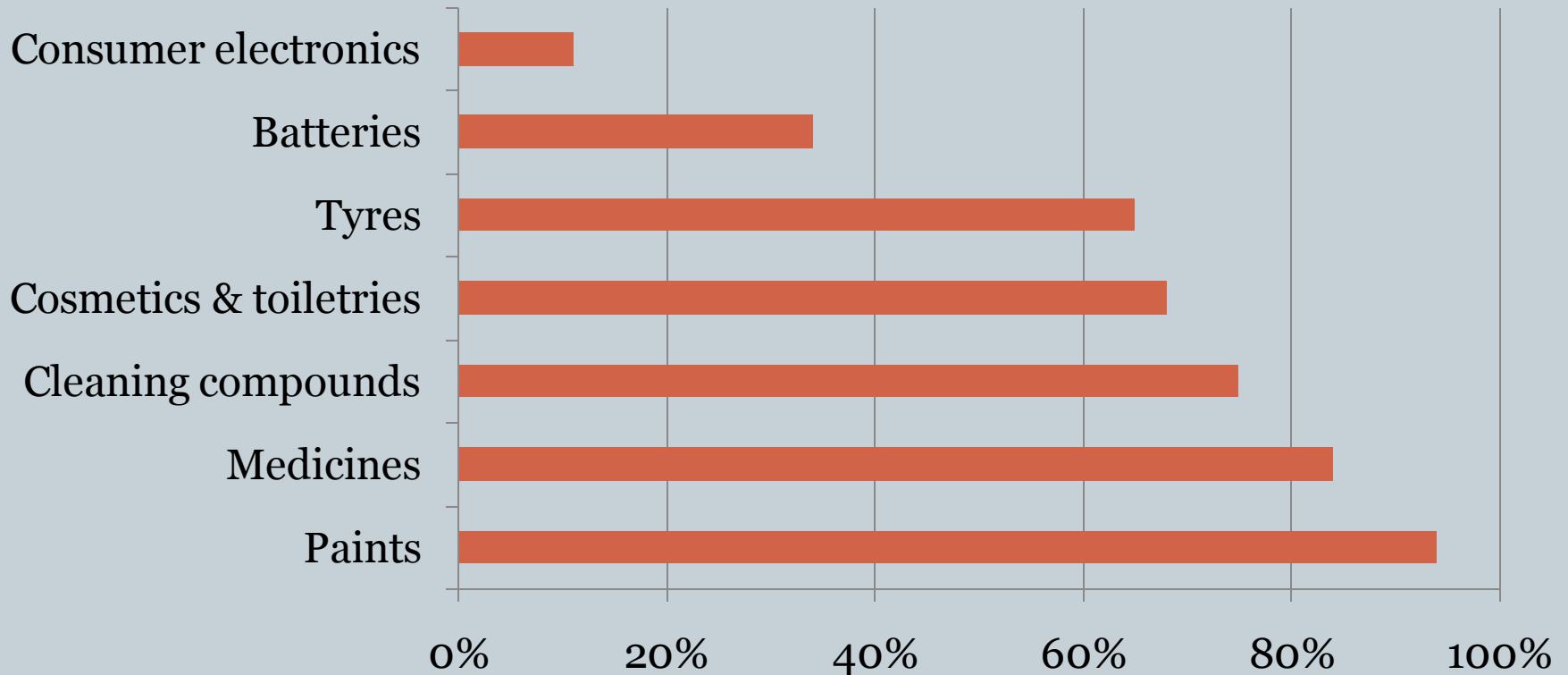
Asia's growing importance in world chemical trade



Vital role of chemicals

6

Chemicals as % of material inputs in manufacture of ...



Source: Kline & Co

Pressure points from end-use industries

7

Example 1: Electronics industry

- **Issue**
 - Dutch blocked 1.3-mn Sony *PlayStation* consoles
 - Cables had Cd levels higher than permitted
- **Concern**
 - No health risks in use
 - But wrong disposal can cause environmental damage
- **Impact**
 - Sony suspended shipments, while it addressed the problem
 - Lost €110-mn in delayed sales

Example 2: Textiles industry

- **Issue**
 - Ban on azo dyes based on 21 amines
 - First in Germany; then quickly elsewhere
- **Concern**
 - Carcinogenicity of amines (not the dye)
- **Impact**
 - 112 dyes were banned in India
 - Manufacturers had to churn their portfolio, often at higher costs
 - End-users in textiles, leather & paper industries had to switch to alternates
 - Compliance assurance needed

Risks from chemicals

8

- Risks from chemicals have two components
 - Intrinsic properties (hazards)
 - ✦ In principle: universal, independent of location
 - Exposure (determined by dose, duration and frequency)
 - ✦ Can be dependent on location/situation/context
- Cooperation efforts so far have primarily focused on hazard assessment
 - Principally amongst OECD countries
- Exposure – measures taken differ
 - E.g. Bisphenol-A in baby bottles
 - ✦ EU – migration limit for many years
 - ✦ US – no measures at federal level; some States have taken measures
 - ✦ Developing Asia – few, if any, have mandated limits or usage

Risks *vs* hazards: Key points

9

- Chemicals cannot be simply divided into hazardous & non-hazardous
 - All substances are hazardous to some degree
 - Removal on basis of hazard alone does not guarantee safety
- Avoidance of a hazardous material does not promote sustainability *per se*
 - Efficient use of energy, water & other resources could be as or more important than marginal reductions in toxicity
- Risk cannot be eliminated, but can and must be assessed & managed (*even imperfectly*)
 - Safe management may involve strict controls on use
 - But bans could have consequences of eliminating beneficial use [e.g. DDT]
- Substances have a profile of hazards, rather than just one
 - Focusing on single hazard may result in substitutions that produce higher risk [e.g. CFCs vis-à-vis HFCs]

Decisions on management & use of substances need to be holistic

Global Environmental regulations & WTO

10

- WTO permits members to restrict trade where it endangers environment and /or affects health.....
 - But, measures must be science based.
 - Must not create unnecessary obstacles to trade or be more restrictive than necessary.
- A 2003 study found 44 international trade barriers introduced in the past decade
 - Majority from EU, which has emerged as the leading player in chemical regulations.

Chemicals regulation is now an integral part of a region's approach to bolster local industry

Current global system on chemical control

11

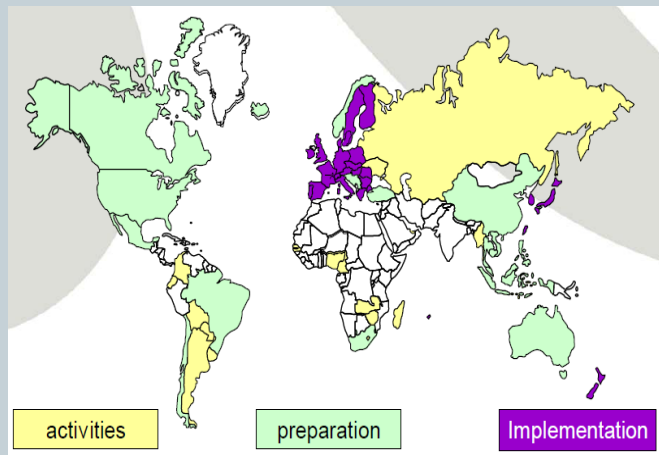
- **Multi-lateral, legally binding agreements**
 - Rotterdam Convention on Prior Informed Consent
 - ✦ Pesticides & few industrial chemicals
 - Stockholm Convention on Persistent Organic Pollutants, POPs
 - ✦ Limited number of chemicals [e.g. pesticides]
 - Basel Convention
 - ✦ Trans-boundary movement
 - Global Harmonised System [GHS]
 - ✦ Global in scope; but focus is on Classification and Labelling [C&L]
- **Voluntary initiatives**
 - OECD
 - Strategic Approach to Integrated Chemical Management [SAICM]

Not comprehensive; restricted to few countries; difficult to integrate

GHS: Example of successful co-operation

12

- Global UN initiative on classification & labeling
 - Proposes harmonized hazard communication elements [labels & safety data sheets]
- Operationalised: 2008
 - Target not met; but progress



C & L requirement for substance with Oral Toxicity LD50: 257-mg/kg

Region	Requirement
EU	Harmful
US	Toxic
Canada	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
New Zealand	Hazardous
China	Not Dangerous

In GHS: Danger (Skull & Cross Bones)

India has decided to implement, but no date finalised & no steps taken as yet

REACH: European chemicals regulation

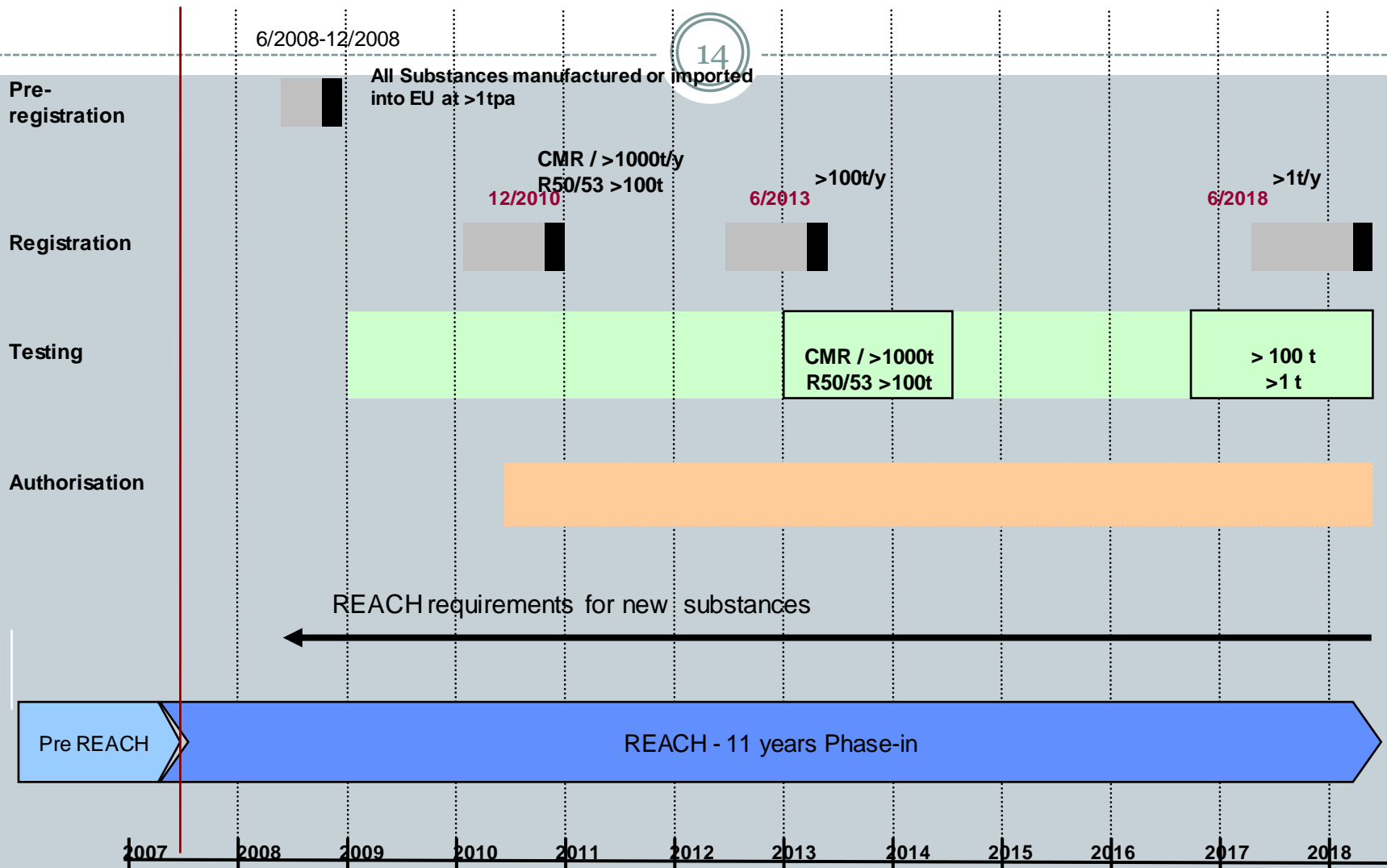
13

- **Largest, most complex & most comprehensive regulatory effort**
 - Applies to EU industry & all who chose to do business with it
 - ✦ Substances (chemical entities) [with some exceptions, e.g. polymers]
 - ✦ Preparations (component of formulations)
 - ✦ Articles intended to be released (e.g. perfume in erasers)
- **Stated objectives**
 - Develop policy reflecting precautionary principle
 - Improve & protect human health and environment
 - Enhance competitiveness & innovation in EU chemical industry
- **Reverses burden of proof for chemical safety & costs onto industry**
 - Industry fears extensive testing for toxicological & eco-toxicological profiling
 - Difficulty of sharing of data (& costs) amongst participants
- **Possible outcomes**
 - Permission to manufacture, import and use chemical
 - Partial ban (in one or more uses)
 - Total ban (for all applications)

No data, no market!

REACH: Time frame

14

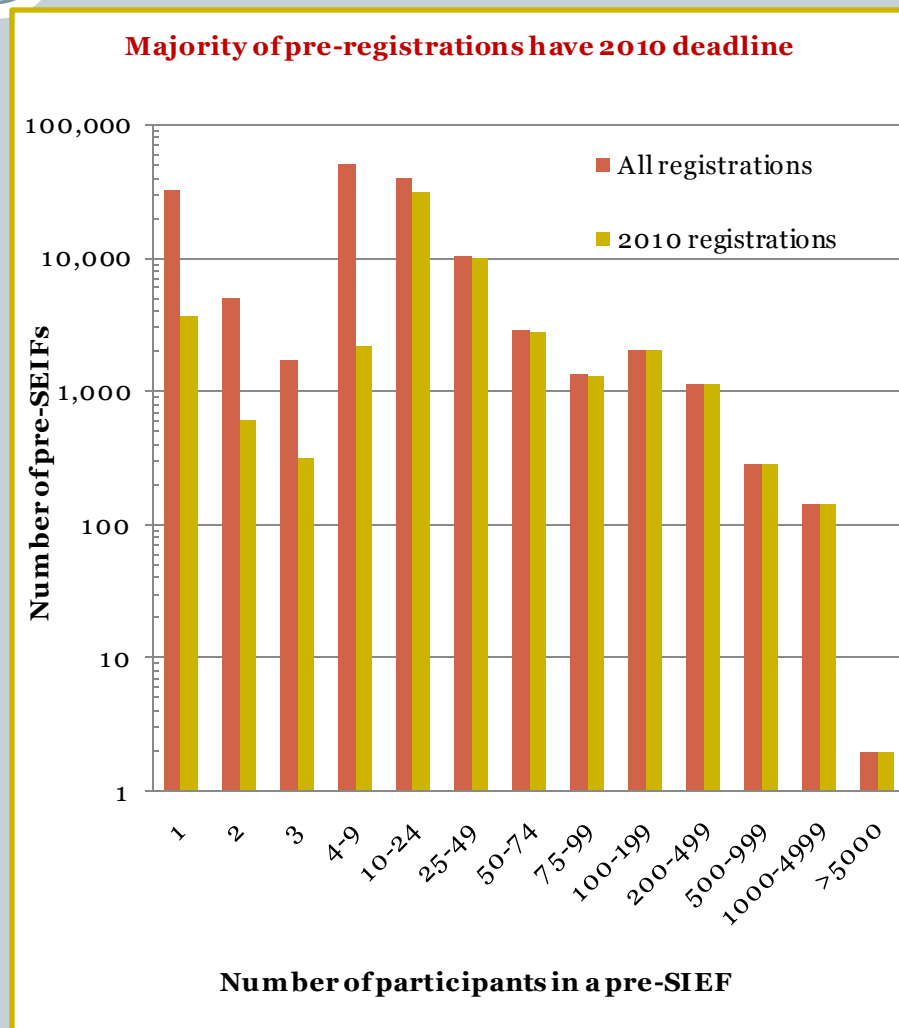


REACH: The mammoth task at hand

15

- Pre-registrations phase [Dec 2010]
 - 2.75-mn received
 - 146,000 substances
 - 65,000 companies
- 2010 deadline [>1000 tons]
 - 5,000 substances
 - 27,500 new dossiers
 - Most bulk chemicals; larger companies
 - Easier availability of data
- 2013 deadline [100-1000 tons]
 - 3,500 substances
 - 14,000 new dossiers
 - Mostly fine & speciality chemicals; mostly SME s
 - Less data availability

Despite concerns & teething troubles, REACH seems to be working



Key concerns over REACH

16

- **Hazard, not risk-based**
 - Significant decisions based purely on intrinsic properties & volumes
 - Economic impacts unrelated to actual risks to consumer or environment
 - NGOs worried whether dossiers are of sufficient quality to ensure safe use of chemicals
- **Substances of very high concern (SVHCs)**
 - Process for listing deemed too easy
 - 25 substances have already been identified
 - NGOs want more
 - ✦ European Trade Union Confederation 'Priority List' of 306 HPV chemicals
 - ✦ 11 European NGOs: SIN (Substitute it Now) list
 - Proliferation of lists – with little science behind it – can confuse stakeholders
- **Workability**
 - 'Unnecessarily' complex/cumbersome
 - Resources?
- **Confidentiality**
 - Especially for chemicals for research

REACH: A model for other countries?

17

The case for REACH ...

- Europe: Huge influencing power in a globalised industry
- REACH works: over 4,500 substances have been registered
- ECHA will accumulate a lot of information on hazards & risks
- Companies can avoid having to adapt to multiple sets of rules
- Many countries have been closely involved in the adoption process

... And against

- Complex & expensive
 - Especially for SMEs
- Suited for developed countries ...
 - Some convergence expected
- ... But not for developing ones
 - Variations in government structures, scientific knowledge & financial support
 - Capacity of industry to take on responsibility varies

Something more pragmatic may be required

GPS – An alternate model proposed by industry

18

Approach

- **Launched (2006) by ICCA**
 - 150 chemical companies [mostly large] committed
 - India & China not represented
- **Risk, rather than volume based approach**
 - No less stringent than REACH
- **Combination of regulation & voluntary programmes**
 - Implementation flexibility to countries
- **Promotes information sharing between companies**
 - Dissemination through ICCA & company web sites

Aims & achievements

- **Improve product stewardship**
 - Communicate safer management down value chain
- **Accumulate base-set of hazard & exposure information**
 - >1000 chemical safety assessment summaries already available
- **Timelines**
 - 2012: companies to report progress
 - 2018: assess safety of chemicals in commerce
 - 2020: ensure chemicals are produced & used in ways that minimize impacts on environment & human health

India's response to chemical regulation

19

- **Reluctant participant to most international treaties**
 - The problem will go away!
 - It is a trade barrier to prevent emerging economies from their rightful place on the world stage!
 - Once size fits all policy is not fair! We deserve to be treated differently!
- **On few occasions [esp. when exports have been threatened] response has been quick**
 - Ban on select azo dyes in Germany (and then Europe)
- **Sections operate outside global standards in local market**
 - F&F industry has resisted efforts to comply with IFRA guidelines for product safety of ingredients used

India's inadequate response to REACH

20

- Late awakening and then 'Wait and watch' approach.
- No centralized body to monitor REACH preparedness
 - Ministries of Chemicals & Fertilizers, Commerce and Environment & Forests
- Awareness & training programs conducted by industry associations
 - Inadequate, untimely & ineffective
 - Many consultants (of varying capabilities & ethical standards)
- Ministry of Commerce: financial assistance for meeting REACH obligations
- How has industry responded:
 - Chemexcil's initiative resulted in ~650 SME's pre-registering ~7,500 substances by Dec 2008 deadline.
 - Figures from other Associations or Individual registrants not available.
 - Best guess: Significant portion of industry taken easy option of having customers register
- How many companies will proceed till end registration?
 - Final costs not yet clear
 - Companies may opt out as business decision
 - Leave registration to their customers or third party

What India must do to prepare for a world with greater regulation?

21

- **Priority 1: Prepare Indian chemical inventory – None exists!!!**
 - Listing of industrial chemicals manufactured in country or imported
 - Minimum content: CAS No; Name; Amount produced / imported; Uses
 - Utility: Chemicals not in inventory can be identified and not manufactured / imported without registration.
- **Improve co-ordination at GOI level amongst ministries**
 - Ministry of Chemicals & Fertilisers (MoCF) best placed to understand full ramifications with inputs from industry
 - Greater co-ordination between key associations (e.g. ICC) and MoCF.
- **Create laboratory infrastructure**
 - Toxicological / eco-toxicological data generation is a huge business opportunity
 - OECD GLP accreditation opens new opportunities for serving new markets
- **Augment human resources**
 - Experts in product safety and regulatory affairs needed

Conclusions

22

- **Current agreements address limited problems of limited chemicals**
 - The scope of coverage will expand
- **Agreement on a globalised model for chemicals regulation seems distant for now**
 - Even so, market forces will make countries outside EU take into account requirements set by REACH
 - REACH will have influence by diffusion of its data and provisions
 - While convergence between OECD & BRIC countries will evolve gradually....
 - A one size fits approach seems unlikely in the medium term
- **Capacity building concerns of developing countries will need to be addressed by any new regulatory regime**
 - GPS could be globally accepted platform in which this may happen
 - Efforts will be needed to bring suspicious developing countries on board
- **Decisions on management & use of chemicals need to be holistic**
 - Simple solutions based on partial understanding of inherent hazard may appear logical, but could have unintended consequences

Conclusions

23

- “I think I’m not exaggerating if I say that Europe is leading the world and making a global benchmark in chemicals legislation. The rest of the world has no other choice than to follow.”



Matti Vanhanen, Prime Minister, Finland
Helsinki Chemicals Forum; 29 May 2009

Chemical Weekly: Leading news magazine

24

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FOREIGN INVESTMENT

Bayer targeting revenues of Euro 1-bn from India by 2015

Bayer AG is in the process of finalizing its India strategy that will see it make significant investments in the country aimed at taking the annual turnover of all its operations from Euro 350-400 mn in 2006-07, to Euro 1-bn by 2015.

This was revealed by Mr. Werner Wenning, Chairman, Board of Management, Bayer AG, during the course of discussions with select media, including *Chemical Weekly*, in Mumbai on 2 October. "We are setting clear goals for India and will support this with adequate investments," he revealed.

On his first visit to India, Dr. Wenning visited Bayer CropScience India's production facilities at Ankleshwar (Gujarat); the Systems House for polyurethanes at Greater Noida (Uttar Pradesh); interacted with employees in Mumbai; visited the plant of Moser Baer, one of Bayer Material Science's biggest customer in India; and Bicon Ltd. in Bangalore.

will come up by 2008 also in Greater Noida and a Coatings Application Development Laboratory, which is being set up at the Thane site to develop new applications for addressing local needs.

Having completed a significant investment in China in Caojing, near Shanghai, Mr. Wenning revealed that Bayer is now examining plans for this business for the next decade.

It is now conducting a feasibility study for world-scale polycarbonate and polyurethane raw materials plants in India. "If such an investment were to come up in India, it would not merely be for the local mar-



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