

Industry perspectives

A review of international regulations: where are the similarities and differences

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Chemical Industries Association

- Regulations and Scope
- Risk vs hazard approach
- Registration and notification of chemicals
- Approach to animal testing
- Data sharing mechanisms
- Costs of registrations/notification
- Restrictions/bans on chemicals



Japan – Chemical substance control law



China – MEP Order 7



US – Toxic Substance control Act



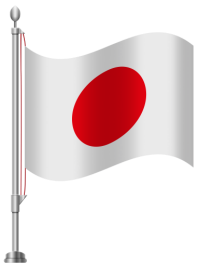
Canada – Canadian Environmental Protection Act



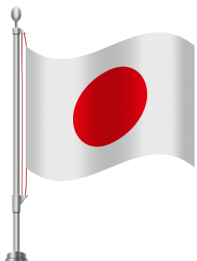
Brazil – Regulaco de Substancia Quimicas Industriais

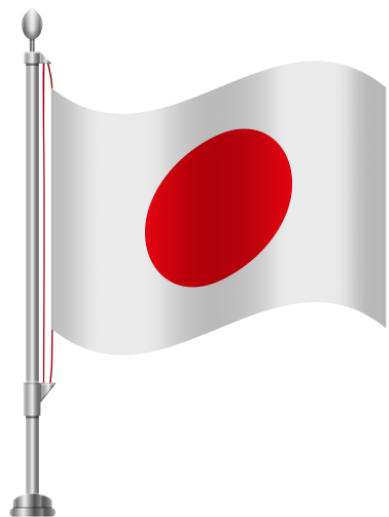
Risk vs Hazard Approach

Hazard approach = Looks at the intrinsic properties of a chemical



Risk approach = Looks at combination of hazard and exposure to a chemical





Standard notification

- >10 tpa in total in Japan
- Bioaccumulation
- Degradation
- Toxicity
- Eco-toxicity

Reduced requirements

- <10 tpa only
bioaccumulation and degradation data
- <1 tpa no testing data required



Regular notification

- >1 tpa (R&D >10 tpa)
- Characterisation data
- Physicochemical
- Toxicological
- Eco-toxicological
- Risk assessment

Reduced Requirements

- <1 tpa only
physiochem and
eco-toxicological
data required
- R&D and isolated
intermediates < 1pa
no testing is required



Pre-manufacture notice

- Existing available date
- Chemical identity
- Product volume
- By –products
- Uses
- Environmental release
- Disposal practices
- Human exposure

Reduced requirements

- <10 tpa
- R&D
- Low release and low exposure
- Test marketing purposes
- Polymers of low concern



New substance notification

- >10 tpa
- Biodegradation
- Mammalian toxicity
- Mutagenicity
- Skin irritation
- Skin sensitisation
- Fish & daphnia acute toxicity

Reduced requirements

- No test data for:
- R&D
- On site intermediates
- Substances for export
- Polymers



Submission to national inventory

- >1 tpa
- Company information
- Substance identity
- Quantity
- Recommended uses
- GHS classification

Data requirements will increase with tonnage bands

Exemptions from registration/notification



- Impurities
- Articles
- Natural substances
- R&D substances



- Natural substances
- Impurities
- Special categories: glass, cements, alloys, articles



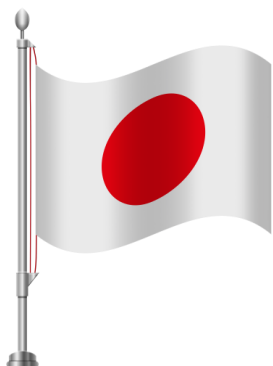
- R&D
- Non-isolated intermediates



- Natural substances
- Products of incidental and end use reactions, by products
- Impurities
- Substances manufactured solely for export
- Non isolated intermediates



- Natural substances
- Alloys
- Polymers & proteins – 2% rule
- By-products
- Impurities

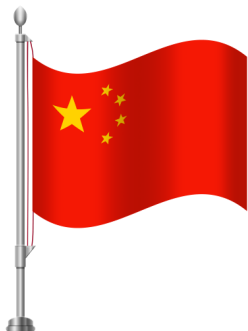


Priority assessment chemical substances (PACS)

- Assessment based on substance potential risks of long-term toxicity

Monitoring chemical substances

- Existing chemicals that are persistent and highly bioaccumulate



Hazchem registration under SAWS order 53

- Register hazardous chemicals with the national registration centre of chemicals (NRCC) prior to import or manufacture
- Chemicals with unknown hazards testing must be conducted
- New and existing substances



Significant new use rule (SNURs)

- EPA can determine that a use of a substance is a significant new use
- Need to submit a significant new use notice to EPA at least 90 days before manufacture/import

Chemical data reporting (CDR) rule

- Manufacturers/importer need to report every 5 years information on their substances
- >25,000 lbs/year



Significant new activity (SNac) provision

- Proposing to use, import or manufacture the substance for a significant new activity
- Submit a new activity notification (SNAN) to the government
- Government assesses the substance for potential risks to human health and/or environment
- Risk identified the government may impose management measures

Further testing and Existing substances



Draft bill

- No further information on what may be required for existing substances

All five of the regulations compared don't contain provisions to minimise animal testing

HOWEVER



Authorities encourage data sharing in order to avoid repeated vertebrate testing



In June 2018 a strategic plan was put in place by the EPA with the aim to reduce the number of vertebrate tests that are conducted for chemical regulation.

Allowed (not mandatory)	No related provisions	Unclear
Japan	Canada	Brazil
China		
US		

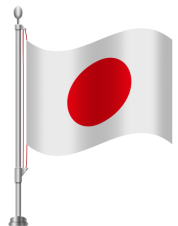


When companies submit a joint notification or share study reports their tonnages are aggregated to determine the right level of notification and information requirements



Section 4 TSCA – entities seeking to use new hazard and exposure information must provide fair and equitable reimbursements for such information

Registration/notification Cost



Admin fee: £0
Testing:
1-10 tpa £65,000
>10 tpa £200,000



Admin fee: £20
Testing: Approx.
several hundred
thousand RMB
Consultancy fee:
minimal

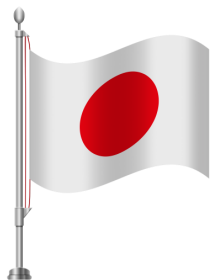


Admin fee: \$2,500
Testing:\$0



Admin fee: £3,500
Testing: £2,500-
£250,000

Restrictions/bans on Substances



CSCL Class I &II



Decree 591 and product safety regulations



TSCA Section 6



Toxic substance list and virtual elimination



Bans and restrictions

- From comparing these five regulations it has become clear that if companies are wanting to place a substance on the market they have to understand that their obligations may differ depending on the market.
- Most established chemical regulations require companies to
 - Register/notify a new substance
 - Provide information on existing substances
- Variations around
 - Animal testing
 - Data sharing
 - Data requirements

What about the science policy interface?

Many thanks.

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