



Prague Chemical Management Cruise 2018

December 6, 2018

Chemical Product Market Eligibility Considerations Americas and Asia Markets Compared to the European Union

Presented by James Eggenschwiler, JD



Introduction

The Redstone Group

- Global regulatory consulting and services firm with capability throughout the Americas, Asia, and Europe.
- Product Focus: market access, compliance maintenance, regulator relationship management

James (“Jim”) Eggenschwiler

- International Trade and Regulatory attorney with 30+ years experience.
- International product and logistics management experience in the Americas, Asia and Europe.

The Americas

UNITED STATES

TSCA (all general chemicals)

- Product ingredients must be listed and certified to US Customs
- Listed substances are market eligible – subject to restrictions
- Confidential listings are numerous
- No allowable volume threshold
- Restrictions are increasing
- New registrations require regulator approval – 90-day to 180-day process.
- Polymers require registration
- FIFRA registered preservatives permitted if registered for such use
- Enforcement – national and state
- Consumer labeling and restrictions separately apply

State Laws

- Disclosure and exposure warning label requirements are increasing
- Generally not permitted to exceed national law requirements

EUROPE

REACH (all general chemicals)

- No inventory listing requirement
- ECHA maintains confidential data, but not confidential registrations
- 1t/y minimum volume threshold permitted to enter
- Joint/Lead Registration effective upon submittal.
- Registrations effective on submittal subject to content completeness
- Polymer Exemption – only monomers must be registered
- Biocidal product preservatives permitted if approved biocide substance in EU.
- Enforcement – Member States
- No separate consumer labeling law

Member State Laws

- Generally not permitted to exceed EU law requirements
- eSDS

The Americas

CANADA

CEPA (all general chemicals)

- Product ingredients must be listed and certified to US Customs
- Listed substances are market eligible – subject to restrictions
- Confidential listings are numerous
- No allowable volume threshold
- Restrictions are increasing
- New registrations require regulator approval – 90-day to 180-day process.
- Polymers require registration
- Preservative biocidal content permitted subject to restrictions
- Enforcement – national, provincial

Provincial Laws

- Generally not permitted to exceed national law requirements
- Dual language requirements on labels

EUROPE

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Member State Laws

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The Americas

OTHERS

Chemical Law (all general chemicals)

- Brazil is in process of adopting a national inventory and registration system.
- Generally none for all others except import licenses and use permits
- Generally no regulation of immediate product preservatives.
- Local permits may apply
- GHS compliance generally required

Local Laws

- Frequently more stringent than national requirements
- Inconsistent treatment of consumer product labeling requirements, if any.

EUROPE

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- Enforcement – Member States
- No separate consumer labeling law

Member State Laws

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- eSDS

East Asia

CHINA (PRC)

Order No. 7 (all general chemicals)

- Product ingredients must be IECSC listed or newly registered
- Listed substances are market eligible – subject to restrictions
- Confidential listings are numerous
- No allowable volume threshold
- Multiple hazard related inventories requiring registration
- Polymers require registration
- Preservative biocidal content permitted subject to restrictions
- Enforcement – national, provincial and local

Provincial / Local Laws

- Differences are permitted within limits

EUROPE

REACH (all general chemicals)

- No inventory listing requirement
- ECHA maintains confidential data, but not confidential registrations
- 1t/y minimum volume threshold permitted to enter
- Joint/Lead Registration effective upon submittal.
- Registrations effective on submittal subject to content completeness
- Polymer Exemption – only monomers must be registered
- Enforcement – Member States
- No separate consumer labeling law

Member State Laws

- Generally not permitted to exceed EU law requirements
- eSDS

East Asia

SOUTH KOREA

K-REACH (all general chemicals)

- Product ingredients must be listed on KECI
- Listed substances are market eligible – subject to restrictions
- No allowable new substance volume threshold
- Inventory listed chemicals now require EU-like joint registration
- 30 June 2019 Preregistration deadline, no late preregistrations
- Polymers require registration
- Preservative biocidal content requires K-BPR registration
- KBPR preregistration by 30 June 2019
- Enforcement – national and state

Chemical Control Act

- 100% product content disclosure
- Chemical use restrictions by region

EUROPE

REACH (all general chemicals)

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- 1t/y minimum volume threshold permitted to enter
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- Registrations effective on submittal subject to content completeness
- Polymer Exemption – only monomers must be registered
- Enforcement – Member States
- No separate consumer labeling law

Member State Laws

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East Asia

JAPAN

CSCCL (all general chemicals)

- Product ingredients must be ENCS listed with assigned MITI number
- Listed substances with MITI number are market eligible – subject to restrictions
- New registrations require approval by 3 agencies.
- No allowable new substance volume threshold
- Polymers require registration
- Preservative biocidal content permitted subject to restrictions
- Enforcement – national, local

Local Laws

- Generally not permitted to exceed national law requirements
- Mostly hazardous chemical use management

EUROPE

REACH (all general chemicals)

- No inventory listing requirement
- ECHA maintains confidential data, but not confidential registrations
- 1t/y minimum volume threshold permitted to enter
- Joint/Lead Registration effective upon submittal.
- Registrations effective on submittal subject to content completeness
- Polymer Exemption – only monomers must be registered
- Enforcement – Member States
- No separate consumer labeling law

Member State Laws

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East Asia

TAIWAN

TCSCA (all general chemicals)

- Product ingredients must be listed on the Taiwan chemical inventory or subject of an approved New Chemical registration
- Listed substances are market eligible – subject to restrictions and additional registration at $\geq 1\text{t/y}$
- Confidential listings are common
- No allowable volume threshold for new substances
- Polymers require registration
- Preservative biocidal content permitted subject to restrictions
- Enforcement – national law

OSHA (Work Safety)

- Dual agency approval of new substance registrations
- Use and worksite permitting/licensing

EUROPE

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- Registrations effective on submittal subject to content completeness
- Polymer Exemption – only monomers must be registered
- Enforcement – Member States
- No separate consumer labeling law

Member State Laws

- Generally not permitted to exceed EU law requirements
- eSDS

East Asia

OTHERS

Chemical Law (all general chemicals)

- Thailand and Vietnam are adopting national inventories and registration systems
- Australia is redesigning its law and system
- Generally none for all others except import licenses and use permits
- Generally no regulation of immediate product preservatives.
- Import licenses and use permits often apply, at least for hazardous substances.
- GHS compliance generally required

Local Laws

- Frequently more stringent than national requirements
- Inconsistent treatment of consumer product labeling requirements, if any.

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Thank You!

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