Global Chemical Registration Strategies for Oilfield Chemicals

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Getting the Product to the Customer

Component Name	Percent Composition
Water	25
Sodium chloride	25
Chemical Y	50

Registration

Jurisdiction A

Jurisdiction A

- Do I have to register?
- What are the data requirements to register?
- What is the time-frame and cost to register?

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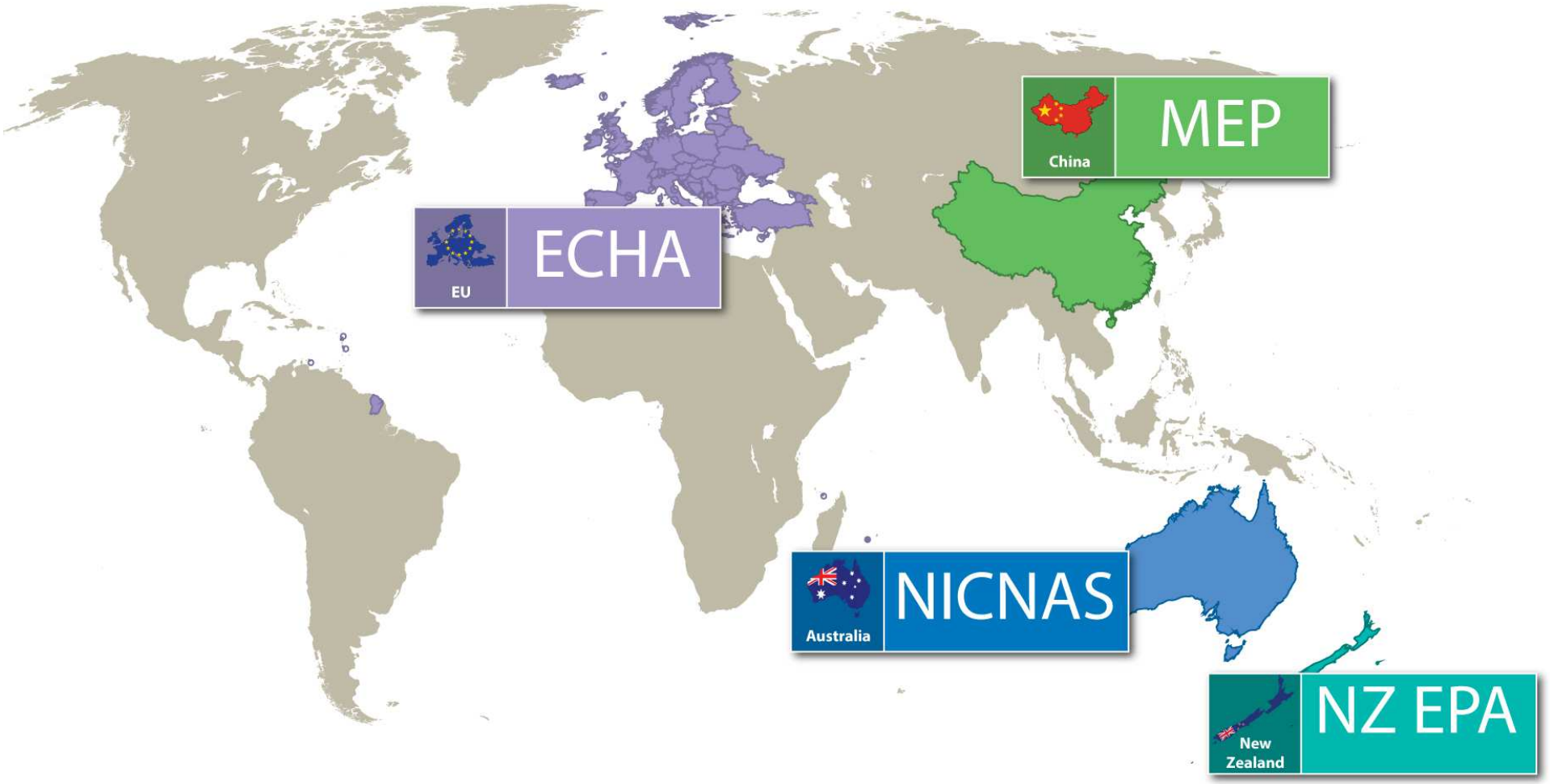
Regulatory Agencies



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Many types of oil and gas chemicals

- Drilling muds
- Cements
- Completion fluids
- Biocides
- Corrosion or scale inhibitors

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What is chemical registration?

- In many countries, new chemicals must be registered with a government agency prior to manufacture or import
- How can we comply with registration requirements?
  - Register new chemicals
  - Evaluate existing product lines for compliance
  - Monitor changing regulations

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Why register new chemicals?

- Rapidly developing chemical technology – many new chemicals
- New chemicals are profitable!
- Lack of compliance is a liability that can lead to:
    - business disruption
    - legal penalties (fines, jail time)
    - increased scrutiny of your company and the industry generally

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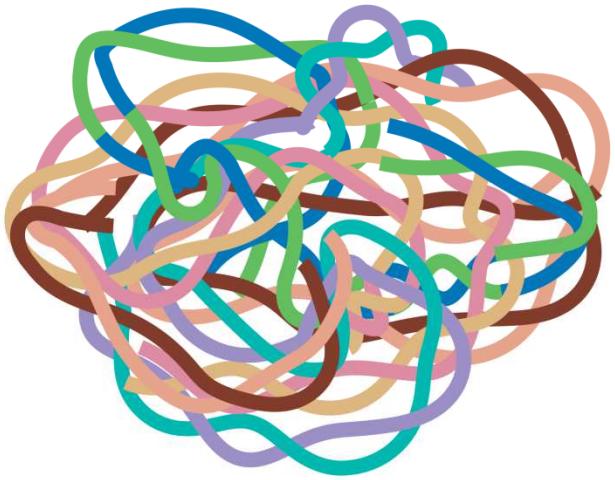
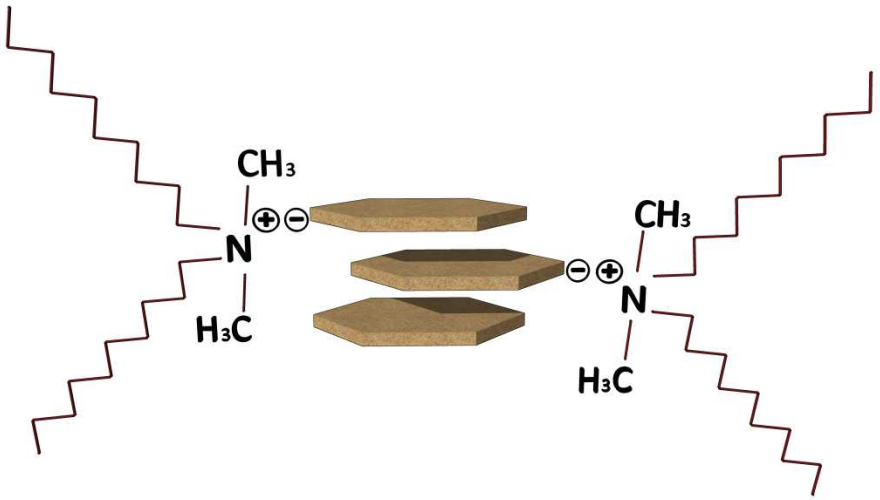
Two examples

Non-hazardous polymer



Organoclay



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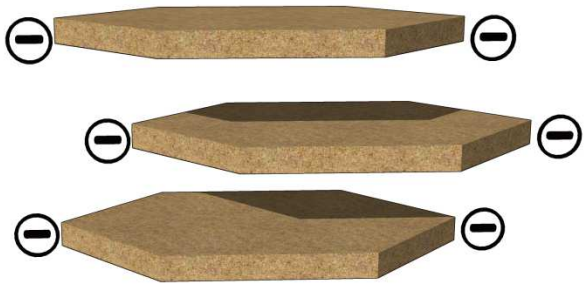
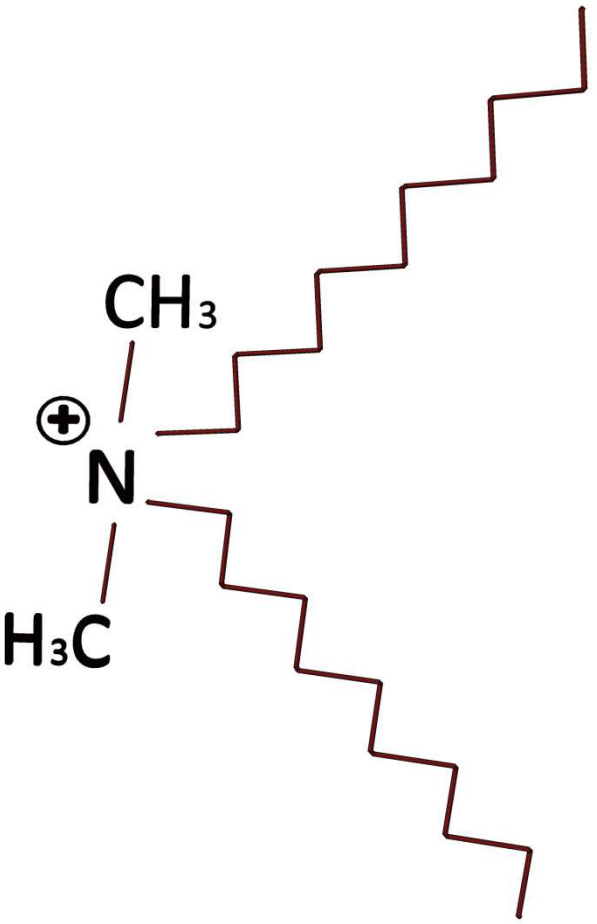
Organoclay = Clay + “Quat”





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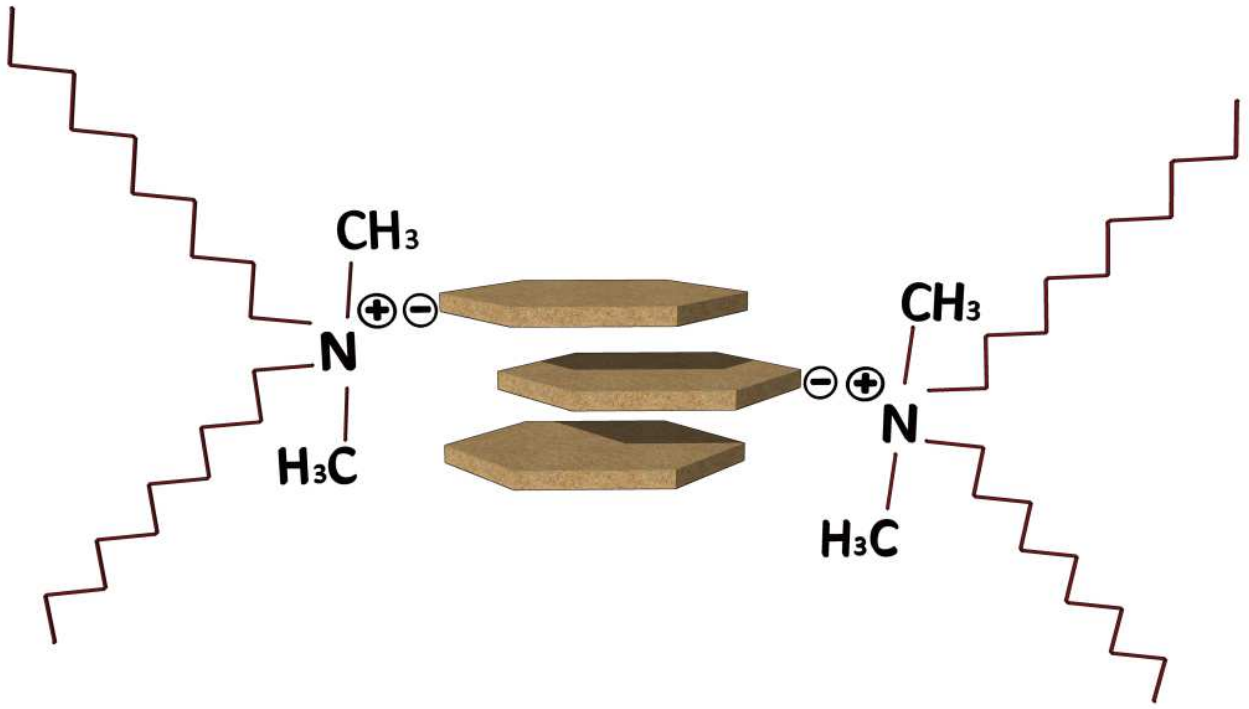

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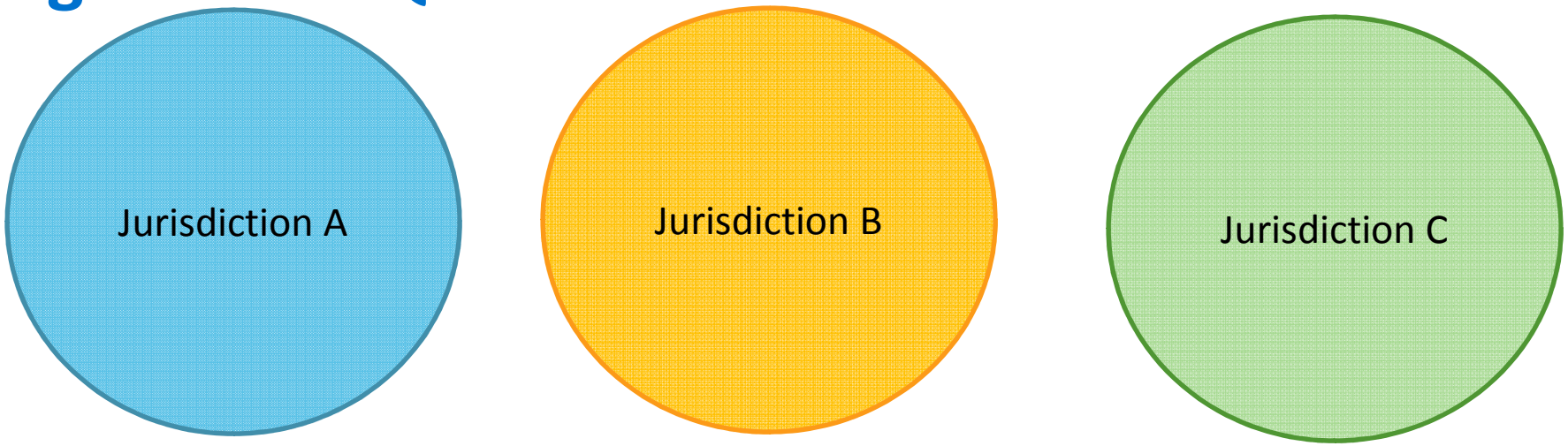
Registration Questions



Jurisdiction

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Registration Questions

Do I have to register?

What are the data requirements to register?

What is the time-frame and cost to register?

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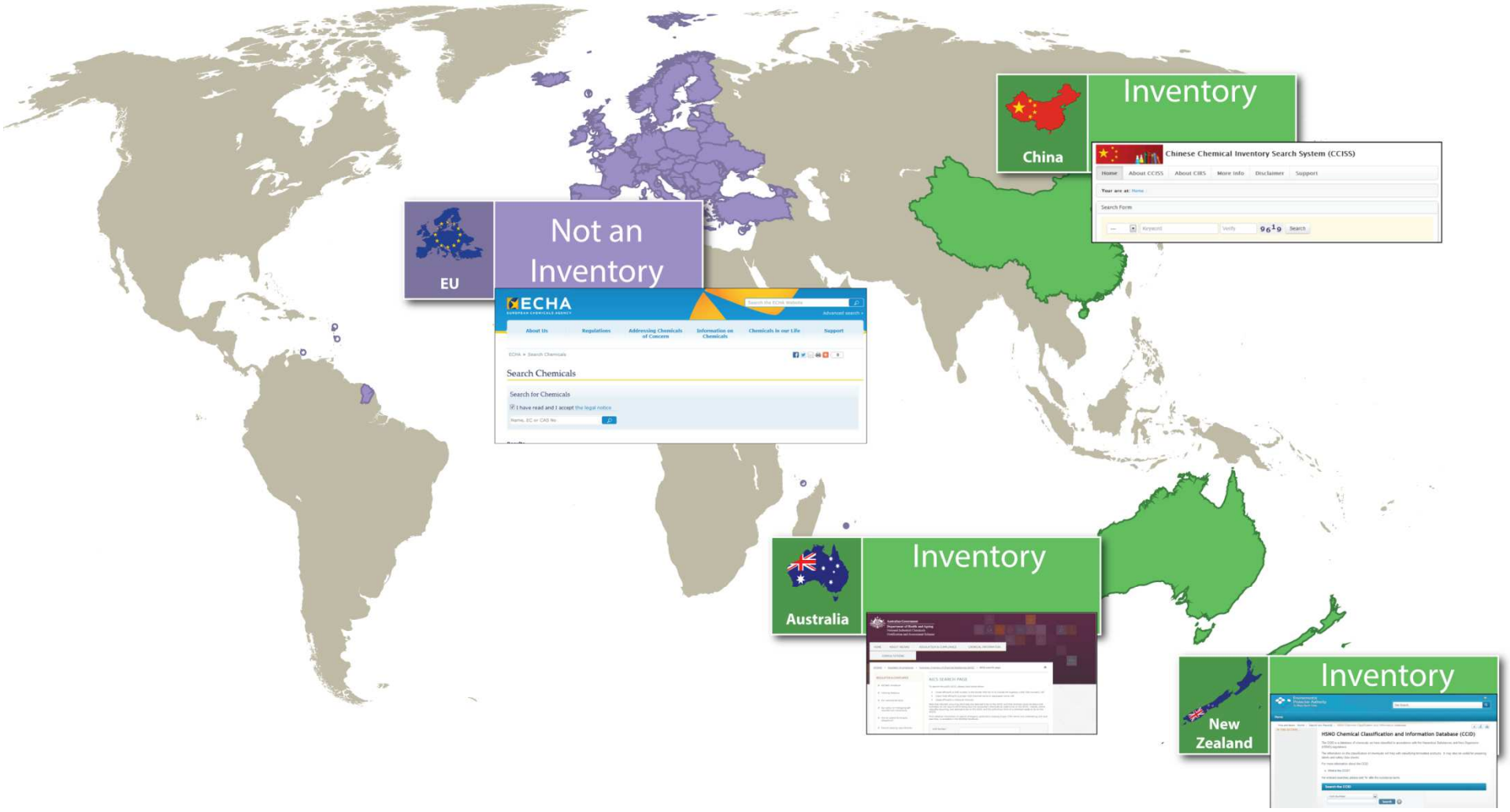
“Do I have to register?” -- Inventory Status



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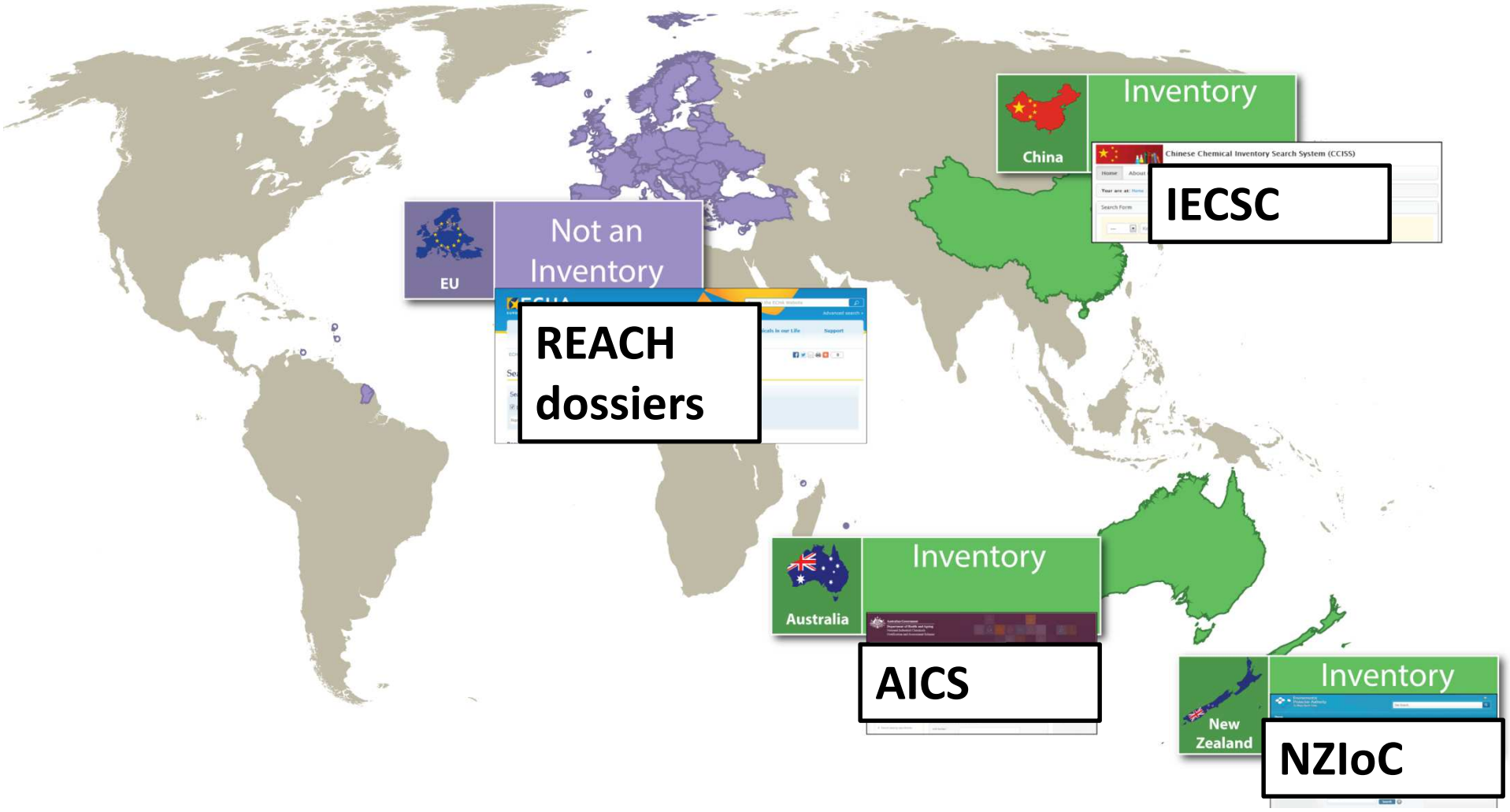
“Do I have to register?” -- Inventory Status



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“Do I have to register?” -- Exemptions

Full exemptions (vary by jurisdiction):

- Naturally-occurring substances
- Articles
- Impurities/reaction intermediates
- EU polymers – register monomers!

Reduced requirements:

- Low volume (e.g., R&D)
- Polymers of Low Concern (PLC)

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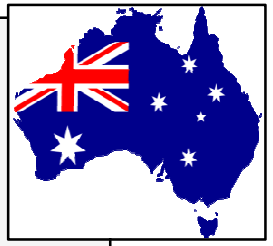

DEFINITION OF A NATURALLY-OCCURRING CHEMICAL

A naturally-occurring chemical is defined in Section 5 of the Act as:

"(a) An unprocessed chemical occurring in a natural environment,

or

(b) a chemical occurring in a natural environment, being a substance that is extracted by:

(i) manual, mechanical, or gravitational means, or

(ii) dissolution in water; or

(iii) flotation; or

(iv) a process of heating for the sole purpose of removing uncombined water

without a chemical change in the substance".

Guidance on these processes is included below.

It is noted that the definition of a naturally-occurring chemical is consistent with equivalent definitions in other notification and assessment schemes.

Unprocessed chemicals occurring in a natural environment

The first part of the definition of a naturally occurring chemical (part (a)) applies to chemicals which can be obtained from, for example, plants, micro-organisms or animals without any processing at all, for example blood and milk from animals. The definition also applies to certain inorganic matter such as minerals, ores, crude oil, coal and natural gas which can be, for example, obtained from the earth or sea without any processing.

Chemicals extracted without a chemical change

The second part of the definition of a naturally-occurring chemical (part (b)) applies to chemicals which occur in nature but which have been processed by certain means without any change in the chemical composition of the chemical. A description of these processes, with examples, is set out below.

Extraction by manual, mechanical or gravitational means

The simplest method of separation is when a naturally-occurring chemical is removed from its matrix or another chemical by hand or machine without any change in the chemical composition. Processes which may be applicable include:

- Filtration, where the solid and liquid phases of a mixture are mechanically separated by passing the mixture through a porous medium
- Centrifugation, where the liquid phases or solid and liquid phases of a mixture are separated by mechanical/gravitational means
- Sedimentation, where the solid and liquid phases of a mixture are gravitationally separated by enabling the settling of solids in liquids
- Cold pressing, where the liquid of a liquid-solid mixture is separated by squeezing the matrix to obtain the liquid
- Sieving, where the solids in a mixture can be separated on the basis of particle size.

Extraction by dissolution in water

In this separation method (for water-soluble chemicals), the only solvent which can be used to extract the chemical from other components in a mixture is water. The dissolution by any other solvent or mixture of solvents or mixture of water with other solvents disqualifies the chemical from being naturally-occurring.

Examples of this process include the extraction of sugar from sugar beets using water, the leaching of soluble tea from tea leaves and the extraction of a water-soluble chemical from a mineral ore.

Extraction by flotation

Flotation is a physicochemical property-based separation process widely used in mineral processing to separate minerals from waste rock or solids. Flotation is based on the use of wettability differences of solid particles, where mineral ore is pulverised and mixed with water and certain special chemicals that cause preferential wetting of the solid particles. The unwetted particles are carried to the surface by air bubbles to obtain a mineral concentrate, for example lead, zinc and copper concentrates.

Extraction by a process of heating for the sole purpose of removing uncombined water

Heat can be used to purify or concentrate chemical compounds by removing uncombined water. For the purposes of meeting the NICNAS definition of a naturally-occurring chemical, the heat applied is not to serve any other purpose, for example the heat necessary for steam distillation. An example of this extraction process would be the drying of a wet clay or mineral, where moisture is not chemically-bound to the substrate.

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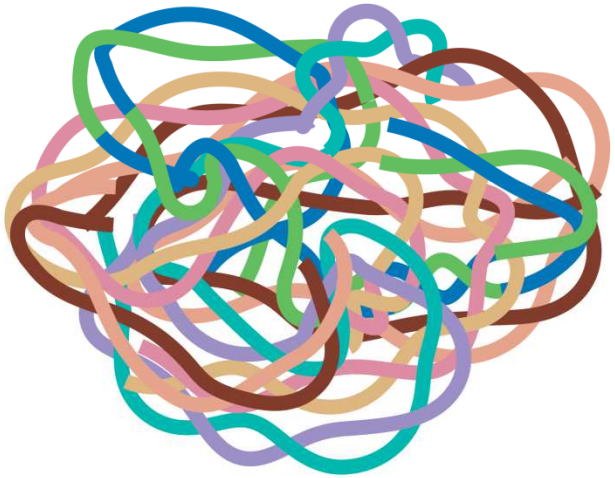
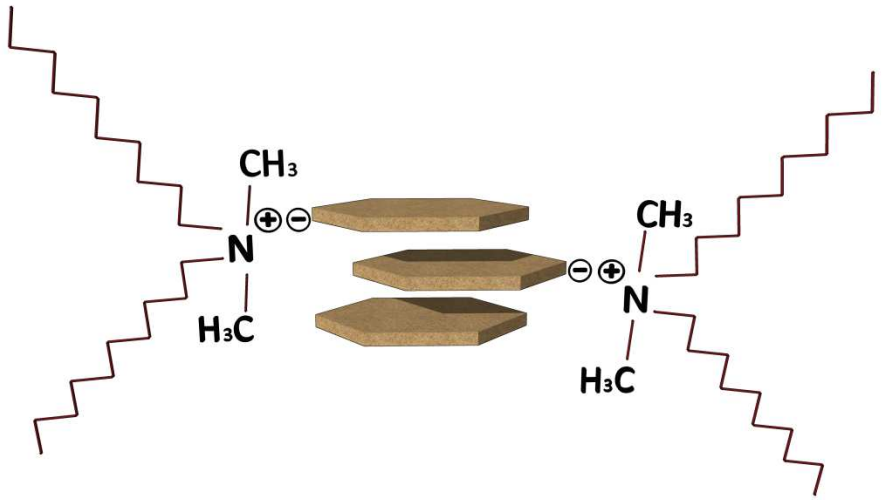
“Do I have to register?” -- Examples

Non-hazardous polymer



Organoclay



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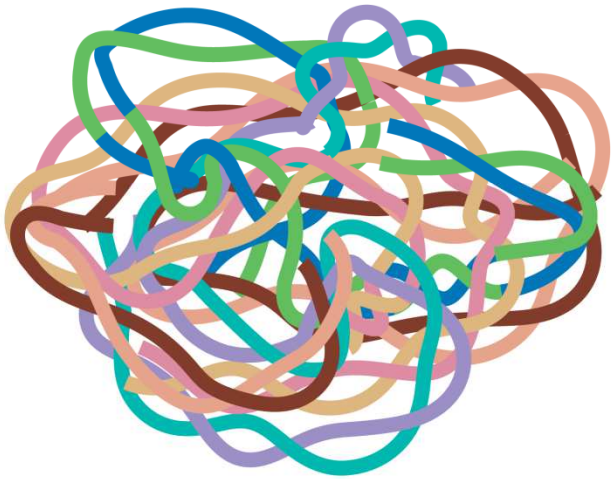
“Do I have to register?” -- Examples

Non-hazardous polymer



EU: Register monomers

Australia: Register as PLC

China: Register as PLC

NZ: Don’t register

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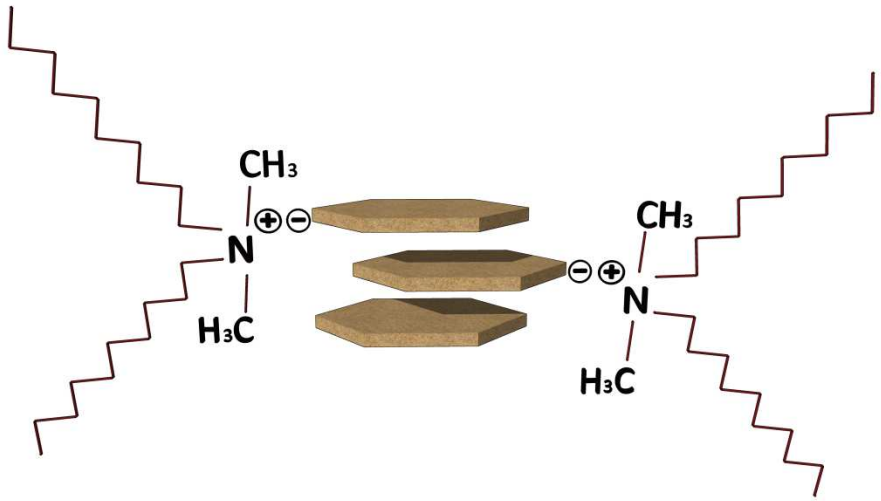
“Do I have to register?” -- Examples

Organoclay



EU: Register quat

Australia: Register organoclay

China: Register quat

NZ: Map to group standard, possibly notify or register

New product

- Multiple components
  - On inventory
  - Not on inventory
  - Not on inventory, but exempt (*e.g.,* naturally occurring)

Component Name	Percent Composition
Water	25
Sodium chloride	25
Chemical Y	50

Who needs to register?

- Importer or manufacturer of **new industrial chemicals** (most countries)
  - Chemical on country inventory – do not register
  - Naturally occurring substance – do not register
  - Food, pesticides, biocides may be covered by different laws
- Importer or manufacturer of **any industrial chemical** (EU)

Registration Questions

Do I have to register?

What are the data requirements to register?

What is the time-frame and cost to register?

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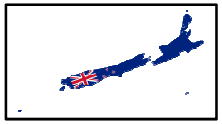
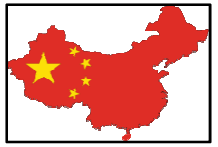
"What are the data requirements to register?" -- Notification Types



Volume (tons)		European Union	Australia	New Zealand	China
>1000	--	Regular (T4)	Standard	Notification not driven by import volume.	Regular (T4)
100-1000	--	Regular (T3)			Regular (T3)
10-100	--	Regular (T2)			Regular (T2)
1-10	--	Regular (T1)			Regular (T1)
< 1	--	No Testing Required	Limited		Simple - Basic
0.1 – 1	Not Hazardous		Low Volume Permit		
< 0.1	--				
< 0.1	Not Hazardous		Non-Cosmetic Exemption		
No Limit	PLC	Register monomers	PLC		PLC
< 0.1	R&D Only	No Testing Required	Not Required		R&D Record
> 0.1	R&D Only	Exempt for up to 5 years (> 1 ton)*	R&D Form 6		R&D Record

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Endpoint	T1	T2	T3	T4	T1	T2	T3	T4
Ecotoxicology data		**EU**				**China**		
Short term aquatic tox on Daphnia								
Growth inhibition aquatic plants (algae)								
Short-term aquatic toxicity to fish					China	China	China	China
Activated sludge respiration inhibition test								
Long-term aquatic toxicity on Daphnia								
Long-term aquatic toxicity on fish						China		
Fish early-life stage toxicity test								
Fish short-term tox test on embryo and sac-fry								
Fish, juvenile growth test								
Biotic degradation								
Ready biodegradability					China	China	China	China
Ultimate degradation in surface water								
Soil simulation testing								
Sediment simulation testing								
Hydrolysis as a function of pH								
Identification of degradation products								
Adsorption/desorption screening								
Bioaccumulation in aquatic species (fish)								
Further information on adsorption/desorption								
Environmental fate and/or degradation products								
Short-term terrestrial toxicity on invertebrates					China	China	China	China
Effects on soil micro-organisms								
Short-term terrestrial toxicity to plants								
Long-term toxicity testing on invertebrates								
Long-term toxicity testing on plants								
Long-term toxicity to sediment organisms								
Long-term or reproductive toxicity to birds								
Daphnia magna reproduction								
Seed germination and root elongation toxicity								
Inherent biodegradability						China	China	China

"What are the data requirements to register?"

	Testing needed (may be waived)*
	Likely superceded by higher tier
	Based on exposure assessment
	Testing after ECHA approval

	Testing needed (may be waived*)
	One of tests to be chosen
China	To be performed in China

T1: 1-10 tons
T2: 10-100 tons
T3: 100-1000 tons
T4: >1000 tons

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Registration Questions

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What is the time-frame and cost to register?

Volume (tons)	Australia	
	$$	Time (Months)
>1000	6k – 300k	6-9
100-1000		
10-100		
1-10		

Volume (tons)	China	
	$$	Time (Months)
>1000	900k – 1500k	11 – 24
100-1000	475k – 625k	11 – 22
10-100	275k – 375k	11 – 18
1-10	200k – 300k	10 – 12

Costs based on laboratory fees and application fees.

Volume (tons)	New Zealand	
	$$	Time (Months)
>1000	1k – 300k	<1 – 4
100-1000		
10-100		
1-10		

Volume (tons)	EU	
	$$	Time (Months)
>1000	350k –2100k	11 – 24
100-1000	150k – 1100k	11 – 22
10-100	50k – 550k	11 – 18
1-10	20k – 120k	10 – 12

Getting the Product to the Customer

Component Name	Percent Composition
Water	25
Sodium chloride	25
Chemical Y	50

Registration

Jurisdiction A

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Your Chemical Compliance Team

- Business and operations
- Local legal counsel
- Technical expertise:
  - chemistry
  - toxicology
  - ecology

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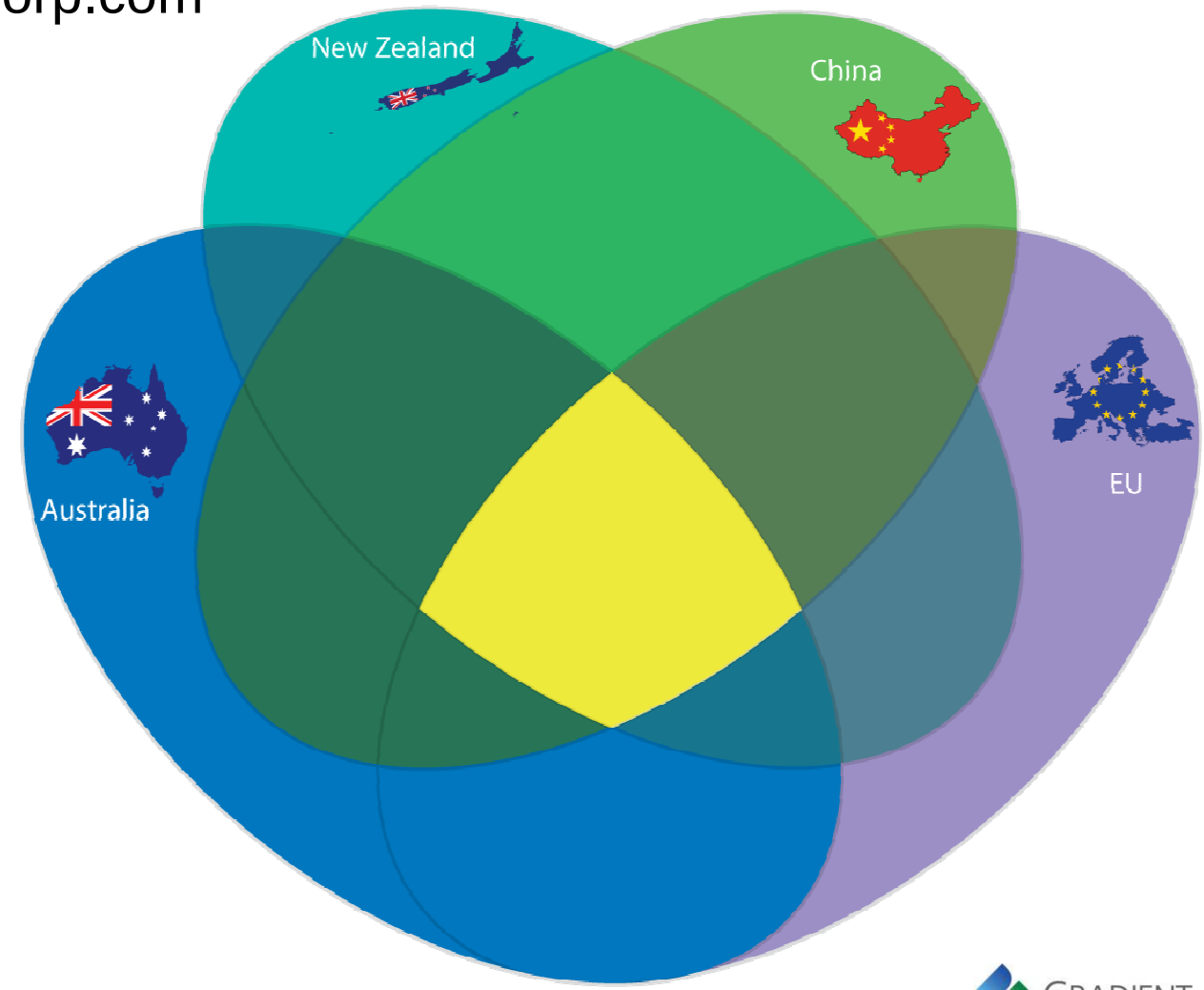
Questions?

jkneeland@gradientcorp.com



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Registration Requirements: EU

What are the data requirements to register?

Is substance already registered by us?

No → Gather data to identify substance

Yes → Will additional usage increase tonnage band?

No → Use / import product

Yes → Submit inquiry dossier to ECHA

Inquiry Successful?

No → Gather data to identify substance

Yes → Other registrant identified?

Yes → Join SIEF, purchase data

No → Gather data, perform tests

Assess Hazards

Submit individual or joint registration dossier

Accepted by ECHA?

No → Gather data, perform tests

Yes → Use / import product

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