

# New Chemical Notifications

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# Eka Chemicals Inc.

- **North American HQ: Marietta, GA**
- **Global HQ: Göteborg, Sweden**
- **Parent company: Akzo Nobel Inc. (HQ Amsterdam, The Netherlands)**
- **Global supplier of bleaching and paper chemicals to the pulp and paper industry, as well as specialty products**

# Global New Chemicals Notification Overview

1. Do you need to notify in the marketplace?
2. Regional variations (e.g. China – notification on 4 or more inventories)
3. Notification steps
4. Contacts and resources
5. Questions

# Fundamental Question: “Do you need to notify?”



Generally, you can manufacture\* if all components are . . .

1. Listed on the region's inventory; AND
2. Are not otherwise restricted

★ Note: Assumes HazCom requirements are met

\* Remember: "manufacture" also includes import!

# What if it is not listed?

## STEP ONE:

- See if an exclusion is available (“path of least resistance”!)

Article	Biocide active ingredient
Biocide intermediate	Biotech chemical
Cosmetic	Drug
Drug intermediate	Foods/food additive
Hydrate	Impurity
Microorganism	Mixture
Natural substance	Non-isolated intermediate
Pesticide active ingredient	Pesticide Intermediate
Radioactive material	Site-limited intermediate
Wastes/By-Product	Veterinary Chemical
“Chemical deemed elsewhere to be harmless”	

- ❖ If so, you MIGHT be eligible for exclusion
- ❖ But not all regions apply exclusions the same way...

# GENERAL TABLE OF EXEMPTIONS

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
Articles	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biocide active ingredients	Yes	No	Yes	Yes	Yes	No	No	Yes
Biocide intermediates	No					Yes		Yes
Biotech chemicals	No	No	No			No		Yes
Cosmetics	Yes	No	No	Yes	Yes	Yes	No	Yes
Drugs	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Drug intermediates	Yes	No		Yes		Yes	No	Yes
Foods/food additives	Yes	No	Yes	Yes	Yes	Yes	Yes (foods)	No
Hydrates	Yes	Yes	No	Yes (informal)	Yes	Yes		No
Impurities	Yes	Yes	Yes	Yes	Yes	Yes (< 1%)	No	Yes

# GENERAL TABLE OF EXEMPTIONS

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
Microorganisms	No	No				Yes	No	
Mixtures	Yes	Yes	Yes	Yes	Yes	Yes	No	No
<b>NANOTECHNOLOGY</b>								
Natural substances	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Non-isolated intermediates	Yes	Yes	Yes	Yes	Yes	Yes		No
Pesticide active ingredients	Yes	Yes	Yes	Yes	Yes	No	No	Yes
Pesticide Intermediates	No	No				Yes		Yes
Radioactive materials	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site-limited intermediates	No	No	No	No	No	Yes	No	No

# GENERAL TABLE OF EXEMPTIONS

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
Wastes/By-Products	Yes	Yes	Yes	Yes	Yes	Yes	Wastes (No) By-Products (Yes)	No
Chemicals deemed elsewhere to be harmless	No	No	No	No	No	No	No	Yes
Veterinary Chemicals	Yes		Yes	Yes	Yes		No	Yes

# What if it is not listed?

## Step Two:

- See if an exemption is available:
  - Could your substance be considered a/an:
    - R&D substance?
    - Low volume?
    - Test Market?
    - Site limited intermediate?
    - Export only?
    - Polymer?
  - If so, may have options for exemptions in full notification requirements

# BUT – Special Rules Apply!

- Notification may or may not be required
- There may be volume restrictions
- There may be certain test data required
- Plus additional rules on polymers
  - 👉 More details at GlobalChem breakout session

***Rules and requirements are not consistent across the globe – even with GHS!!***

# RESEARCH AND DEVELOPMENT AND LOW-VOLUME EXEMPTIONS TABLE

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
<b>R&amp;D</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Maximum volume (kg/yr)	Unlimited	1,000 or 10,000	50		≤100 (renewable) or ≤1000 (1 year, not renewable)	Unlimited	No volume specified	Unlimited initial volume; unlimited cumulative volume
Notification required?	No	Yes	No		Yes	No	No	No
Test data required?	N/A	Existing only	No		No	No	No	No
<b>Low volume</b>	Yes	Yes	Yes	Yes	Pending Development	Yes	No	Yes
Max volume (kg/yr)	>0/10,000	100 or 1,000	100	1000		1000 or 10000		100/ company
Notification required?	Yes	Yes	Yes	Yes		Yes		No
Test data required?	Existing Only	Existing only	No			No		No

# TEST MARKET, SITE-LIMITED INTERMEDIATES AND EXPORT ONLY TABLE

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
<b>Test Market</b>	Yes		Yes	No	No	No	No	No
Max volume, kg	Qty requested		4000					No
Notification required?	Yes		Yes					No
Test data required?	Existing Only		No					No
<b>Site limited intermediates</b>	No	Yes	Yes	Yes	No	Yes		No
Max volume, kg	None	1,000 or 10,000	10,000	5,000		None		None
Notification required?	Yes	Yes	No	Yes		No		Yes
Test data required?	Existing Only	No	Yes			No		No
<b>Export only</b>	Yes	1,000 to 10,000	Yes	Yes - 5,000 kg	No	Yes	No	No

# POLYMERS TABLE

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
Polymers							No	
"2% rule"	Yes	Yes	Yes	Yes	Yes	No (1%)	No	No
New polymer from existing monomers	Yes	No	No	Yes	Yes	No		No
New polymers from new monomer	No	No	No	No	No	No		No
Polymers of "low concern"	Yes	Yes	Yes	No	Yes	Yes		No

# What if a Component is Not Listed, Not Excluded and Not Exempt?

1. If you make it:
  - ❖ Decide whether timing, cost, and resources are favorable for going through notification process.
2. If you buy it:
  - ❖ Ask the supplier to notify (\$) or to supply information required to notify (confidentiality issues).

# DSL / NDSL “UP FRONT” COSTS (2004)

<u>Schedule</u>	<u>Tox/Ecotox Testing Cost range</u>
II	\$41,925 - \$58,119 (USD)
III	\$150,706 - \$226,326
V	\$10,913 - \$21, 663
VII	\$35,750 - \$66,917
VIII	\$116,986 - \$150, 251

# OTHER CONSIDERATIONS

Listed? **No**

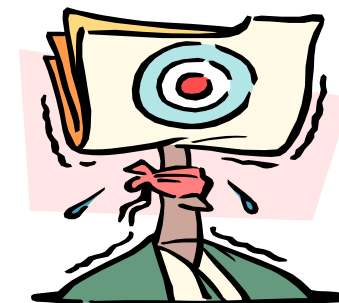
Exclusion or Exemption available? **No**

Have commercial intent ? **Yes**

**Notify!**

## Considerations

- Cost
- Time
- One country or more? (MON)



# TIMING CONSIDERATIONS

## Time for approval (days)

- ✘ US: 90 minimum
- ✘ Canada: 30 – 140 (depends on Schedule type)
- ✘ Australia: 90 for certificates; 4-20 days for permits
- ✘ Philippines: 180
- ✘ China: 120 (*note: actual practice is much longer*)
- ✘ Japan: 90
- ✘ New Zealand: 85 (depends on notification type)
- ✘ Korea: 45

# TESTING CONSIDERATIONS

- ❑ Some regions require specific test data with the notifications:
  - ◆ Data requirements may be linked to production volume thresholds
  - ◆ Some require up front data (e.g. Environment Canada/CEPA), while others require later (if at all)

# REQUIRED TEST DATA OVERVIEW

	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
Required with notification	Existing info	Higher tier notices	Yes		Yes	Yes	No	Yes
Additional may be required (e.g. with volume increases)	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Tox and environ data needed for new polymers, >1000 MW	No	Yes	Yes if not Polymer of Low Concern (PLC)		Yes	Yes if not low concern	Yes (if hazardous)	No

# COSTS – NOTIFICATION FEES

- ★ All regions have full notification fees
- ★ Other potential fees could include
  - Limited notification fees
  - Polymer fees
  - Confidential claims
  - Test variations

# NOTIFICATION FEES TABLE

	US (USD)	CANADA (CDN) (1 CDN = \$0.98 USD)	AUSTRALIA (AUS) (1 AUS = \$0.92 USD)	PHILIPPINES (Ph. Peso) (1 PHP = \$0.025 USD)	CHINA	JAPAN (YEN) (1 JPY = \$0.01 USD)	NEW ZEALAND (NZD) (1 NZD = \$0.79 USD)	KOREA (KRW) (1 KRW = \$0.001 USD)
Full notification	\$2,500	\$ 875 – 3,500	\$14,971	3,750.00		30,000	Varies depending on notification type	52,000
Limited notification	N/A	\$50 – 2,000	\$12,539	2,150.00			\$562.50NZ (rapid assessment or containment)	
Polymers of low concern	\$2,500	\$125 – 500	\$4,223			3,000	N/A	
Commercial evaluation	N/A	\$50 – 3,500	\$3,327				N/A	
Low-volume chemicals	N/A		\$3,327				N/A	2,000
Confidential claim	N/A	\$150 - 600	\$657				N/A	30,000
Test variation	N/A		\$1,184				N/A	
Existing Chemicals Assessments	N/A							

# COSTS – POTENTIAL PENALTIES

- Just be aware that all regions have penalties associated with their regulations
  - ❖ Individual & company penalties
    - “Stop sale”
    - Product seizure
  - ❖ Fines and jail time possible
  - ❖ Civil and criminal (local) liability

# SPECIAL THANKS

ACC's Regulatory Advocacy and Information Network (RAIN)  
sub team

✧ Especially:

- ★ Kathleen Roberts
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# Questions/Comments?

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