

Worldwide R&D & Low Volume Exemptions

GlobalChem 2008
Baltimore, Maryland

March 19, 2008

Mark Grenda
Regulatory Affairs
Afton Chemical Corporation





Presentation Outline




- Exemption Benefits
- Research and Development Exemptions
 - Commonalities
 - Worldwide R&D Exemption Snapshot
 - R&D Exemption under REACH
- Low Volume Exemptions
 - Commonalities
 - Worldwide LVE Snapshot
 - Obtaining an LVE in Japan

Benefits of Exemptions

 Allows certain limited activities without costly notifications.

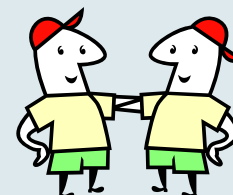
 Shorter or no governmental review times.

 Reduced work for both Industry and Govt. Agencies.

Research & Development



Commonalities



- In all cases, use under the R&D Exemption is for Research and Development only and not for conventional commercial use.
- Definition of R&D varies slightly from country to country but in general, includes;
 - Synthesis of a new chemical substance
 - Analysis and testing of a new chemical substance
 - Process Technology demonstrations
 - Performance Testing

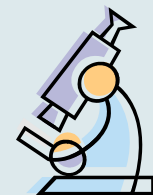
R&D Exemptions in Brief

Country	Specified Volume Limits	Notification Required
US	No	No
Canada	Tiered	Yes at certain thresholds
Japan	No	No
Korea	No	No
Philippines	Yes	Yes
China	Yes	Yes
Australia	Yes	No
EU - REACH	Yes	Yes at 1,000 kg threshold
New Zealand	No	No

R&D under REACH



- In general, under REACH (June 1, 2008), substances not otherwise restricted or authorized can be imported at < 1,000 kg/yr.
- < 1,000 kg/yr - the authorization and restriction provisions do not apply to Scientific Research and Development activities.





PPORD under REACH

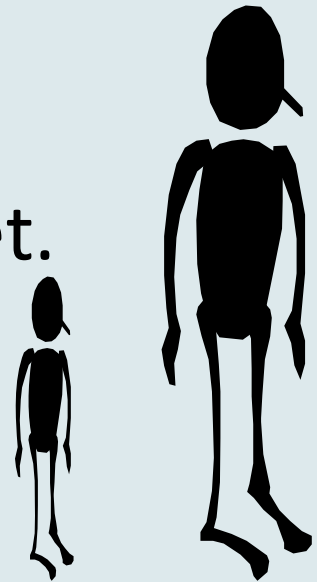
- < 1,000 kg/yr - For Product and Process Oriented Research and Development (PPORD) activities, the authorization and restriction provisions may apply (Annex XIV and XVII).
- > 1,000 kg/yr – Product and Process Oriented R&D activities can be exempted from registration activities for a period of 5 years.

PPORD under REACH

- At $> 1,000$ kg/yr, a company must submit a PPORD notification to the Agency.
- Can be extended for another 5 years.
- Up to 10 years if not yet placed on the market and for medicinal product development.

Low Volume Commonalities

- Notification is generally required.
- Shorter review times – faster to market.
- Only applies to the notifying entity.
- Substance not listed on the Inventory.



Low Volume Exemptions in Brief

Country	Volume Limits (kg/yr.)	Review Time (days)	Other
US	10,000	30	No Notification fee
Canada	Tiered	0 - 60	Notification and fees at specified vol. levels
Japan	1,000/10,000	Variable	Notification under 2 distinct regulations
Korea	<100	None	No notification
Philippines	1,000	20+	Regional approval, notification w/each import, annual report

Low Volume Exemptions in Brief

Country	Volume Limits (kg/yr.)	Review Time (days)	Other
China	None	None	LVE being developed
Australia	100	20	Good for 3 yrs. Can renew Significant fees.
EU	<1,000	None	Must check if authorized or restricted.
New Zealand	None	None	No LVE exists. Non-haz = not regulated.



Japan Low Volume Exemptions

- Two separate laws to consider
 - The Industrial Safety and Health Law (ISHL)
 - “Chemical Substances Control Law” (CSCL)
- ISHL covers substances used in the workplace.
- CSCL chemical control scheme has a focus on environmental fate and ecotoxicological effects.
- Each law maintains a separate and distinct chemical control and low volume scheme.

CSCL – Small Quantity Exemption

- METI / MHLW / MOE
- 1,000 kg/yr total domestic limit.
- If multiple applicants, the volume will be shared between all applicants.
- Application/Approval is 4 times per year (Jan./April, June/July, Sept./Oct. & Dec./Jan.)
- Each SQE expires on March 31 of each year.



CSCCL – Small Quantity Exemption

- An SQE granted on Jan. 1 is only good for 3 months; however,
- It allows import up to 1,000 kg during that time & renewal on April 1 will allow another 1,000 kg/yr until March 31 of the following year.
- Minimal information (Identity, impurity profile, physical properties, use/application, stability).
- Annual renewal required.

ISHL – Notification

- Allows 100 kg/yr per office/facility the notifier owns in Japan (up to 10) until a full ISHL notification has been completed.
- A full ISHL notification requires the information provided under the CSCL SQE application plus an Ames test.
- If the Ames test is positive, additional testing (Chromosomal Aberration) may be required as well.

ISHL – Notification

- Can be applied for at any time 30 days in advance.
- However, even with full ISHL notification, the total allowable market quantity is limited to what you have approval for under the CSCL.

CSCCL – Low Quantity Exemption

- Allows up to 10 MT/yr (total domestic volume) if the substance either not persistent (i.e. METI ready biodegradation test shows > 60% biodegradation) or;
- Persistent but not highly bioaccumulative, and considered not to present a significant risk to human health or the environment.

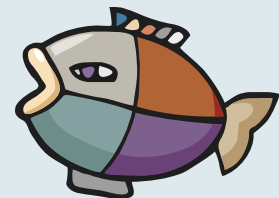


CSCCL – Low Quantity Exemption

- The METI biodegradation is first conducted. If the substance is readily biodegradable (> 60% biodegradation), then no further testing is required.
- If not readily biodegradable, then negotiation with METI/MHLW is required to determine;
- whether further testing can be conducted on simply the parent substance and/or if environmental degradants (“children”) will be further evaluated as well.
- Dependent upon the substance type, it is possible to not have to run a full fish bioaccumulation study if certain other data (read-across or Log P_{ow}) is available.

CSCL – Low Quantity Exemption

- If the estimated or actual bioconcentration factor (BCF) is < 1000 , then the substance is regarded as “not highly bioaccumulative”.
- If the BCF is determined to be ≥ 1000 , an elimination test must be incorporated into the study .
- METI/MHLW will reach a decision on whether a substance is bioaccumulative based on all the measured parameters.



CSCCL – Low Quantity Exemption

- If the (persistent) substance is deemed to not be bioaccumulative, then a 10 MT LQE will likely be issued (designated as “safe”).
- If the substance is deemed persistent and not bioaccumulative, METI may still require further testing if they have concern for human health or the environment (generally unlikely).
- Once 10 MT LQE is granted, annual renewal is a routine matter.



Key Items for 10MT LQE

- If persistent and METI/MHLW/MOE require bioaccumulation testing, it is imperative to negotiate testing on just the parent substance or of the substance + “standards” representing the degradants as a whole.
- Good analytical support and expertise is a must.
- If BCF is concentration dependent, run water solubility before incorporating a 3rd concentration into the bioaccumulation test.
- A good Japanese consultant is worth the investment.

Thank you
Questions??

