

R&D and Low Volume Exemptions

Country Comparison Table

Country/Region	R&D Exemption	Low Volume Exemption
United States	<p>Self executing - No submission to EPA required.</p> <p>No specified volume limits.</p>	<p>10,000 kg/yr limit.</p> <p>Notification to EPA required (minimal information) - 30-day EPA Review Period.</p> <p>No notification fees.</p> <p>Provide existing test data.</p>
European Union (EU)	<p>< 1,000 kg/yr - the authorization and restriction provisions do not apply to Scientific Research and Development activities.</p> <p>< 1,000 kg/yr - For Product and Process Oriented Research and Development (PPORD) activities, authorization and restriction provisions <u>may</u> apply (as specified in Annex XVII or XIV).</p> <p>>1,000 kg/yr – PPORD R&D activities can be exempted from registration for a period of 5 years. A PPORD notification must be supplied to the Agency.</p> <p>Can be extended for more 5 years.</p>	<p>Under REACH (June 1, 2008), substances not otherwise restricted or authorized (i.e. Annex XVII – substances to be restricted or Annex XIV – substances to be authorized) can be imported at < 1,000 kg/yr.</p>
Japan	<p>R&D – No specified volume limits.</p> <p>No submission required.</p>	<p>Type 1 Small Quantity Exemption (SQE): 1,000 kg/yr limit.</p> <p>The opportunity to apply is open only 4 times per year.</p> <p>Can be renewed each year.</p> <p>Type 2 Low Quantity Exemption (LQE): 10,000 kg/yr limit.</p> <p>Biodegradation test required. If not readily biodegradable then bioaccumulation related information or testing itself is required.</p> <p>If Persistent but not bioaccumulative and not expected to pose a risk to human health or the environment, then LQE will be granted.</p> <p>ISHL is a separate law under which notification must be made. Two types; 100 kg/yr/site: Can be applied for at any time 30</p>

		<p>days before manufacture or import. No test data required.</p> <p>Annual renewal.</p> <p>Full notification: Ames test required. If Ames test is positive, then additional testing (Chrom Aberration) may be required as well.</p>
Australia	<p>R&D (“analytical/scientific”) – Up to 100 kg/yr/applicant. No submission required.</p> <p>Annual report to NICNAS required.</p> <p>To import over 100 kg/yr up to 1,000 kg/yr a Limited Notification must be submitted.</p>	<p>100 kg/yr/applicant; however, if two or more companies jointly apply, the volume is split between the applicants.</p> <p>Notification required.</p> <p>Must be renewed every 3 years. Can be renewed any number of times.</p> <p>Annual report required on or by 28 SEP of each year.</p> <p>To import over 100 kg/yr up to 1,000 kg/yr a Limited Notification is required.</p>
Canada	<p>Under CEPA Research & Development includes both scientific and technological R&D.</p> <p>There are currently no fees for Notification of Research & Development Substances.</p> <p><u>Chemical Substances</u> At least 30 days prior to exceeding 1000 kg/yr; Sch. 1 information is required. At least 30 days prior to exceeding 10,000 kg/yr, Sch. 1 update information is required.</p> <p><u>Biochemical Substances</u> At least 30 days prior to exceeding 1000 kg/yr; Sch. 1 and items 1 and 2 of Sch. 2 information is required. At 10,000 kg/yr additional “update” information is required.</p> <p><u>Polymers</u> At least 30 days prior to exceeding 10,000 kg/yr, Sch. 3 information is required. (if biochemical polymer then add items 1 and 2 of Sch. 2).</p>	<p><u>Non-Polymeric Substances</u> <u>Not on NDSL</u> ≤100 kg/yr – no notification >100 kg/yr to 1,000 kg/yr - Sch. 4 (5 day review). >1,000 to 10,000 kg/yr – Sch. 5 (60 day review).</p> <p><u>If listed on NDSL</u> ≤1,000 kg/yr – no notification >1,000 to 10,000 kg/yr - Sch. 4 (30 day review) >10,000 to 50,000 kg/yr – Sch. 5 (60 day review)</p> <p><u>Polymers</u> All Polymers: ≤ 1,000 kg/yr – no notification.</p> <p>RRR – > 1,000 to unlimited kg/yr Sch. 9 (30 day review).</p> <p><u>NDSL listed or all components DSL/NDSL >1000 to 10,000 kg/yr – Sch. 9 (30 day review).</u> 10,000 to 50,000 kg/yr – Sch. 10 (60 day review).</p> <p><u>NOT NDSL listed and all components not DSL/NDSL listed</u> >1000 to 10,000 kg/yr – Sch. 9 (30 day review)</p>
China	<p>R&D Exemption is NOT self-executing – it requires the submission of “Notification Exemption Application Form” and 30-day SEPA review.</p>	<p>There is currently no "low volume provisions" or reduced notification that applies to small quantities of manufactured or imported new chemicals.</p>

	<p>A "Notice for Exemption" will be sent from CRC-SEPA.</p> <p>Up to 100 kg for "Scientific R&D" – can be renewed annually.</p> <p>Up to 1,000 kg for "Technological R&D" – approval is valid for one year and cannot be renewed.</p>	Implementation of a Low Volume Provision in China is pending development.
Philippines	<p>R&D < 1,000 kg/yr</p> <p>A "Letter of Intent to Manufacture or Import for Research" must be submitted to DENR.</p>	<p>Small Quantity Importation (SQI) Certificate: <1,000 kg/yr</p> <p>Notification to DENR required.</p> <p>Document Importation and submit within 60 days of import.</p> <p>Annual report required.</p>
Korea	<p>R&D – No specified volume limits.</p> <p>No submission required.</p>	<p>Limited to 100 kg/yr per company – no notification required.</p> <p>A "confirmation document" required for every shipment of LVE chemicals.</p>
New Zealand	<p>R&D – No specified volume limits.</p> <p>No submission required.</p>	No Low Volume Exemption option exists on hazardous substances for New Zealand.

Australia

Research and Development Exemption

The amount manufactured or imported for analytical/scientific research and development use only must not exceed 100 kg/yr.

No submission is required.

An annual report must be sent to NICNAS for what was imported from Sept. 1 - August 31. The report is due on or before September 28 of the following year.

To import over 100 kg/yr up to 1,000 kg/yr a Limited Notification is required.

Annual Reports and/or Limited Notifications can be sent to:

National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
GPO Box 58
Sydney NSW 2001
AUSTRALIA

Low-Volume Exemption

100 kg/yr/applicant; however, if two or more companies jointly apply, the volume is split between the applicants.

The LVE is good for a maximum of 3 years and must be applied for using Form 1-LVC (minimal information is required). It can be renewed any number of times.

The LVE permit application fee is \$3,204 (AUS) and the renewal fee is \$633 (AUS)

Assessment timeframe by NICNAS is 20 days after which a "Low Volume Chemical" (LVC) permit is issued. The permit can be renewed any number of times.

Recordkeeping of R&D activities is required to be kept for 5 years.

If certain things should change, such as a significant change in use, exposure or new adverse effects information is obtained, the permit holder must notify NICNAS.

The MSDS must reflect that the chemical or product containing it is being manufactured or imported under an LVC permit.

A Limited Notification is required for those small volume chemicals that do not qualify for the Low Volume Chemical (LVC) permit. It can be sent to NICNAS at the address previously indicated.

Canada

R&D Exemption

An R&D substance is a “Special Category Substance” under CEPA. It includes both chemicals and polymers.

Under CEPA Research & Development includes both scientific and technological R&D.

There are currently no fees for Research & Development Substances.

At least 30 days prior to exceeding 1,000 kg/yr, Schedule 1 information is required.

At least 30 days prior to exceeding 10,000 kg/yr, Schedule 1 update information is required.

(Note, if the substance is a biochemical, the information in Schedule 1 and items 1 and 2 of Schedule 2 is required at 1,000 kg/yr and update information at 10,000 kg/yr.)

If a polymer, at least 30 days prior to exceeding 10,000 kg/yr, Schedule 3 information is required.

(If the substance is a biochemical polymer then add items 1 and 2 of Schedule 2)

Low Volume Exemption

Canada generally addresses chemicals in two ways (1) non-polymeric vs. polymeric and (2) DSL listing vs. NDSL listing. These two matters play a role in the volumes and what is required.

Non-Polymeric Substances - Not NDSL Listed

≤100 kg/yr: No notification is required.

>100 kg/yr to 1,000 kg/yr: Five (5) days before exceeding 100 kg/yr requires the submission of a Schedule 4.

>1,000 to 10,000 kg/yr: Sixty (60) days before exceeding 1,000 kg/yr requires the submission of a Schedule 5.

Non-Polymeric Substances – Listed on the NDSL

≤1,000 kg/yr: No notification is required.

>1,000 to 10,000 kg/yr: Thirty (30) days before exceeding 1,000 kg/yr requires the submission of a Schedule 4.

>10,000 to 50,000 kg/yr: Sixty (60) days before exceeding 10,000 kg/yr requires the submission of a Schedule 5.

Polymeric Substances

For all Polymers with a volume of $\leq 1,000$ kg/yr, no notification is required.

For Polymers qualifying for RRR (Reduced Regulatory Requirements); the submission of a Schedule 9, 30 days prior to exceeding 1,000 kg/yr will allow unlimited volumes into Canada.

Non-RRR Polymers that are NDSL listed or all components are DSL or NDSL Listed

>1,000 to 10,000 kg/y: Thirty (30) days before exceeding 1,000 kg/yr requires the submission of a Schedule 9.

10,000 to 50,000 kg/yr: Sixty (60) days before exceeding 10,000 kg/yr requires the submission of a Schedule 10.

Non-RRR Polymers that are not NDSL listed and all components are not either DSL or NDSL listed

>1000 to 10,000 kg/yr: Thirty (30) days before exceeding 1,000 kg/yr requires the submission of a Schedule 9.

China

R&D Exemption

The amount of new chemical substance being manufactured or imported for scientific research purposes must not exceed 100 kg per year.

The amount of new chemical substance being manufactured or imported for technological research and development must not exceed 1000 kg, the manufacturer or importer may apply for one-year exemption, but no further extensions are granted.

A notifier who intends to apply for Notification Exemption must submit the notification exemption to CRC-SEPA, and provide information on their intent to import for R&D purposes. The notifier must also keep a record of the scientific research information on the substance, the technological research and development, the quantities of the manufactured or imported substances and customer's names.

The required application Form (Attachment 5) and Instructions can be downloaded from:
big5.sepa.gov.cn/.../special_reports/chemical_regulation/newchemicals/200712/P020071217518150802043.pdf

Mail 1 copy of the Exemption Form to;

Branch of New Chemical Substance Management
Chemical Registration Center of SEPA
No. 8, Dayangfang, Beiyuan, Andingmenwai, Chaoyang District
Beijing, P. R. China
Zip Code: 100012
Telephone and Fax: (+86=10) 8491-7656
Email: ncn@crc-sepa.org.cn
Web Site: www.crc-sepa.org.cn

Low-Volume Exemption

There is currently no Low-Volume Exemption in China; however, SEPA has agreed to develop a “Low Volume Provision”. SEPA’s main concern at this time is regarding how to inspect and prove compliance.

European Union

Research and Development Exemption

With respect to R&D activities under REACH;

< 1,000 kg/yr - the authorization and restriction provisions do not apply to Scientific Research and Development activities.

< 1,000 kg/yr - For Product and Process Oriented Research and Development activities, the authorization and restriction provisions may apply (as specified in Annex XVII or XIV).

≥ 1,000 kg/yr – Product and Process Oriented R&D activities can be exempted from registration activities for a period of 5 years. To be exempted, a company must submit a PPORD notification to the Agency. PPORD notifications can be extended for another 5 years.

Under REACH, the following scenario (and others) is possible; If a company imports 2,000 kg/yr of a substance, of which >1,000 kg are for PPORD purposes, then there is no registration requirement for the < 1,000 kg/yr that is imported for commercial purposes.

Low Volume Exemption

Under REACH (June 1, 2008), substances not otherwise restricted or authorized (i.e. Annex XVII – substances to be restricted or Annex XIV – substances to be authorized) can be imported at < 1,000 kg/yr.

Japan

Research and Development Exemption

There are no specified volume limits for chemicals imported or manufactured in Japan for R&D purposes.

The R&D Exemption is Self Executing (no submission is required). R&D products being imported into Japan need to be clearly marked as such otherwise there will be difficulties passing Customs in Japan.

Low Volume Exemption

See separate hand out.

Korea

Research and Development Exemption

There is no specified volume limit on new chemical substances imported/manufactured exclusively for research and development purposes . No submission is required.

Low Volume Exemption

Under the TCCL, any new chemical manufactured or imported in an amount of ≤ 100 kg/yr is exempted from toxicity examination requirements. There is no notification to the MOE required, however, a “confirmation document” is required at Customs each time the substance/product containing it is imported.

New Zealand

Research and Development Exemption

There are no specified volume limits for hazardous substances imported into New Zealand for R&D purposes and the exemption is self executing (i.e. no submission is required).

“Research and Development” in New Zealand includes scientific investigations, experimental or analytical chemistry, or use in a teaching environment, provided these activities are managed in facilities (i.e. essentially laboratories) which meet the standards set out in the HSNO regulations. A facility can extend to use outside of the laboratory for purposes of packaging and transport as needed to transfer any substance to the laboratory from the place of import and for purposes of disposal.

This exemption does not include substances which have been assessed and approval has been declined under the

Low-Volume Exemption

There is currently no Low-Volume Exemption in New Zealand; however, if the substance is “non-hazardous” then it is not regulated under the Hazardous Substances and New Organisms (HSNO) Act and can be freely imported into New Zealand without restriction.

Philippines

Research and Development Exemption

< 1,000 kg/yr for substances that are imported, manufactured, or distributed exclusively for non-commercial research and development purposes.

A Letter of “Intent to Manufacture or Import for Research” must be submitted to DENR.

Low-Volume Exemption

< 1,000 kg/yr is allowed. This exemption does not extend to substance listed on the Philippines Priority Chemicals List (PCL) or for which a Chemical Control Order (CCO) has been issued.

Notification to the Department of Environment and Natural Resources (DENR) is required and a Small Quantity Importation (SQI) Certificate will be issued.

Importation must be documented and reported to the DENR within 60 days of import.

An annual report to the DENR on volumes imported is required.

Environmental Management Bureau (EMB)
Department of Environment and Natural Resources (DENR)
Topaz Building, 99-101 Kamias Road
Quezon City
Philippines

Phone: 632-928-3773

Fax: 632-924-7540

United States

Research and Development

There is no specified volume limit for chemicals imported or manufactured for R&D purposes.

This R&D Exemption is Self Executing with no submission being required. Certain recordkeeping is required.

Details regarding the US R&D Exemption can be found at;

Code of Federal Regulations Reference: 40 CFR Section 720.36

R&D Guidance: www.epa.gov/oppt/newchems/tmeranddbulletin.pdf

Under TSCA R&D can include;

- Synthesis of a new chemical substance
- Analysis and testing of a new chemical substance
- Process demonstrations
- Performance Testing

Low Volume Exemption

Manufacture/Import of up to 10,000 kg/yr is allowed.

Requires the submission of Form 7710-25 (the standard PMN form) to the US EPA.

EPA does not charge a user fee for LVEs.

Required Information is: CAS Chemical name, impurities & byproducts, 12 mo. production/import volume, use information, available exposure and release information (if not provided, EPA will use their own "worst case" estimates), any test data in the submitter's possession.

Review period is 30 days. Manufacture/Import can commence once the review period is expired unless you hear otherwise from the EPA.

If certain information should change, such as the site of manufacture, environmental release information, etc... then you may need to notify EPA or resubmit 30 days before such changes. EPA will reply if the modified information is accepted or not.

Further details regarding the US Low Volume Exemption can be found at: Code of Federal Regulations Reference: 40 CFR Sec. 723.50