REACH Workshop:

How to Prepare for Registration and Notification

30 May 2008

Hong Kong Productivity Council
香港生產力促進局

Agenda

1) Your Role and Obligation in REACH
2) The REACH Workflow
3) REACH Registration Schedule
4) Pre-registration Schedule
5) How to pre-register
6) Information required for Registration
7) Information required for Authorization
8) Information required for Notification of Substances in Article
9) How to Prepare?

Your Role and Obligations in REACH Regulation

The role of a company includes:

- Manufacturer, importer, only representative, downstream user

Who should register:

1) EU manufacturers and importers of substances/ preparations
2) EU producers and importers of articles
3) EU based " only representatives" appointed by a manufacturer, formulator or article producer outside EU

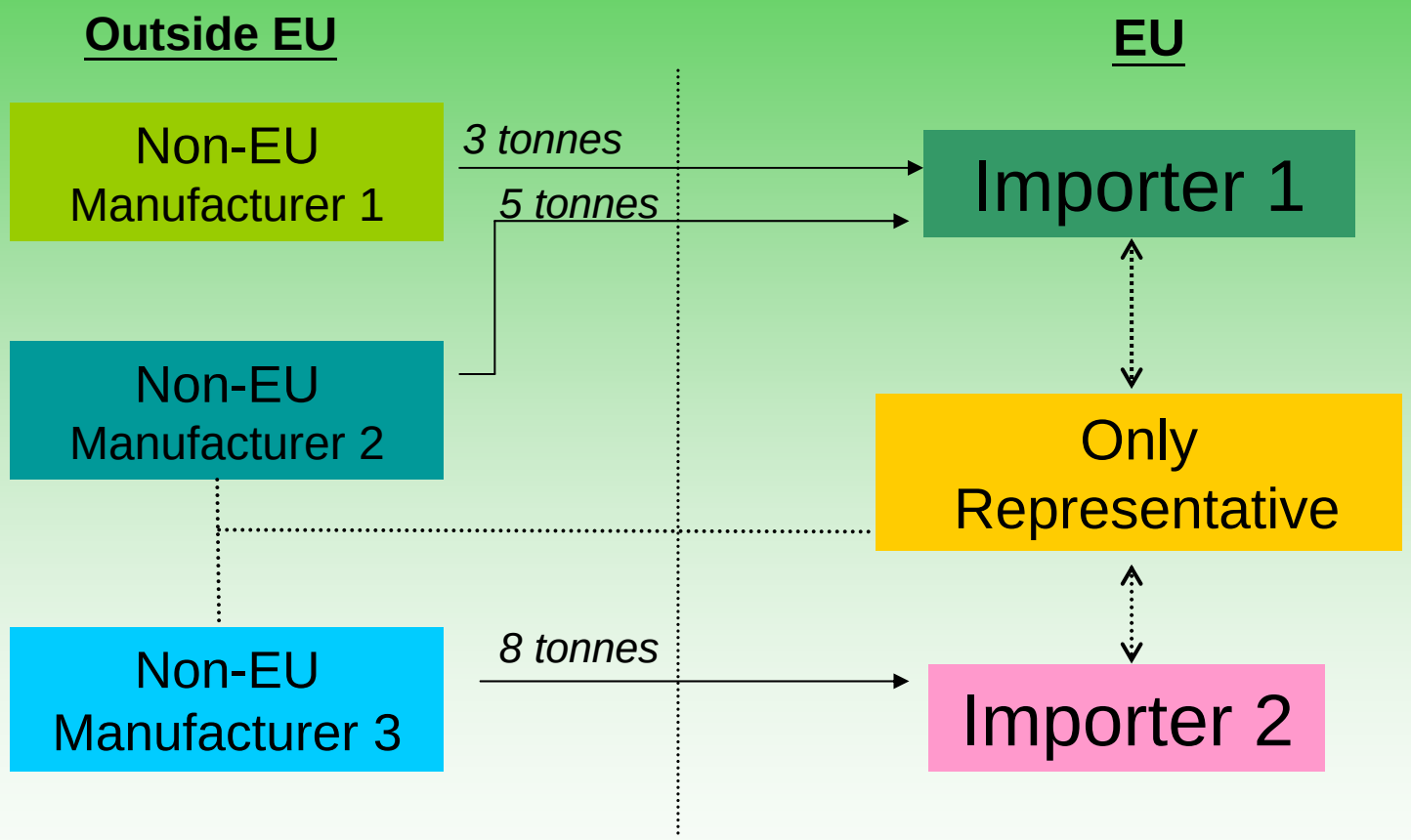
Non-EU manufacturer should:

1) appoint an "Only Representative" for Registration; or
2) register through their "subsidiaries" located in EU

The " Only Representative" should:

a) be located within the EU
b) have sufficient background in the practical handling of substances and related information.
c) keep available and up-to date information on quantities imported and customers sold to
d) keep the latest information of safety data sheet

Identify Your Role & Registration Obligations

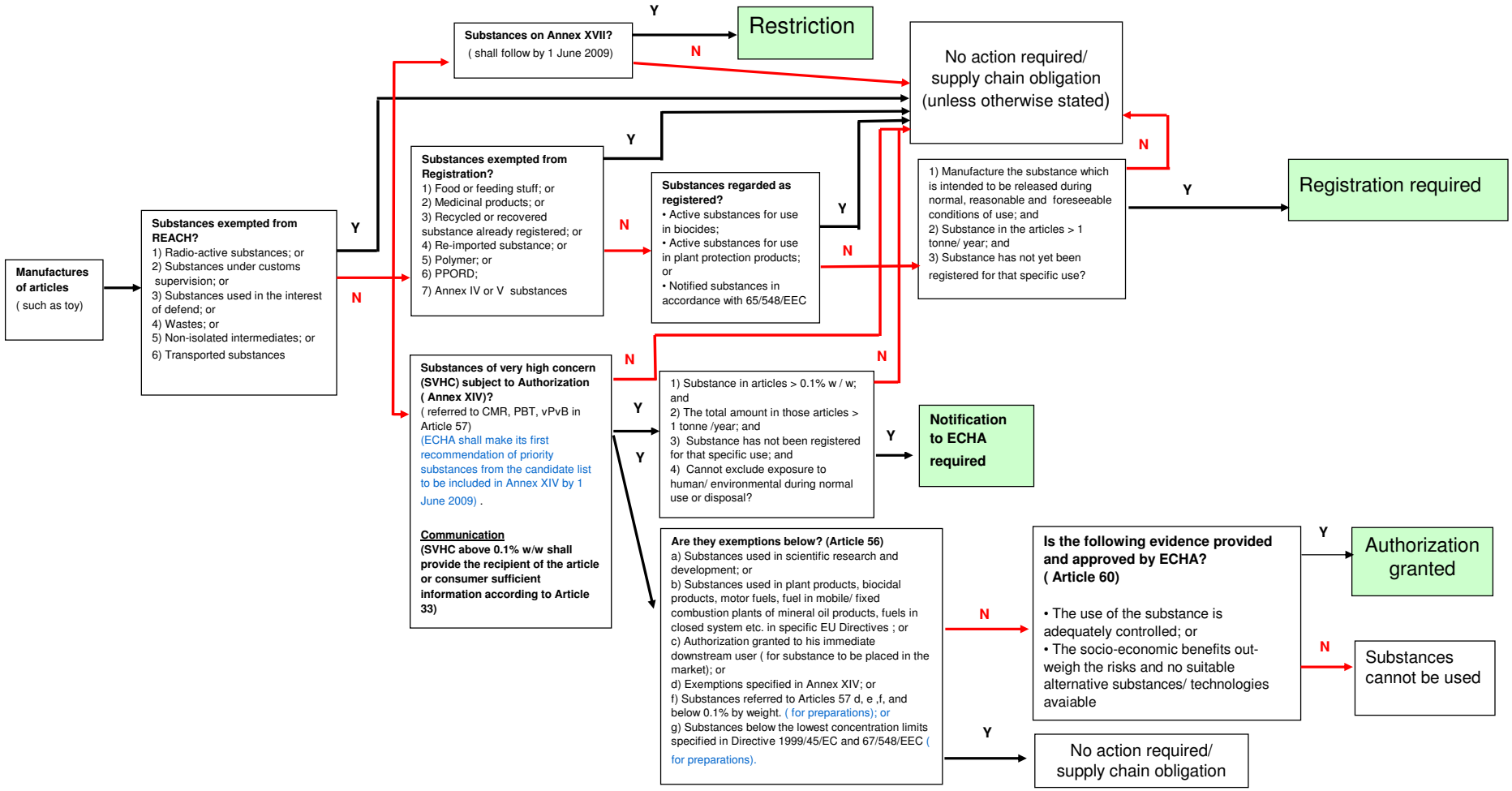


The REACH Workflow

- Manufacturers of Articles

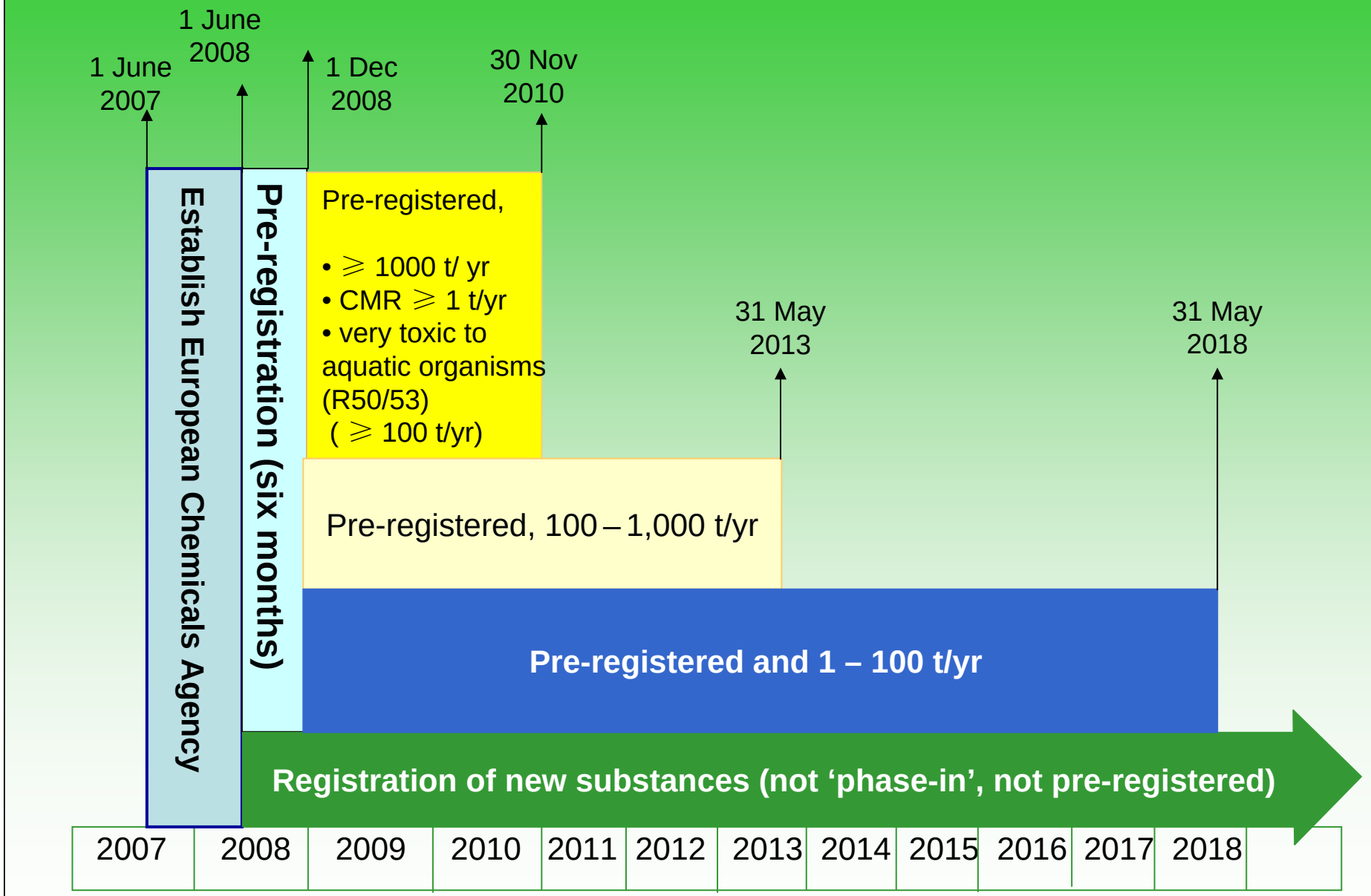
Article- pdf

Workflow on Identification of Potential Requirements Related to Substances in Articles



Remark :
PPORD :5 years exemption can be granted after notifying the Agency

REACH Registration Timeframes



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Pre-registration schedule

Pre- Registration for phase-in substances:

-The REACH Regulation creates a pre-registration period for “phase-in substances” between 1 June and 1 December 2008

-Benefit: The registration deadlines can be extended depending on tonnage and properties. (by 1 Dec 2010, 1 Jun 2013 and 1 Jun 2018)

-If fails to register within the pre-registration period, a company has to register for its substances by 1 Dec 2008, for continuing manufacturing or importing.

(If registration occurred after 1 Dec 2008, the company may have to wait for 3 weeks for continuing manufacturing or importing).

Registration for non-phase in substances:

- Non-phase in substances must be registered before they can be manufactured or imported after 1 June 2008.

- The manufacturer/ importer should make an inquiry to ECHA for whether any previous registration of that substance has been made.

How to pre-register

1) Information required for pre-registration:

a) Name of the substances
b) Name, address of the pre-registrant, and contact person
c) Envisaged deadline for registration and tonnage band
d) Names of other substances for which the available information is relevant for performing adaptations to the testing requirements
e) Indicator indicates whether the pre-registrant is willing to act as “facilitator” in the pre-SIEF discussions.

2) Method of submitting pre-registration

a) Direct encoding the information on the REACH-IT website
b) Uploading one or more pre-registration files prepared off-line (format required by ECHA)

(If many substances are registered in a single step, IUCLID 5 pre-registration plug-in can be used for the preparation of XML files, the files may also be created by other applications as long as the required format is followed.)

What is SIEF

- Substance Information Exchange Forum (SIEF)
- Formation of SIEF for data sharing and avoidance of unnecessary testing
- Exchange of information within SIEF facilitated by a co-ordinator

Information required for Registration

Manufacturers/ importers have to classify the substances according to tonnage and the nature of the substances

all substances subject to Registration

Substances manufactured or imported more than 10 tonnes per year

Y

Substances present in preparations below the concentration limits in 1999/45/EC

N

Technical dossier

- includes:
a) identity of manufacturer/importer
b) identity of the substances
c) classification and labeling of the substances
d) guidance on its safe use
e) intrinsic properties of the substances
f) proposal for further testing
g) exposure related information
h) information on manufacture and use

Chemical Safety Report

- includes:
a) environmental and human health hazardous properties
b) information on the manufacture and uses

Assessment according to 67/548/EEC; PBT or vPvB assessment

Substances classified as dangerous; or fulfilled the PBT or vPvB criteria

Y

Chemical Safety Report

- further includes:
a) exposure assessment
b) risk characterization

Information required for Authorization

Substances of very high concern (SVHC) subject to Authorization (Annex XIV)

Date: ECHA shall make its first recommendation of priority substances from the candidate list to be included in Annex XIV by 1 June 2009.

Authorization by ECHA can only be granted if the applicants can show:

a) The use of a substance is adequately controlled; or
b) The socio-economic benefits outweigh the risk to human health and the environment and there are no suitable alternatives.

The following information should be provided by applicants: (Article 60)

a) The risks posed by the use of the substance and appropriateness and effectiveness of the risk management measures proposed; and
b) The socio-economics benefits of the use of substance, and the implication of a refusal to authorize; and
c) The analysis of alternatives or substitution plan; and
d) The information about the risks to human health or the environment of any alternative substances or technologies.
(See also Article 62 : Application for Authorizations)

Communication (Article 33)

Supplier of an article containing SVHC on the candidate list > 0.1% w/w shall supply the recipients with sufficient information. For example :

- Substance name
- CAS number
- Registration number (if provided by supplier)
- Classification and SVHC properties
- Concentration (or its range) in the article
- Information on safe handling including safe disposal, if relevant

Information Required for Notification of Substances in Article (Article 7)

a) The identity and contact details of producer or importer
b) The registration number (if available); and
c) The identity of substance (Annex VI); and
d) The classification of substance (Annex VI); and
e) A brief description of the uses of the substance; and
f) The tonnage range of the substance

Manufacturers of Articles – How to Prepare

- Know your products; start from BOM
- Prepare BOS – materials list down to substances level

Manufacturers of Articles – How to Prepare (cont'd)

- Analyze your BOS

Part	Substance	CAS#	% w/w	SVHC	Potentially Requiring	
					Registration	Notification
A						
B						
C	S1	…	xx%		✓	
	S2	…	xx%	✓	✓	✓
	S3	…	xx%		✓	
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Check Registration

Check Notification