



CIRS

SIEF AND COST SHARING UNDER K-REACH



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CIRS Ireland

30th July 2019



Official Website: <http://www.cirs-reach.com/>

Who we are?

- Leading product safety regulation consulting firm founded in 2007
- Main offices: China, Ireland (OR), US
- No. of Employees: 250+
- Shares 70% Chinese consulting markets;
- Has 3000+ Clients including 300+ oversea companies

What we do?

Business Units:

- Industrial Chemicals,
- Cosmetics,
- Pesticides & Biocides,
- Food Contact & Food,
- Medical Devices

Main service:

- EU REACH, China REACH, K- REACH, Taiwan TCSCA, and chemical regulation in other Asian countries
- Global GHS, etc.
- Testing Services

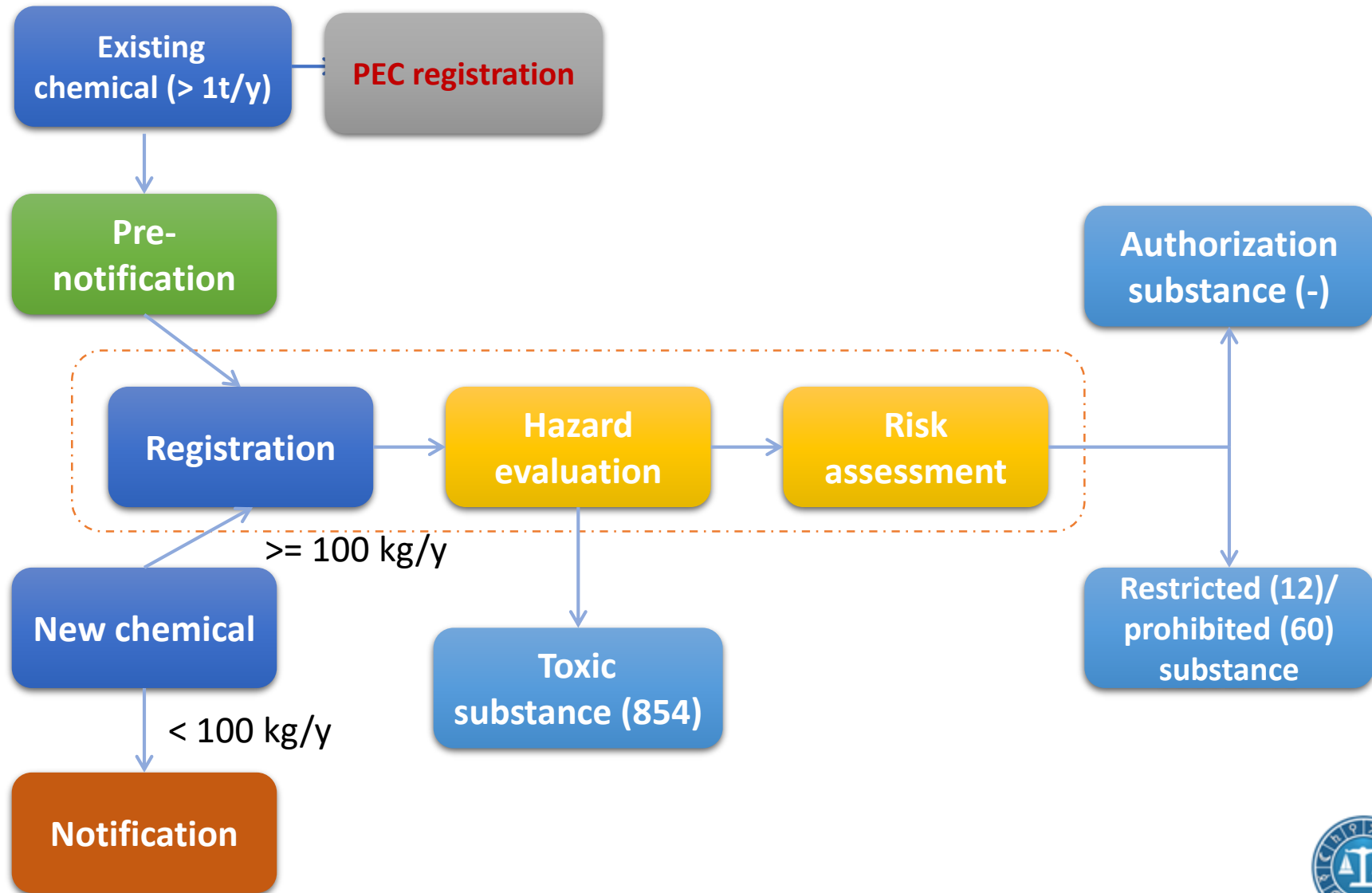
K-REACH Brief



K-REACH Brief

1. K-REACH Introduction
2. Grace Period
3. K-REACH Pre-registration
4. Late Pre-registration
5. Data Request
6. SIEF Roles
7. Case Study
8. K-REACH Support

K-REACH System



Scope of Registration

- Registration scope encompasses existing and new chemicals

Category	Tonnage	Obligation
New Chemical	< 0.1 t/a	Notification
	≥ 0.1 t/a	Registration
Existing Chemical	≥ 0.1 t/a	Registration

- Manufacture/ importer information
- Chemical name and identity
- Tonnage
- Classification & Labelling
- Usage



K-REACH Pre-Registration



CIRS Group Korea Co., Ltd.
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WEBSITE: <http://kz.cirs-group.com/>

No.:

Confirmation Letter of K-REACH Pre-Registration

To

2019-07-17

With the authorisation of [REDACTED] we act as Only Representative to fulfil the obligations under Article 10 (Registration of Chemicals and Others) of "ACT ON REGISTRATION, EVALUATION, ETC. OF CHEMICALS. No. 15844" (hereinafter referred to as "K-REACH") for the chemical substances listed in Annex of Power of Attorney [REDACTED]

We hereby confirm that, we have successfully submitted and completed pre-registrations and acquired pre-registration numbers for the substances listed under 'Annex I. List of Pre-Registrations'.

Congratulations on your successful pre-registrations under K-REACH regulation and wish you well in your business.

Important Notice: Application of K-REACH Tonnage Coverage Certificate

It shall be noted that CIRS, as Only Representative, shall maintain the list of importers and keep up-to-date information on quantities imported under K-REACH. When appointing an Only Representative, it is necessary that the "non-Korean manufacturer" provides his only representative with up-to-date information on the list of Korean importers who are to be covered by the pre-registration of the Only Representative and the quantities imported into the Korea.

[REDACTED] shall inform CIRS of the importers in Korea and the quantities imported by applying for a K-REACH tonnage coverage certificate from CIRS.

It is also recommended that the importers get their chemical substances certified by applying for K-REACH Tonnage Coverage Certificate for their imports from CIRS free of charge. The certificate guarantees that the tonnage of imported chemical substances are covered by the pre-registration(s) of CIRS Group Korea Co., Ltd. (OR) and the importers will be regarded as downstream users (DU) who do not need to submit their own K-REACH pre-registration(s).

Pre-registration Dossier Update

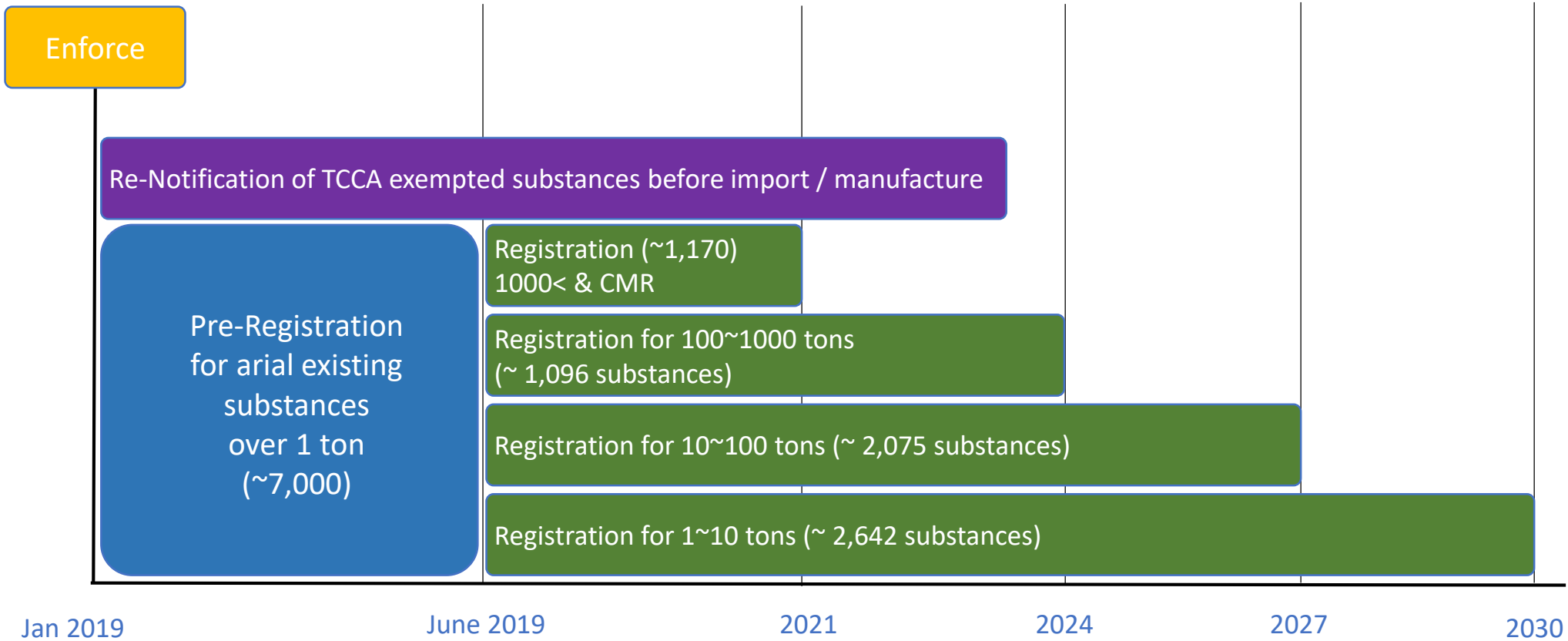
1. Tonnage Information
2. Importers Information
3. Classifications
4. Consumer Use Information

Late Registration

1. No official statement yet
2. Currently can be operated if less than 1 ton each year of 2016-2018



Grace Period



No Pre-Registrations = No GRACE PERIOD
Existing Polymers satisfying PLC exemption criteria?



SIEF Roles



SIEF - Roles

- **1. LR (Lead Registrant)**

The LR will lead the formation and work of the consortium and joint submission of substances, such as releasing SIP, C&L classifications, internal communication of the consortium, development of the consortium agreement, cost sharing, financial management, data collection, data gap analysis, obtaining data (conducting experiment and data sharing, existing data purchase), preparation of dossier and CSR, submission of dossier, response to technical reviews, selling LOA (letter of access) to potential co-registrants, etc.

- **2. AM (Active Member)**

Active members will participate in the formation and work of the consortium as a member of the consortium, including internal communication of the consortium, discussion of cost sharing, financial management and the development of the consortium agreement.

- **3. PM (Passive Member)**

Passive members will participate in the relevant work of joint submission without joining the consortium. They are not required to bear the registration expenses in the early stages and can purchase the LOA from the consortium to participate in the joint submission.

- **4. Dormant (Late Registrant)**

If an enterprise has no registration intention, it will not participate in the relevant work of joint submission and will not join the consortium. It does not need to bear the registration expenses in the early stages. Before expiration of the pre-registration number, the enterprise can still purchase the LOA from the consortium to participate in the joint submission as a passive member.



SIEF – Roles Comparison

Role	Advantage	Disadvantage	Cost Structure
Lead Registrant	LR has decision rights (data selection and cost sharing principle), data ownership and registration initiative. LR can complete registration first, get reimbursements and the final input cost of LR is lower.	LR needs to invest more for relevant expenses in the early period.	Consortium management fee, data/testing fee, CSR fee, labor fee, consulting fee.
Active Registrant	Active member also has decision rights (data selecting and cost sharing principle), data ownership and registration initiative. Active member may complete registration first, get reimbursement and the final input cost is lower.	Active member needs to invest more for relevant expenses in the early period.	Consortium management fee, data/testing fee, CSR fee, labor fee, consulting fee
Passive Registrant	No upfront investment.	Passive member has no decision rights, no data ownership, no registration initiative and no reimbursement. If the volume and use of its substance is not covered by consortium, individual CSR is required. Its overall cost could be higher than LR and active member.	LOA fee, consulting fee
Dormant (Currently no registration intention)	No upfront investment.	It is unable to get up-to-date registration information from the LR or consortium in time. It has no data ownership, no registration initiative and no reimbursement. The volume of its substance is not covered by consortium, individual CSR is required. Its overall cost could be higher than LR and active member.	LOA fee, CSR fee, consulting fee



General Procedure of Joint Registration:

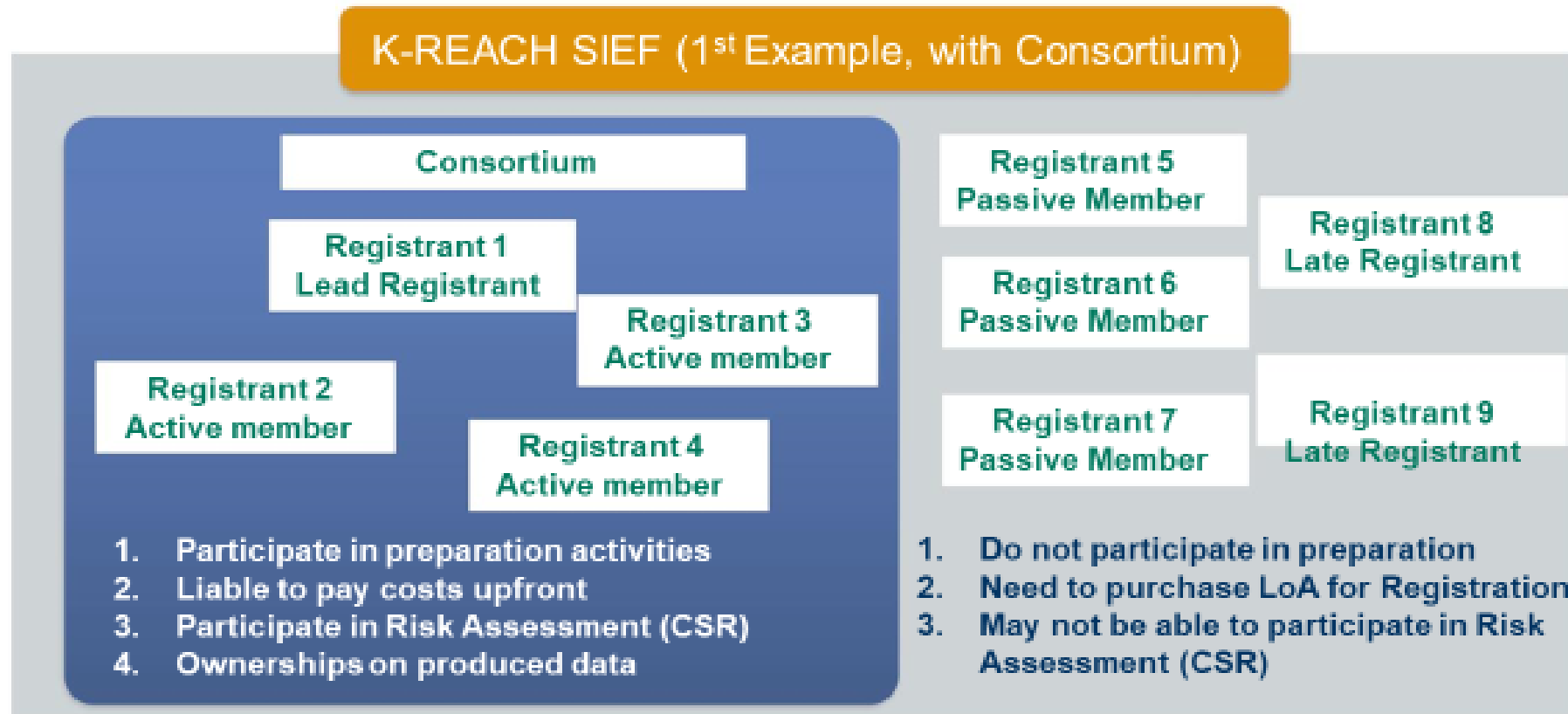


- Data in registration dossier (e.g. hazard data) must be submitted by consortium jointly;
- Data includes hazard classification and labelling, physicochemical properties, hazard and risk data;
- Data sharing and prevention of duplicating animal testing.
- Opt-out is also available under K-REACH

Case Study



◆ By the end of Pre-Registration Phase



One SIEF(CICO) will be formed for one substance : Consortium Agreement between LR and Active members will need to be agreed and signed before proceeding with the preparation

SIEF - Operation

Consortium

1 LR & 3 Active Members

Consortium Management USD 70,000

- 2020 : USD 35,000
- 2021 : USD 35,000

Data cost USD 200,000

CSR USD 30,000

- 2021 : USD 30,000

Total Expense : USD 300,000

- 2020: USD 235,000
- 2021 : USD 65,000

Cost Sharing per member : USD 75,000

- 2020 : USD 235,000/4 = USD 58,750
- 2021 : USD 65,000/4 = USD 16,250

Reimb. To each member : USD 37,500

- USD 150,000/4 = USD 37,500

Money spent by each member : USD 37,500

- Spent – Reimb. : USD 75,000 – USD 37,500

Reimb. To each member : USD 25,000

- USD 100,000/4 = USD 25,000

Money spent by each member : USD 12,500

- Spent – Reimb. : USD 37,500 – USD 25,000

SIEF

1 LR & 3 Active Members & 3 Passive members & 2 Latter

Calculation of LoA

Total Expense of Joint Reg. Prep. : USD 350,000

- Consortium Expense : USD 70,000
- Data : USD 200,000
- CSR : USD 30,000
- Sweat Equity (of 4 cons. members) : USD 50,000

Cost Sharing per SIEF (7members) : USD 50,000

- USD 350,000/7 = USD 50,000

LoA Cost : USD 52,000

- Cost Sharing : USD 50,000 (for consortium)
- Consultant LoA Handling : USD 2,000 (for consultancy)

Total Cost of LoA sold : USD 156,000

- 3 LoA : USD 50,000x3 (for consortium)
- 3 Handling : USD 2,000x3 (for consultancy)

Reimbursed amount to Consortium : USD 150,000

2 Late Registrants

LoA cost for 1 Late Registrant : USD 60,000

- Cost Sharing : USD 50,000 (for consortium)
- Consultant LoA Handling : USD 2,000 (for consultancy)
- Individual CSR : USD 8,000 (for consultancy)

Further Reimbursement to Consortium : USD 100,000

Total Money spent for K-REACH

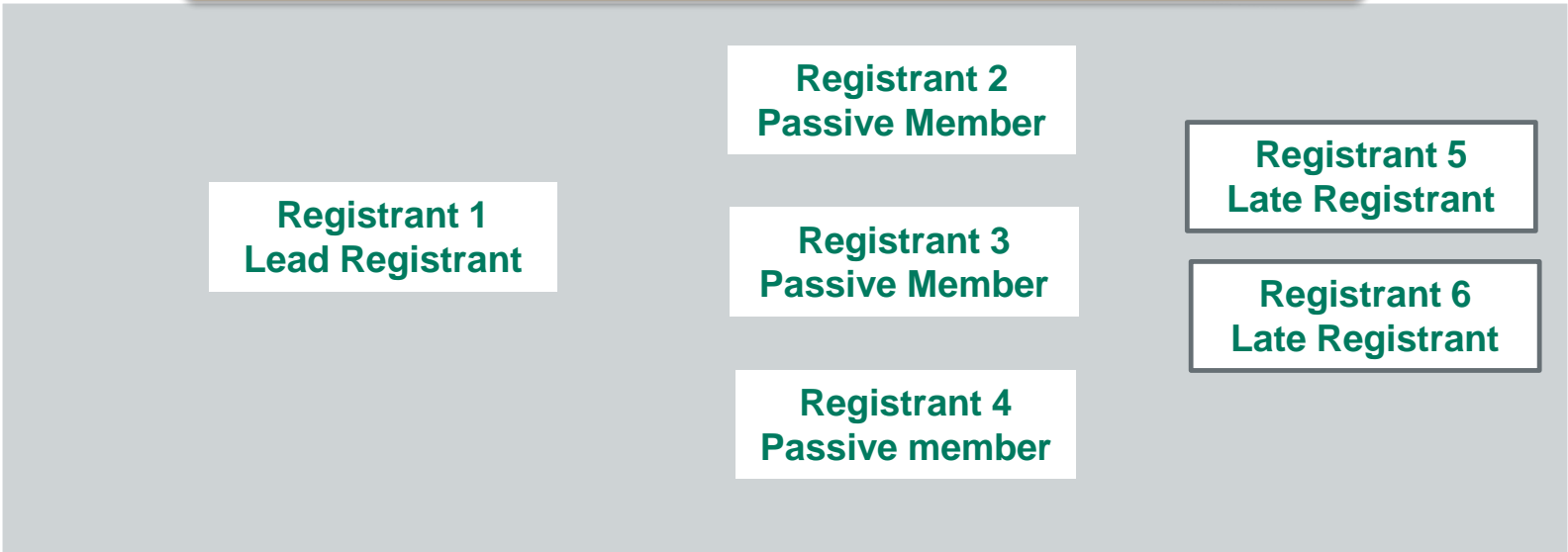
	LR	AM	PM	Late
Consortium	17,500	17,500		
Data	50,000	50,000		
CSR	7,500	7,500		
LoA			50,000	50,000
LoA Handling			2,000	2,000
Ind. CSR				8,000
Reg. Consult.		15,000	7,000	7,000
Reimb.	-37,500	-37,500		
Late Reimb.	-25,000	-25,000		
Total Expense	12,500	27,500	59,000	67,000



K-REACH Joint Registrations

◆ By the end of Pre-Registration Phase

K-REACH SIEF (2nd Example, without Consortium)



One SIEF(CICO) will be formed for one substance

Cost sharing

Consortium

1 LR & 0 Active Members

Consortium Management USD 70,000

- 2020 : USD 35,000
- 2021 : USD 35,000

Data cost USD 200,000

CSR USD 30,000

- 2021 : USD 30,000

Total Expense for LR : USD 300,000

- 2020 : USD 235,000
- 2021: USD 65,000

Reimb. To each member : USD 240,000

- USD 240,000/1 = USD 240,000

Money spent by each member : USD 60,000

- Spent – Reimb. : USD 300,000 – USD 240,000

Reimb. To each member : USD 160,000

- USD 160,000/1 = USD 160,000

Money spent by each member : - USD 100,000

Spent – Reimb. : USD 60,000 – USD 160,000

SIEF

1 LR & 0 Active Members & 3 Passive members

Calculation of LoA

Total Expense of Joint Reg. Prep. : USD 320,000

- Consortium Expense : USD 70,000
- Data : USD 200,000
- CSR : USD 30,000
- Sweat Equity (of 1 Cons. members) : USD 20,000

Cost Sharing per SIEF (4members) : USD 80,000

- USD 320,000/4 = USD 80,000

LoA Cost : USD 82,000

- Cost Sharing : USD 80,000 (for consortium)
- Consultant LoA Handling : USD 2,000 (for consultancy)

Total Cost of LoA sold : USD 246,000

- 3 LoA : USD 80,000x3 (for consortium)
- 3 Handling : USD 2,000x3 (for consultancy)

Reimbursed amount to Consortium : USD 240,000

2 Late Registrants

LoA cost for 1 Late Registrant : USD 90,000

- Cost Sharing : USD 80,000 (for consortium)
- Consultant LoA Handling : USD 2,000 (for consultancy)
- Individual CSR : USD 8,000 (for consultancy)

Further Reimbursement to Consortium : USD 160,000

Total Money spent for K-REACH

	LR	AM	PM	Late
Consortium	70,000			
Data	200,000			
CSR	30,000			
LoA			80,000	80,000
LoA Handling			2,000	2,000
Ind. CSR				8,000
Reg. Consult.			7,000	7,000
Reimb.	-240,000			
Late Reimb.	-160,000			
Total Expense	-100,000		89,000	97,000

Data Requirements



Data Requirements

	0.1-1 ton/year	1-10 ton/year	10-100 ton/year	10-100 ton/year	> 1000 ton/year
Physicochemical data	5	8	11	13	13
Health hazard data	2	4	10	11	15
Environmental hazard data	2	3	5	12	18
Total	9	15	26	36	46

- GLP (Good Laboratory Practice) institutes are required;
- There are 18 GLP institutes in Korea;
- Tests reports from EU GLP lab should be acceptable under K-REACH



Data Requirement – Physicochemical data

	0.1-1 ton/year	1-10 ton/year	10-100 ton/year	100-1000 ton/year	> 1000 ton/year
Substance's state	✓	✓	✓	✓	✓
Water solubility	✓	✓	✓	✓	✓
Melting/ Freezing point	✓	✓	✓	✓	✓
Boiling point	✓	✓	✓	✓	✓
Vapor pressure	✓	✓	✓	✓	✓
Octanol-water partition coefficient		✓	✓	✓	✓
Density		✓	✓	✓	✓
Grain-size analysis		✓	✓	✓	✓
Combustibility			✓	✓	✓
Explosiveness			✓	✓	✓
Corrosiveness			✓	✓	✓
Viscosity				✓	✓
Dissociation constant				✓	✓



Data Requirement – Health hazard data

	0.1-1 ton/year	1-10 ton/year	10-100 ton/year	100-1000 ton/year	> 1000 ton/year
Acute oral toxicity (Acute inhalation toxicity)	✓	✓	✓	✓	✓
Reverse mutation	✓	✓	✓	✓	✓
Skin irritation/ corrosion		✓	✓	✓	✓
Skin hypersensitivity		✓	✓	✓	✓
Acute dermal toxicity/ Acute inhalation toxicity			✓	✓	✓
Eye irritation/ corrosion			✓	✓	✓
Chromosomal anomalies			✓	✓	✓
Genotoxicity			✓	✓	✓
Repeated-dose toxicity (28 days)			✓	✓	✓
Reproductive & Developmental toxicity screening			✓	✓	✓
Additional genotoxicity (genotoxicity to reproductive cells, etc)				✓	✓
Repeated-dose toxicity (90 days)					✓
Teratogenicity					✓
Two-generation reproductive toxicity					✓
Carcinogenicity					✓



Data Requirement – Environmental hazard data

	0.1-1 ton/year	1-10 ton/year	10-100 ton/year	100-1000 ton/year	> 1000 ton/year
Fish acute toxicity (or Acute toxicity with Daphina Magna)	✓	✓	✓	✓	✓
Easy degradability	✓	✓	✓	✓	✓
Acute toxicity with Daphina Magna		✓	✓	✓	✓
Growth inhibition of frsehwater algae			✓	✓	✓
Hydrolysis according to pH valuse			✓	✓	✓
Inherent degradability				✓	✓
Identification of degradation product				✓	✓
Fish chronic toxicity				✓	✓
Chronic toxicity to daphina magna				✓	✓
Acute toxicity to land invertebrate				✓	✓
Respiratory inhibition caused by activated sludge				✓	✓
Adsorption & desorption				✓	✓
Additional information on environmental fate & dynamics					✓
Chronic toxicity to land plant					✓
Chronic toxicity to land invertebrates living					✓
Additional information on adsorption & desorption					✓
Chronic toxicity to benthos					✓
Bioaccumulation					✓



K-REACH Helpdesk

The screenshot shows the K-REACH Helpdesk website. At the top left is the CIRS logo and the text "K-REACH Helpdesk". To the right are navigation icons for home, China, and USA, and a search bar with the placeholder "Input keywords". Below the header is a horizontal menu with the following items: "About K-REACH", "Existing Chemical", "New Chemical", "News & Events", "Tools", "Downloads", and "About CIRS". The main content area features a large banner with the text "K-REACH Inventory Searching Tool and Compliance Suggestion" and an illustration of a calculator, a magnifying glass over a laptop screen displaying "K-reach", and a flask. Below the banner are two columns: "Recent Press Releases" and "Coming Events".

Recent Press Releases

K-REACH Annual Report System will be Shut Down from 30 March 2019	2019-03-28
Korea has Officially Issued Several Inventories under K-REACH Regulations	2019-01-29
Revised K-REACH - The Act on the Registration and Evaluation of Chemicals	2019-01-23
South Korea MOE Released the Final List of CMR Substances, Priority Control Subs...	2019-01-07

Coming Events

- 1 Comprehensive Training on K-REACH for Foreign Industry
- 2 K-REACH Webinar Series: Understanding the Amended K-REACH (Free Webinars)
- 3 Free Webinar: K-REACH Practical Guidance for 2019
- 4 Free Webinar: Chemical Verification under CCA Amendment

<http://kreach.cirs-group.com/>

K-REACH Inventory Searching Tool

K-REACH Inventory Searching Tool

CAS Number or Chemical Name

Popular Keywords 160306-02-5 | 98219-28-4 | 12626-81-2 | 12217-78-6 | 30697-40-6

PEC Substance | Toxic Substance | Exempted Substance | Restricted Substance | Prohibited Substance | CMR Substance

Propyl hydrogen alkenyl(C=6-30) succinate

CAS:160306-02-5 KE:KE-05-1121

Compliance Suggestion

It can be preregistered and the deadline is June 30, 2019

List	Status
Existing Substance	Listed
PEC Substance	Unlisted
Toxic Substance	Unlisted
Exempted Substance	Unlisted
Restricted Substance	Unlisted
Prohibited Substance	Unlisted
CMR Substance	Unlisted

<http://kreach.cirs-group.com/tools/index.php?l=en>

Up Coming Events





Asian Helsinki Chemical Forum and the 4th Summit Meeting on Chemical Regulations in Asia Pacific

2019.10.24-25 Shanghai • China

Register online: <http://smcr.cirs-group.com/hcf&smcr/>



EU-Asia Chemical Regulations Conference – Dublin

26 September 2019 Dublin, Ireland

Register online:

<http://www.cirs-reach.com/news-and-articles/EU-Asia-Chemical-Regulations-Conference-Dublin.html>





CIRS

Thank you



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CIRS Ltd

30th July 2019