Comparison and Data-sharing among EU REACH, China REACH and K-REACH

Enabling Chemical Compliance for A Safer World

www.cirs-reach.com

Bryan. Zhou
Senior Regulatory Consultant
CIRS Europe
bryan.zhou@cirs-group.com

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2. How to use one set of data to comply with China REACH, K-REACH and EU REACH

How to use one set of data to comply with China REACH, K-REACH and EU REACH

Comparison of EU REACH, China REACH and K-REACH

1.1 General Comparison

	EU-REACH	China-REACH	K-REACH
Authority	Legislation: European Committee Implementation: ECHA Supervision: Member States	Competent authorities: MEE Operating center: SCC Supervision: local Environmental Protection Agency	Competent authorities: MOE Pre-registration & Exemption Confirmation: KECO Dossier evaluation: NIER
Registrant	EU Manufacturer/ Importer/ Non-EU Manufacturer (OR)	Chinese Manufacturer/ Importer/ Foreign Manufacturer (OR)	Korean Manufacturer/ Importer/ Non-Korean Manufacturer (OR)
Scope	Phase in / Non-phase in substance	New chemical in China (not listed in IECSC)	Existing chemical substance/ New chemical substance

Comparison of EU REACH, China REACH and K-REACH

1.1 General Comparison

	EU-REACH	China-REACH	K-REACH
OR Appointment	POA is included in dossier	POA is included in dossier	OR Confirmation
Polymer registration	Monomer/ Reactant	Polymer Simplified notification (PLC)	Polymer Exemption confirmation (PLC)
Transported isolated intermediate	Foreign company can register it as TII SCC Intermediate	x	Foreign company can not register their intermediate as Transported isolated intermediate
Notification of Priority Control Substance	o	x	o
Annual report	x	o	x

Comparison of EU REACH, China REACH and K-REACH

1.2 General Comparison

	EU-REACH	China-REACH	K-REACH
Inquiry	• SIP test is required; • ECHA will share SIEF information; • POA is not required	• Chemical identity is required; • Authority will check if the chemical is new in China; • POA is not required	• Chemical identity is required; • Authority will check if the chemical is new in Korea and registered by any company; • POA is required
Pre-registration	o	x	o
Registration requirement of low tonnage band	x	• <0.1tpa (SRR Notification) • New chemical <1tpa (Simplified notification	New chemical notification<0.1t/a
Registration tonnage band	• 1-10 tpa • 10-100 tpa • 100-1000 tpa • 1000+ tpa	• 1-10 tpa • 1000+tpa • 10-100 tpa • 100-1000 tpa	• 0.1-1tpa(New substance) • 1-10 tpa • 10-100 tpa • 100-1000 tpa • 1000+ tpa
Dossier evaluation	At least 5% dossiers every year	All dossier	All dossier
Assessment standard	Risk assessment	Risk assessment	Risk assessment
New chemical is listed in existing chemical list?	x	o	x

Comparison of EU REACH, China REACH and K-REACH

1.2 Exemption_EU-REACH

Exempted from REACH

- Radioactive substances, Substance supervised by Customs, Non-isolated substance and Transported substance;
- Waste;
- Exempted by Member States because of national defense

Exempted from Registration

- Human or Animal Pharmaceutical;
- Food Additives, Flavors, Feed Additives;
- Same substance exported from EU and then imported into EU by other role in the supply chain
- Recycling Substances in EU

Substances which are considered as being registered

- Active substances and compounding agent used in plant protection
- Active substance used in biocidal products

Comparison of EU REACH, China REACH and K-REACH

1.2 Exemption_EU-REACH

Annex IV. 68 substances which have very low hazard

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(a)

Einecs No	Name/Group	CAS No
200-061-5	D-glucitol $C_6H_{14}O_6$	50-70-4
200-066-2	Ascorbic acid $C_6H_8O_6$	50-81-7
200-075-1	Glucose $C_6H_{12}O_6$	50-99-7
200-233-3	Fructose $C_6H_{12}O_6$	57-48-7
200-294-2	L-lysine $C_6H_{14}N_2O_2$	56-87-1
200-334-9	Sucrose, pure $C_{12}H_{22}O_{11}$	57-50-1
200-405-4	α-tocopheryl acetate $C_{31}H_{52}O_3$	58-95-7
200-416-4	Galactose $C_6H_{12}O_6$	59-23-4
200-432-1	DL-methionine $C_5H_{11}NO_2S$	59-51-8
200-559-2	Lactose $C_{12}H_{22}O_{11}$	63-42-3
200-711-8	D-mannitol $C_6H_{14}O_6$	69-65-8
201-771-8	L-sorbose $C_6H_{12}O_6$	87-79-6
204-664-4	Glycerol stearate, pure $C_{21}H_{42}O_4$	123-94-4
204-696-9	Carbon dioxide CO_2	124-38-9
205-278-9	Calcium pantothenate, D-form $C_9H_{17}NO_{5.1/2}Ca$	137-08-6
205-756-7	DL-phenylalanine $C_9H_{11}NO_2$	150-30-1
208-407-7	Sodium gluconate $C_6H_{12}O_7.Na$	527-07-1

Annex V. chemical which occur accidentally, by-product……

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.

2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, ►M3 mixture ◄ or article.

3. Substances which result from a chemical reaction occurring upon end use of other substances, ►M3 mixtures ◄ or articles and which are not themselves manufactured, imported or placed on the market.

4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:

   (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or

   (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.

5. By-products, unless they are imported or placed on the market themselves.

6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.

Comparison of EU REACH, China REACH and K-REACH

1.2 Exemption_China-REACH

Regulated by other specific regulations

- Radioactive substances; Military industry products; Pyrotechnics; Biological substances; Pesticides; Veterinary drugs; Pharmaceuticals; Cosmetics; Foods; Food additives; Feed; Feed additives; Tobacco and tobacco products.

Substances existing in nature

- Extracted from the atmosphere through various means;
- Natural polymers;
- Biomacromolecules;

Categories of non commercial purpose/ unintentionally produced

- Impurities: total content of impurities shall not exceed 20%;
- Products of random reactions;
- Products of unintentionally reactions in final use;
- Waste water, waste gas, solid waste, and by-products

Special categories

- Special materials: Glass; Frit; Pottery raw materials and ceramic ware ; Steel and steel products; High-alumina cement; Portland cement
- Alloys;
- Non-isolated intermediate substance ;
- Articles

Comparison of EU REACH, China REACH and K-REACH

1.2 Exemption_K-REACH

Regulated by other specific regulations

- Medicine, Narcotic, Cosmetic, Pesticide, Radioactive substance, Fertilizer, Feed, Military supplies, Health care products, Medical device

Exemption without confirmation

- Chemical substance imported together with relevant machineries or equipment for the purpose of trial operation
- Chemical substance imported as already equipped machinery
- Chemical substances in articles with no intended release
- Impurities and By-product

Exemption confirmation

- Chemical substance imported/manufactured for export-only use
- Chemical reagents
- Substances for R&D use
- Polymer of low concern(PLC)
- Non-isolated intermediates
- Isolated intermediates (which can be technically blocked from leakage or exposure)
- Surface treated substances

Comparison of EU REACH, China REACH and K-REACH

1.2 Exemption_K-REACH

Impurity, by-product, chemical from nature source without chemical modification……

◉환경부고시제2018-234호

환경부고시 「화학물질 제조 등의 보고 제외대상 기존화학물질」(제2014-239호, 2014.12.30.)을 다음과 같이 개정합니다.

2018년 12월 28일

환 경 부 장 관

등록 또는 신고 면제대상 화학물질

제1조(목적) 이 고시는 「화학물질의 등록 및 평가 등에 관한 법률」(이하 "법"이라 한다) 제11조제1항제2호에 따라 등록 또는 신고 면제대상 화학물질을 정함을 목적으로 한다.

제2조(등록 또는 신고 면제대상 화학물질) 화학물질 가운데 등록 또는 신고 면제대상 화학물질은 다음의 각 호와 같다.

1. 자연에 존재하는 물질 등 별표 1에서 정한 화학물질
2. 포도당, 녹말 등 별표 2에서 정한 화학물질

부칙

이 고시는 2019년 1월 1일부터 시행한다.

[별표1]

1. 불순물(우연히 또는 비의도적으로 다른 화학물질에 생성되거나 존재하는 성분으로서 그 자체로 수입 또는 시장에 출시되지 않는 물질)
2. 부산물(의도한 화학물질의 제조과정에서 비의도적으로 함께 생성되는 물질로서 그 자체로 수입 또는 시장에 출시되지 않는 물질)
3. 자연에 존재하는 물질 등 다음 각 목의 물질로 화학적인 구조가 변경되지 않는 경우
   가. 광물, 광석, 정광, 천연가스, 원유, 석탄
   나. 유리, 세라믹 프릿(ceramic frits)
   다. 액화석유가스, 천연가스 응축액
   라. 공정가스 및 그 구성성분
   마. 코크, 시멘트 클링커, 산화 마그네슘
   바. 가목부터 마목까지 이외의 자연에 존재하는 물질 그 자체 또는 자연에 존재하는 물질로부터 이

연번	CAS번호	화학물질명
1	50-70-4	D-글루시톨(D-glucitol C6H14O6)
2	50-81-7	아스코르브산(Ascorbic acid C6H8O6)
3	50-99-7	포도당(Glucose C6H12O6)
4	57-48-7	과당(Fructose C6H12O6)
5	56-87-1	L-리신(L-lysine C6H14N2O2)
6	57-50-1	순수 자당(Sucrose, pure C12H22O11)
7	58-95-7	α-토코페릴 아세테이트(α-tocopheryl acetate C31H52O3)
8	59-23-4	갈락토오스(Galactose C6H12O6)
9	59-51-8	DL-메티오닌(DL-methionine C5H11NO2S)
10	63-42-3	유당(Lactose C12H22O11)
11	69-65-8	D-만나당(D-mannitol C6H14O6)
12	87-79-6	L-소르보스(L-sorbose C6H12O6)
13	123-94-4	순수 글리세롤 스테아레이트(Glycerol stearate, pure C21H42O4)
14	124-38-9	이산화탄소(Carbon dioxide CO2)
15	137-08-6	D-형 판토텐산칼슘(Calcium pantothenate, D-form C9H17NO51/2Ca)
16	150-30-1	DL-페닐알라닌(DL-phenylalanine C9H11NO2)
17	527-07-1	글루콘산나트륨(Sodium gluconate C6H12O7Na)
18	1338-43-8	솔비탄 올레이트(Sorbitan oleate C24H44O6)
19	7439-90-9	크립톤(Krypton Kr)
20	7440-01-9	네온(Neon Ne)
21	7440-37-1	아르곤(Argon Ar)
22	7440-59-7	헬륨(Helium He)
23	7440-63-3	제논(Xenon Xe)
24	7727-37-9	질소(Nitrogen N2)
25	7732-18-5	물(Water H2O)

Comparison of EU REACH, China REACH and K-REACH

1.3 Cost Comparison

Registration Cost

EU-REACH	China REACH	K-REACH
• Data fee • Administration fee (ECHA)	• Data fee • Administration fee (Inquiry)	• Data fee • Administration fee (MOE)

Other Cost

EU-REACH	China-REACH	K-REACH
• Legal entity change • Tonnage upgrade • Registration dossier confidential	• N/A now, but may have fee in the future	• Exemption confirmation • Dossier update • Notification of Priority Control Chemical

Comparison of EU REACH, China REACH and K-REACH

1.4 Public Announcement after Registration

EU-REACH

- ECHA: https://echa.europa.eu/

China REACH

- MEE official website. http://www.mee.gov.cn/hjzli/hxphjgl/xhxwz/

K-REACH

- N/A

Comparison of EU REACH, China REACH and K-REACH

1.5 Registration type

EU-REACH

- Joint Submission
- Individual Submission

China REACH

- Serial Notification
- Joint Notification
- Repeated Notification

K-REACH

- Joint Submission (Existing chemical)
- Individual Submission (New chemical)

Comparison of EU REACH, China REACH and K-REACH

1.6 Required information of Pre-registration under EU REACH and K-REACH

Required Information	EU-REACH	K-REACH
Registrant	o	o
Chemical Identity	o	o
Tonnage	o	o
Classification and Labelling	x	o
Use	x	o
Importer	x	o

Comparison of EU REACH, China REACH and K-REACH

1.7 Required information

Required information	EU-REACH	China-REACH	K-REACH
Registrant	o	o	o
Chemical Identity	o	o	o
Classification and Labelling	o	o	o
Use	o	o	o
Importer	Not mandatory	Not mandatory	o
Physicochemical/ Health toxicity/ Eco-toxicity data	o	o	o
Safe Use Guidance	o	o	o
Chemical Safety Report	o (≥10tpa)	o (Typical Notification)	o (2019, ≥20tpa)
Testing Proposal	When tonnage band is 100+, TP is mandatory to firstly provide; Real tests can only be processed after get approval from ECHA	x	When tonnage band is 100+, TP can be firstly provided if some tests are not completed.

Comparison of EU REACH, China REACH and K-REACH

1.8 Requirements on laboratory

	China REACH		EU REACH	K-REACH
	Chinese Lab	Foreign Lab		
Physico-chemical Tests	CNAS/ CMA/ Ministry Of Agriculture (MOA) GLP	ISO 9001/ ISO 17025/ GLP/ Other international accredited labs	No lab certification requirement	No lab certification requirement Except Log Kow test
Health toxicity Tests	➢GLP from CFDA; ➢Toxicity Identification agency authorized by Department of Health; ➢China GLP	GLP	GLP	GLP or designated lab from MOE
Eco-toxicity Tests	CNAS/ China GLP	GLP	GLP	GLP or designated lab from MOE

Comparison of EU REACH, China REACH and K-REACH

1.9 Common Alternative Methods

	EU-REACH	China-REACH	K-REACH
Read across	Yes	Yes(only for Serial notification)	Yes (case by case)
QSAR	Yes	Yes(only for Toxic kinetics)	Yes (case by case)
In-vitro testing	Yes (Skin irritation or skin corrosion /Eye irritation /Skin sensitization prefer in-vitro testing)	Yes (if positive results shown in in-vitro testing for skin irritation or skin corrosion/Eye irritation/Skin sensitization, then in-vivo testing will be exempted.) In-vivo testing is more appealing.	Yes (in-vitro testing is acceptable for skin irritation or skin corrosion/Eye irritation) In-vivo testing is more appealing.

How to use data in EU REACH to comply with China REACH and K-REACH

Test Strategy

- Polymer is not included;
- Specific Eco-toxicity tests are required to carry out in China;
- Physico-chemical tests: Non-GLP;
- Health toxicity/ Eco-toxicity tests: GLP;
- In vitro tests are firstly required under EU REACH

Test Strategy

Physico-chemical Tests

- Use EU data as standard data
- Carry out Log Kow test in GLP lab
- Extra pH test is required for liquid (China)
- Exemption condition under EU/ China/ Korea REACH is similar

Test Strategy

Physico-chemical Tests

No.	Endpoints	Test Method (OECD TG)	China	Korea	EU
1	IR/(CNMR,HNMR)/UV/ (MS)/HPLC or GC		○	/	○
2	Substance state (color; form)		/	○	○
3	Melting Point	OECD 102	○	●	○
4	Boiling Point	OECD103	●	●	●
5	Density	OECD 109	○	○	○
6	Vapour pressure	OECD104	●	●	●
7	Partition coefficient n-octanol/water	OECD107/117/123	○	○	○
8	Water solubility	OECD 105	○	○	○
9	Surface tension	OECD 115	●	/	●
10	PH value	GB/T 9724-2007/OPPT S830.7000	●	/	/
11	Flash point	EEC A9	●	/	●
12	Granulometry/Particle size	OECD110	●	●	●
13	Oxidising properties	EEC A17	●	○	●
14	Self-ignition temperature	EEC A15/A16	●	/	●
15	Flammability	EEC A10	○	○	○
16	Explosive properties	EEC A14	●	●	●

1)● marks are the endpoints which can request for exemption if meet certain conditions for exemption.
2)○ marks are the endpoints which needs to be conducted.
3) / marks are the endpoints not required.

Test Strategy

Health Toxicity Tests

- All tests are carried out in GLP lab with OECD methods
- Data requirement under EU and China REACH is very similar; K-REACH is included
- In vitro Skin Corrosion/ Irritation, Eye Irritation and Skin Sensitization should firstly be carried out (EU REACH)
- In vivo Skin Corrosion/ Irritation, Eye Irritation and Skin Sensitization (China REACH)
- Acceptance of In vitro tests under K-REACH is unknown now
- In vivo mutagenicity test (China REACH) Vs Testing proposal (EU & Korea REACH)

Test Strategy

Health Toxicity Tests

No.	Endpoints	Test Method (OECD TG)	Tonnage10-100t		
			China	Korea	EU
1	Acute toxicity by oral	OECD401/420/423/425	○	○	○
2	Acute toxicity by dermal	OECD402	○	choose one of them	choose one of them
3	Acute toxicity by inhalation	OECD403/436	○		
4.1	In Vitro skin irritation	OECD 439	/	/	○
4.2	In Vitro skin corrosion	OECD 431	/	/	●
4.3	Skin irritation or skin corrosion In Vivo	OECD404	○	○	●
5.1	In Vitro Eye irritation	OECD 437/438/492	/	/	○
5.2	In Vivo Eye irritation	OECD405	○	○	●
6.1	In Vitro skin sensitization	OECD442C-D	/	/	○
6.2	In Vivo Skin sensitisation	OECD406/429	○	○	/
7	Repeated dose 28-day toxicity study（by oral）	OECD407	○	○	○
8	In vitro gene mutation study in bacteria	OECD471/472	○	○	○
9	In vitro mammalian chromosome aberration test In vitro Mammalian cell micronucleus test	OECD473/487	○	○	○
10	In vitro mammalian cells gene mutation	OECD476/490	●	/	●
11	In vivo gene mutation(Such as Transgenic rodent somatic and germ cell gene mutation assays)	OECD486/488/489	●	/	/
12	In vivo chromosome aberration test	OECD474/475	●	●	/
13	Reproduction / Developmental Toxicity Screening Test	OECD421/422	○	○	○
14	Assessment of toxicokinetic behavior	OECD417/QSAR	○	/	◇

Test Strategy

Eco-toxicity Tests

- China REACH has highest data requirement
- All tests are carried out in GLP lab with OECD methods
- Tests are required to be carried out in China with Chinese sample (OECD 201, 202, 203)
- Acute toxicity test with Earthworm may be considered (water solubility < 1mg/L and Log Koc > 3.5, China REACH)
- Adsorption/Desorption may be required (China REACH)

Test Strategy

Eco-toxicity Tests

No.	Endpoints	Test Method (OECD TG)	Registration Tonnage10-100t		
			China	Korea	EU
1	Algae growth inhibition study	OECD201	○	○	○
2	Acute toxicity study with Daphnia magna	OECD202	○	○	○
3	Acute toxicity study with Brachydanio rerio (Chinese)	OECD203	○	/	/
4	Acute toxicity study with Brachydanio rerio	OECD203	/	○	○
5	Activated sludge respiration inhibition testing	OECD209	○	/	○
6	Adsorption/desorption properties	OECD106 (priority) / 121	○	/	●
7	Ready biodegradability	OECD301 A-F	○	○	○
8	Inherent biodegradability	OECD302A-C	●	/	/
9	Hydrolysis as a Function of pH	OECD111	●	○	●
10	Earthworm, acute toxicity test	OECD207	●	/	/
11	Daphnia magna reproduction study	OECD211	○	/	/
12	Bioaccumulation in aquatic species, preferably fish	OECD305A-D	●	/	/

Thank You

If you have any questions about chemical regulation compliance, please contact

bryan.zhou@cirs-group.com

CIRS Europe: Room 002, Regus Harcourt Centre, Dublin D02 HW77, Ireland
Tel: +353 (1) 477 3708