

K-REACH

K-REACH Overview

Regulatory Summit - Brussels

2014. 10. 15.

Jun Ho Lee

Risk Assessment Center

Chemical and Environmental Division

KTR History



- JUN 25 '13** ○ Established the Materials and Parts Center in Busan
- JUN 11 '13** ○ Established the Health Care Research Institute
- JUN 27 '12** ○ Registration as an Energystar EPA designated testing lab
- OCT 18 '11** ○ The nation's first KOLAS registration of HEMP protection facilities assessment testing
- JUL 08 '10** ○ **New KTR** (Korea Testing&Research Institute and EMC Research Institute integrated)
- MAY 12 '10** ○ New substances registration service at the European REACH(KTR Testing Results)
- DEC 29 '09** ○ Accredited by American Bureau of Shipping
- OCT 29 '09** ○ Accredited by Renault(French Republic)
- MAR 10 '09** ○ Accredited by Det Norske Veritas
- OCT 13 '08** ○ Accredited by Chrysler Testing·Inspection·Failure factor analysis Institute
- MAY 23 '08** ○ Established KTR Europe GmbH (Germany)
- MAR 22 '07** ○ Established Ulsan laboratory
- FEB 07 '07** ○ Established a branch in China
- DEC 12 '02** ○ Established Incheon Laboratory
- APR 17 '02** ○ Established Gimpo Laboratory
- APR 01 '69** ○ Foundation of KTR

KTR Network

KTR is legally founded under the Framework Act on National Standards of Korea



Organization Structure

- ▶ Total 20 Offices
(Headquarters, 7 Laboratories,
12 branches, 3 overseas branches)

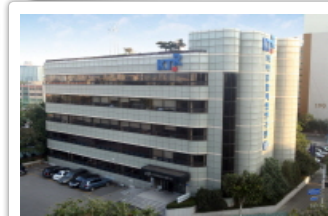


Employees

- ▶ Total 900 employees



Gimpo Lab



Headquarters



Yongin Lab



Incheon Lab



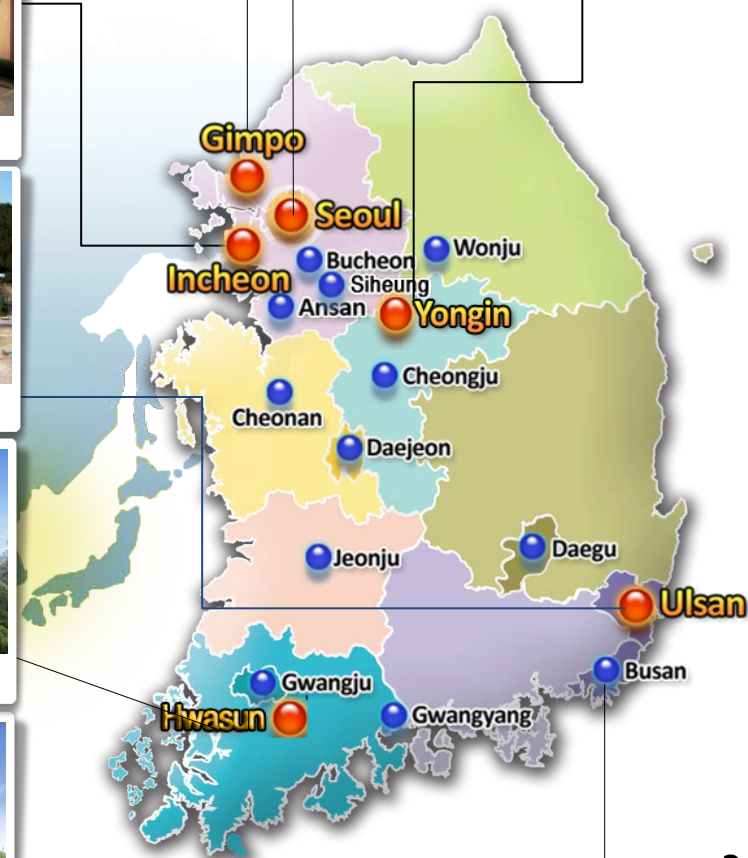
Ulsan Lab



Health Care
Research Institute



Material & Components
Laboratory



Germany Branch



China Branch

Contents

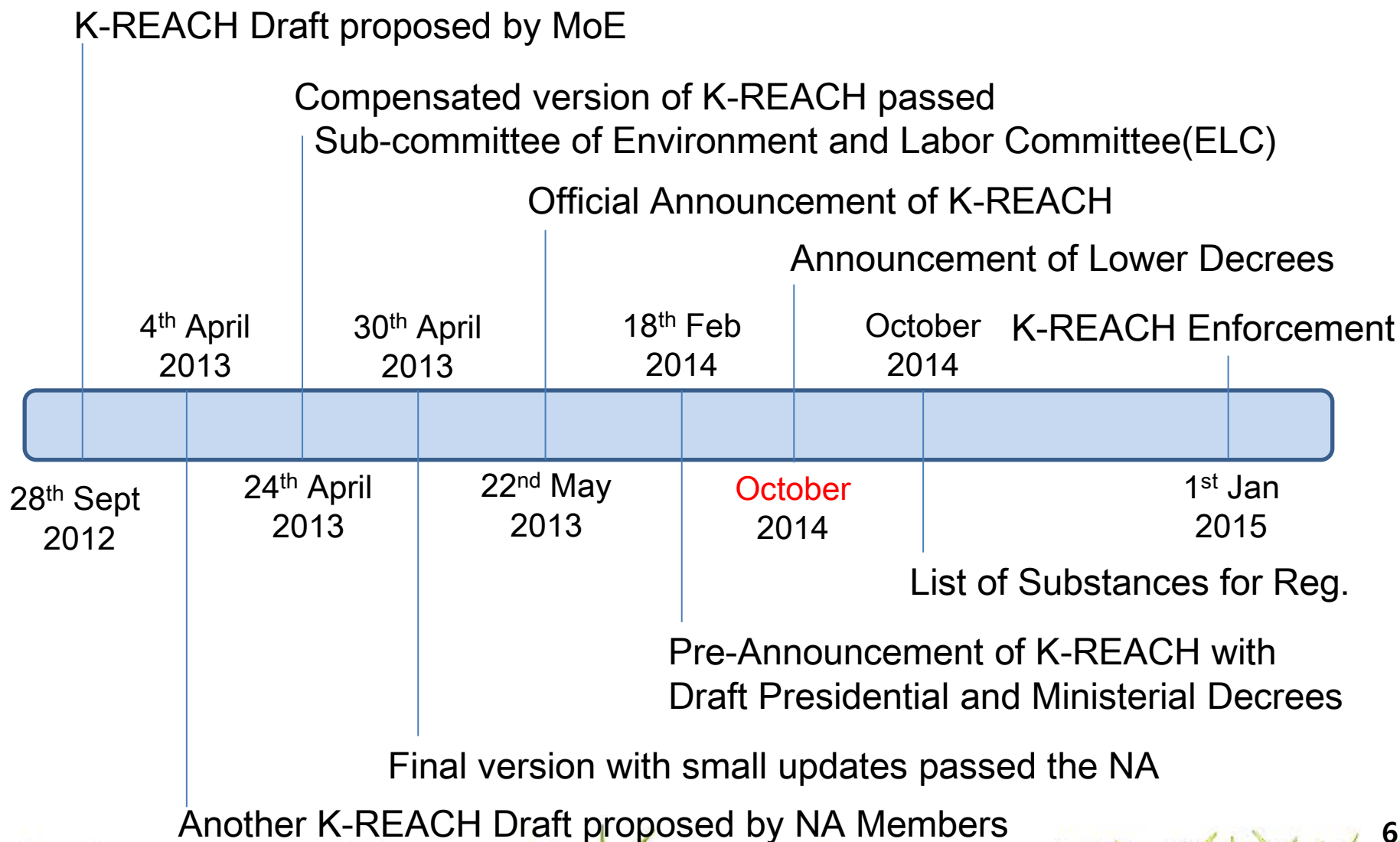
- 1 Introduction
- 2 Annual Reporting
- 3 Registration
- 4 Notification
- 5 High Risk Concerned Products
- 6 Others



Introduction



Introduction - History



Introduction - Comparisons

	Korea		EU
	TCCA	K-REACH	REACH
Subject to Registration	New chemicals	Designated existing chemicals New Chemicals	Existing chemicals New Chemicals
Annual report of tonnages	X	O	X
Registrants	Manufacturer, Importer	Manufacturer, Importer, Representative	Manufacturer, Importer, Representative
Registration tonnage	0.1~1T >1T	<1T 1~10T 10~100T 100~1000T >1000T	1~10T 10~100T 100~1000T >1000T
Evaluation	All dossiers before Registration no.	All dossiers before Registration no.	5% of all dossiers After Registration
Evaluation criteria	Hazards	Risks	Risks
Listing as existing	After 3 years	X	X
Product	X	O	O

Obligations – Only Representative

Only Representative	
Requirement	<ul style="list-style-type: none"> Knowledge on chemical substances More than 3 years of experience on chemical managements
What ORs can do	<ul style="list-style-type: none"> Annual report (updates) Registration (updates, changes, exemptions) Enquiry for registration Notification Communication of information
Considerations	<p>A legal entity to represent foreign companies for K-REACH</p> <ul style="list-style-type: none"> Reliability and Sustainability are important Appointment of OR is to be notified to authorities

한국화학안전정보시스템 (K-REACH) 등록신청서

제 목

국외 제조(생산)자에 의한
선입(배입) 사실 신고 확인증

1. 신청(발행처) : Company Name
2. 사업등록번호 : (Business registration no.)
3. 신청(대표자) : Name of Representative
4. 신청(소재지) : Address
5. 신고대상 : ☐ Foreign Representative ☒ Foreign Branch
6. 국외 제조(생산)자 : Information of Foreign Manufacturer

제출물품의 등록 및 평가 결과, 화학 물질, 화학제품 및 혼합물
의 등록 및 평가 결과에 따라 화학 물질, 화학제품 및 혼합물
의 등록 및 평가 결과에 따라 화학 물질, 화학제품 및 혼합물
의 등록 및 평가 결과에 따라 화학 물질, 화학제품 및 혼합물

년 월 일

제출(발행처) 관 관 관 관

제출(발행처) 관 관 관 관



Annual Reporting



Obligations – Annual Reporting

Annual Reporting	
Which	<ul style="list-style-type: none">• New chemical substances• Existing substances manufactured, imported or sold more than 1 ton per annum
Who	Manufacturer, Importer or Seller (OR for foreign companies)
What	<ul style="list-style-type: none">• Reporter information (name, address, contact info)• Substance information (name, CAS no)• Tonnage• Uses
Seller	Someone who sells chemical substances for industrial uses
Tonnage	Amount from 1st Jan till 31st Dec
When	By 30 th April next year
Update	<ul style="list-style-type: none">• Change of reporter information (within 1 month)• Change of uses (within 1 month from the date of acknowledgement of the change)
First AR	30th April 2016 (Tonnage form 1st Jan 2015 ~ 31st Dec 2015)



Obligations – Annual Reporting

Exemptions

- Chemical substances imported as incorporated in machines;
- Chemical substances imported along with machines or devices for commissioning test
- Chemical substances in products in solid form, performing certain functions and does not release during normal condition of use
- Other chemical substances as listed in the Presidential Decree that are manufactured or imported for uses in research, studies, etc
 - Reagents
 - R&D
 - Non-isolated intermediates



Obligations – Annual Reporting

Annual Report Template

Template

The screenshot shows a web-based form for an annual report. At the top, there are checkboxes for '제조업' (Manufacturing), '수입업' (Import), and '판매업' (Sales). Below these, there are sections for '제조업' (Manufacturing), '수입업' (Import), and '판매업' (Sales). Each section contains a table with columns for '제품명' (Product Name), '수량' (Quantity), '단위' (Unit), and '가격' (Price). The '제조업' section has a table with 4 columns and 1 row. The '수입업' section has a table with 4 columns and 1 row. The '판매업' section has a table with 4 columns and 1 row. At the bottom, there are checkboxes for '제조업' (Manufacturing), '수입업' (Import), and '판매업' (Sales).

Attachment

- Confirmation of appointment of an OR
- OEM contract (if reported by OEM manufacturer)



Registration

- General Registration
- Simplified Registration (<1 tpa)
- Polymer Registration
- Intermediate Registration

Obligations – Registration (General)

Registration (General)	
Which	<ul style="list-style-type: none">• New chemical substances• Designated Existing substances manufactured or imported more than 1 ton per annum (or ≤ 1 tpa when requested by Minister of Environment)• Substances will be designated every 3 years• 3 years of grace period from the date of official announcement
Who	Manufacturer or Importer (OR for foreign companies)
What	<ul style="list-style-type: none">• Registrant information (name, address, contact info)• Substance information (name, CAS no, concentration, molecular formula, impurities, etc)• Tonnage, Uses, C&L• Physico-Chemical Properties• Hazardous and Risk Information• Guidance on safe use• Other information requested by Ministerial Decree
Tonnage	Amount from 1st Jan till 31st Dec of the year of submission
Announcement	<ul style="list-style-type: none">• Substance name and cas no/KE no, Grace period• Required test data (for substances ≤ 1 tpa, requested by MoE)

K-REACH Registration Data Requirement

- Data requirements : Physico-Chemical Properties

Test requirement	0.1~1t	1~10t	10~100t	100~1000 t	>1000t
Physical State	○	○	○	○	○
Melting Point/Freezing Point	○	○	○	○	○
Boiling Point	○	○	○	○	○
Vapor Pressure	○	○	○	○	○
Water Solubility	○	○	○	○	○
Partition coefficient n-octanol/water (GLP)		○	○	○	○
Relative Density		○	○	○	○
Granulometry		○	○	○	○
Flammability			○	○	○
Explosive properties			○	○	○
Oxidising properties			○	○	○
Viscosity				●	●
Dissociation constant				●	●

○ : Test requirement ● : Submission of test proposals

K-REACH Registration Data Requirement

- Data requirements : Toxicological

Category	Test requirement	0.1~1t	1~10t	10~100t	100~1000t	>1000t
Acute toxicity	Oral (TG420/423/425)	○	○	○	○	○
	Dermal (TG402) or Inhalation (TG403)	Δ	Δ	○	○	○
Irritation	Skin (TG404)		○	○	○	○
	Eye (TG405)			○	○	○
Sensitization	Skin (TG406/429)		○	○	○	○
Mutagenicity	Ames test (TG471)	○	○	○	○	○
	In vitro chromosome aberrations Assay (TG473/485)			○	○	○
	In vitro cytogenicity study in mammalian cells (TG476) or In vivo gene mutation study in mammalian cells(Mammalian Erythrocyte Micronucleus bone marrow chromosome aberration test, TG474/475)			Δ	Δ	Δ
	Additional In vivo gene mutation study [UDS(TG486)/transgenic mice/comet]				●	●
Repeat dose toxicity	Repeated Dose 28day Oral Toxicity in Rodents (TG407,410,412)			○	○	○
	Repeated Dose 90day Oral Toxicity Study in Rodents [TG408(409,411,413)]					●
Carcinogenicity	Carcinogenicity (TG451/453)					●
Reproductive/ Developmental toxicity	Screening for reproductive/developmental toxicity, one species (TG421/422)			●	●	●
	Pre-natal developmental toxicity study, (TG414)					●
	Two-generation reproductive toxicity study, (TG416)					●

○ : Test requirement ● : Submission of test proposals

K-REACH Registration Data Requirement

- Data requirements : Ecotoxicalogical

Category	Test requirement	0.1~1t	1~10t	10~100t	100~1000t	>1000t
Aquatic toxicity	Short-term toxicity testing on fish (TG203)	○	○	○	○	○
	Short-term toxicity testing on invertebrates (TG202)		○	○	○	○
	Growth inhibition study aquatic plants (TG201)			○	○	○
	Long-term toxicity testing on fish (TG210/212/215)				●	●
	Long-term toxicity testing on invertebrates (TG211)				●	●
Effects on terrestrial organisms	Short-term toxicity to plants (TG227)				●	●
	Earthworm, Acute toxicity tests (TG207)				●	●
	Long-term toxicity to plants (ISO22030)					●
	Earthworm Reproduction Test (TG222)					●
STP Microbial toxicity	Activated sludge respiration inhibition testing (TG209)				●	●
Toxicity using spiked sediment	Sediment-water chironomid toxicity using spiked sediment (TG218/219)					●
Degradation	Ready biodegradability (TG301/310)	○	○	○	○	○
	Inherent biodegradation (TG302)				●	●
	Hydrolysis (TG111) (Non-GLP)			○	○	○
	Identification of degradation products (Non-GLP)				●	●
	Additional fate and behavior information for degradation products					●
Bioaccumulative	Bioconcentration : Flow-through Fish Test (TG305)					●
Adsorption / Desorption	Adsorption / desorption screening (TG106/121) (Non-GLP)				●	●
	Additional Information for adsorption/desorption (Non-GLP)					●

○ : Test requirement ● : Submission of test proposals

Obligations – Registration (Simplified)

Registration (Simplified)				
	Before 2020	After 2020		TCCA
Tonnage	< 1ton	<100 Kg	100Kg ~ 1 tpa	< 1 ton
Registration	Simplified	Simplified	General	Low Volume
Required data	<ul style="list-style-type: none"> • Registrant information • Uses • Substance information • Exposure information • No hazard data 		Additional Data <ul style="list-style-type: none"> • Physico-chemical • Hazard data <ul style="list-style-type: none"> ▪ Acute Oral ▪ AMES ▪ Acute Fish ▪ Biodegradability • C&L • Guidance on safe use 	<ul style="list-style-type: none"> • Physico-chemical • Hazard data <ul style="list-style-type: none"> ▪ Acute Oral ▪ AMES ▪ Chromosomal Aberration ▪ Biodegradability



Obligations – Registration (Polymers)

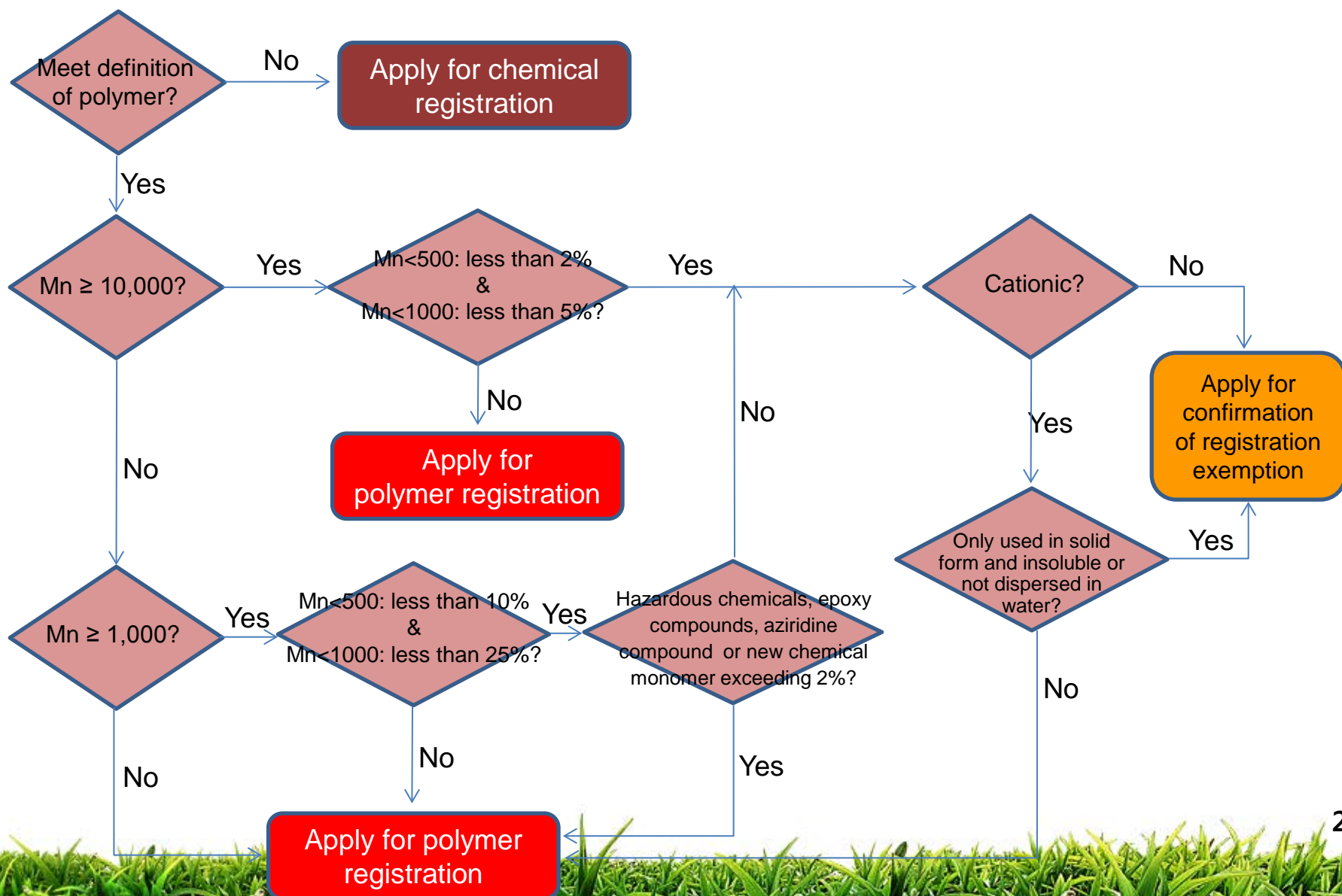
Tonnage	Data for Polymer properties	Data Requirements	TCCA
1 ~ 10	<ul style="list-style-type: none"> Number-average molecular weight (Mn) and its distribution Data on monomer and residual monomer content Content of oligomers with less than 1,000 Daltons Acid/alkali stability 	<ul style="list-style-type: none"> Physical state Water solubility Melting point Boiling point Vapor pressure 	<ul style="list-style-type: none"> Physico-Chemical properties AND Option 1 Number-average molecular weight (Mn) and its distribution Data on monomer and residual monomer content Acid/alkali stability Content of Mn<1,000 OR Option 2 Acute oral AMES OR Option 3 AMES Acute fish toxicity
10 ~ 100		Above endpoints plus <ul style="list-style-type: none"> Acute Oral AMES, Acute fish Ready Biodegradability 	
100 ~ 1000		General Data Requirement for 1 ~ 10 tpa	
1000~		General Data Requirement for 10 ~ 100 tpa	

Obligations – Registration (PLC Exemption)

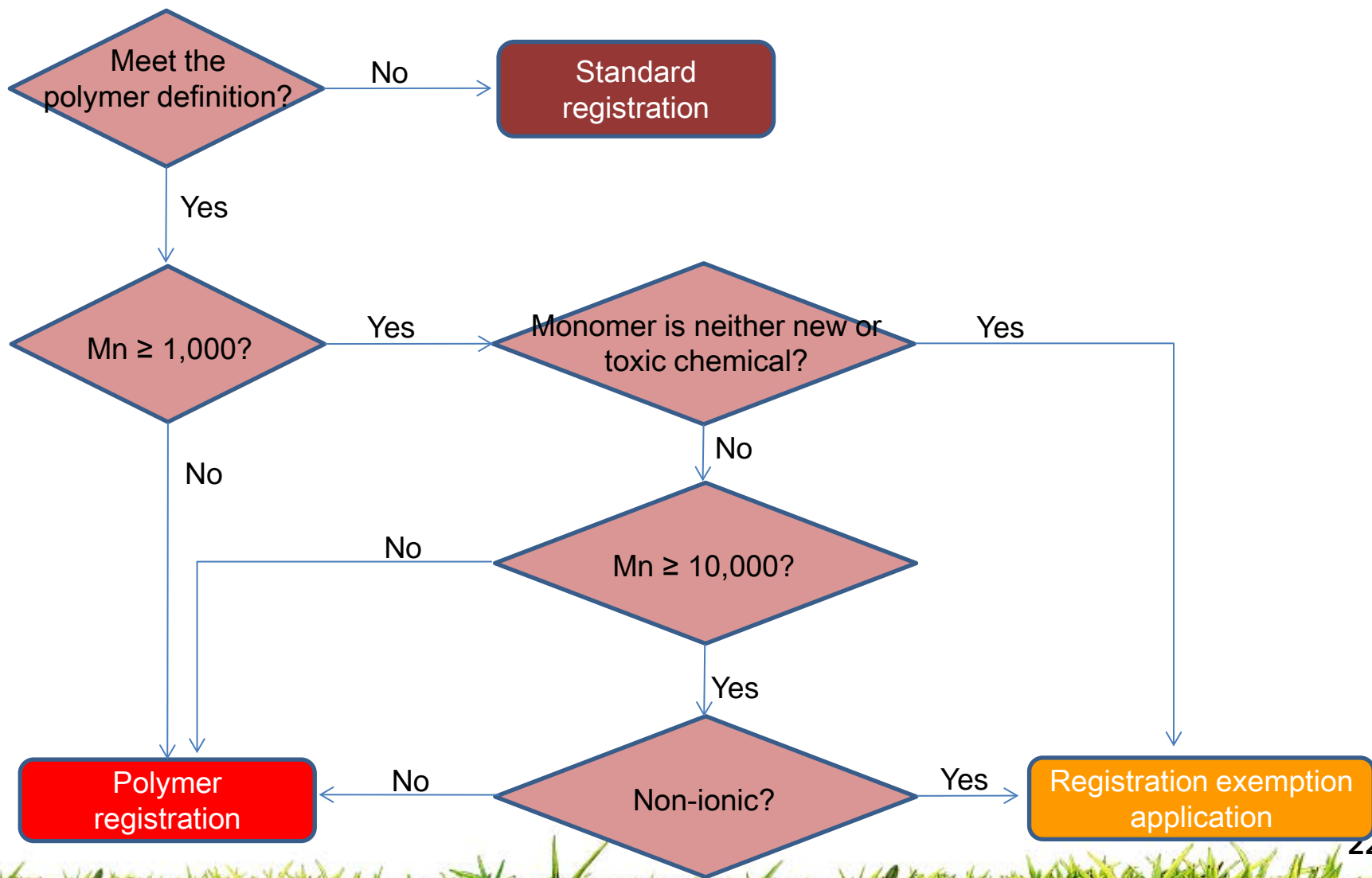
PLC Exemptions	
Exemption Condition 1	<ul style="list-style-type: none">• Number-average molecular weight \Rightarrow 10,000 Daltons• Oligomer content less than 2 percent by weight below 500 Daltons• and less than 5 percent by weight below 1,000 Daltons.• Not satisfying sub exemption condition 1
Exemption Condition 2	<ul style="list-style-type: none">• Number-average molecular weight \Rightarrow 1,000 Daltons and $<$ 10,000 Daltons• Oligomer content less than 10 percent by weight below 500 Daltons• and less than 25 percent by weight below 1,000 Daltons.• Not satisfying sub exemption condition 1 & 2

PLC sub-Exemptions conditions	
Sub Exemption Condition 1	<ul style="list-style-type: none">• Cationic polymer (except if in solid form not soluble or dispersible in water)
Sub Exemption Condition 2	<ul style="list-style-type: none">• Polymer with Monomer(of Hazard chemical substances, epoxy compound, aziridine compound or new chemical substance) over 2% by weight• and number-average molecular weight below 10,000 Daltons

Flow Chart for Polymer under K-REACH



Flow Chart for Polymer under TCCA



Obligations – Registration (Intermediates)

Registration (Intermediate)	
Which	<ul style="list-style-type: none">• Substances produced during the production of another substance.• All amount is used within the process to produce the other substance• Do not include non-isolated intermediates
What	<ul style="list-style-type: none">• Registrant information (name, address, contact info)• Substance information (name, CAS no, concentration, molecular formula, impurities and etc)• Uses• C&L• Physico-Chemical Properties of General data requirement• Hazardous and Risk Information (if available)• Guidance on safe use (if available)• Other information requested by Ministerial Decree (if available)



Obligations – Registration (Biocides)

Tonnage	General data requirements	Data Requirements
0.1 ~ 1 (from 2020)	Data regarding active ingredients	General Data Requirement for 1 ~ 10 tpa (15 endpoints)
1 ~ 10		General Data Requirement for 10 ~ 100 tpa (26 endpoints)
10 ~ 100		General Data Requirement for 100 ~ 1000 tpa (37 endpoints)
100~		General Data Requirement for 1000 ~ tpa (47 endpoints)



Obligations – Registration (Exemptions)

Registration Exemptions

No confirmation
required

- Chemical substances imported as incorporated in machines;
- Chemical substances imported along with machines or devices for commissioning test
- Chemical substances in products in solid form, performing certain functions and does not release during normal condition of use

Confirmation
Required

- Manufactured or imported less than 10 ton per annum AND all of the manufactured or imported chemical substances are exported
- Reagents for scientific study, analysis or research
- R&D purpose of
 - Development of chemicals or products
 - Improvement or development of process
 - Testing application scope of chemicals
 - Pilot production
- Polymer with Low Concerns (temp name)
- Surface treated substance where treating and treated are both not subject to registration

Obligations – Registration (Uses)

1. 흡수/흡착제 (Absorbents and Adsorbents)	18. 비료 (Fertilisers)
2. 접착제 (Adhesive, binding agents)	19. 필러 (fillers)
3. 에어로졸추진제 (Aerosol Propellants)	20. 고정제 (Fixing agents)
4. 응축방지제 (Anti-condensation agents)	21. 내화/방염제, 난연제 (Flame retardants and fire preventing agents)
5. 부동액 (Anti-freezing agents)	22. 부유제 (Flotation agents)
6. 접착방지제 (Anti-set-off and anti-adhesive agents)	23. 주물용 flux (Flux agents for casting)
7. 정전기발생 방지제 (Anti-static agents)	24. 발포제/기포제 (Foaming agents)
8. 표백제 (Bleaching agents)	25. 식품 및 식품첨가물 (Food/foodstuff additives)
9. 세제 및 세정, 세척제 (Cleaning/washing agents and additives)	26. 연료 (Fuel)
10. 염료안료 및 색소 (Colouring agents)	27. 연료첨가제 (Fuel additives)
11. 복합제 (Complexing agents)	28. 열전달제 (Heat transferring agents)
12. 전도체 (Conductive agents)	29. 유압액 (Hydraulic fluids and additives)
13. 부식방지제 (Corrosion inhibitors)	30. 주입제 (Impregnation agents)
14. 화장품 (Cosmetics)	31. 단열제 (Insulating materials)
15. 분진결합제 (Dustbinding agents)	32. 합성출발물질 및 중간체 (Intermediates)
16. 전기도금제를 포함한 금속 표면처리 약품 (Metal surface treatment products, including electroplating products)	33. 윤활유/첨가제 (Lubricants and additives)
17. 화약, 폭발제 (Explosive)	34. 방오제, 방부제, 살균제 등 비농업용 농약 (Non-agricultural pesticides)

Obligations – Registration (Uses)

35. 향료 (Odour agents)	51. 가황제/가황촉진제 (Vulcanising agents)
36. 산화제 (Oxidising agents)	52. 용접제 (Welding and soldering agents)
37. Ph 조절제 (pH-regulating agents)	53. 단량체 등 고분자원료 (Monomer etc.)
38. 농약 (Pesticides)	54. 도료, 잉크 및 코팅제 (Coatings and paints, ink, paints)
39. 의약품/의약품중간체 (Pharmaceuticals)	55. 이온교환수지 (Ion exchange resin)
40. 사진현상재료 등 광화학물 (Photochemicals)	56. 전기전자재료 (Electricity and Electronics materials)
41. 촉매등 공정조절제 (Process regulators)	57. 섬유 및 섬유처리약품 (Textile and textile treating agents)
42. 환원제 (Reducing agents)	58. 건조 및 분리제 (drying and separation agents)
43. 복사용 물질 (Reprographic agents)	59. 합성수지 등 최종 고분자 물질 (Final polymer and its preparation)
44. 반도체 (Semiconductors)	60. 기초 금속 및 합금 (Base metals and alloys)
45. 연화제/경화제 (Softner/hardner)	61. 종이 및 보드 염색, 마감, 보강제품 (Paper and board treating agents)
46. 탈지제, 용매 및 희석제 (Cleaning agent, solvent, thinner)	62. 광택제 및 왁스 혼합물 (Polishes and wax blends)
47. 안정제 (Stabilisers)	63. 건축용 물질 및 첨가제 (Construction materials additives)
48. 계면활성제/표면활성제 (Surface-active agents)	64. 연구시험용 물질 (R & D chemicals)
49. 가죽처리 약품 (Leather tanning, finishing, impregnation and care products)	65. 기타 (Others)
50. 점도조정제 (Viscosity adjusters)	

Obligations – Registration

Registration Template

Template

물품 신장서 (Product Registration Certificate) form. The form includes sections for: 물품 정보 (Product Information), 제조업체 정보 (Manufacturer Information), 시험결과 (Test Results), and 안전성 평가 (Safety Assessment). It contains fields for product name, CAS number, molecular weight, and various test results.

Attachment

- PhysicoChemical Data
- Toxicity/EcoToxicity Data
- Chemical Safety Report
- Guidance of safe use
- Information and backup reasons for waiving of testing
- Test Proposal
- Risk information including Exposure Scenario
- Confirmation of appointment of an OR
- OEM contract (if reported by OEM manufacturer)



Notification



Obligations – Notification

Notification of products containing hazardous chemical substances

Notification	<ul style="list-style-type: none">• When consumer products contain hazardous chemical substances more than 0.1% by weight• AND manufactured or imported over 1tpa
Product	<p>means an item or its component or part used by an end user with a possibility to cause consumers to be exposed to a chemical substance, including</p> <ul style="list-style-type: none">• An item of preparation• An item in which the chemical substance contained in it performs a certain function in the form of a solid without leaking during use
Information required for Notification	<ul style="list-style-type: none">• Notificant information (Name, address, contacts, etc)• Product Information (Name, contents, instruction manual, etc)• Containing Hazardous Chemical substance information (name, %)• Available classification and hazards information of HCS• Function of HCS within the product• Use of the product



Obligations – Communication (Notified Product)

Communication of information within supply chain for Notified products

Information communication

Suppliers of notified products containing hazardous chemical substances are required to provide related information to downstream users and consumers

Information

- Product name
- Containing hazardous chemical substance name and content %
- Possible/restricted uses
- Instruction manual and use conditions
- Exposure measures and safe handling information





5 High Risk Concerned Products



Obligations – High Risk Concerned Products

High Risk Concerned Products	
Safety and labelling criteria	Minister of Environment will perform Risk Assessments on product categories containing hazardous chemical substances which may cause harmful damages to human health and environment
High Risk Concerned Product	<p>High risk concerned products: means a chemical product listed by the Minister of Environment after consultation with the head of the relevant central authority as one deemed to have potential risk to human health or the environment, including, but not limited to:</p> <ul style="list-style-type: none">• A product used by consumers on their daily lives such as detergent, air freshener, adhesive, polisher, deodorant, bleach or fabric softener.• A product used to kill, interrupt or immobilize harmful organisms except for human beings and animals such as insect repellent, sanitizer or preservative.
Products	<ul style="list-style-type: none">• Products not satisfying safety and labelling criteria can not be sold• Substances in high risk concerned products with no safety and labelling criteria can be requested for registration





Others



What to expect

Substances subject to Registration

- Draft list is to be expected by October, 2014

Announcement of Presidential and Ministerial Decrees

- Final version is expected by the end of October, 2014
- **CW Webinar with new Lower Decree contents within 2 weeks**

Enforcement of K-REACH

- 1st January, 2015

K-REACH IT Platform

- To be prepared and opened before the enforcement date
- Similar to EU REACH-IT system

2nd Pilot Project on K-REACH Registration

No	Substance Name	CAS No.	Authority
1	Diisocyanatomethylbenzene	26471-62-5	Korea Chemical Management Association (KCMA)
2	Benzoyl peroxide	94-36-0	
3	4,4'-Methylenedianiline p-xylene (lack of tonnage)	101-77-9 106-42-3	
4	Hydrogen bromide	10035-10-6	
5	2,4-Diisocyanatotoluene Hydrogen chloride (substance sameness, no 1.)	584-84-9 7647-01-0	
6	Trichloroethylene	79-01-6	Korea National Cleaner Production Center (KNCPC)
7	(Butoxymethyl)oxirane 1-Chloro-2,3-epoxypropane (use of substitution)	2426-08-6 106-89-8	

Known information of Lower Decrees(Final)

Submission of Registration

- Registration deadline will be extended(3months) to those who submitted the registration within 2 months before the deadline.

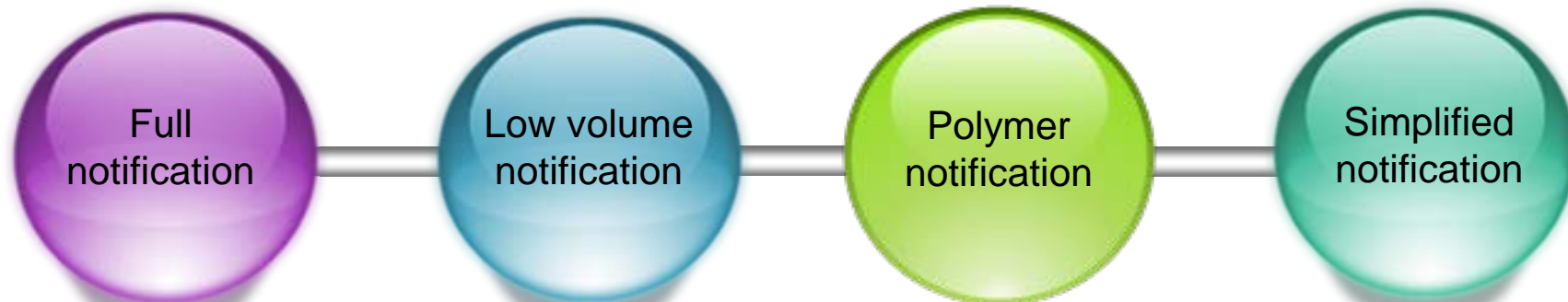
Data Requirement for Registration

- QSAR (for 1~10 tpa)
- ReadAcross
- **Klimish 2?**

Use of available animal Testing data

- DataHolder needs to share unless they have appropriate reasons
- Data refused to shared without appropriate reason, will not be able to be used for registration by the owner

TCCA Registration Data Requirement



- Main uses and physico-chemical properties such as melting point, boiling point, vapor pressure, solubility, n-octanol/water partition coefficient, etc.
- Data on main discharge route to the environment and expected discharge quantity.

- Acute oral toxicity test
- AMES
- Chromosomal Aberration
- Biodegradability test
- Acute fish toxicity
- Acute Daphnia magna toxicity
- Acute algae toxicity
- Skin irritation test
- Eye irritation test
- Skin sensitization test

- Acute oral toxicity test
- AMES
- Chromosomal Aberration
- Biodegradability test

- Number-average molecular weight (Mn) and its distribution
- Data on monomer and residual monomer content
- Acid/alkali stability
- Content of Mn < 1,000

OR

- Acute oral toxicity test
- AMES

OR

- AMES
- Acute fish toxicity

- Acute oral toxicity test
- AMES

OR

- AMES
- Acute fish toxicity

* Depending on the results of Ames test and Chromosomal Aberration, micronucleous test may be required.

THANK
YOU

Jun Ho Lee

Senior Researcher

Risk Assessment Center

Korea Testing and Research Institute

Tel : 031-999-3065, Email : junho78@ktr.or.kr