

# 기업의 본등록 준비

2009. 8. 18



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# | REACH 최신동향



# 사전등록 결과 통계 (1/4)

약 15만개 물질에 대한 275만 건의 사전등록 접수

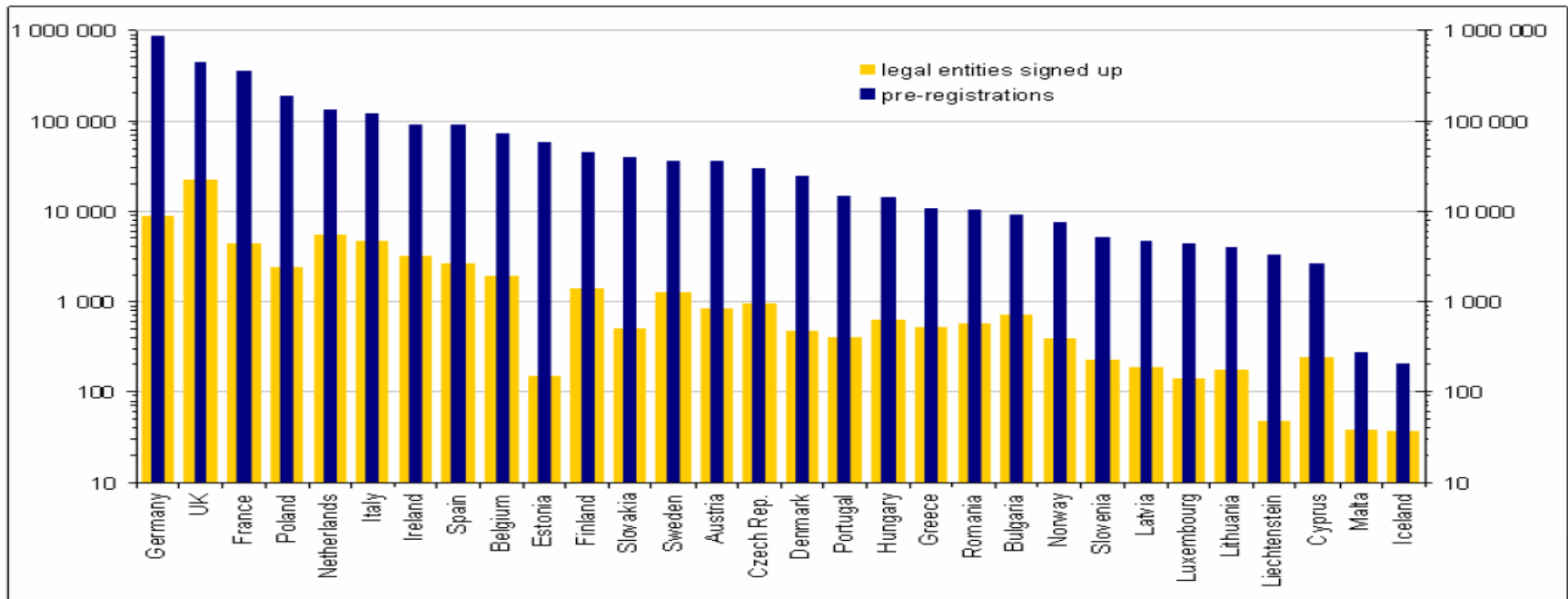
- \* 모든 EC Inventory 물질
- \* 17,000개 물질은 CAS No로 등록
- \* 9,500개 물질은 화학물질명으로 등록
- \* 14,500개의 다성분 물질 등록

ECHA에서는 CAS와 공동 확인 작업 실시

ECHA는 물질이 아닌(예를 들면, 신발 같은 완제품) 사전등록은 삭제

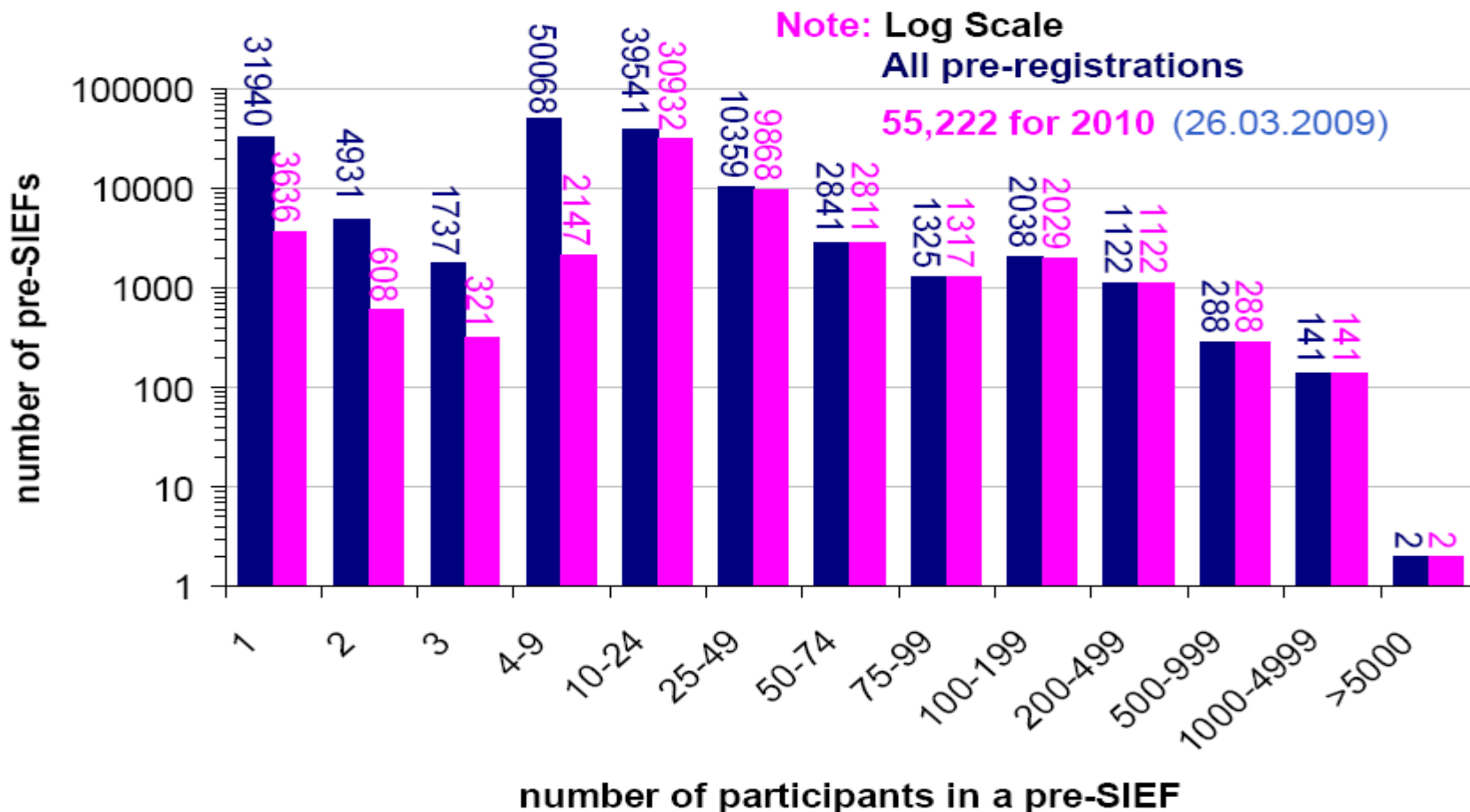
동의어(synonym)인 물질들을 하나의 pre-SIEF로 합병

# 사전등록 결과 통계 (2/4)



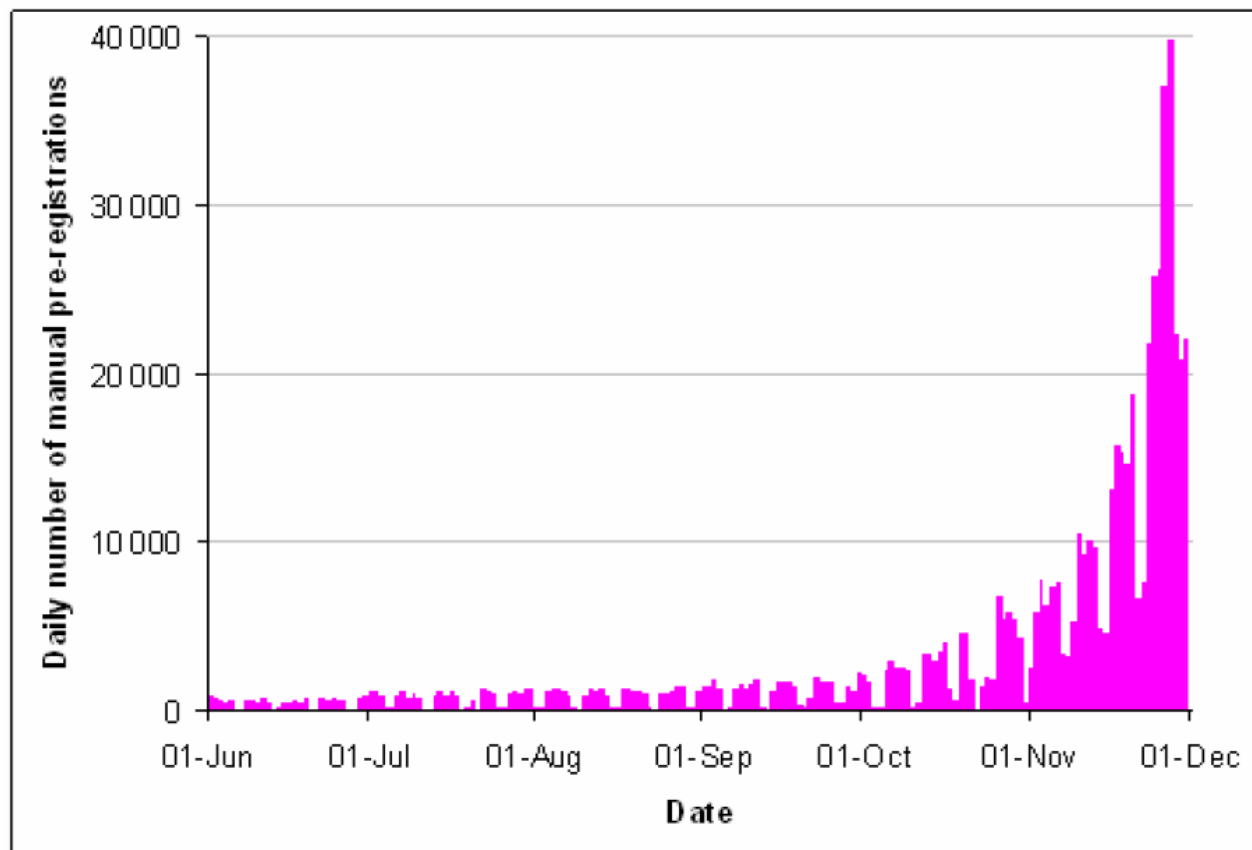
- 독일과 영국이 전체 사전등록의 50% 이상을 차지
- 65,000 개의 기업에서 사전등록 (그 중 85%가 중소기업)
- EU/EEA 內가 아닌 기업에 의해 제출된 사전등록은 삭제
- 일부 동유럽 국가의 경우 사전등록률은 30~50% 수준 (Disaster?)

# 사전등록 결과 통계 (3/4)



100개 기업 이상의 회원수가 있는 SIEF는 전체의 2.5%에 불과

# 사전등록 결과 통계 (4/4)



사전등록마감 이전 2주일 동안에 **전체 사전등록의 50%를 등록**  
**본등록은 ?**

# SIEF 동향

일부 SIEF의 경우, Facilitator가 제 역할을 하지 못함으로써 SIEF 진행이 전혀 되지 않는 경우가 있음.

최근 몇몇 기업에서는 Facilitator의 연락을 기다리다 못해 Leading기업 위주로 직접 Facilitator 변경을 요구하는 사례가 발생

ECHA에서도 SIEF 진행의 시급성을 알리기 위해 다음과 같은 로고를 만들어 캠페인을 실시하고 있음



CEFIC(유럽화학산업협회)에서 제시하는 SIEF 표준일정에 따른다고 가정한다면, 09.7월에는 이미 SIEF Code 조사, 물질 동질성에 대한 조사, SIEF 운영 규정에 대한 동의절차가 모두 완료 되어 있어야 함.



# Facilitator 변경을 요구하는 사례

**Gesendet:** Dienstag, 16. Juni 2009 12:57

**Betreff:** 2-ethoxyethanol (EINECS 203-804-1; CAS 110-80-5) - **Change of SFF**

Dear members of the SIEF,

Novasol S.A. Belgium as an importer and Sanofi Chimie, France as a major user of the above described substance have a strong interest in a timely registration of the substance. Therefore these two companies would like to start the pre-SIEF and SIEF activities related to this substance.

**ABC as current SFF (SIEF formation facilitator) does not initiate any activities up to now.**

In addition the registration of this substance needs some special knowledge for the registration.

Therefore these two companies does not recognize any advantages to use ABC as SFF. Therefore the two companies have asked KFT Chemieservice GmbH as consultancy company for Novasol S.A. and as a competent and reliable partner of the chemical industry to take over the role of the SFF.

**We have informed today ABC about this decision** (see attached copy of the fax to ABC).

If members of the SIEF does not like this decision or have other proposals for the SIEF formation process please respond to this message immediately with your proposals or concerns.

If we do not get any objection we will proceed at the end of the week with the first steps for the SIEF formation process. For the communication we will use the SIEFREACH platform.

**Please do not communicate in this matter any longer with ABC.** If you would like to get a letter of authorization for KFT Chemieservice from Novasol or Sanofi please do not hesitate to contact me.

Best regards

on behalf of Novasol S.A. Mechelse Steenweg 26, B-1970 Wezembeek-Oppem, Belgium

# Facilitator 사칭에 대한 주의 요청 사례

## Information from the SIEF formation facilitator

### !!! Important note !!!

Dear member of the Ethanol SIEF,

**please be informed that currently other parties pretend to be the SIEF Formation Facilitator (SFF) for Ethanol and claims for information.**

CropEnergies as unique SFF circulated a questionnaire to all members of the pre-SIEF and finished finally the formation process. The SIEF for Ethanol is installed now (see message below).

Members of the SIEF have now the option to join the consortia EtOH-REACH or asking the Lead registrant (ABENGOA Bioenergies) for a "letter of access" ("one substance, one registration").

Any dubious activities of SIEF members will be reported to the ECHA.

Kindly regards

Steffen Krämer

on behalf of CropEnergies

SIEF Formation Facilitator

Member of EtOH-REACH Association

출처 : 에탄올 REACH-IT

# Facilitator가 없는 경우

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**Sent:** 2009-06-25 15:17:10

**Subject:** No SIEF Formation Facilitator (SFF) for EC no. 271-528-9

Dear All,

We have pre-registered the substance having CAS No 68584-22-5 and EINECS No 271-528-9.

As you must be aware that at this point in time,

**there is no SIEF Formation Facilitator (SFF) in our SIEF.**

This is not a very encouraging scenario; considering that many of us who have pre-registered this substance, have a REACH Registration deadline of 1st Dec' 2010.

We therefore write to all of you to seek your views on this situation prevailing in our SIEF. On our part,

**we would welcome any company or an "only representative" who wants to volunteer to be the SFF.**

We will be glad to co-operate with him to move ahead with the discussions leading to registration.

We would welcome suggestions on how to get this SIEF moving fast since we all need to be aware that "the clock is ticking"

Thanking you all

Kind Regards,

Co-ordinator,

Sustainability Support Services (Europe) AB

# 사전등록자를 대상으로 한 마케팅 사례

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**Sent:** 2009-06-24 16:34:28

**Subject:** Maleic Anhydride & Sodium Benzoate

Dear Sirs,

We write to introduce ourselves as one of the leading suppliers, from China, of a wide range of Chemical products and related services.

**It will be a great pleasure to receive your inquiries for any item of our chemical product against which we will send you our lowest quotations.**

We found you have registered in Reach. In order to establish a business relationship with you, we take pleasure in sending you our latest price for our main products. Hope you would contact us if you find any item is interesting to you.

# 선도등록자 (Lead Registrant)

Active Lead Registrants	
Date	Formed SIEF
29/07/2009	982
21/07/2009	922
14/07/2009	797
07/07/2009	650
30/06/2009	574
24/06/2009	515
16/06/2009	474
12/06/2009	448
06/06/2009	376
27/05/2009	293
08/05/2009	108
22/04/2009	57
07/04/2009	42

출처 : ECHA 자료 (09.7.29)

## 2. AGREEMENT ON CEZUS AS LEAD REGISTRANT (LR)

Position	My position (please indicate the appropriate cell)
YES, we agree on CEZUS acting as LR	
NO, we disagree on CEZUS acting as LR	

No assignment of position will mean an agreement of Cezus as

- 
1. CEZUS?
  2. No 일 경우 누가?

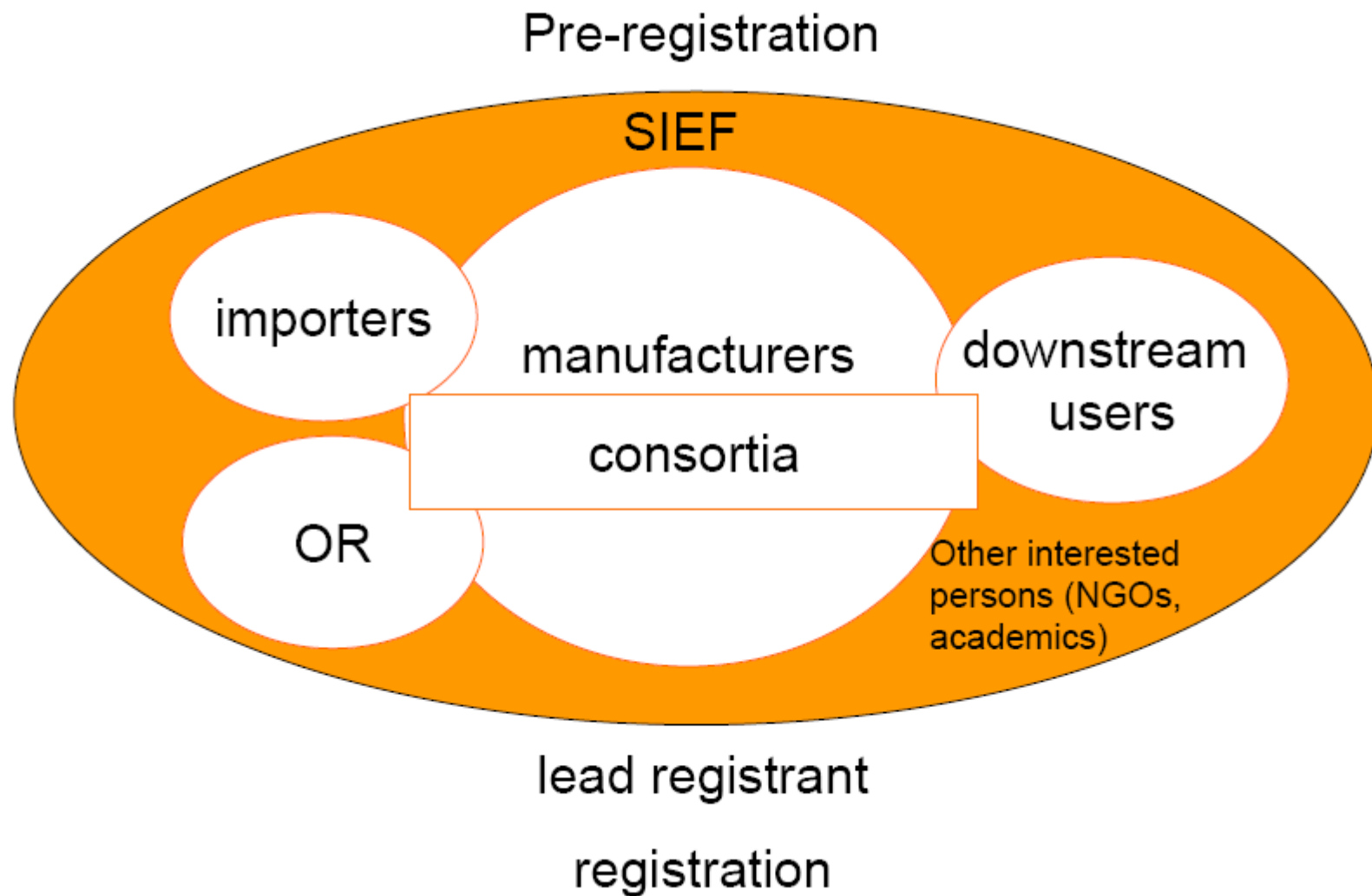
선도등록자 선정 설문 사례

- 2010.11월까지 약 55,000개의 SIEF개의 SIEF가 등록해야 하나, 09.7월 현재 선도등록자가 정해진 SIEF의 수는 982개임 (약 2% 수준)
- 대부분 선도등록자로 나서지 않으려고 하는 경우가 대부분 이지만, 복수의 선도등록자가 있는 SIEF 도 있음.
- 선도등록자는 ECHA에 선도등록자 Information을 제공해야 함.

## II SIEF/컨소시아 운영 사례



# SIEF 구성원



# SIEF vs 컨소시엄

## SIEF

- 시험 Data 및 비용 공유를 위해 만들어진 법적인 Platform
- Member : Single Legal Entity
- 범위 : 하나의 물질
- 구성시기 : 2009.1~

## 컨소시엄

- 시험 Data, 비용 공유 및 공동등록을 위해 만들어진 자발적인 Platform
- Member : 모든 이해 관계자
- 범위 : Member에 의해 정해짐
- 구성시기 : 컨소시엄 설립시점 이후



# Pre-SIEF

## 동질성 확인 절차

Sameness of substance

agree

yes

Substance Information  
Exchange Forum (SIEF)

no

Sub-SIEF

another-SIEF

## 동질성 확인 사례 (Phosgene)

- Names: Carbonyl Dichloride, Carbon Oxychloride, Chloroformyl Chloride, Phosgene, Carbonic Dichloride,
- CAS No.: 75-44-5
- EEC No.: 200-870-3
- Index No.: 006-002-00-8
- Classification: T+ R26 ; C R34
- Formula:  $\text{COCl}_2$
- Molecular Weight: 98,9165 kg/kmol
- Purity: typical value: 99 weight %
- Range: 90-100 w. %
- Impurities:  $\text{CO} < 10 \text{ w.}\%$ , Cl  $< 1 \text{ w.}\%$ ,  $\text{CCl}_4 < 1 \text{ w.}\%$

# SIEF 설문서 샘플

## III. COMMUNICATION.

It is proposed to use the SIEFreach system (ex REACHLink) to manage communications within the SIEF. Given the urgency of the timeframe effective information exchange is imperative to enable the dossier deadlines to be met.

There is single cost of 300 Euro per legal entity for this service.

Please indicate if you are willing to use this SIEFreach service.

SIEFreach service acceptable.

## IV. DATA AND REFERENCES.

It is mandatory under REACH for all parties within a SIEF to identify all available information on the substance irrespective of their envisaged registration tonnage.

Please indicate whether you own/hold/have access to data relating to the REACH end points specified in the Table below. More details will be requested later from potential registrants in the SIEF who have confirmed that they hold the specified data.

DATA REQUIRED. (Physical Chemical - toxicity - ecotoxicity - environmental fate).	Do you own/hold/have access to this data? Yes / No.	Study Reference (optional but helpful at this time).
<b>PHYSICAL CHEMICAL DATA</b>		
Physical state		
Melting point		
Freezing point		
Boiling point		
Relative density		
Vapour pressure		
Surface tension		
Water solubility		
Partition coefficient in-octanol/water		
Flash-point		
Flammability		
Explosive properties		
Self-ignition temperature		
Oxidising properties		
Granulometry		
Stability in organic solvents		
Identity of relevant degradation products		

# SIEF Code (참여형태)

SIEF Code	권한 및 의무 요약
1) Leading	- 선도등록자
2) Involved	- 적극적 참여, 진도보고서 수령, SIEF운영비용 부담
3) Passive	- 소극적 참여, 진도보고서 수령, SIEF운영비용 부담, Passive 이상은 선택해야 SIEF 동향 등을 수령할 수 있음
4) Dormant	- 정보수령안함, SIEF 운영비용 부담 없음, 동질성확인이 끝난후에는 더 이상 SIEF정보를 제공하지 않음

☐ **LEADING:** This is a substance of high strategic importance for my company and I have available resources to (co-)lead at completion. Main discussions will take place in SIEFreach. For this leading role, we strongly recommend to join SIEFreach.

☐ **INVOLVED:** My company has the intention to register and may be actively involved. Please be informed that the main discussion will take place in SIEFreach. You may benefit from either an 'Active' role or 'Observer' access to key SIEF information.

☐ **PASSIVE:** My company has the intention to register this substance and is interested to receive information about progress in a SIEF, the 'Observer' access will be suited for this level of engagement.

☐ **DORMANT:** My company has no intention to register.

Do you have data relevant for the registration of this substance?

☐ Yes

☐ No

If yes, are these data involving tests on vertebrate animals?

☐ Yes

SIEF Code 조사 사례

# SIEF 설문결과

## Nickel의 SIEF Code 조사 결과

물질명	EC NO.	CAS NO.
Nickel	231-111-4	7440-02-0

구분	참여자수	비율(%)	SIEF Code 분포(%)
사전등록자수	3,889	-	<p>A pie chart illustrating the distribution of SIEF codes among respondents. The chart is divided into four segments: a large green segment for 'Dormant' (90%), a red segment for 'passive' (8%), a small red segment for 'Involved' (1%), and a small blue segment for 'Leading' (1%). A legend to the right of the chart identifies the colors: blue for Leading, red for Involved, red for passive, and green for Dormant.</p>
응답자수	651	17	
SIEF Code	Leading	30	1
	Involved	58	1
	Passive	327	8
	Dormant	3,474	90

# 시험 Data 보유여부 설문

Substance	Zr	
EINECS number	231-176-9	
Name of legal entity		
UUID		
Contact name		
E-mail		
Please, indicate your tonnage band :		
>1000 T	<input type="checkbox"/>	
100 - 1000 T	<input type="checkbox"/>	
10 - 100 T	<input type="checkbox"/>	
1 - 10 T	<input type="checkbox"/>	

Test number	Information requirement	Data Availability		
		My company has access to study report	Reference to data in open literature	Klimish rating (optional)
Physico-chemical tests				
7.1	State of the substance at 20° C and 101,3 kPa	<input type="checkbox"/>		
7.2	Melting/freezing point	<input type="checkbox"/>		
7.3	Boiling point	<input type="checkbox"/>		
7.4	Relative density	<input type="checkbox"/>		
7.5	Vapour pressure	<input type="checkbox"/>		
7.6	Surface tension	<input type="checkbox"/>		
7.7	Water solubility	<input type="checkbox"/>		
7.8	Partition coefficient n-octanol/water, flask shake method	<input type="checkbox"/>		
7.9	Flash-point	<input type="checkbox"/>		
7.10	Flammability, liquids	<input type="checkbox"/>		
7.11	Explosive properties	<input type="checkbox"/>		

# Data Gap 분석 사례

**KEY studies : 1000 ton substance**

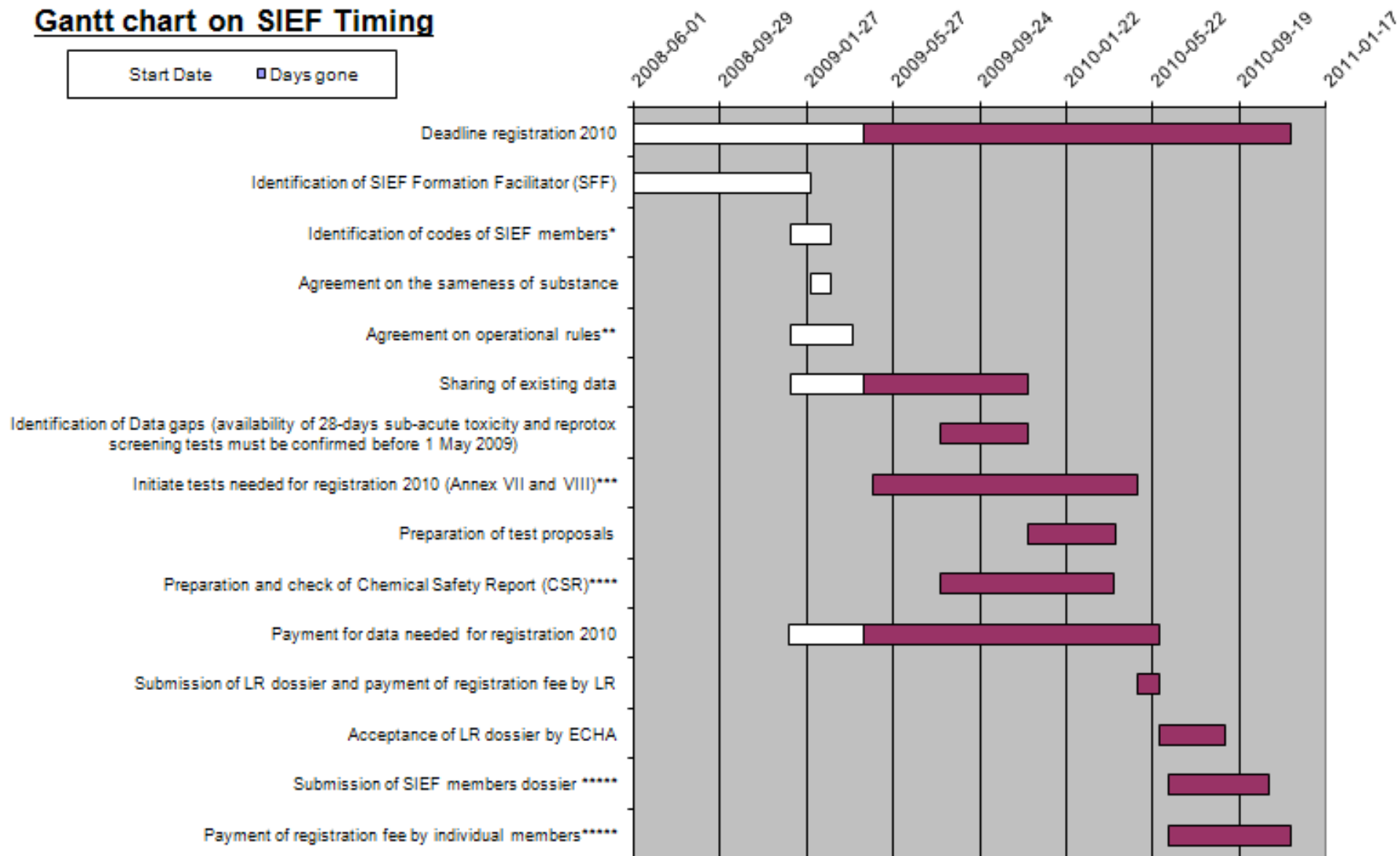
**Data gap analysis for Trisodium hexafluoroaluminate** ↓  
(CAS N° 13775-53-6, EINECS N° 237-410-6).

Annex VII

Study Report	Study reference	klm	Rationale klm
Melting P	"	"	"
Boiling P	"	"	"
Density	"	"	"
Vapour pressure	"	"	"
Surface tension	"	"	"
W. Solubility	Fox, et al. Determination of water solubility including effect of pH, Safepharm lab, Report number 2506-0001, 2008. Sjöberg, Chemical speciation in aqueous Al(3+), F-, OH- systems of relevance to natural waters and body fluids, Opinion, University of Umea, Sweden.	1. 2.	OECD and GLP compliant. Peer reviewed opinion paper.
Flash point	"	"	"
flammability	"	"	"
explosivity	"	"	"
Self ignition	"	"	"
Oxidising properties	"	"	"
Granulometry	"	"	"
Toxicity	"	"	"
toxicokinetics	Largent, Rates of elimination, Arch. Ind. Hyg. Occ. Med. vol 6, 1952. Largent, Metabolism of fluorides in Man, Arch. Ind. Health vol 21, 1960. Grandjean, P. et al, Fluoride, Aluminum and phosphate kinetics, J. Occ. Med. vol 32 (1), 1990. Largent, E., et al., The absorption and excretion of fluorides II, J. Ind. Hyg. Tox. vol. 31 (3), 1949. Largent, E., et al., The absorption and excretion of fluorides III, J. Ind. Hyg. Tox. vol. 31 (3), 1949. Largent, E., The comparative toxicity of cryolite, rats and rabbits, J. Ind. Hyg. Tox.	3. 3. 2. 3. 3. 4.	Volunteer study not acceptable. Fluoride only, Glp unknown. Acceptable method and reporting. Essential parameter inclusion in study missing, (as support only). Essential parameter inclusion in study missing, (as support only). Insufficient detail of protocol and findings.

# SIEF 진행 스케줄

**Gantt chart on SIEF Timing**



# NaOH의 등록 진행 현황 (1/3)



## REACH Status Update



### Sodium hydroxide - NaOH

#### Identification

Name: Sodium hydroxide (caustic soda)  
EINECS 215-185-5  
CAS: 1310-73-2

#### Classification and labelling

Label: C; R35  
CMR 1 or 2: NO  
PBT or vPvB: NO  
SVHC: NO

#### GHS

Skin Corr. 1A H314 GH05  
Dgr

#### Pre-consortium work

Lead companies: Solvay, A Berends (albert.berends@solvay.com)  
Euro Chlor secretariat: D van Wijk (dvw@cefic.be)  
Kick-off meeting: 10 January 2008  
Preliminary agreement finalised: February 2008  
Main consultant: Arcadis (Belgium)

#### REACH status:

- Mainly intermediate and industrial uses, some wide dispersive use
- Annex VII, VIII, IX and X
- No authorisation required



# NaOH의 등록 진행 현황 (2/3)

## Consortium work plan

Final agreement:	< March 2009
SIEF communication with partners:	< April 2009
New partners' signature:	< May 2009
Dossier ready:	< June 2010
Registration:	< July 2010

## Dossier content (Annex VII)

Identity: Mono-constituent (> 80%, impurities <10%)

Classification and labelling C; R35

Available data on phys/chem., health, environment in the form of IUCLID5 dossier: NO (IUCLID4, OECD SIDS, EU RAR available)

Use description: intermediate and various others

Risk management: Done under EU Existing Substances Report

## Available information

IUCLID4, OECD SIDS, EU RAR

## Cost sharing model

Official launch date: 10 January 2008

Membership: manufacturers, importers, only representatives

**No entrance fee before 1 May 2009, late entrants (starting the process of joining after 1 May 2009) to pay pro rata fee plus progressive advantage compensation (20% between May 1st and December 31st 2009, 30% at entry during 2010)**

**Letter of access to non-members: 50% advantage compensation, providing all rights for dossier use**

# NaOH의 등록 진행 현황 (3/3)

## Budget estimation

Secretariat (hours spent and travel)	80,000
Legal support	5,000
Invoicing costs ReachCentrum	10,000
Accounting costs (outsourced)	20,000
Meetings	20,000
Lead Company (hours spent and travel)	80,000
Consultancy	80,000
Technical Committee	35,000
Data sharing	-
Additional studies	-
Total costs	330,000
Estimated costs per company (based on 50 members)	6,600

## Current activities and next steps

Consultant has drafted IUCLID5 and initial exposure scenarios

Consortium Agreement to be signed before 1 March 2009, late entrants to be added before 1 April 2009

# IRON (철)의 등록 진행현황 (1/9)

EC number	CAS number	Name
231-096-4	7439-89-6	iron

## IRON 관련 물질의 사전등록자수

**-Iron**  
(EC No. 231-096-4) : 5,430개 기업

**-Iron, Furnace**  
(EC No.265-998-4) : 380개 기업

**-Iron Ores, Agglomerates [pellets]**  
(EC No. 265-996-3): 78개 기업

**-Iron, Sinter**  
(EC No. 265-997-9) : 73개 기업

**-Diiron trioxide**  
(EC No. 215-168-2): 1,871개 기업

## 설문 사례



### Substance Sameness Survey: Iron, Furnace



Sent to you by the Iron Platform, the REACH consortium for iron and related substances. The Iron Platform is acting on behalf of Rio Tinto plc, the SIEF Formation Facilitator for Iron, Furnace.

The aim of this Survey is two-fold:

- 1) To check 'sameness' of substance, which is the purpose of the Pre-SIEF phase of the REACH registration process.
- 2) To understand the different levels of interest amongst Pre-Registrants in the REACH Registration process. This is necessary in order to develop effective, transparent and cost-effective working practices within the SIEF, and to develop dossier cost formulations for different levels of access, that will minimise the burden for all SIEF members.

If you are an Only Representative, or a company with several legal entities that has pre-registered, please complete a SEPARATE survey for each company/organization you represent.

The closing date for responses to this Survey is \*\*06 MARCH 2009\*\*

#### \* 1. Please provide your contact details below:

Your contact name:   
 Company name:   
 Email Address:   
 Company phone number:

#### \* 2. Please enter the UUID number you received from ECHA when you Pre-Registered on the ECHA REACH-IT website.

#### \* 3. Does your substance match the indicated typical composition for this substance? (See below)

Fe : >90.0 %  
 Si [incl. as SiO<sub>2</sub>] : <4.5 %  
 C : <4.5 %  
 Al, Ca, Mg [incl. as oxides] : <3.0 %  
 Mn : <2.0 %  
 P : <0.2 %  
 S : <0.1 %  
 Other elements : <1.0 %

Physical form :  
 Pig Iron : Ingots  
 HBI : Briquettes  
 DRI : Pellets/lumps

# IRON (철)의 등록 진행현황 (2/9)

## 동질성 확인

- 우측의 IRON의 동질성범위에 포함되어야 공동등록 가능
- IRON은 다른 물질에 비해 사전등록 기업의 수가 많은 관계로 동질성확인 절차가 비교적 늦게 진행됨.
- Iron(EC No. 231-096-4)과 Iron, Furnace(EC No. 265-998-4)는 REACH의 목적상 같은 물질로 볼수 있지만, Sameness(동질성) 및 Classification and Labelling에서 서로 차이가 있을수 있으므로, 일단 2개의 별도 SIEF로 운영하기로 하였음.

그러나 2개 SIEF간의 자료공유 등의 협력은 지속하기로 하였으며, 향후에도 2개 SIEF의 합병에 대한 문제는 지속적으로 논의가 될 예정임.

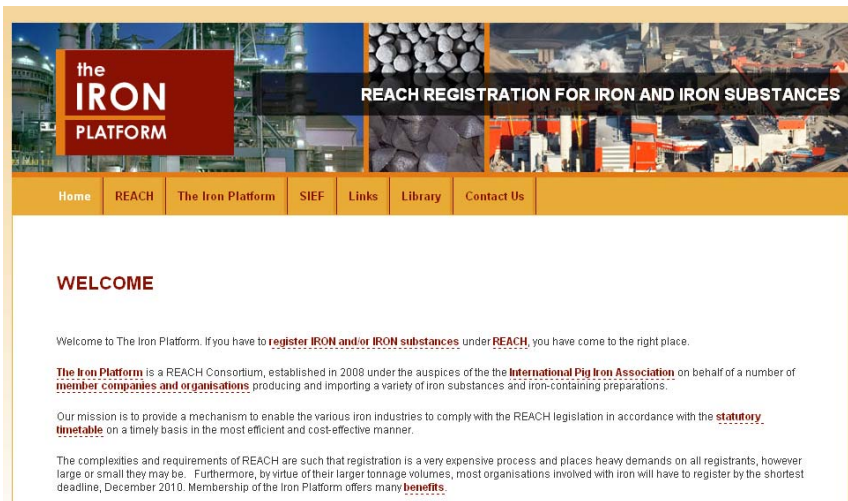
- IRON Platform쪽에서 2개 물질에 대한 Lead Registrant가 되기로 함.

Chemical analysis	Value
Fe	>80.0% up 99.9%
C	< 5%
Si [incl. as SiO <sub>2</sub> ]	< 5%
Ni	< 5%
Cu	< 5%
Mo	< 5%
Al, Ca, Mg [or as oxides]	< 3%
Mn	< 2%
Cr	< 1.5%
P	< 0.2%
S	< 0,1%
Other	<1%

# IRON (철)의 등록 진행현황 (3/9)

## Facilitator 및 컨소시아 현황

- SIEF구성 초기에는 CIRS(Cheical Inspection and Regualtion Service)에서 Facilitator로 등록을 하고, European REACH Joint Submission of IRON이란 컨소시아에서도 등록을 별도로 준비하는등 사전등록자들에게 약간의 혼란이 있었음.
- 현재는 관련 기관들간의 협의를 통해, Facilitator가 Rio Tinto로 변경이 되었으며, IRON Platform에서 Rio Tinto와 함께 주도적으로 본등록 준비를 하고 있음.



IRON Platform 홈페이지



European REACH Joint Submission of IRON 홈페이지

# IRON (철)의 등록 진행현황 (4/9)

## 복수 Facilitator 관련 질의 사례

**From:** Chris & Sue Barrington

**To:** 'KTR Europe GmbH'

**Subject:** RE: SFF?? when will we get information, 231-096-4 iron

Dear Dr. Hoerth:

I understand your frustration - this is not as straightforward as it could be. The Iron Platform is working with the candidate Lead Registrant for di-iron trioxide, Lanxess, and we hope to have a sameness questionnaire out to pre-registrants shortly. At this point we are in process of developing an appropriate specification. Our data gap analysis is nearly complete and Lanxess has moved a long way to completing the registration dossier. Please bear with us! **I have a meeting tomorrow with CIRS in order to try and clarify their position in all this.**

**The company EUROPEAN REACH JOINT SUBMISSION OF IRON has nothing to do with the iron Platform, nor with CIRS as far as I am aware.**

Best wishes

**Chris Barrington**

# IRON (철)의 등록 진행현황 (5/9)

## Iron Platform

- IRON Platform은 2008년에 국제선철협회(IPIA International Pig Iron Association) 주도로 철 및 철을 포함하는 혼합물의 REACH 대응을 위해서 만들어진 컨소시아임.
- 非 컨소시아 회원(SIEF 회원)에게는 Letter of Access(유료)를 제공할 예정임

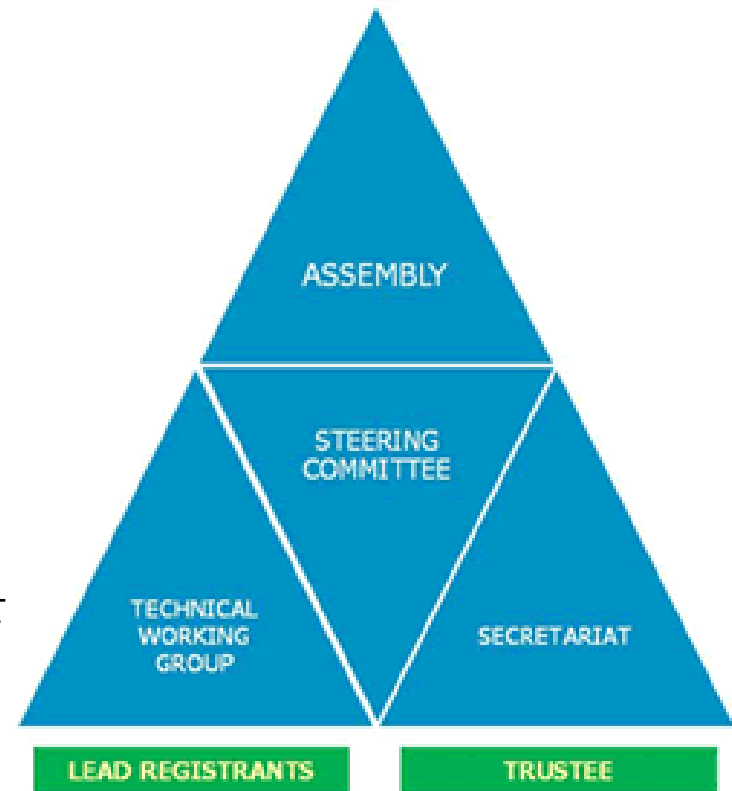
### Iron Platform에서 다루고 있는 물질 범위

Reference name	Formula	EINECS Number	CAS Number
<i>Group I</i>			
Iron	Fe	231-096-4	7439-89-6
Iron, furnace	Fe	265-998-4	65996-67-0
<i>Group II</i>			
Iron (II) oxide	FeO	215-721-8	1345-25-1
Di-iron trioxide (Iron III oxide - haematite)	Fe <sub>2</sub> O <sub>3</sub>	215-168-2	1309-37-1
Iron Ores, Agglomerates	Fe <sub>2</sub> O <sub>3</sub>	265-996-3	65996-65-8
Iron, sinter	Fe <sub>2</sub> O <sub>3</sub>	265-997-9	65996-66-9
Iron (II, III) oxide (magnetite)	Fe <sub>3</sub> O <sub>4</sub>	215-277-5	1317-61-9
Iron (III) oxide hydroxide	FeO(OH)	243-746-4	20344-49-4
Iron (II) hydroxide	Fe(OH) <sub>2</sub>	234-346-0	11113-66-9

# IRON (철)의 등록 진행현황 (6/9)

## Iron Platform 조직

- **총회 (Assembly) :**
  - 최고 의사 결정기구
- **운영위원회 (Steering Committee) :**
  - 일반적인 Platform 운영에 대한 의사결정 기구
- **Technical Working Group**
  - 시험 Data 평가 등을 위한 기술 패널 그룹
- **Trustee :**
  - 운영위원회에서 지정하는 제 3자 독립 업무위탁 기관
- **The Secretariat :**
  - 감사역할 (회의록 작성, 회원연락, 예산집행 등)





# IRON (철)의 등록 진행현황 (7/9)

## Iron Platform 가입비용

- 컨소시아 회원에 대한 비용분담 원칙은 톤수(Pro-rata tonnage)에 따른 비용 부과임.
- 컨소시아는 주로 다음 2가지 방법에 따른 수입으로 운영됨.

### ① 최초가입비

- 300,000 t/y 이상 : 25,000 € (43,000천원)
- 300,000 t/y 미만 : 15,000 € (24,000천원)
- 5,000 t/y 미만 : 7,500 € (13,000천원) → 운영위원회의 승인 필요

### ② 연회비

- 컨소시아 내에서 결정된 톤수(Pro-rata tonnage)에 따라 부과되는 비용 또는 15,000€ 중에서 더 많은 비용을 부과  
(※ 운영위원회에서 승인된 경우 및 5,000 t/y 미만에 한해서는 7,500 €)
- 신규회원 가입등에 따른 수입을 고려하여 연말에 비용이 최종적으로 조정됨.

※ 2009.3.31일 이후의 정회원 가입자는 일반적인 분담금액에서 25%를 추가적으로 부담해야 함.

# IRON (철)의 등록 진행현황 (8/9)

## Iron Platform 진행 스케줄

IRON PLATFORM ROADMAP												
Task	2008	2009					2010					
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Deal with pre-registration issues	■											
Data gap analysis	■	■										
Pre-SIEF management: sameness, lead registrant		■	■									
Preparation for testing: identify labs/book capacity		■	■	■								
Preparation for testing: prepare test material		■	■	■								
Review data and determine test strategy		■	■	■								
Life cycle description		■	■	■								
Develop questionnaire for ES		■	■	■								
Compilation of identified uses + exposure scenarios			■	■	■	■						
Determine/validate analytical methods			■	■								
Entry of existing data to IUCLID5 file			■	■	■							
SIEF: agreement on co-operation and data sharing			■	■	■							
Agreement on classification and labelling			■	■	■	■	■					
Initial PNEC and DNEL derivation					■	■						
Iterative environmental risk assessment/testing					■	■	■	■	■	■		
Iterative human health risk assessment/testing					■	■	■	■	■	■		
Preparation of draft Chemical Safety Reports						■	■	■	■			
Additional testing as necessary						■	■	■	■			
Additional exposure measurements as necessary						■	■	■	■			
Develop refined Exposure Scenarios										■	■	
Update IUCLID5 file											■	■
Review Classification and Labelling											■	■
Finalise Chemical Safety Reports											■	■
Submission of registration dossiers												■

# IRON (철)의 등록 진행현황 (9/9)

## Letter of Access 포맷

### LETTER OF ACCESS FOR REFERRAL

European Chemicals Agency  
Helsinki, Finland

**Letter of Access for the Registration of the Substance .....[insert the short name of the Substance to be Registered]** under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisations and Restrictions of Chemicals, hereinafter “**REACH**”.

Dear Sirs,

The Platform<sup>1</sup> for the Registration of the Substance ..... [insert the short name of the Substance to be Registered] under **REACH** (hereinafter referred to as "the Platform") agrees that the data, Studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments specified in detail below owned by Members of the Platform and submitted by the Platform in support of the Registration under **REACH** of Substance ..... [insert the exact name of the Substance to be Registered] (hereinafter collectively referred to as the “Dossier”), may be referred by Applicant: *Company XYZ* in order to support Applicant's Registration of the above mentioned Substance under **REACH**.

The Dossier covers documents as follows: [if reference is restricted to certain parts of the Dossier insert exact name of the data, Studies, summaries, waiving arguments, testing proposals and/or assessments]

The right to refer to the Dossier is subject to the following restrictions:

1. The right of referral is only in respect of the Dossier of the Substance for the Registration as specified above.
2. The right of referral is granted solely in favour of *Company XYZ* and is not transferable or assignable to any other entity or person.
3. *Company XYZ* is not authorised to receive any copies of the Dossier nor is *Company XYZ* authorised to inspect or view the Dossier or any related specific document in whole or in part.
4. This Letter of Access shall in no event be construed as granting *Company XYZ* any property or other rights whatsoever in the Dossier or any part thereof.
5. Nothing in this letter shall require the Platform to file any additional data.

**Signature: [Authorized Representative of the Platform]**

# TiO<sub>2</sub> 사례(1/2)

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- TiO<sub>2</sub> 컨소시아(Titanium Dioxide Industry Consortium)에서는 REACH 등록을 위한 Data Gap 분석을 완료하고 추가적으로 필요한 시험을 진행 중에 있음.
- TiO<sub>2</sub>에 대한 시험결과등을 종합하여 검토한 결과, TiO<sub>2</sub>는 유해하지 않은 물질에 해당하는 것으로 나타남.
- TiO<sub>2</sub> 컨소시아에서 기존 시험 Data 및 잠재적인 등록자수 등을 종합적으로 검토한 결과 다음과 같은 톤수별 Letter of Access 비용을 발표함.

# TiO2 사례(2/2)

## Letter of Access 비용

\* 환율 1,700원/1€ 기준

- CSR을 포함한 총 등록서류 준비에 소요된 비용 (1,000t/y 이상 등록서류)
  - 3,000,000 € (약 51억원)
- TiO2 Letter of Access 구입 예상 기업
  - 1,000 t/年 이상 : 25개 기업
  - 100~1,000 t/年 : 50개 기업
  - 100 t/年 이하 : 불확실성이 너무 커서 예측하기 어려움
- TiO2 Letter of Access 비용 (Legal entity 수가 아닌 Company별로 지불)
  - **1,000 t/年 이상 : 60,000 € (약 1억원)**
  - **100~1,000 t/年 : 30,000 € (약 5천만원)**
  - **10~100 t/年 : 15,000 € (약 2천5백만원)**
  - **1~10 t/年 : 3,000 € (약 5백만원)**

# LOA (Letter of Access) 비용 사례

EC No.	물질명	LOA 비용 (단위 : Euro)	비고
201-143-3	Isoprene	- 10,000 (전체 등록서류, Full Dossier) - 5,000 (중간체 등록 서류)	LOA REACH CONSORTIUM
204-066-3	2-methylpropene	- 20,000 (전체 등록서류) - 10,000 (중간체 등록 서류)	LOA REACH CONSORTIUM
206-991-8	SiC	- 10,000 (전체 등록 서류) (2009.05.31 이후 delay fee 적용)	Silicon Carbide Manufacturers Association

# Carbon black 본등록 완료

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## ☐ Status of Registration

The comprehensive registration dossier for the substance Carbon Black, covering the data requirements of Annexes VII – X of the Regulation, has already been successfully submitted to the ECHA, Helsinki, by the Consortium's Lead Registrant Evonik Degussa GmbH. The dossier was approved by the European Chemicals Agency on April 28, 2009 and the lead registrant has received a registration number.

## ☐ Options to cooperate

The CB4REACH Consortium invites every party interested in the registration of Carbon Black to participate in the Joint Submission of the Consortium. The Consortium will provide a complete registration package, including a Letter of Access to the technical part of the dossier (parts 4 – 13), a prepared template of the company specific part of the dossier (parts 0 – 3, except CBI), and the Chemical Safety Report at a reasonable cost. Please bear in mind that the Letter of Access refers to an already approved registration dossier.

### III EU의 REACH 집행 및 제재방안





# REACH 각 국가별 Penalty (1/2)

EU 국가	PENALTIES	LEGISLATION
벨기에	- 벌금 : EUR 52 ~ 4,000,000, 금고형 : 8일 ~ 3 years	
체코	- 벌금 : CZK 500,000 ~ CZK 5,000,000	
덴마크	- 2년 이하의 금고형	Chemical substances and products Act no. 175
핀란드	- 벌금 또는 2년 이하의 금고형	Chemical Act No. 744/1989 and Penal Code of Finland No. 39/1889
독일	- EUR 50,000 이하의 벌금이나 1년 이하의 금고형 - EUR 100,000 이하의 벌금이나 5년 이하의 금고형 (인명 사고를 동반하는 경우)	
헝가리	- HUF 50,000 ~ 20,000,000	Government decree on chemical load penalty
네델란드	- 최대 670,000 EUR 까지의 벌금 또는 6년 이하의 금고형	Economic Offences Act
슬로바키아	- 벌금 : EUR 9,958 ~ 99,582	Act No. 405/ 2008

# REACH 각 국가별 Penalty (2/2)

## 프랑스

- 2년 이하의 금고 또는 75,000유로 이하의 벌금
- 정확한 SDS를 제공하지 않을 때에는 3개월 이하의 금고 또는 20,000유로 이하의

벌금

## 스웨덴

위반사항	제재조치
등록하지 않은 경우	벌금 또는 2년 이하의 금고형
잘못된 정보로 물질을 등록하는 경우	
SDS를 물질 또는 혼합물 수령자에게 제공하지 않는 경우 SDS에 틀리거나 충분하지 않은 정보를 제공하는 경우	벌금 또는 2년 이하의 금고형
스웨덴어로 SDS를 제공하지 않을 경우	5,000 SEK

# REACH 집행(Enforcement) 프로젝트 시행

- REACH-EN-FORCE-1(공동 REACH 집행 프로젝트)가 유럽 전역에서 시행됨 (09.4.30 ECHA Press Release)
- 각 국가 **Inspector**는 기존물질을 집중적으로 기업들이 사전등록이나 등록서류를 제출했는지를 확인하고 필요한 경우 SDS가 제공되었는지를 확인
- 위 프로젝트로 인해 REACH 집행 기관(enforcement authorities)의 권한이 강화될 것으로 예상됨.
- 프로젝트 결과는 2009년 말에 취합되어 2010년 초에 리포트로 발행될 예정임.
- 각 국가 세관과 협력 예정

## Press Release:

ECHA/PR/09/05

Helsinki, 30 April 2009

### FIRST COORDINATED REACH ENFORCEMENT PROJECT STARTED

REACH-EN-FORCE-1, a joint REACH enforcement project, has started across Europe. National inspectors are checking pre-registrations, registrations and – where applicable – the provisions for Safety Data Sheets. The Forum for Exchange of Information on Enforcement, meeting for the fourth time this week in Helsinki, reviewed the start of the project and agreed on the further steps.

The enforcement project of the Forum enforces the core principle of REACH: *no data, no market*. Inspectors in the participating countries will focus on the phase-in substances (existing substances) and check through inspections whether companies have submitted a pre-registration or a registration and, where necessary, whether a Safety Data Sheet has been supplied.

The project will thus give a first impression of the level of compliance by manufacturers and importers (including only representatives) with REACH in the European Union and European Economic Area. At the same time, the capacity of the enforcement authorities to enforce REACH will be enhanced.

A designated national coordinator will oversee the implementation of the project in each participating country and provide training for local inspectors. For that purpose, the national coordinators were trained by the Forum Working Group at ECHA's premises earlier in April.

The results of the project will be collected by the end of 2009 and the Forum Working Group will analyse the results and produce a report in early 2010.

The Forum is also preparing a second coordinated project to be launched in 2010.

## IV SIEF 대응방안



# SIEF 대응방안

## 해당 SIEF의 진행 상황 파악

- Facilitator 및 Lead Registrant 선임 여부 등
  - Facilitator라고 모두 등록 의사가 있는 것은 아님.
- 활동상황이 전혀 없는 경우, Facilitator에게 진행계획등에 대한 문의

## 신뢰성 있는 컨소시아 선택

- 각종 협회, 단체 등이 가입된 컨소시아를 선택
- 일반적으로 高 Tonnage는 컨소시아 가입, 低 Tonnage는 Letter of Access를 통해 등록하는것을 권고하지만, 개별 SIEF/컨소시아의 특성에 따른 결정이 필요함.
- 아직 Letter of Access에 대한 비용은 거의 나와 있지 않음.

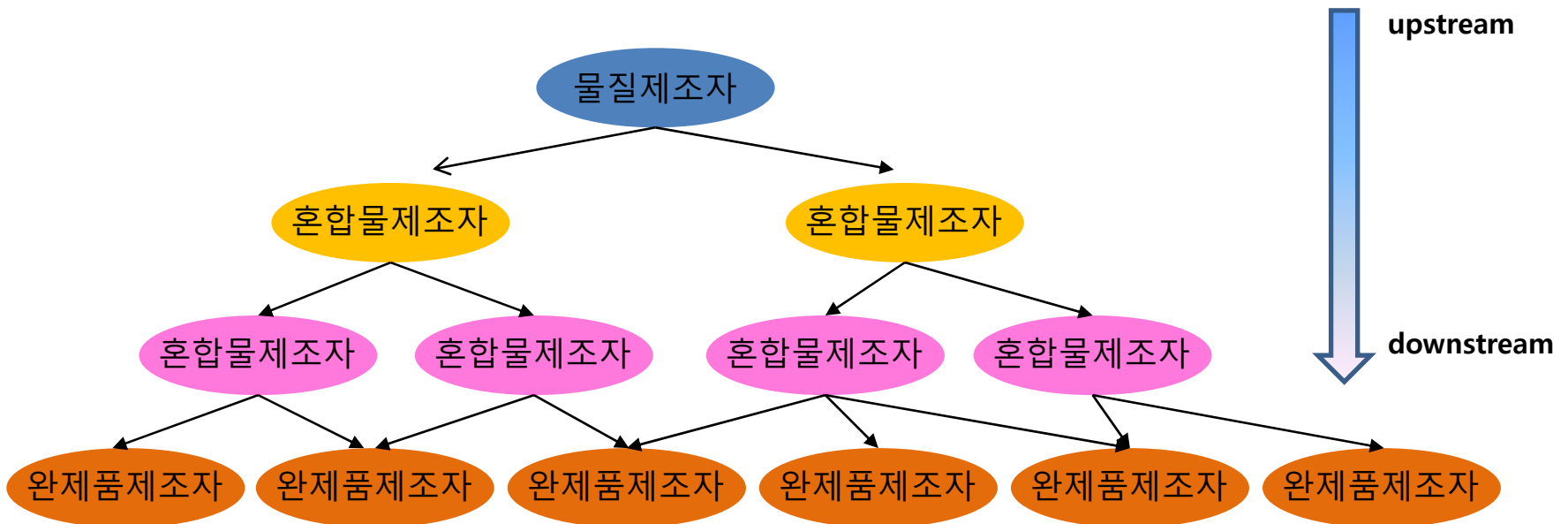
## Lead Registrant 및 Joint submission

- Lead Registrant가 등록서류를 제출하기 전까지 대기
- Joint submission List에 포함이 되었는지를 확인
- 최종 등록서류 제출후 등록번호를 받기까지 최소 3주 이상 소요되는 점을 고려

# 결론

The clock  
is ticking

- 공급망 상에서 누가 등록을 할 것인지?
- 컨소시엄에 가입할 것인지? 참조권(Letter of Access)를 이용할 것인지?
- 적극적으로 REACH 대응



# 감사합니다.

문의사항이 있으신 경우에는 다음 연락처로 연락주시기 바랍니다.

- 한국화학시험연구원(KTR) 양영길 선임연구원

-Email : [ygyang@ktr.or.kr](mailto:ygyang@ktr.or.kr) - Tel : 02)2164-0037