



Case study On Registration process of EFC products under REACH

Presented by

Chem. Ahmed Moawad

REACH coordinator

October 2009



C.V. Form



Name: Ahmed Moawad Hibah

Position: Safety Section Mgr

Company: Egyptian Fertilizers Company

Academic background:

- B.SC. Degree, chemistry, faculty of science.
- **Certified NEBOSH** (National Examination Board for Occupational Safety & Health) UK
- Certified team lead auditor for OHSAS 18001-Mgt system
- platinum – OSHA certified. USA

Membership:

International member, the American Society of Safety

Robust Summary

- EFC in brief
- **REACH introduction**
- **REACH team work of EFC**
- **REACH awareness and competences**
- Only Representative selection
- **pre-registration**
- **Registration stages**
 - SIEF Management OR 100124
 - **SIEF code**
 - **Join registration**
 - **LR voting**
 - **Substance identity**
 - **Data availability**
 - **Registration dossier**





Image © 2009 DigitalGlobe

2009 Google
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37°29'43.63"شمالاً 3°32'55.26"شرقياً

ارتفاع: 400 متر (1312 قدم) 5 آذار (مارس) 2005







EFC in brief

- The Egyptian fertilizers Company, EFC, one of the pioneer fertilizers companies in Egypt.
- EFC's main product is granular urea, the most commonly used Nitrogen fertilizer in developing countries.
- **Daily Production:**
 - 2400 Ton / Day (Ammonia) **EFC I&II**
 - 3500 Ton / Day (Urea) **EFC I&II**

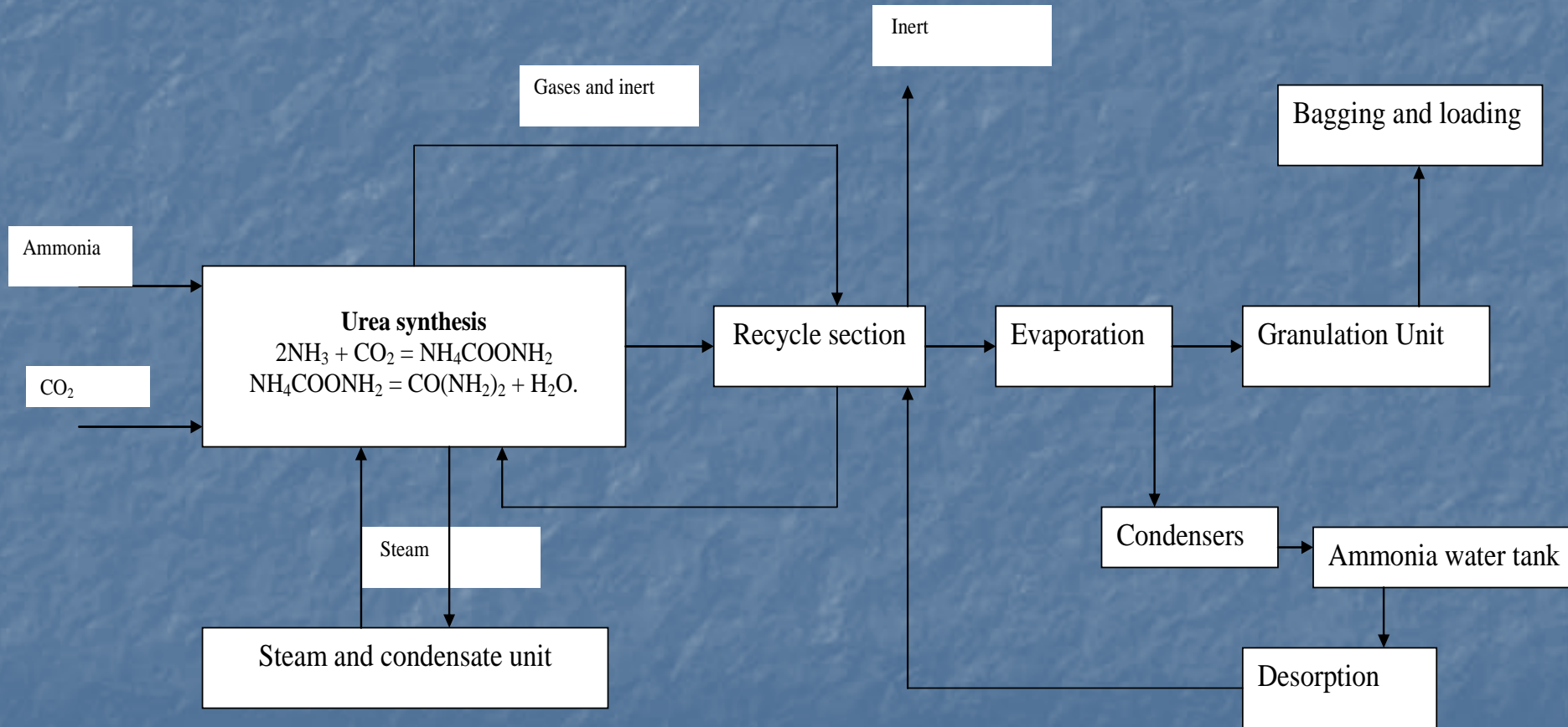


EFC Plants Overall Technology and Production Systems

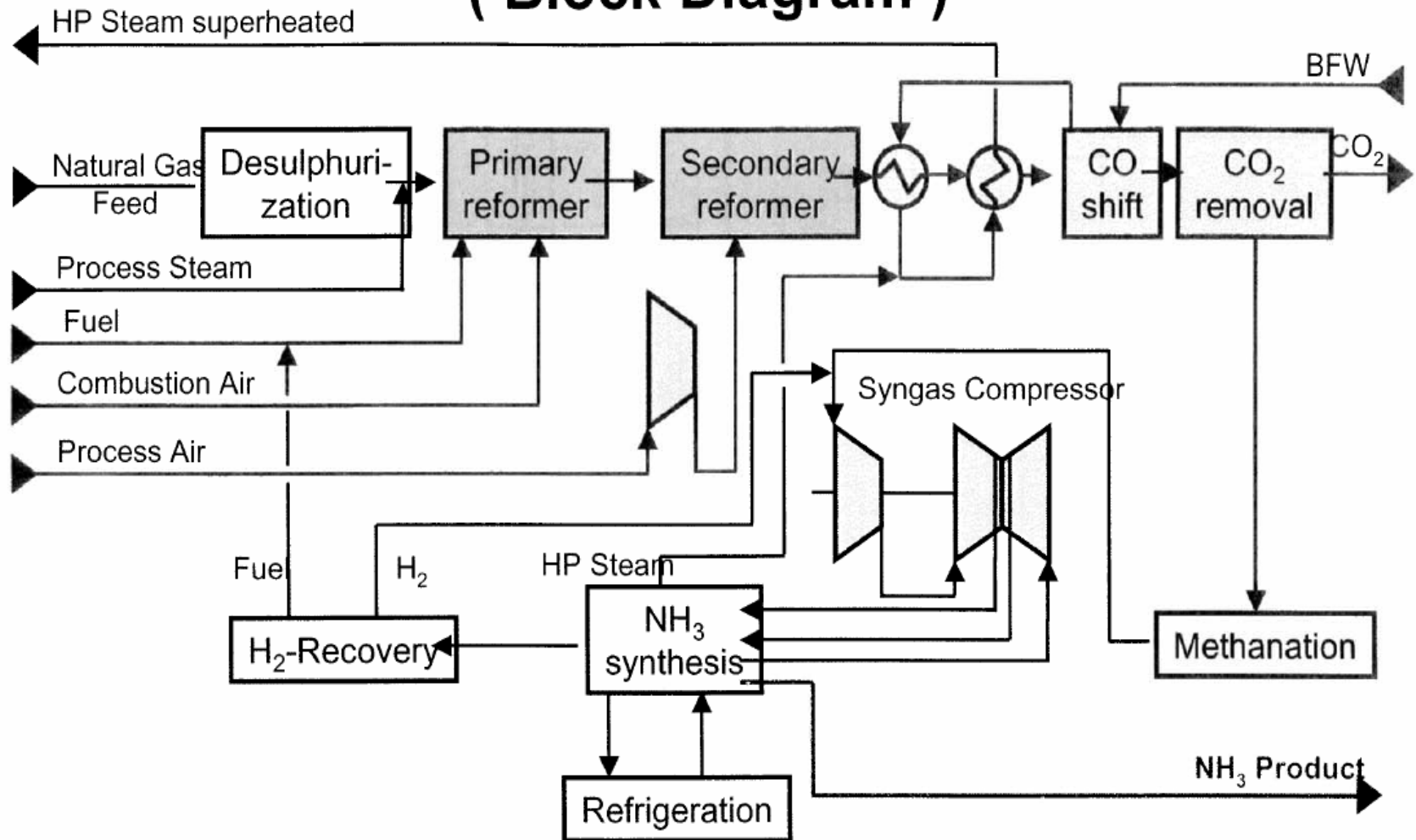
EFC has two production trains as follows:

- a. Train I:** Ammonia/Urea plant with the following processes:
Ammonia Plant with Haber-Bosch process and Krupp Uhde license.
Urea plant with:
"Stamicarbon" CO₂ stripping total recycle process for synthesis section.
"Hydro Agri (Yara)" Process for Granulation Section.
- b. Train II:** Ammonia/Urea plant with the following processes:
Ammonia Plant with Haber-Bosch process and Krupp Uhde license.
Urea plant with:
"Stamicarbon" CO₂ stripping total recycle process for synthesis section.
"Stamicarbon" Process for Granulation Section.

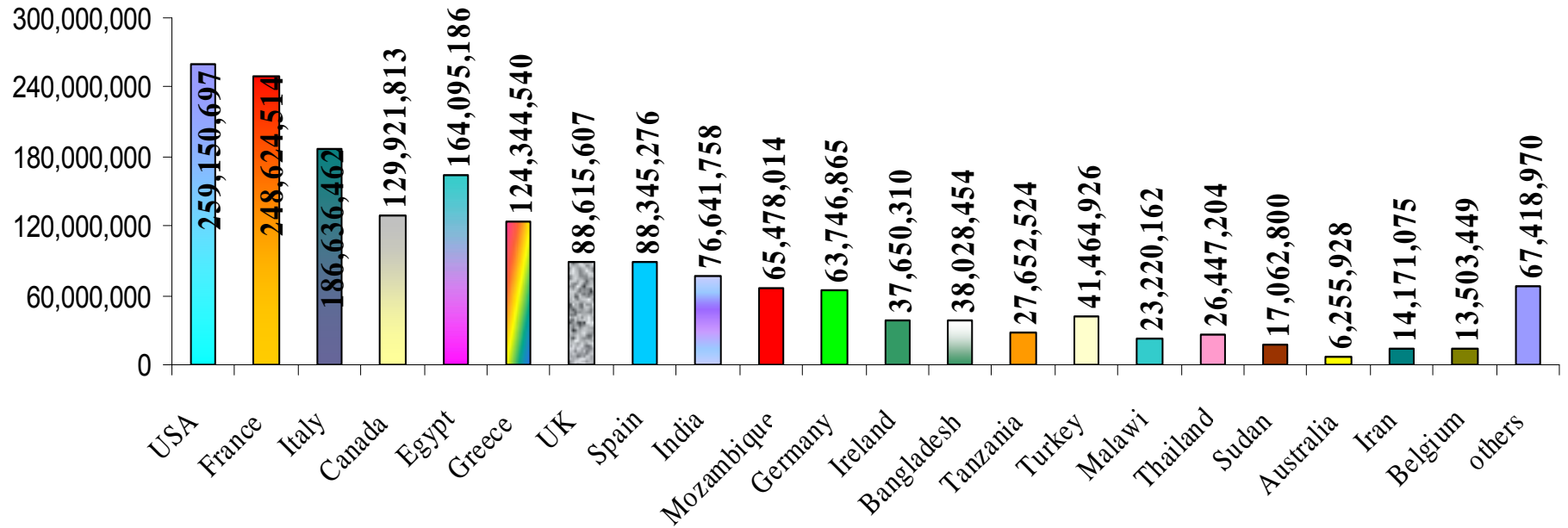
Simple block diagram for the Urea plant



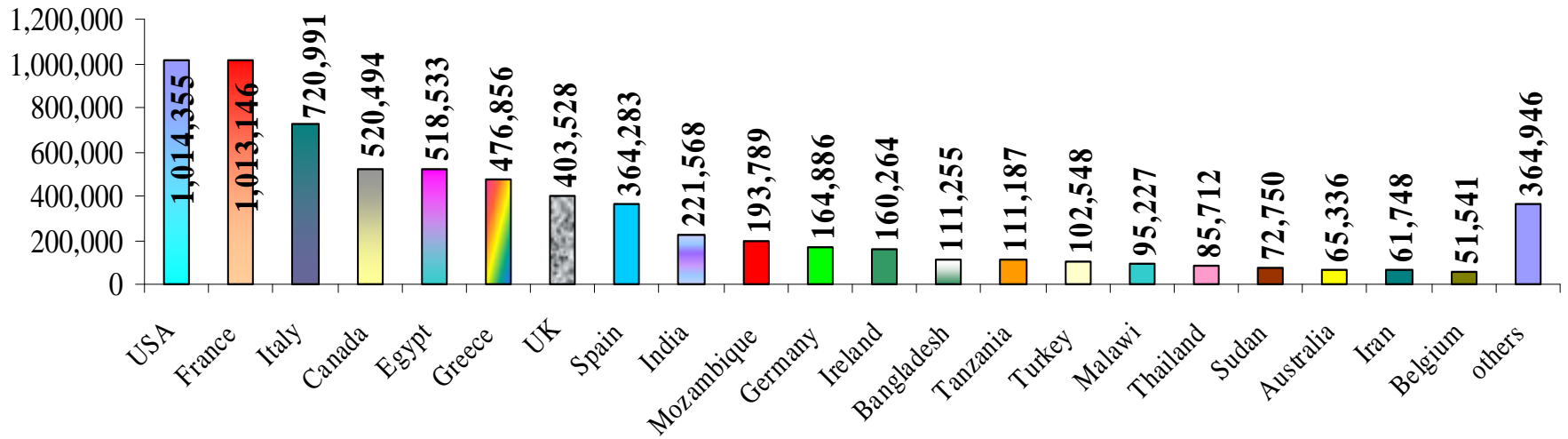
Ammonia Plant (Block Diagram)



Value/USD



Quantity/ton





Spirit of REACH

no data no market

Ensure all chemicals are identified and adequately assessed to enable communication of hazards and to enable the determination of suitable risk management measures



REACH

- REACH is the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals. It improves the former legislative framework on chemicals of the European Union (EU).



Objectives

- Improve the protection of human health and the environment from the risks that can be posed by chemicals.



Why REACH?

- REACH has been designed not to overlap or conflict with the other chemical legislation



How will REACH work?

- REACH makes industry most responsible to manage the risks posed by chemicals and provide appropriate safety information to their users



What is scope covers?

- REACH is very wide in its scope covering all substances whether manufactured, imported, used as intermediates or placed on the market, either on their own, in preparations or in articles. Other substances are exempted from parts of REACH, where other equivalent legislation applies.



REACH - **five parts**

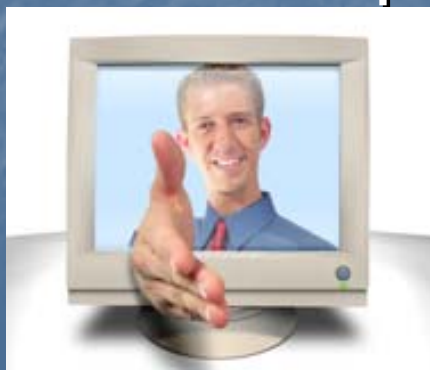
- Registration - Filling in forms
- Evaluation of hazards - CLP Regulation
- Identification of risk - Use in relation to hazard
- Control of risk - Restriction and Authorisation
- SDS Writing - Communication





How to apply the REACH elements to implement together the regulations?

- EFC consulted and communicated with the Federation of Egyptian Industries (FEI) to determine the honest agent in local or foreign (only representative). To implement the basic requirements.





What are the advantages of pre registration?

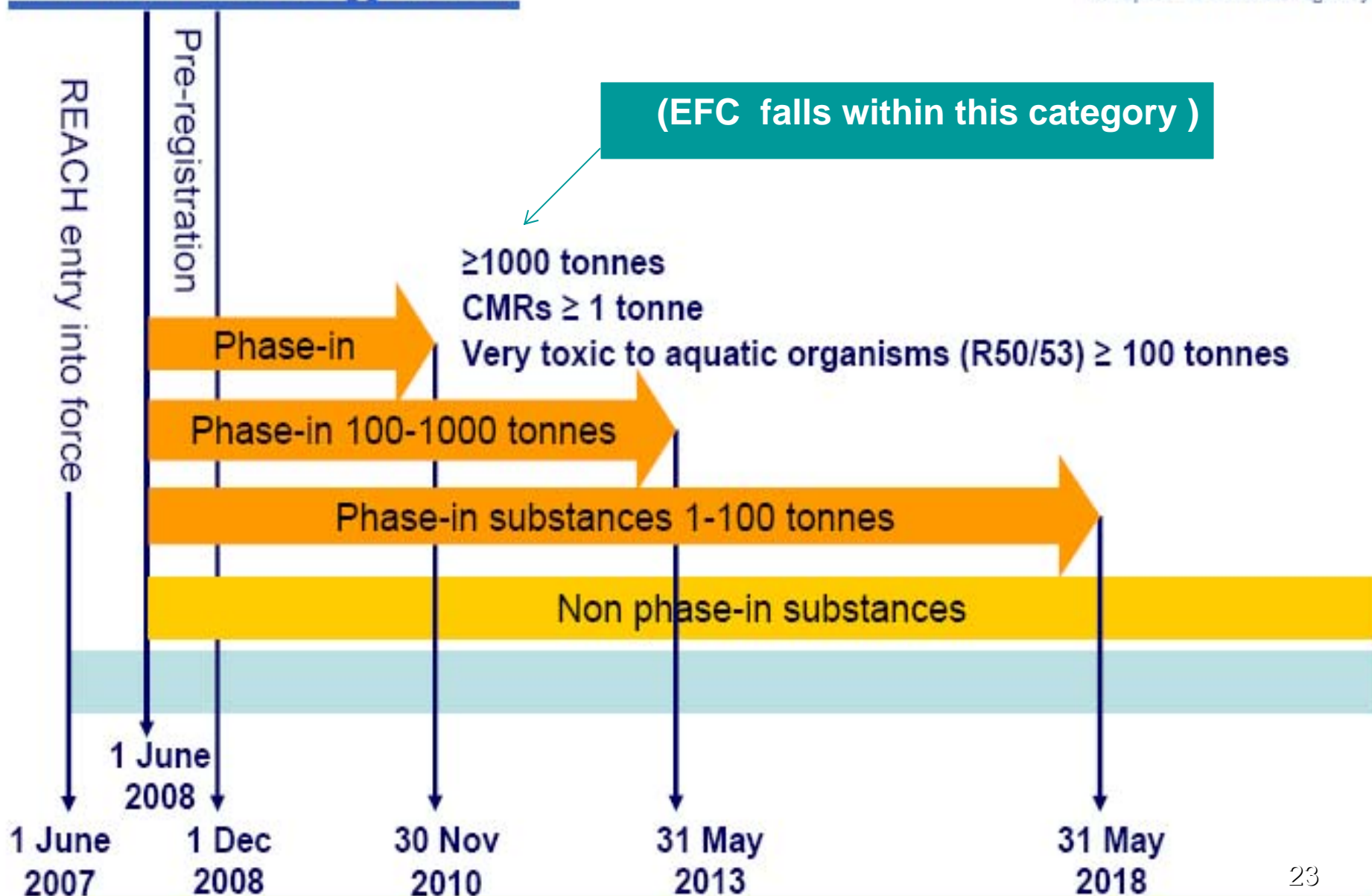
- Besides the fact that pre-registration allows companies to benefit from extended registration deadlines, it also allows industry to adapt gradually to the new system.



What is meant with extended registration deadlines?

- Article 23 of the REACH Regulation provides for a scheme with staggered registration deadlines for so-called 'phase-in substances', depending on the tonnage band and hazards of the substance:

When to register

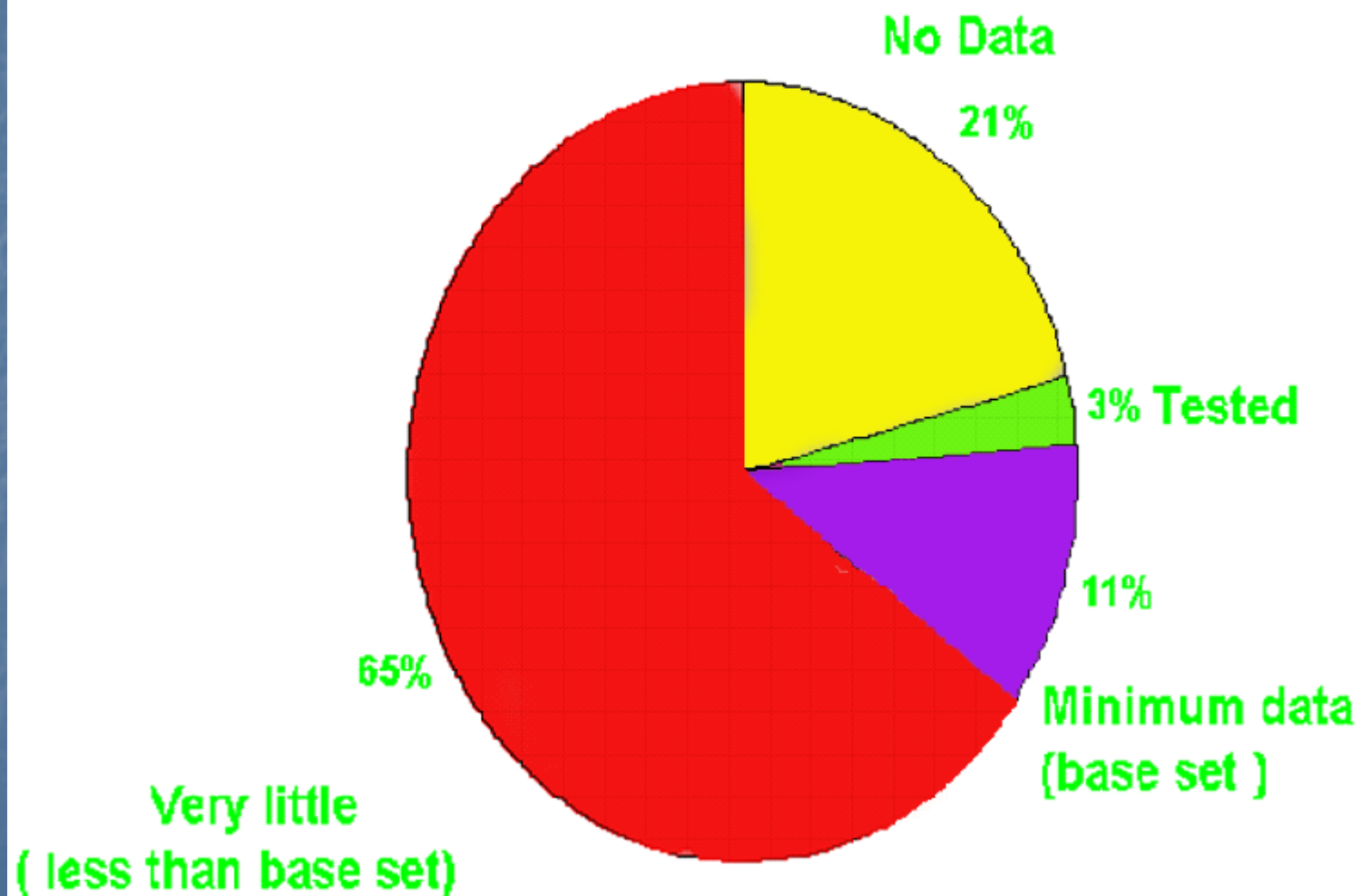


Internet

Information on chemical may differ depending on who has published

- Industry group?
- Environmental lobby group?
- Academic, sponsored by industry?
- Academic, sponsored by environment group?
- NGO SINlist ? (www.sinlist.org)

Information about high - volume chemicals



ECHA publications prepared to help use
and assess existing data

- [illegible]



How EFC can prepare for

Main steps :

1. **Identify within EFC who will be responsible for REACH compliance**
2. **Create an inventory of all substances**
3. **Collect available information**
4. **Locate other relevant information holders**
5. **Share Data**
6. **Chemical Safety Assessment and write Chemical Safety Report**
7. **Compile Registration Dossier**



REACH team work of EFC

A project team is formed for handling of the REACH requirements,

- **Mr. Ahmed Saeed**

is assigned as the team leader and

- **Mr. Ahmed Moawad**

is assigned as coordinator who will follow the progress of registration until attaining the authorization.



Egyptian Fertilizers Company SAE

Minutes of Meeting

Date: 6/8/08

Time: 11:00 am

Place: plant GM office

Called by: Plant General Manager

For Information:

Subject: kick of meeting for fulfillment the requirements of REACH regulations

Attendance :

Name:

Title

Hossam Khattab

Plant General Manager

Ahmed Saeed

Production General Manager

Ezz El Din Shaaban

Lab Department Manager

Ahmed Moawad

Safety Section Head

Moheb Basta

Production Control Section Head



REACH awareness and competency

- Attended all seminars ,workshops regarding REACH issues
- Attended and passed master level accredited training course in UK on "Postgraduate Certificate of Competence in REACH Registration".





THIS IS TO CERTIFY THAT

AHMED HEIBA

Egyptian Fertilizers Company

HAS SUCCESSFULLY COMPLETED

**POSTGRADUATE CERTIFICATE OF COMPETENCE IN REACH
REGISTRATION**

Module 2: REACH: Scientific and Technical Foundation

THURSDAY 10TH SEPTEMBER 2009

PROGRAMME MANAGER

SENIOR SCIENTIFIC AND
REGULATORY CONSULTANT





Only representative

[Article 8]

- Non-EU companies can appoint an “only representative”, who takes over all responsibilities of an EU-importer
- The importers in the same supply chain shall be informed of the appointment. They shall be considered downstream users.
- Only representatives can be appointed by a legal or natural person outside of the EU that
 - manufactures a substance (to be used on its own, in preparations and/or to produce articles),
 - formulates preparations or,
 - produces articles
- carry out the required registration of their substances that are imported into the Community.
- required to have sufficient background in the practical handling of substances and the information related to them.
- must submit a separate registration dossier for each non-EU manufacturer they represent
- When the only representative submits the registration(s) he is advised to submit copy(-ies) of the letter(s) officially assigning him.



**The only representative
takes over all obligations
of the importer under
REACH!**



Only Representative selection

- EFC opted **The Reach Center TRC**, that operating under the department of environment of Lancaster University in the UK, to undertake the Only Representative duties for EFC defined within the meaning of regulation (EC) No.1907/2006 of European parliament and council concerning **REACH**.



IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate by placing their signatures, and each party shall keep one copy of the originals.

the REACH CENTRE

REACH ONLY REPRESENTATIVE APPOINTMENT REQUEST & ACCEPTANCE AGREEMENT


REQUEST

I hereby confirm that Egyptian Fertilizer Company wishes to place individual orders on The REACH Centre Limited, for the services as defined in the 'Only Representative Agreement', dated 13th October 2008, and appoint The REACH Centre Limited as the Only Representative within the meaning of Regulation (EC) No. 1907/2006 of the European Parliament and council for the substances listed in the 'ONLY REPRESENTATIVE SUBSTANCE LIST'.

Company name: Egyptian Fertilizer Company

Department: Safety Section

Address: Industrial Zone, Ain Sokhna, Egypt


Signed: 

Name: Ahmed Moawad Mohamed Hibah

Date: 13th Oct 2008

ACCEPTED

I hereby confirm that The REACH Centre Limited accepts to undertake the Only Representative duties for Egyptian Fertilizer Company defined within the meaning of Regulation (EC) No 1907/2006 of the European Parliament and council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) for the substances accepted in the 'ONLY REPRESENTATIVE SUBSTANCE LIST'.

Signed: 

Name: Jonathan Lutwyche

Date: 13th Oct 2008

For office use only



Costs of registration and data generation?

PRICES

Prices per Substance (€Euro)**	Substances (<10 tpa*)	No. of Substances (>10 tpa*)				Terms
		1 - 9	10 - 99	100-999	1000+	
Initial Setup	500	1,500	1,350	1,275	1,200	payable in advance of pre-registration
Registration Submission	250	500	450	425	400	payable in advance of registration
Management & Communication	250	500	450	425	400	annual fee commencing Jan 2009
Pre-SIEF & SIEF Representation	120 per hour					
ECHA fees	ECHA Fees + 10% management fee					payable in advance

Tonnes per annum

** Prices are indicative and do not constitute an offer. TRC reserves the right to amend these prices which in all cases must be subject to quotation and formal acceptance of order by TRC.



Schedule D

Additional Services and Prices (TRC charges to the Client)

*All costs given are indicative and subject to confirmation

Service	Estimated Minimum Cost	Comments and variables	Cost for checking and TRC commission if the Client carries out the task
Registration: this is a date from TRC acting as OR.	1. £140 2. £122/hour 3. £300	1. Good quality data received in appropriate format for pre-registration. 2. Analysis and discussions needed. 3. Reliable substance identity information received. This would be relevant, for example, when helping an importer in the EU from a Japanese company prepare their registration as an importer (not an OR).	1. £30 2. £25/hr 3. £60
Data collection (incl. literature search) and evaluation	£3,500	For example, advance preparation for SIEFs, ahead of registration of non phase-in substances or un pre-registered non phase-in substances	£700
Gap analysis and recommendations to fill	£1,250 – 2,500	Depends on complexity of case. Low volumes will normally be at the low cost end of the spectrum.	£250 – 500
Gap programme recommendation	£1,250 – 2,500	Depends on complexity of case.	£250 – 500
Management of testing programme	£122/hour		£25/hr
Registration: Phase-In Substances		After SIEF deliberations for phase-in substances or data collection and evaluation for non phase-in substances (or un pre-registered phase-in substances)	
1st	£7,500 (£5,000 if reduced registration requirements)	'Lead' registrant	£1500 (£1000)
2nd	£11,000	'Lead' registrant	£2300
3rd	£18,000	'Lead' registrant	£3300
4th	£22,000	'Lead' registrant	£4500
5th	£2500 per use £122/hour for subsequent related work	Depends on number of uses, generic or specific, complexity, and number of 'joint' registrants.	£500 per use £25/hr
1st	£1,500	'Joint' registrant	£300
2nd	£2,500	'Joint' registrant	£500
3rd	£3,500	'Joint' registrant	£700
4th	£4,500	'Joint' registrant	£900
Writing registrations SRs prepared by client.	£2,000 + £122/hour for subsequent related work.	The £2,000 figure relates to completeness and English language checks (if appropriate). Detailed technical checking would be on an hourly basis.	£500 £25/hr

* Any travel and accommodation costs (e.g. to attend SIEF meetings) will be additional; hotels, flights, travel (50% of normal hourly rate).



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pre-registration

- EFC acquired the pre-registration of two chemical substances at the European Chemical Agency (ECHA) under REACH regulations

Commercial name	chemical name	CAS / EINECS number	pre-registration no. under REACH
Anhydrous Ammonia	Ammonia	7664 – 41 – 7 231 – 635 – 3	05-2116382693-35-0000
Urea	Carbonyldiamide	57 – 13 – 6 200 - 315 - 5	05-2116382654-37-0000



EFC Registration stages

- SIEF Management OR 100124
- SIEF code
- Join registration
- LR voting
- Substance identity or characterization
- Data availability
- Registration dossier



Data Sharing & Substance Information Exchange Forum (SIEF)

- To limit vertebrate animal testing as far as possible, while balancing that with the generation of necessary information to identify the hazard of substances.



SIEF Management OR 100124

- SIEF code
- Join registration
- LR voting
- Substance identity
- Data availability
- Registration dossier



People on this project

Egyptian Fertilizers Co



Egyptian Fertilizers Co



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ataha@eco-fei.net


Ahmed Moawad

safety section manager

moawad67@gmail.com

M: 0020101727405

F: 0020623710312

[Edit](#)


Moheb Basta

moheb.basta@orascomci.com

The REACH Centre



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Administrator



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Administrator



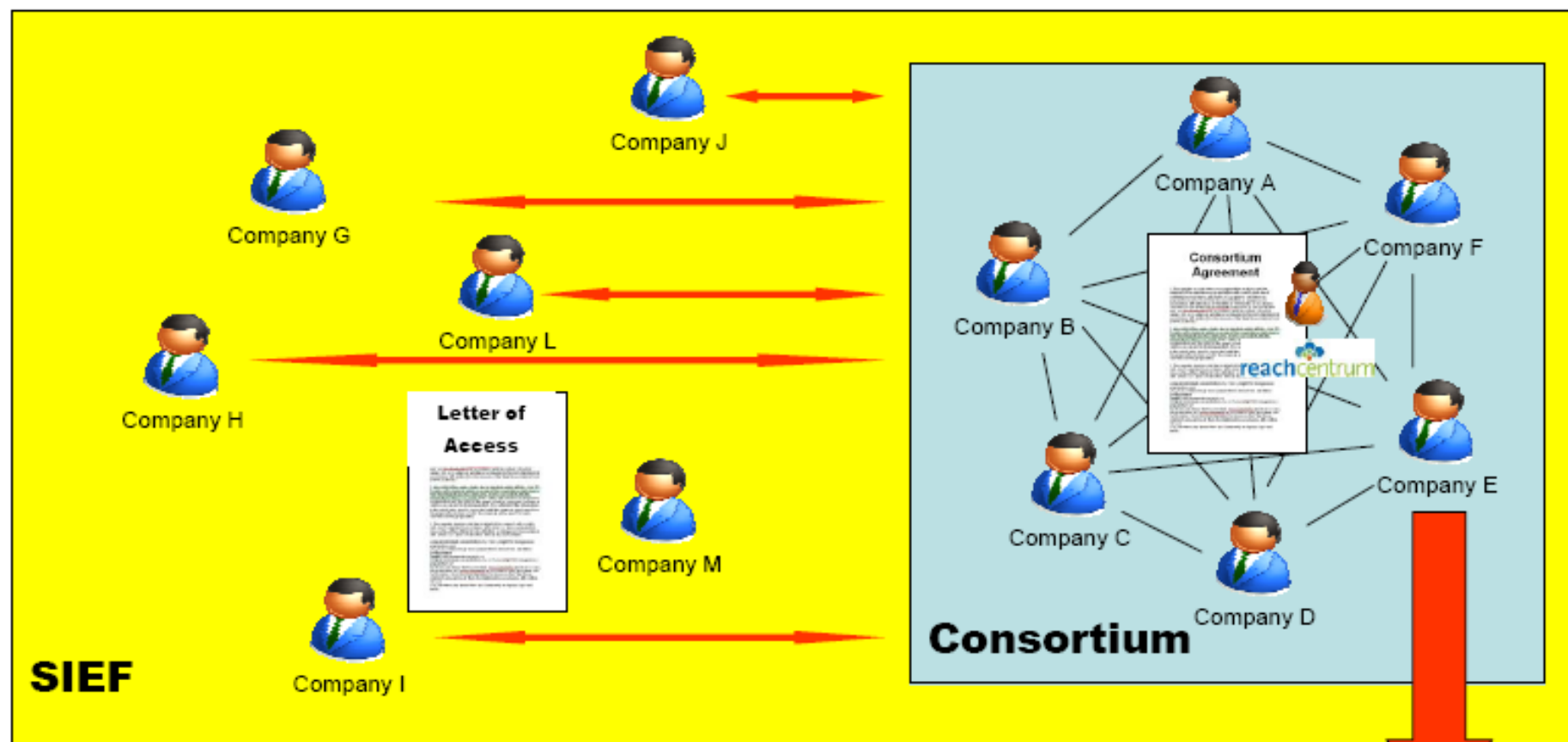
The aims of a SIEF:

- Facilitate data sharing for the purpose of registration
- Agree on classification & labeling
- Prepare joint submission of a registration dossier
- **Participation in a SIEF is mandatory for all pre-registrants**
- **Industry – not ECHA - is fully responsible for SIEF organization**
- **A SIEF is not a legal entity or a consortium**
- SIEF participants should set **clear priorities** and prepared to **accept compromises**

SIEF code

SIEF Code	Position	My position (please indicate the appropriate cell)
1 Leading	This is a substance of high strategic importance for my company and I have available resource to (co) lead and drive registration to completion	<input type="checkbox"/>
2 Involved	My company is registering and may be actively involved. My company will receive a SIEF progress report, an invoice and an invitation to comment	<input checked="" type="checkbox"/>
3 Passive	My company has the intention to register this substance. My company will receive a SIEF progress report and an invoice	<input type="checkbox"/>
4 Dormant	My company has no intention to register nor to spend money. My company will receive no communications and no invoice (besides mandatory data sharing).	<input type="checkbox"/>

SIEF vs Consortium



Joint Submission



For further information

Cefic Guidance on SIEFs:

<http://www.cefic.org/Templates/shwStory.asp?NID=494&HID=645&PHID=643&PPHID=494>

ECHA Guidance on SIEF:

http://echa.europa.eu/sief_en.asp

ECHA Guidance on data sharing:

http://reach.jrc.it/docs/guidance_document/data_sharing_en.pdf

Business rules:

http://echa.europa.eu/doc/reachit/reachit_data_submission_manual_8_business_rules_validation_20090417.pdf



Joint submission of data by multiple registrants within the SIEF

- Certain registration information has to be submitted jointly and this is done by the lead registrant within the SIEF
- Certain registration information has to be submitted separately by each registrant

Jointly	Separately or jointly	Separately
<ul style="list-style-type: none">■ C&L■ Study summaries (Annexes VII-XI)■ Testing proposals	<ul style="list-style-type: none">■ Guidance on safe use■ Chemical safety report	<ul style="list-style-type: none">■ Identity of registrant■ Identity of substance■ Uses and manufacture■ Exposure info for 1-10 ton substances



Join registration

REACH Registration - Data Questionnaire for UREA SIEF

12.06.2009

Company details

Company name

Company address

Contact name

Contact email

Contact telephone number

Lead Registrant

I agree with AMI Agrolinz Melamine International GmbH as Lead Registrant for UREA.

Scrol & select

If you answered "No" to the question above, please propose an alternative Lead Registrant.

Registration Deadline

When do you intent to register UREA?

Scrol & select

Substance Data

Do you own any studies for UREA?*

Scrol & select

If you answered "Yes" to the question above, please complete the substance worksheet.

**please note: all studies supplied will be assessed independently for relevancy and quality and an assessment report will be circulated to data holders.*



LR voting

Registration of Urea

- AMI Agrolinz Melamine International GmbH is Lead Company for urea within the FARM Consortium
- AMI Agrolinz Melamine International GmbH offers to act as Lead Registrant
- Registration Deadline: 1.12.2010
- The Registration Dossier to be prepared within the FARM Consortium will include the technical part as well as the CSR



Substance identity or characterization

- Establishing substance identity by analytical characterization
 - Testing proposal by *registrant EFC*
 - sufficient spectral data to confirm the structure
 - of their substance and to use suitable chromatographic methods to verify composition and purity.
 - Where there are other main substance identifiers such as morphology, these should also be included



Substance identity or characterization

- EFC was given a general document prepared by TRC regarding substance characterization, explaining what is needed and listing analytical methods and their suitability for different types of substances.
- It was agreed that TRC will research the most appropriate methods for analysing urea and will provide EFC with a proposal for tests to be carried out including estimated costs.



QF-M.LAB-05	
Rev.	01

Testing proposal

قدم لك في رسالتي
لما عرفت انك
لما عرفت انك

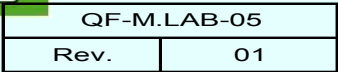
certificates Special Samples Analysis Report

Plant	Lab. No.	sample	sample location	Time	Date
EFC	3429	Urea Final Product	335H013	12:00	12/10/2009

Required Analysis	Requested By	Department
Check Quality	Chemist /Ahmed Meawad	Safety

Serial No.	Item	Unit	Result	Specification
1	Biuret (Bi)	% wt	0.88	1.0 max.
2	Formaldehyde (HCHO)	% wt	0.546	0.5 - 0.6
3	Moisture (H2O)	% wt	0.26	0.3 max.
4	Crushing Strength	% wt	3.8	3.0 min.
5	Bulk Density	Kg/Cm3	751	740 -760
6	Free Ammonia (NH3)	ppm	4.5	100 max.
7	Total Nitrogen (N2)	% wt	46.23	46.0 min

Comment :-



Special Samples Analysis Report

Required Analysis	Requested By	Department
Check Quality	Chemist /Ahmed Meawad	Safety

Comment :-

Laboratory Department Manager

**EFC2**

قد تم لك يصر لها كشرلا
لماع لها قراد

	QF-M.LAB-01	
	Rev.	02

RAW MATERIAL**UREA FORMALDEHYDE SOLUTION ANALYSIS REPORT**

<i>Date:</i>	<i>13/10/2009</i>	<i>Time:</i>	<i>12:00</i>
<i>Truck No.</i>	<i>Tank</i>	<i>=</i>	
<i>Vendor</i>	<i>=</i>		
<i>Sample Collected By</i>		<i>hany</i>	
<i>Sample Analysed By</i>		<i>Tarek</i>	
<i>Sample Lab. No.</i>		<i>3428</i>	

Chemical Analysis

Item	Unit	Specification	Results	Method
Formaldehyde	% W/W	60 ± 0.5	59.95	Vendor's P M
Urea	% W/W	23 ± 2	24.55	A.O.A.C 2.4.05
Water	% W/W	Balance	15.50	By Balance
Chloride	ppm	3 Max.	0.99	vogel A.M

Comment:

- The Material accords to Specifications

Lab.Supervisor

Laboratory Deartment Manager

Formaldehyde issue



Minutes of the meeting between Egyptian Fertilizer Company ("EFC", represented by Ahmed Moawad and Moheb Basta) and The REACH Centre Ltd ("TRC", represented by Sandra Meijer), held in Lancaster England on the 9th of September 2009.

The following issues were discussed:

1. Formaldehyde issue

Background: On a previous occasion, EFC had sought advice on the registration obligations with respect to urea-formaldehyde resin which is added by EFC to the urea granules as an anti-caking agent. TRC had on that occasion sought guidance from the UK REACH Competent Authority and based on their advice had informed EFC that both urea and formaldehyde need to be registered. Since formaldehyde was not pre-registered, this might have been a potential problem for EFC's importers, but EFC subsequently found out that their 3 (non-EU) suppliers had each pre-registered formaldehyde through an Only Representative.

During the meeting, we discussed the supply chain issues associated with formaldehyde. It was explained (as before) that because EFC are in the same supply chain as their suppliers and their EU importers, the (pre)registration by the suppliers' OR would normally cover EFC's importers, provided that the importers' tonnages of formaldehyde are explicitly included in the OR agreements of the non-EU suppliers of UF resin.

It was explained that, even though EFC was given statements by the 3 Only Representatives about the pre-registration and intended registration of formaldehyde, this would not be considered enough. It is important that the names and tonnages of EFC's importers are included on the list of importers of the Only Representatives of the 3 non-EU suppliers of UF resin.

EFC will provide TRC with 3 lists (one for each non-EU supplier of UF resin) containing the names of EU importers and their tonnages of imported formaldehyde.

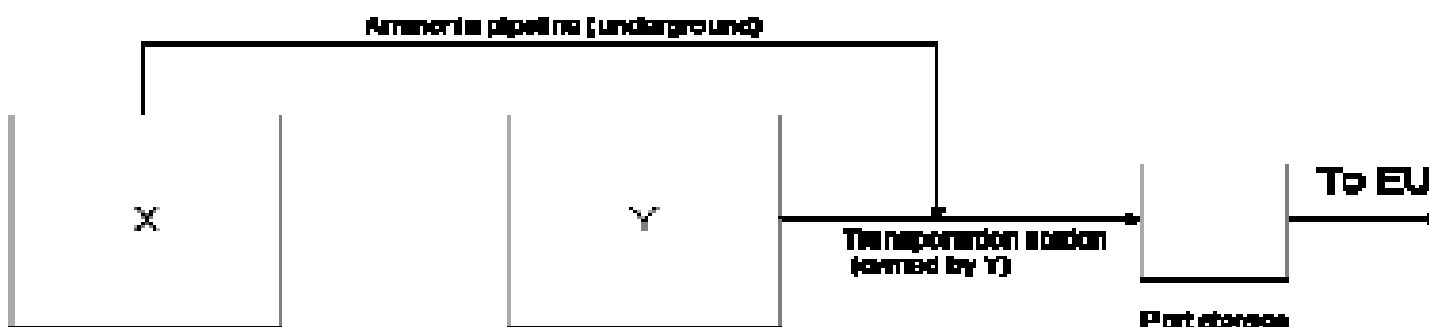
Subsequently, TRC will help to contact the 3 non-EU suppliers and their ORs to ensure the tonnages are covered by the OR agreement.

Ammonia issue

4. Ammonia

EFC are not currently supplying ammonia to the EU, and estimate supply will start in 2011; however this is not yet certain. Therefore they do not wish to register before the 2010 deadline, but wish to wait until the supply is certain. It was agreed that TRC will clarify the deadline for registration if EFC start supply after Dec 2010. TRC will also give an indication of the timescales involved in preparing the registration dossier for EFC for ammonia, which is dependent on things like obtaining the joint registration token from the lead registrant and processing of international payments.

In addition, the following (hypothetical) situation was sketched by EFC for consideration:



Company Y is a daughter of company X. Company Y owns the transportation station to the port where ammonia is shipped to the EU. Company Y has pre-registered ammonia. Company X sends ammonia to the transportation station.

The question was: if an OR will be appointed to register on behalf of the EU importers, is it company X or company Y or both, who should appoint the OR?

TRC will seek advice to clarify this export situation for ammonia, as requested by EFC



Classification & Labelling

- The classification and labeling system of the Directive 67/548/EEC will be substituted by the implementation of the Globally Harmonized System (GHS).

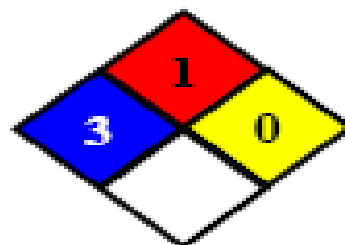


Safety Data sheets (SDS) for dangerous substance

(Art. 31)

❖ has to be fulfilled by manufacturers or importers for registered substances on

- ❖ their own, or
- ❖ in a preparation, manufactured
- ❖ or imported in quantities of 10 tones or more per year,



T-Toxic

1. IDENTIFICATION OF THE PRODUCT AND THE COMPANY

1.1 Identification of the Product

Designation	Ammonia, Anhydrous
Commonly used synonyms	Ammonia, Liquid Ammonia, Liquefied Ammonia, Anhydrous Ammonia. See Note 1.
CAS Number	7664-41-7
EINECS Number	231-635-3
EINECS Name	Ammonia, anhydrous
Molecular formula	NH ₃

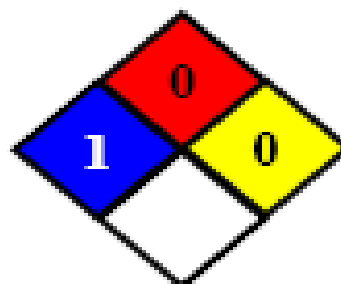
1.2 Company

Name Egyptian Fertilizers Company
Telephone No. (+2) 062 3710310 Telefax No. (+2) 062 3710312
E-mail ahmed.mouwad@orascomci.com
moawad87@gmail.com

Emergency calls +2 062 3310710 EXT.888

Address: Industrial area – Ain sokhna – Suez - Egypt – P.O.B. 181 Ain sokhna, postal code 4311 Suez

Egyptian Fertilizers Company
Material Safety Data sheet
UREA granular
Revised: March, 2009.



1. IDENTIFICATION OF THE PRODUCT AND THE COMPANY

1.1 Identification of the Product

Designation	Urea granular
Commonly used synonyms	Carbamide, Carbonyl Diamide
CAS Number	57-13-6
EINECS Number	200-315-5
EINECS Name	Urea
Molecular formula	$\text{CH}_4 \text{ N}_2\text{O}$

1.2 Company

Address Industrial area – Ain sokhna-Suez –Egypt – P.O.B. 181 Ain sokhna, postal code 4311 Suez

Telephone No. (+2) 062 3710310
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Chemical Safety Assessment

- Needs to document this assessment in his chemical safety report (CSR) as part of his registration dossier
- A methodology for assessing whether risks from the use of substances to human health and the environment are adequately controlled as well as the format for the chemical safety report must be devised.



Registration dossier

- **Contains:**

- 1. **Technical dossier**

- Identity of registrant
- Identity of substance
- Classification and labelling
- Information on exposure for substances between 1-10 tons
- Study summaries and robust study summaries for key studies
- Proposals for testing
- Request for confidentiality of information

- 2. **Chemical Safety Report**

- For substances > 10 tons

- Generated with IUCLID5 and submitted to REACH-IT



Registration dossier

- TRC will provide a list of information and actions needed from EFC in order to successfully prepare and submit the registration dossier.

The expected time for
Final registration is *1st of*
June 2010

**Thank you for your
attention**