

LEAD REGISTRANT REACH CHALLENGES

ECHA LEAD REGISTRANT WORKSHOP

2 FEBRUARY 2012, HELSINKI

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<http://www.molybdenumconsortium.org>

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BEING A REACH LEAD REGISTRANT IS A VERY SIGNIFICANT CHALLENGE!

REACH REGISTRATION MAY 2013



LEAD REGISTRANT TEAM SKILLSET:



ADMINISTRATORS

ACCOUNTANT/
BOOK-KEEPER

IT-TOOLS & SOFTWARE

LEGAL COUNSEL

COMMUNICATORS

ENVIRONMENTAL SCIENTISTS,
TOXICOLOGISTS, CHEMISTS,
INDEPENDENT REVIEWERS

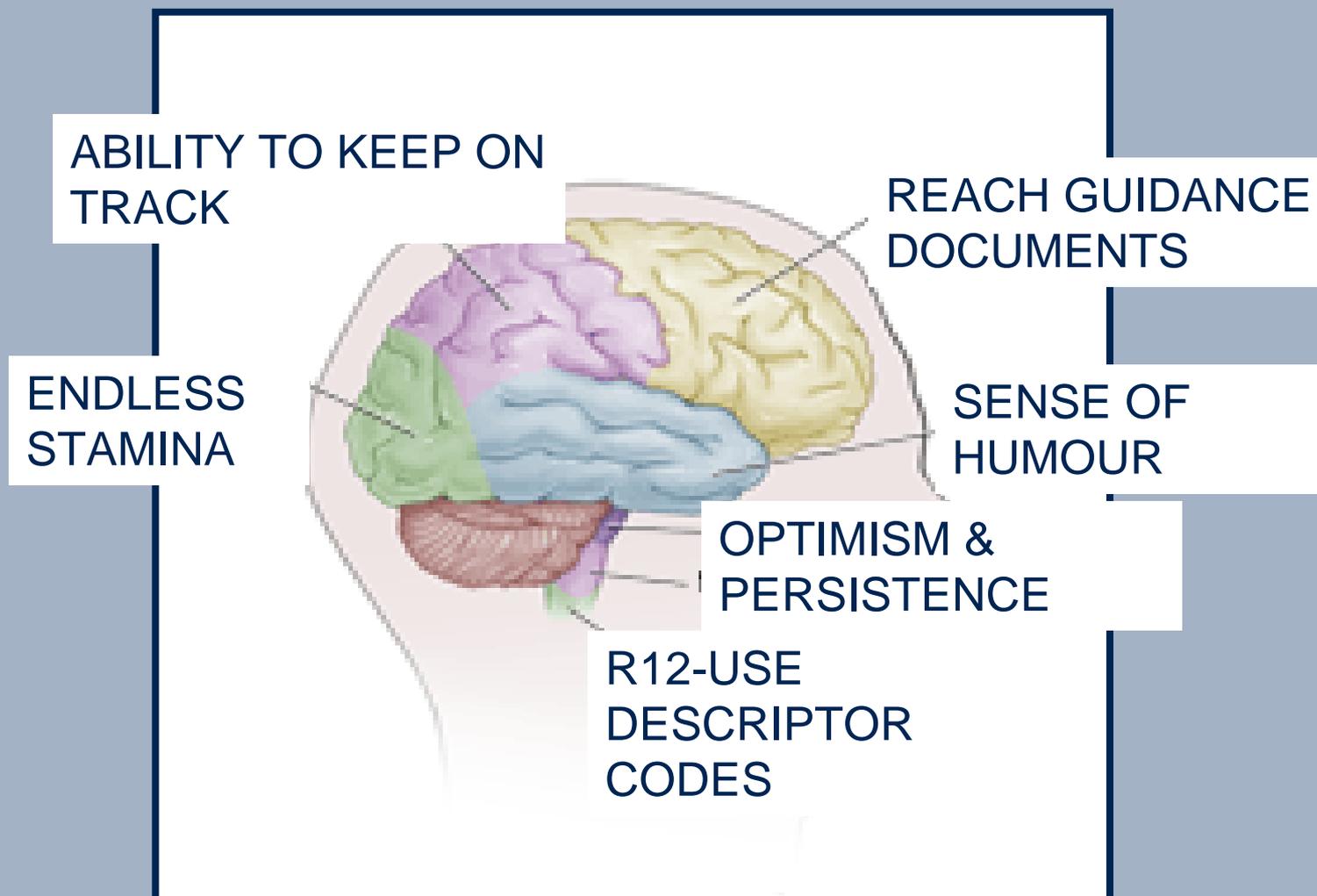
PROJECT MANAGER/S

QUALITIES OF REACH

LEAD REGISTRANT TEAM MEMBERS?

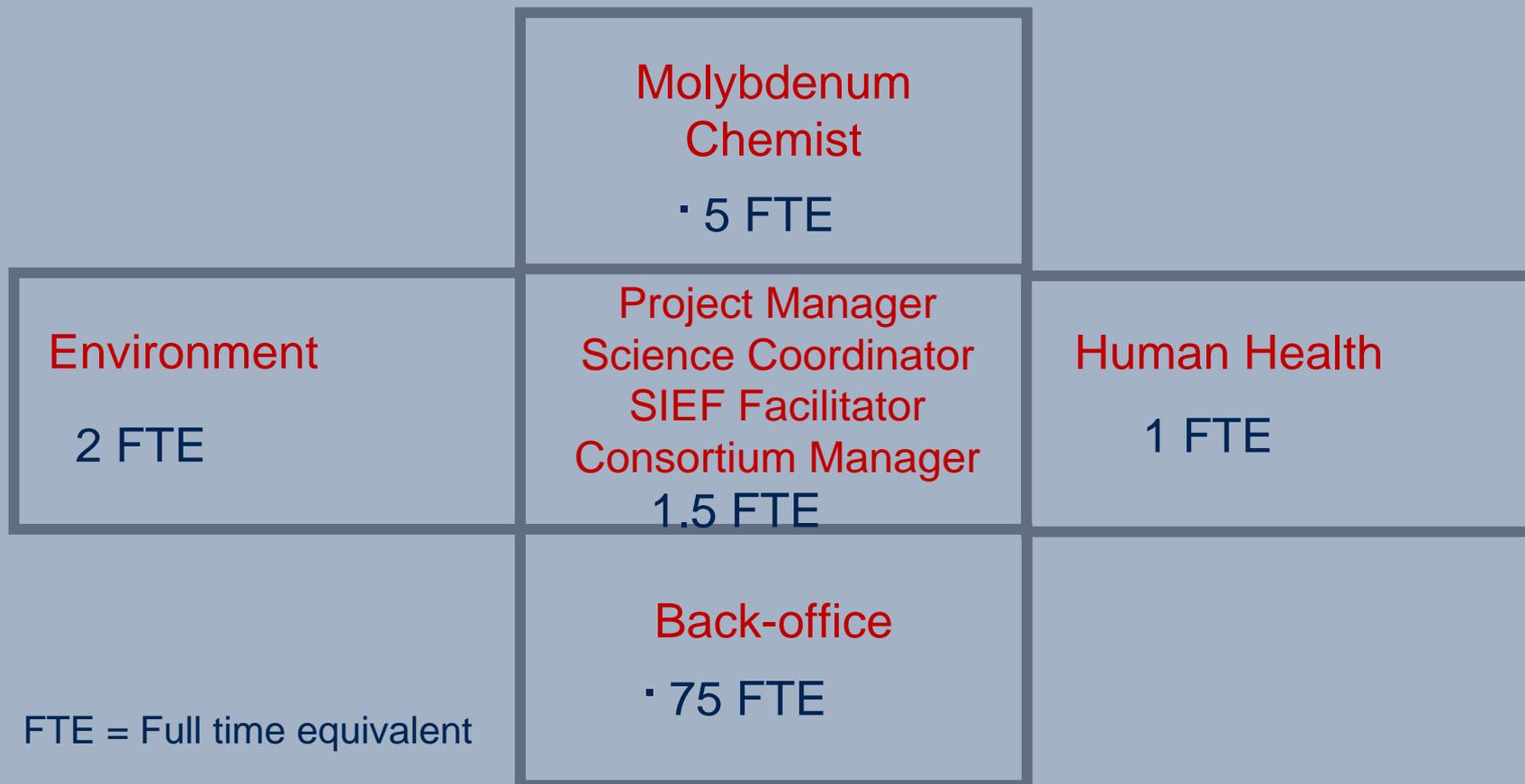


REACH BRAIN CONFIGURATION:



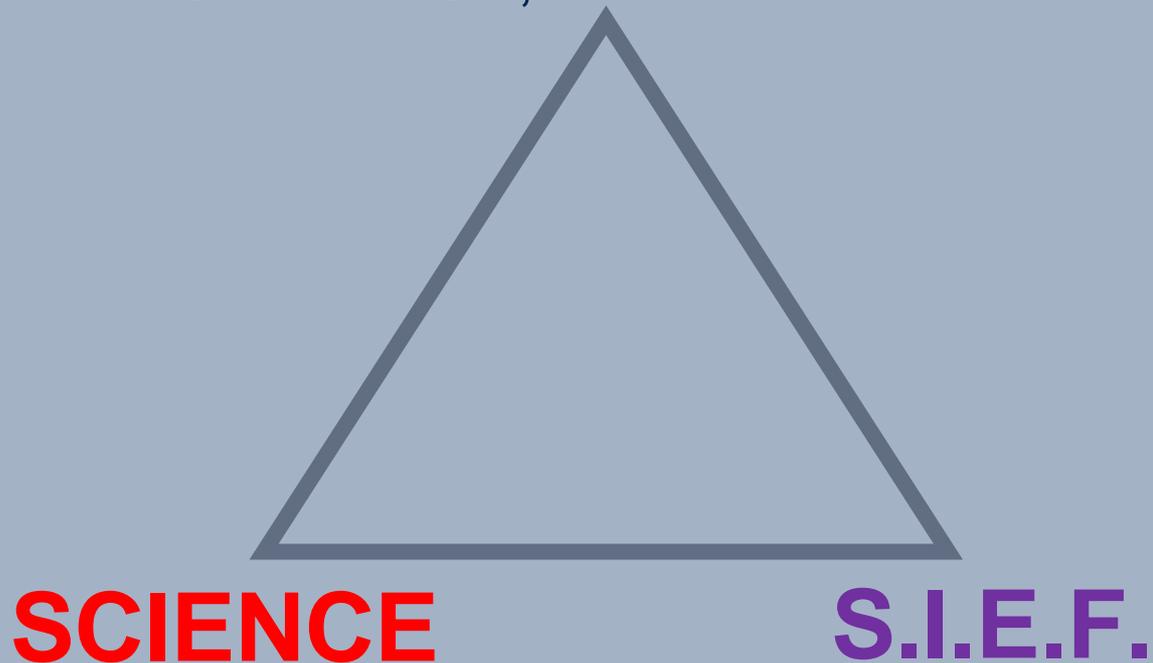
Molybdenum Consortium resourcing

(11 substances inc. 2 UVCB, 2010 registration - > 1000 tonnes)



SYSTEMS: Mass E-mailing, IUCLID-online, e-Room

TWO KEY AREAS FOR
LEAD REGISTRANT
TO MANAGE, IN PARALLEL



SCIENCE RECOMMENDATIONS

BASED ON LEAD REGISTRANT

EXPERIENCE IN ACHIEVING 2010

REGISTRATION DEADLINE

SCIENCE – invest time & effort in:

✓ SCOPING OUT THE SIZE OF THE TASK/LENGTH OF TIMELINE

- KNOW PRECISELY THE REACH DATA REQUIREMENT ANNEXES FOR YOUR TONNAGE BAND
- WHICH DATA-GAPS TO FILL/MAKE TEST PROPOSALS FOR?
- TEST LABORATORIES ALREADY BUSY – GET IN QUEUE **NOW**
- NEED A CHEMICAL SAFETY REPORT? FAMILIAR WITH IUCLID CHESAR TOOL?
- BUILD-IN SUFFICIENT TIME FOR REVIEWING/REVISING
- MAKE LoA AVAILABLE SUFFICIENTLY IN ADVANCE (JAN) OF MAY 2013 DEADLINE

SCIENCE – invest time & effort in:

✓ SUBSTANCE IDENTITY AND SUBSTANCE SAMENESS

- UNAMBIGUOUSLY CHARACTERIZE THE SUBSTANCE:
 - READ REACH GUIDANCE ON SUBSTANCE IDENTITY (FOR METALS WE GENERATED ANALYTICAL DATA AND X-RAY DIFFRACTION DATA)

WHAT YOU DO WILL DEPEND ON YOUR TYPE OF SUBSTANCE - FOLLOW THE REACH GUIDANCE

ECHA HAS ISSUES WITH INADEQUACY OF SUBSTANCE IDENTITY INFORMATION IN 2010 SUBMITTED DOSSIERS

SUBSTANCE SAMENESS SURVEY:

POSE QUESTIONS TO:

- **ESTABLISH SAMENESS** TO TYPICAL COMPOSITION
- **CHARACTERIZE** THE RESPONDENT SIEF MEMBER
- **OBTAIN FEEDBACK** RE STUDIES/EXPOSURE DATA AVAILABILITY

RESPONDENTS INTEND VARYING (low) LEVELS OF ENGAGEMENT WITH REACH PROCESS

SCIENCE – invest time & effort in:

- ✓ DATA-GATHERING, GAP ANALYSIS, DATA-SHARING
 - TWO IN ONE: ASK FOR INDICATION OF STUDY AND EXPOSURE DATA AVAILABILITY AS PART OF THE SIEF SUBSTANCE SAMENESS SURVEY
 - ANY DATA HOLDERS IN OTHER (RELATED) SIEFS?
 - ASK ALL PARTIES EARLY ON, TO AVOID POSSIBILITY OF COMMISSIONING A STUDY THAT A SIEFER SUBSEQUENTLY OFFERS (AND ASKS PAYMENT FOR)
 - SEVERAL STUDIES ON SAME ENDPOINT: USE WEIGHT OF EVIDENCE APPROACH
 - BE FAMILIAR WITH REACH DATA-SHARING RULES

**ESSENTIAL
READING
FOR LEAD
REGISTRANTS:**



SCIENCE – invest time & effort in:

✓ SCREENING STUDIES FOR SCIENTIFIC RELEVANCE & RELIABILITY

- USE KLIMISCH ET AL RANKING SYSTEM (K1 – K4)
- AN ESSENTIAL PROCESS TO MAXIMISE SCIENTIFIC ROBUSTNESS OF STUDIES INCLUDED IN DOSSIER
- DATA RICH SUBSTANCE?: SCREEN AND USE K1/K2 STUDIES. INCLUDE K3 STUDIES IF TIME PERMITS
- USE KLIMISCH RANKING TO PRIORITIZE FOR WEIGHT OF EVIDENCE APPROACH IF HAVE SEVERAL STUDIES ON SAME END-POINT

SCIENCE – invest time & effort to:

✓ READ-ACROSS AND INTELLIGENT TESTING STRATEGY

- NOT NECESSARY TO TEST EVERY SUBSTANCE FOR EVERY ENDPOINT.
- INTELLIGENT TESTING STRATEGY: FOR A GROUP OF SUBSTANCES COULD TEST THE MOST SOLUBLE (I.E. WORST CASE) AND THEN READ-ACROSS TO LESS SOLUBLE, DEPENDING UPON THE TEST RESULT
- UNDERPIN YOUR READ-ACROSS STRATEGY WITH SCIENCE (E.G. SOLUBILITY, BIO-AVAILABILITY, UV SPECTRA, LIMITED in VIVO DATA, ETC)

MOLYBDENUM CONSORTIUM EXAMPLE:

THE PHYSIOLOGICALLY AND ENVIRONMENTALLY SIGNIFICANT SPECIES IS THE MoO_4^{2-} ION, AND THAT AT THE pHs AND MO CONCENTRATIONS WHICH INTEREST US FOR REACH, MO COMPOUNDS TRANSFORM TO MoO_4^{2-} AND ENTER THE ORGANISM AS SUCH

FACILITATES READ-ACROSS ... WHERE APPROPRIATE

**BACKED THIS UP WITH WATER SOLUBILITY,
BIO-ELUTION AND UV SPECTRA DATA**

UV SPECTRA SUPPORT FOR READ-ACROSS BASIS (I.E. ALL MOLYBDENUM CONSORTIUM (MoCon) SUBSTANCES TRANSFORM TO MoO_4^{2-}) – UNDERPINS MOCON INTELLIGENT TESTING STRATEGY

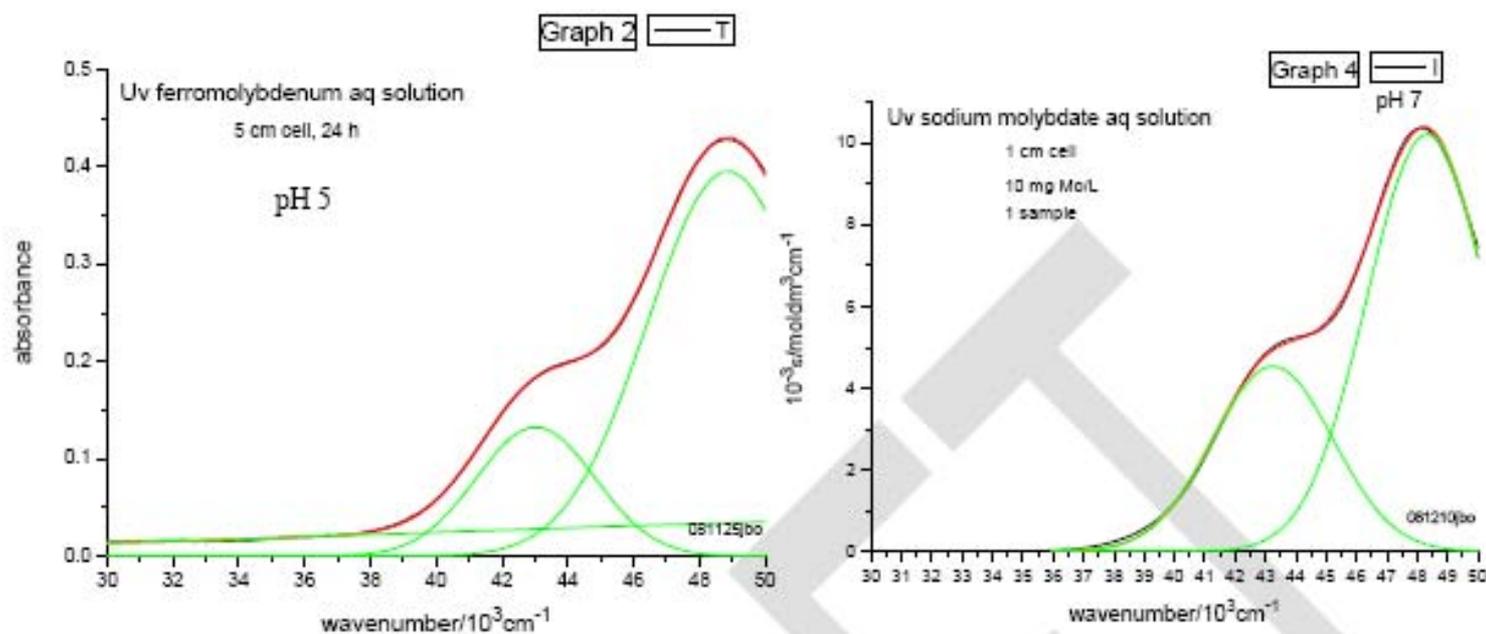


Figure 14. Uv spectra of ferromolybdenum and sodium molybdate

SCIENCE – invest time & effort in:

✓ USE RANKING CRITERIA TO SELECT SERVICE PROVIDERS

- SEVERAL TEST QUOTATIONS AND DISAGREEMENT ABOUT WHICH ONE TO CHOOSE?
- POSSIBLE SOLUTION: SET SOME RANKING CRITERIA TO OBJECTIVELY EVALUATE THE QUOTATIONS.
- CAUTION: USE FOR HIGH-COST TESTING AS PROCESS EATS INTO YOUR MOST VALUABLE COMMODITY: TIME

EXPECT TO FEEL LIKE THIS SOME DAYS!



SCIENCE – invest time & effort in:



✓ KNOW HOW THE IUCLID SOFTWARE WORKS

- THE DATA-ENTRY VEHICLE FOR YOUR REACH DOSSIER
- TAKES TIME TO SET UP AND BECOME FAMILIAR WITH FORMATS (ENDPOINT SUMMARIES, ROBUST STUDY SUMMARIES, ETC)
- CHESAR TOOL CAN GENERATE CSR, BUT INCLUDES DEFAULT SAFETY VALUES – KNOW IF THEY ARE JUSTIFIED IN YOUR CASE?
- DEVELOP CSR IN E-ROOM?
- LR CAN PREPARE TEMPLATE CO-REGISTRANT IUCLID .5Z FILES

SCIENCE – invest time & effort in:

- ✓ **PREPARING EXPOSURE SCENARIOS (FOR HAZARDOUS SUBSTANCES)**
 - EXPOSURE SCENARIOS ARE COMPLEX AND TIME-INTENSIVE TO BUILD- DO NOT WAIT UNTIL THE LAST 6 MONTHS BEFORE YOU START TO BUILD THEM

THREE PERSPECTIVES TO COVER:
WORKER, PROFESSIONAL AND CONSUMER
EXPOSURE

S.I.E.F. RECOMMENDATIONS

BASED ON LEAD REGISTRANT

EXPERIENCE IN ACHIEVING 2010

REGISTRATION DEADLINE

S.I.E.F. – invest time & effort in:

✓ ADEQUATE LR-SIEF COMMUNICATION

(MoCON SIEF COMMUNICATIONS: SIXTEEN)

- ENGAGE AND INFORM THE SUBSTANCE SIEF MEMBERS
(BUT LR ROLE IS NOT REACH TEACHER ‘URBI ET ORBI’ –
DIVERT TO NATIONAL HELP DESKS)
- HAVE AN ADEQUATE COMMUNICATIONS MECHANISM
(SMALL GROUP: STANDARD E-MAIL,
LARGE GROUP: CUSTOMISED, MASS E-MAILING)

REAL 'SIEF-LIFE' EXPERIENCE:

- ONLY ABOUT **30 - 45%** OF SIEFERS RESPOND
- **MAJORITY** OF RESPONDENTS WANT TO BE EITHER **DORMANT OR PASSIVE**
(Important nevertheless to keep them always in SIEF communication loop, & their obligation to respond remains)
- **ALMOST NO-ONE** OFFERS STUDIES/DATA !!
- **BOTTOM LINE** FOR MOST SIEFERS:
 - IS 'SOME-ONE' PREPARING THE DOSSIER?
 - WILL IT BE READY ON TIME?
 - HOW MUCH FOR THE LETTER OF ACCESS?

CIRCA 55% OF 2009 PRE-SIEF COMMUNICATIONS TO PRE-REGISTRANTS WERE NOT EVEN OPENED!

blue spark *

Overview

Create/Send

Lists & Subscribers

Reports

Sent Campaign Reports

Campaign Name	Sent ▼	Recipients	Opened	Clicked
Ammonium octamolybdate - Substance Sameness Survey - reminder	4 Mar 2009	66	29.23%	57.89%
Pre-SIEF Activity Alert	4 Feb 2009	1,382	40.74%	15.88%
Molybdenum metal - Substance Sameness Survey	23 Jan 2009	1,429	43.59%	43.48%
Sodium molybdate - Substance Sameness Survey	23 Jan 2009	336	47.38%	50%
Ferromolybdenum slags - Substance Sameness Survey	23 Jan 2009	34	34.38%	63.64%
Pure molybdenum trioxide - Substance Sameness Survey	23 Jan 2009	320	49.19%	58.55%
Roasted molybdenite concentrate - Substance Sameness Survey	23 Jan 2009	114	50%	74.55%

S.I.E.F .– invest time & effort in:

✓ **OBLIGATORY & ‘MILESTONE’ COMMUNICATIONS WITH THE SIEF MEMBERS**

- YOUR SIEF NOMINATION & APPOINTMENT AS LR
- SIEF SUBSTANCE SAMENESS INFORMATION SURVEY
- STUDIES & EXPOSURE DATA CALL-IN & FOLLOW-UP
- SIEF-AGREEING SUBSTANCE CLASSIFICATION AND LABELLING
- CREATION OF JOINT SUBMISSION – ACCESS TO TOKEN
- LETTER OF ACCESS - AVAILABILITY & ACCESS
- SUCCESSFUL LR REACH REGISTRATION

S.I.E.F. – invest time & effort in:

✓ IDENTIFICATION OF USES

- START REACHING OUT DOWNSTREAM **NOW** TO ‘CAPTURE’ USES (AND EXPOSURE DATA IF A HAZARDOUS SUBSTANCE) – TAKES A LONG TIME TO DEVELOP EFFECTIVE DIALOGUE!
- BE CLEAR THAT A LIST OF USE DESCRIPTOR CODES WITHOUT A TEXT DESCRIPTION IS AN INADEQUATE AND UN-USEABLE RESPONSE.
- **SECTOR TRADE ASSOCIATIONS** CAN BE INFORMATIVE COUNTERPARTS. BEWARE QUESTIONNAIRE ‘FATIGUE’ WITHIN INDUSTRY.
- USE A **WEBPAGE** TO REPORT USES AND VIEW DRAFT LISTS
- IUCLID 5.4 MAY CHANGE SECTION 3.7 REPORTING

MOCON WEBPAGE ON IDENTIFIED USES

You are invited to view the lists and check that your use has been included. **If it is not yet included, please use this E-mail form to provide us, with the Identified Use Name and the relevant Use Descriptors.** We will then consider your use for inclusion in the first update to the REACH Dossier, planned for 2011. It is important to do this because these are the Lists that will be included in the Lead Registrants dossier submission to ECHA (Section 3.5 of IUCLID).

When checking these lists it's useful to keep in mind that the Reach Regulation, Article 3(26) defines an 'Identified Use' as meaning "a use of a substance on its own or in a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user."

More background about this topic is available on:

<http://www.molybdenumconsortium.org/identification-of-uses.html>

Hazardous Substances:

Substance	EINECS Number	Uses List submitted in 2010
Roasted Molybdenite Concentrate (RMC)	EINECS 289-178-0	<u>Uses List</u>
Molybdenum Trioxide	EINECS 215-204-7	<u>Uses List</u>

Report on Assessment of 'Consumer Exposure' under REACH for RMC and for molybdenum trioxide.

Non-Hazardous Substances:

Substance	EINECS Number	Uses List submitted in 2010
Molybdenum	EINECS 231-107-2	<u>Uses List</u>
Ammonium Dimolybdate	EINECS 248-517-2	<u>Uses List</u>

S.I.E.F. – invest time & effort in:

- ✓ REVIEW OF DRAFT CHEMICAL SAFETY REPORT
- FACTOR-IN TIME FOR ACTIVE SIEF PARTICIPANTS/SIEF TEAM LEADERS TO REVIEW ANY CHEMICAL SAFETY REPORTS FOR JOINT-SUBMISSION – CO-REGISTRANTS ARE SIGNING UP TO THE CONTENTS TOO!

S.I.E.F. – invest time & effort in:

✓ LETTER OF ACCESS

- BE CLEAR ABOUT THE DELIVERABLES
- HAVE AN LoA CONTRACT
- FAIR, TRANSPARENT AND NON-DISCRIMINATORY COST
- APPLY FOR AN LoA WELL IN ADVANCE OF THE REGISTRATION DEADLINE.
- IF ANTICIPATE SIGNIFICANT NUMBERS OF LoA's, OFFER WEBSITE ON-LINE ORDERING

MOCON WEBSITE LoA ON-LINE ORDERING

The screenshot displays the Molybdenum Consortium website interface. At the top left, the logo and name 'Molybdenum Consortium' are visible. A navigation menu on the left includes links for Home, SIEF Introduction, Letter of Access (highlighted with a red box), Classification & Labelling - CLP, e-SDS & PIDS, About REACH, and Contact Us. A 'members only login' button is located in the top right corner. The main banner features the text 'Are YOU prepared for REACH?' with a background image of people in a meeting. Below the banner, a breadcrumb trail reads 'Home > Letter of Access'. The central heading is 'Letter of Access', followed by a red callout: 'Please read this webpage fully before you proceed to the Buy LoA Portal'. The content is organized into sections: 'OTHER SIEF INFORMATION' with a list of links (Letter of Access, Lists of Identified Uses, REACH Registrations, Identification of Uses-Background, IUCLID5, Lead Registrants, Joint Submission, Read-Across Strategy, REACH Registration fees, Resources & Downloads, Pre-SIEF, Pre-Registration), and 'SIEF SUBSTANCES' with a list of chemical names (Ammonium Dimolybdate, Ammonium Heptamolybdate, Ammonium Octamolybdate, Calcium Molybdate). The bottom section explains 'What is a Letter of Access (LoA)?', 'What does an LoA look like?', and 'What does it cost to buy an LoA?'. The cost information is partially visible, mentioning 'LoA costings for REACH MoCon molybdenum substances:'.

LoA COMMUNICATION TO SIEF (extract)

REACH Molybdenum Consortium (MoCon)
An initiative of the International Molybdenum Association

28 June 2010

Letter of Access

This E-mail is to inform you that the on-line facility to purchase a Letter of Access from the Molybdenum Consortium is now available at:

<http://www.molybdenumconsortium.org/letter-of-access.html>

**Molybdenum Consortium
SIEF Facilitator contacts:**

Sandra Carey / Frank Martin
Molybdenum Consortium Secretariat

Email:
sief@molybdenumconsortium.org

Tel:

A Letter of Access is a document that grants you the right to:

- refer to the Lead Registrant (LR) REACH-registration dossier for the sole purpose of making your REACH-registration for a specific substance.

LAUNCH LoA FACILITY SEVERAL MONTHS BEFORE
REACH REGISTRATION DEADLINE

ZOOM LENS VIEW:

MAY 2013 IS
JUST AROUND
THE CORNER!



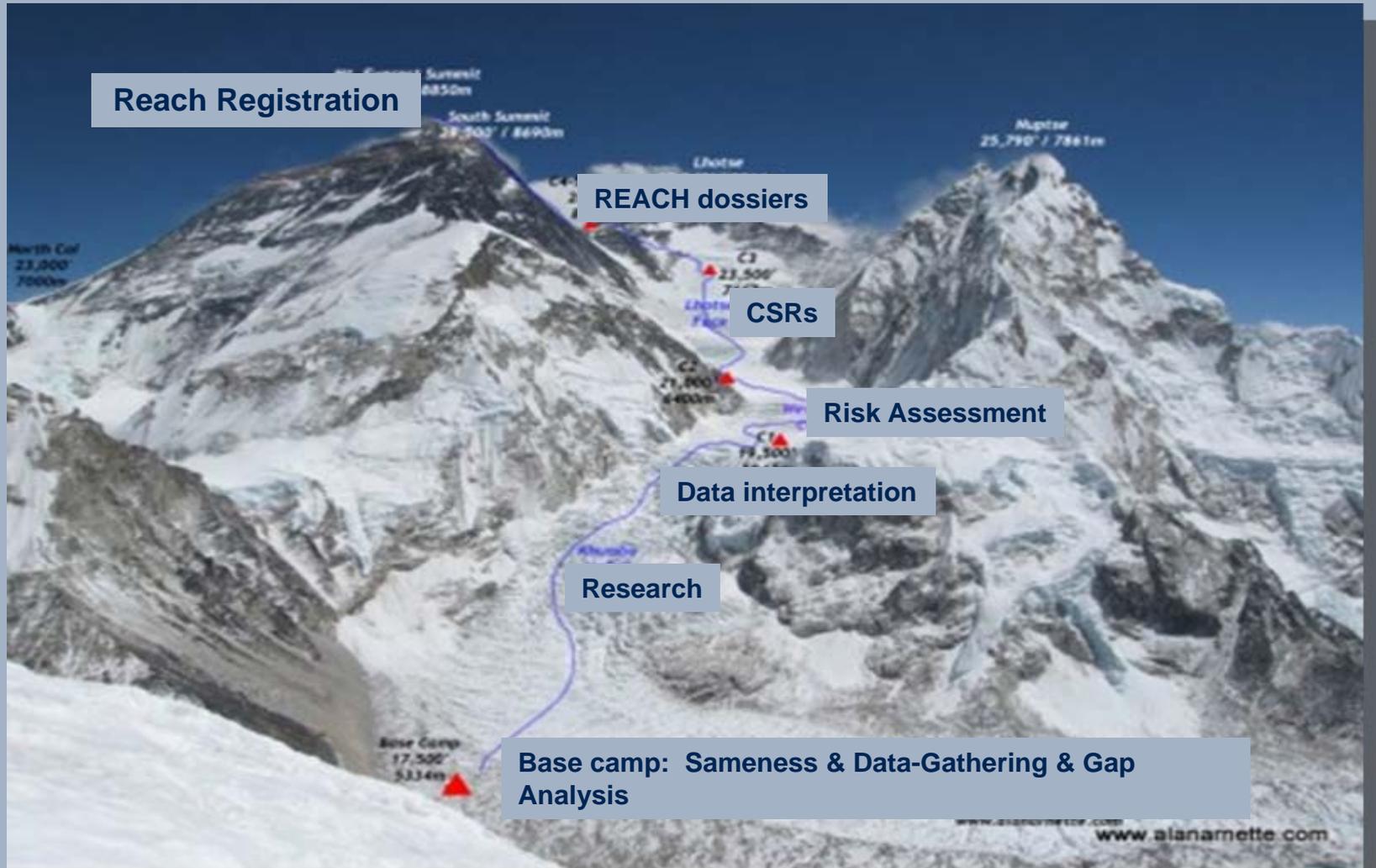
ACT NOW!
REACH
2013



**THE CLOSER THE SUMMIT
THE HARDER THE
CHALLENGE!**



WIDE ANGLE VIEW: Lead Registrant REACH-Mountain Trek



WORTH KEEPING IN MIND, AS YOU CLIMB

THE REACH DOSSIER YOU SUBMIT MAY BE USED BY ECHA

TO REGULATE YOUR INDUSTRY ... SO IN YOUR OWN

INTERESTS.... INVEST IN MAKING IT A ROBUST ONE!

POST-REGISTRATION:

LR RESPONSIBILITIES DON'T END AFTER REACH-REGISTRATION

LR REMAINS 'ON THE HOOK' WITH ECHA FOR **DOSSIER UPDATES** AND ALL COMMUNICATIONS RELATING TO THE DOSSIER TEST PROPOSALS, DOSSIER EVALUATION, SVHC, CANDIDATE LIST, AUTHORISATION , RESTRICTION

CHECK YOUR REACH-IT MESSAGE BOX PERIODICALLY ...

UNTIL MAY 2018!



THANK YOU
FOR YOUR ATTENTION!



INTERNATIONAL MOLYBDENUM ASSOCIATION
THE VOICE OF THE MOLYBDENUM INDUSTRY

Member of:

