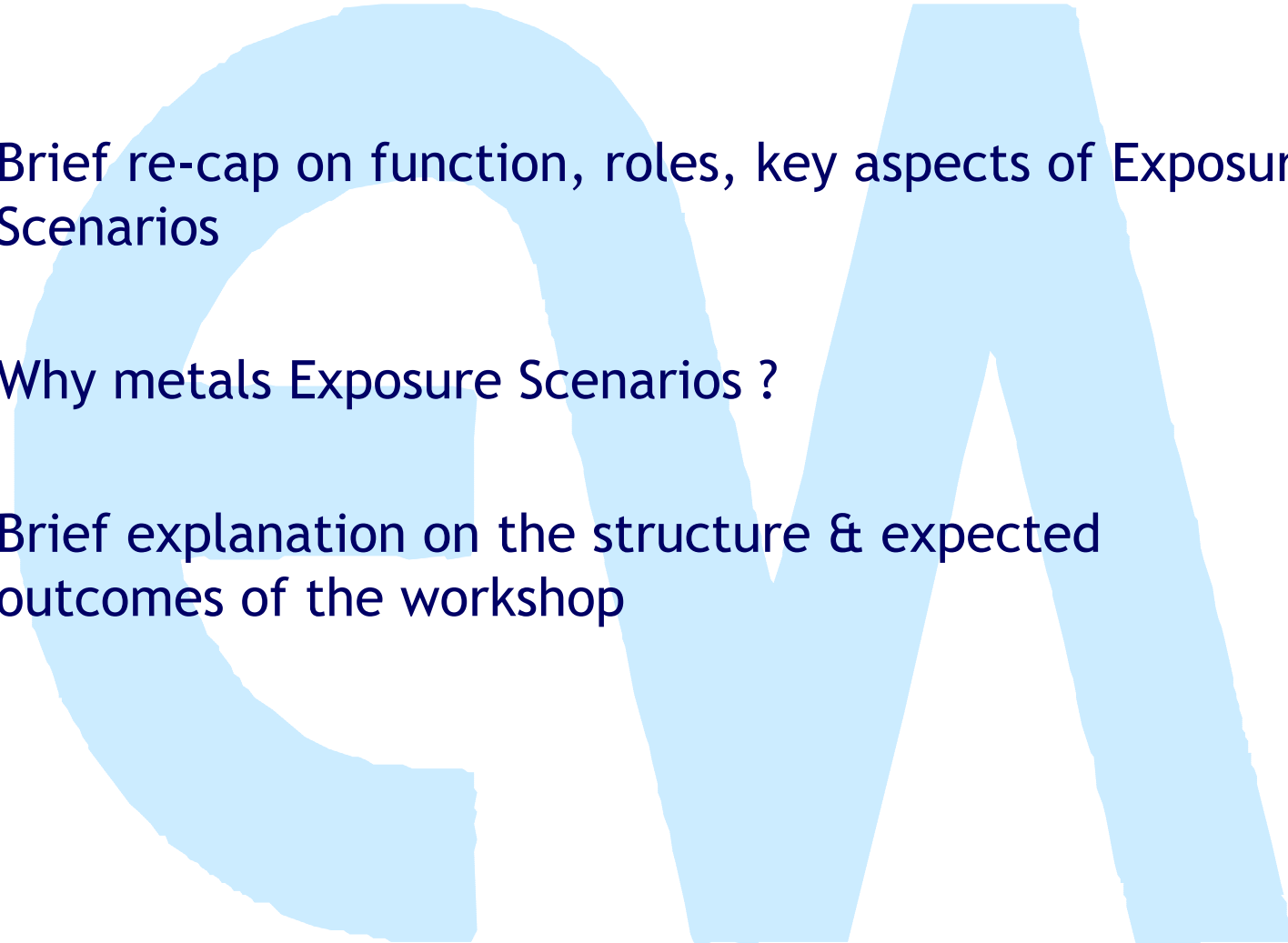


# ENM

## Exposure Scenarios



- 
- Brief re-cap on function, roles, key aspects of Exposure Scenarios
  - Why metals Exposure Scenarios ?
  - Brief explanation on the structure & expected outcomes of the workshop

# Introduction



# REACH and Exposure Scenarios (1)

- An Exposure Scenario (ES) is a set of information describing the conditions under which the risks associated with identified use(s) of a substance can be controlled (*REACH Article 3, 37*)
- When? Registering substances that are manufactured or imported in quantities of 10 tonnes/year or above and which are classified as dangerous or as a PBT/vPvB substance.
- Compiled in the context of the Chemical Safety Assessment (CSA), documented in the Chemical Safety Report (CSR), annexed to the Safety Data Sheet (SDS)

# REACH and Exposure Scenarios (2)

An Exposure Scenario describes:

- how a substance is manufactured/used during its lifecycle
- how the M/I controls or recommends DU to control exposure and risks

It includes:

- Operational conditions
- Risk management measures:
  - Process control
  - Emission control
  - Hygiene/Working Practice
  - Personal Protection Equipment
- Other relevant information

...when properly implemented, ensure that the risks for humans and environment resulting from the uses of the substance are adequately controlled...

**Focus is on exposure and its control!**

# REACH and Exposure Scenarios (3)

## Dual role of the Exposure Scenario (ES)

1. Basis for exposure estimation
2. Communication tool



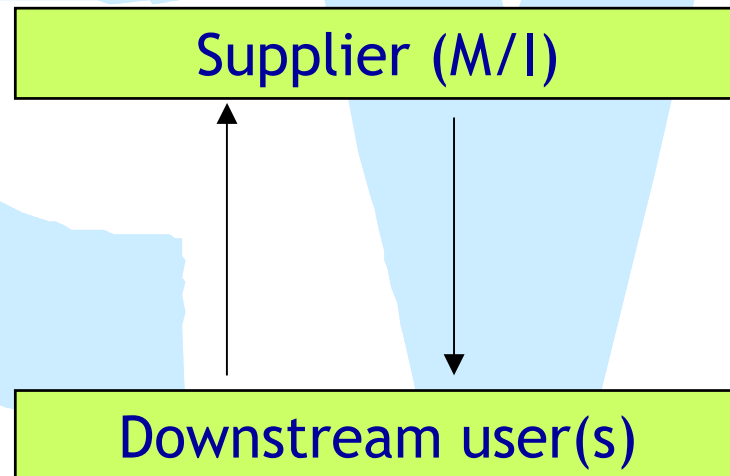
# 1. Basis for exposure estimation

Exposure Scenarios enable a **quantitative** release and exposure estimation by describing the **determinants** of exposure, i.e. parameters that affect exposure levels, as well as the models used for exposure estimation, if need be

## 2. Communication through the supply chain (1)

Exposure Scenarios constitute a **communication tool** for the user on **how** to use the chemical in such a way that risks are under control, including specifying the necessary risk management measures.

It requires the establishment of an effective communication system up and down the supply chain of a substance

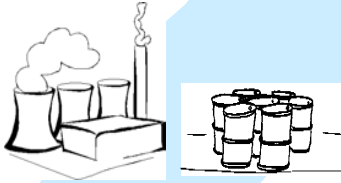
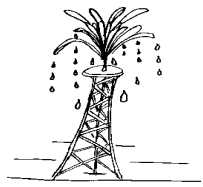


## 2. Communication through the supply chain (2)

- The Manufacturer/Importer (M/I) is responsible for preparing ES, covering manufacture and all 'identified uses'
- The Downstream User (DU) will need to check the ES for compliance with its uses and provide the information required to enable the M/I to develop ES for additional uses
- On the basis of the data in the ES, the Downstream User should be able to judge whether his own uses are safe. He must check whether his use conditions comply with the specifications in the ES and whether he is applying the relevant RRMs

Terminology should be consistent, concise and comprehensible, translatable (common understanding of 'exposure potential', ...)!!

## 2. Communication through the supply chain (3)



### Safety Data Sheets / Chemical Safety Reports

- exposure scenario
- risk management measures
- registration number
- authorization/restriction info

**Data: on uses, operational conditions, processes, exposure, RMM, hazard...**

### Information on use/ exposure scenarios

- uses
- sufficient info for exposure scenarios
- risk management measures
- new info on hazardous properties



End User

## 2. Communication through the supply chain (4)

- More about “Best Communication Techniques”: presentation by France Capon



# REACH and Exposure Scenarios: Guidance (1)

RIP 3.2-2

PART D



**TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE  
CHEMICAL SAFETY ASSESSMENT**

**Part D**

more contents of an exposure scenario under REACH.

standard workflow of 14 steps + output,

recommended descriptor system for uses,  
operational conditions determining  
exposure, RMM, waste life stage

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D.1 CONTENTS OF EXPOSURE SCENARIOS .....

D.1.1 Aim of section .....

D.1.2 Overview of core information to be taken into account in ES development .....

D.1.3 Overview on Development Steps .....

D.2 OVERALL WORKFLOW AND DIALOGUES .....

D.2.1 Aim of the module .....

D.2.2 Workflow of building exposure scenarios .....

D.2.3 Organization of Dialogues .....

D.2.3.1 Start with in-house knowledge .....

D.2.3.2 Get feedback from customers .....

D.2.3.3 Agree with DU sector organization on how to make uses known to suppliers .....

D.3 DEVELOPING THE CONTENT OF AN EXPOSURE SCENARIO .....

D.3.1 Aim of the chapter .....

D.3.2 Activities and processes within the life cycle of a substance .....

D.3.3 Brief general description of use and short title of exposure scenarios .....

D.3.3.1 Sectors of use [SU] .....

D.3.3.2 Chemical product category [PC] .....

D.3.3.3 Process category [PROC] or operation unit [OU] .....

D.3.3.4 Article Categories [AC] .....

D.3.3.5 Combining the four descriptors and grouping of uses .....

D.3.3.6 Example for the general brief description of uses in a CSR .....

D.3.4 Compile available in-house information on conditions of use .....

D.3.5 Select suitable approach to run a tier 1 exposure estimate .....

D.3.5.1 Selection of tool .....

D.3.5.2 Assignment of process categories, product categories and release categories .....

D.3.6 Risk management measures and related operational conditions of use .....

D.3.6.1 Aim of this module .....

D.3.6.2 Interrelation between operational conditions and risk management .....

D.3.6.2.1 Physical form of product and product specifications .....

D.3.6.2.2 Operational conditions of use and risk management measures for workers .....

D.3.6.2.3 Operational Conditions and risk management measures for consumers .....

D.3.6.2.4 Operational conditions and risk management for the environment .....

D.3.6.2.5 Operational Conditions and risk management for substances in articles .....

D.3.6.2.6 Risk management and operational conditions related to the waste life stage .....

D.3.6.3 Risk management under REACH and in other frameworks .....

D.3.6.4 M/T's in information sources with regard to risk management .....

D.3.6.5 Effectiveness of RMMs .....

D.3.6.6 The RMM library .....

D.3.6.6.1 Organisation of the library .....

D.3.6.6.2 Estimation and documentation of RMM effectiveness in the library .....

D.3.6.6.3 How to work with the library .....

exposure assessment

risk characterisation.

final ES

bridge ESR in CSR and eSDS

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# REACH and Exposure Scenarios: Overall...

The ES represents a model of how substances are used in practice, in all applications from synthesis/import to the waste stage.

- A quantitative assessment of potential exposures is made
- Outcomes of the exposure assessment are compared to the effects levels of the substance: NO RISK??
- The ES includes RMMs
- During the CSA process, if safe use cannot be demonstrated for a given operation, then iteration is required until an acceptable outcome is achieved

=> ES are associated with significant data requirements (exposure, RMM, process, hazard...)

# REACH and Exposure Scenarios: format

An ES format is proposed  
in the CSA/CSR  
guidance part D

1	Short title of the exposure scenario
2	Processes and activities covered by the exposure scenario
Operational conditions of use	
3	Duration and frequency of use <i>Specify for workers, consumers, environment ( where relevant)</i>
4.1	Physical form of substance or preparation; surface to volume ratio of articles <i>Gas, liquid, powder, granules, massive solids; Surface area per amount of article containing the substance (if applicable);</i>
4.2	Concentration of substance in preparation or article
4.3	Amount used per time or activity <i>Specify for workers, consumers, environment ( where relevant)</i>
5	Other relevant operational conditions of use <i>For example• Temperature, pH, mechanical energy input; capacity of receiving environment (e.g. water flow in sewage/river; room volume x ventilation rate) wear and tear with regard to articles (if applicable); conditions related to service-life- time of articles (if applicable)</i>
Risk Management Measures	
6.1	Risk management measures related to human health (workers or consumers) <i>Type and effectiveness of single options or combination of options on exposure to be quantified [options to be phrased as instructive guidance]; specify for oral, inhalation and dermal route;</i>
6.2	Risk management measures related to the environment <i>type and effectiveness of single options or combination of options to be quantified [options to be phrased as instructive guidance]; specify for waste water, waste gas, protection of soil;</i>
7	Waste management measures at the different life cycle stages of the substances (including preparations or articles at the end of service life);
Information on estimated exposure and DU guidance	
8	Exposure estimation and reference to its source <i>Estimation of exposure resulting from the conditions described above (entries 3-7 and the substance properties; make reference to the exposure assessment tool applied; specify for routes of exposure; specify for workers, consumers; environment)</i>
9	Guidance to DU to evaluate whether he works inside the boundaries set by the ES <i>Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of variables (and a suitable algorithm) which together indicate control of risk, but which have some flexibility in the respective values for each variable. Note: This will mostly be specific conditions for a certain type of product; this section may also include a link to a suitable (e.g. easy-to-use) calculation tool. Where relevant: Other methods for DU to check whether he works within the</i>

# REACH and Exposure Scenarios: format

1. Title (Example 3)				
Free short title	Professional Manual Spray Painting for car repair			
Systematic title based on use descriptor	PC9, PROC8, PROC 11, ERC8a			
Processes and tasks covered	Spraying including mixing of paint and filling of spray gun			
2. Operational conditions and risk management measures				
Spraying outside industrial setting and applications. Thus wide disperse use in open system is to be assumed. The substance does not end up in the finished product and is not fully consumed. Therefore internal recovery or environmental risk control measures are likely to be required, unless the amounts are negligible.				
2.1 Control of workers exposure				
Frequency and duration of use				
Duration of exposure	Mixing	< 0.5 hours/day		
Duration of exposure	Spraying	< 4.5 hours/day		
Frequency of exposure	Mixing	Repeated per day		
Frequency of exposure		< 240 days/year		
Product characteristics				
Physical state of the product	Liquid			
Concentration of substance in product	< 40%			
Vapour pressure of the substance	< 1.2 kPa			
Amounts used				
Amounts used	Mixing	< 0.2 L/min		
Amounts used	Spraying	< 0.1 L/min		
Other given operational conditions affecting exposure or workers				
Inside/outside	Inside			
Room volume	100 m <sup>3</sup> to 1000 m <sup>3</sup>			
Distance of worker from source <sup>1</sup>	< 1 m			
Other sources in the room	Yes			
Human factors not affected by risk management				
Type of skin contact	Light (touching contaminated surfaces and/or limited deposition of dust or aerosols)			
Conditions and measures to control dispersion from source towards the worker				
Closed ventilated spray cabin with airflow away from worker needed	Spraying	Yes		
Use local exhaust ventilation	Mixing	Yes	Required efficacy: 65%	Explanation on efficacy: based on analyses under STOFFENMANAGER
Avoid significant aerosols or splashes	Mixing	Yes		
Conditions and measures related to personal protection, hygiene and health evaluation				
Apply respiratory protection ( half mask with organic vapour filter)	Spraying	Yes	Required efficacy: 60%	Explanation on efficacy: based on assigned protection factors used in STOFFENMANAGER
Use butyl rubber gloves during spraying	Spraying	Yes	Required efficacy: 90%	Explanation on efficacy: based on default assumption for the efficacy of proper gloves (ECB, 1996)
Regularly clean work area	Yes			
Regularly inspect and maintain equipment	Yes			
2.2 Control of environmental exposure				
3. Risk characterization ratios and exposure estimation				

Work on a "revised format" ongoing in the context of the CSA/CSR IT tool

Principles: keep it easy, standardised for processing and presenting, but flexible, 'similar' in CSR and in the eSDS, including the key info from exposure estimation and risk characterisation (presented in the CSR) in the ES communicated to the customers.

# Generic exposure scenarios (1)

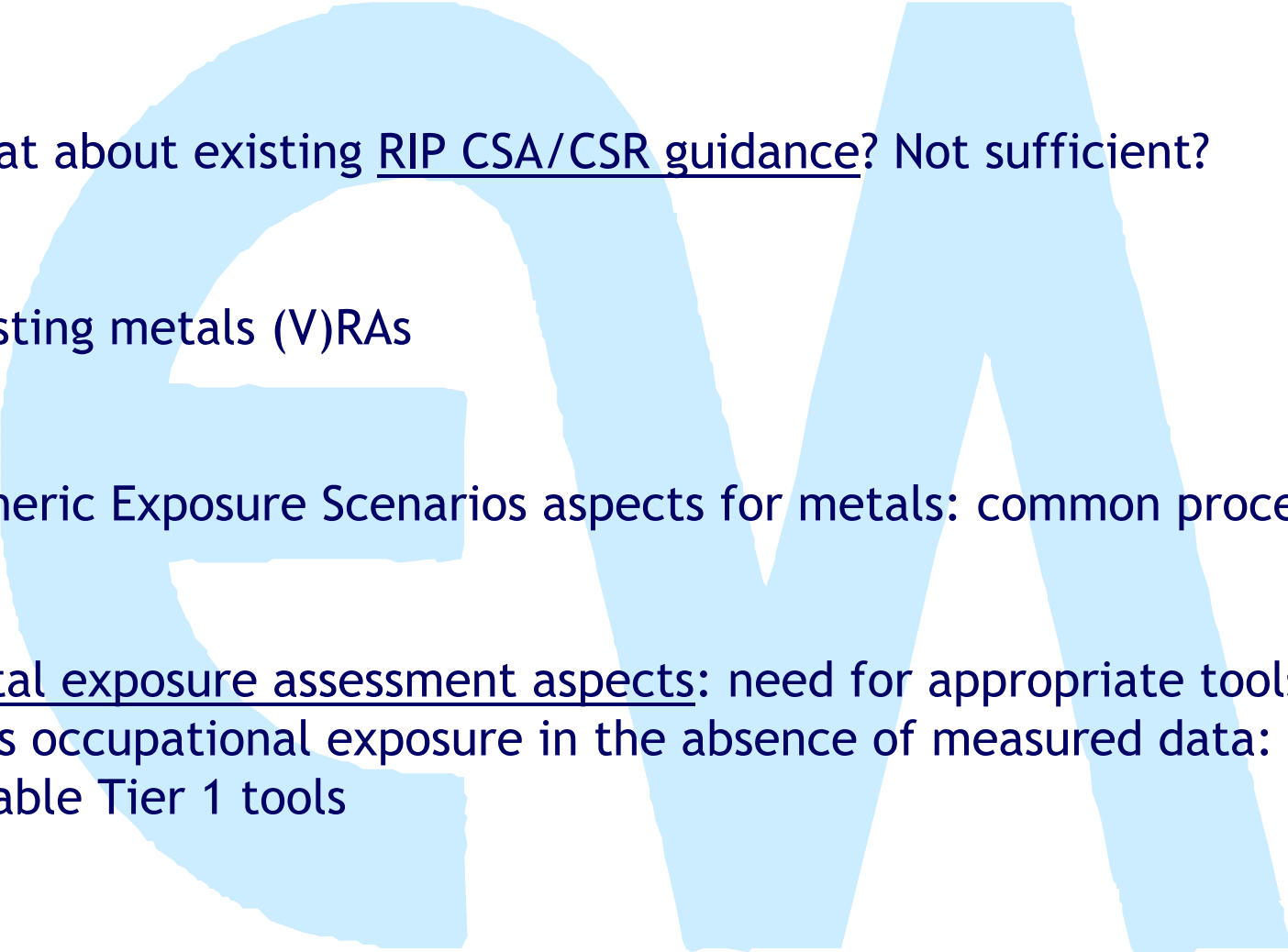
Concept: make it more manageable!!

GES describe the necessary OCs and RMMs that should be implemented to control the risks to human health and the environment associated with the use (or uses) of a substance/product within a general area of industry.

*By definition, it will be comprised of the ESs for the various tasks and activities that constitute the general use of the substance/product within a specific sector.*

# Why metals ES?



- 
- What about existing RIP CSA/CSR guidance? Not sufficient?
  - Existing metals (V)RAs
  - Generic Exposure Scenarios aspects for metals: common processes
  - Metal exposure assessment aspects: need for appropriate tools to assess occupational exposure in the absence of measured data: available Tier 1 tools



exposure assessment

**Metal specific issues: Process categories**  
**Assessment of exposure (inhalation, dermal routes)**  
**Biological monitoring**  
**Recycling**

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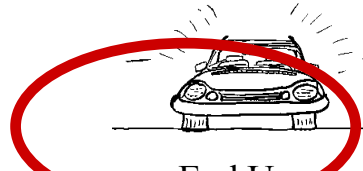
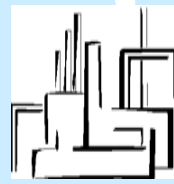
**Metals risk assessments under ESR**

# Safety Data Sheets / Chemical Safety Reports

- exposure scenario
- risk management measures
- registration number
- authorization/restriction info

## Information on use/ exposure scenarios

- **uses**
- sufficient info for **exposure** scenarios
- risk management measures
- new info on hazardous properties



# Generic ES aspects for metals

Key: exposure scenarios are linked to **exposure** and how to control exposure

Metals industry: a number of **common processes** can be identified

A process is defined as *the procedures involving thermal, mechanical or chemical steps to aid in the manufacture of a metal or metal product generating emissions/ exposures*

Examples:

- ✓ Furnace and high temperature operations
- ✓ Packaging/unpacking metal powder

***variation in complexity is possible but commonalities in operational conditions, generated exposures, RMMs***

# Exposure assessment methodologies for metals

Exposure data:

- Measured data for workers and the environment:
  - Databases
  - (V)RAs
  - Biological monitoring
  - Emission data

In the absence of data: models??

- EUSES?
- EASE??
- ConsExpo?
- RiskofDerm??
- ...



This Workshop...



# REACH and (Metals) Exposure Scenarios: conclusions

ES require simplification...

ES require a simple, stepwise approach

ES require extensive data gathering

ES require best available communication techniques

ES require good exposure assessment techniques

ES require refinement

ES require clear 'rules of the game'

ES require work and patience....

# REACH and (Metals) Exposure Scenarios: conclusions

ES require simplification... *Frank*

ES require a simple, stepwise approach *Ilse*

ES require extensive data gathering *Anja, Alistair, Daniel*

ES require best available communication techniques *France*

ES require good exposure assessment techniques *Rodger*

ES require refinement *Frederik*

ES require clear 'rules of the game' *France*

ES require work and patience.... *Noömi, Eric, Katia, Claire*