



MISA workshop in practice

2 October 2018

Brussels





Welcome



Getting to an interactive workshop...(1/3)

09:50 – 12:00 MORNING PLENARY BREAKOUT SESSIONS

BREAKOUT SESSION	
TOPIC	READ-ACROSS
RAPPORTEURS	Kimmo LOUEKARI & Agnes KOVARI and Koen OORTS & Violaine VEROUGSTRAETE
PLENARY DISCUSSION	<ul style="list-style-type: none">▪ Introduction to the topic: main issues and expectations (ECHA)▪ How consortia have addressed the requirements (industry case study)▪ Interactive exchange: questions on presentations▪ Tour de table to list specific methodologies

Cobalt case
See your
handout and
presentation

Vanadium
case



Getting to an interactive workshop...(2/3)

BREAKOUT SESSIONS run in parallel	
13.00 READ-ACROSS	13.00 EOGRTS / ROUTE OF EXPOSURE
Kimmo LOUEKARI and Violaine VEROUGSTRAETE	Agnes KOVARI and Hugo WAETERSCHOOT
<ul style="list-style-type: none"> ▪ Discuss in details the morning plenary exchanges ▪ Achieve agreements to successfully fulfil the regulatory requirements 	<ul style="list-style-type: none"> ▪ Introduction to the topic: main issues and expectations (ECHA) ▪ How consortia have addressed the requirements (industry case study) ▪ Interactive exchange ▪ Achieve agreements to successfully fulfil the regulatory requirements
	14.00 MUTAGENICITY
	Jos MOSSINK and Hugo WAETERSCHOOT
	<ul style="list-style-type: none"> ▪ Introduction to the topic: main issues and expectations (ECHA) ▪ How consortia have addressed the requirements (industry case study) ▪ Interactive exchange ▪ Achieve agreements to successfully fulfil the regulatory requirements

Zinc case

Aluminium

Getting to an interactive workshop...(3/3)

- 15:00 – 15:15 COFFEE BREAK



- 15:15 – 16:15 PRESENTATION OF THE OUTCOME OF THE BREAKOUT SESSIONS by Rapporteurs

NOTES TEMPLATE

Breakout session: _____

ECHA expectations	Industry proposals	Topics discussed	Conclusions (agreements / open questions / remaining issues)

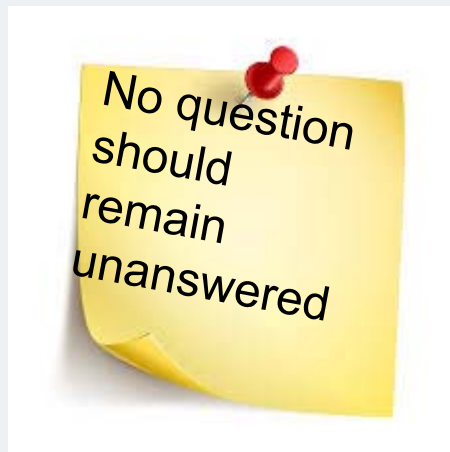
- 16:15 – 17:00 CONCLUSIONS AND FOLLOW-UP: deliverables, timing consortia workplan, blog for questions

Important notes: case studies

- Case studies are presented to **trigger discussions** and not to be evaluated as being 'right' or 'wrong'
- The common aim is to achieve a common understanding of what should be included in the registration file to fulfil the standard information requirements and how it could be reported/explained:
 - Case studies are here to help!
 - They will help you to compare what you have with what is presented
 - Case studies are presented to raise some technical issues and/or requirements we may have overlooked
 - Please do not circulate the case studies outside this workshop

Important notes: make it your workshop!!!

- Be active/interactive (Chatham House rules during breakouts)
- Take notes for yourself of points to check (paper)
- Note down outstanding questions
- Use post-its



Topic: READ-ACROSS	
Contact information:	Name and surname: _____ Affiliation: _____ Email address: _____ Phone number: _____
Generic questions on human health information requirements:	
Substance-specific questions/issues:	
Confidential?	[yes] [no]