

Setting the scene (I)

Substance Identification and Sameness Workshop

6-7 October 2014

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Outline

- Looking back: A few milestones of Substance Identification under REACH
 - Events that have shaped current SID understanding and questions
- SID challenges ahead
- Objectives of the workshop

Looking back:

SID in a few dates



SID in a few dates

2008-2009 early years under REACH

- June 2008 - Entry into operation
 - Substance identification in continuation with 7th amendment of Directive 67/548/EEC
 - Role of Annex VI.2
- Dec 2009 - 1st SID workshop with stakeholders
 - ECHA's advice to prepare a dossier, pre-2010

SID – the early years

Trust the rules

In-line with
the rules



Same
Substances

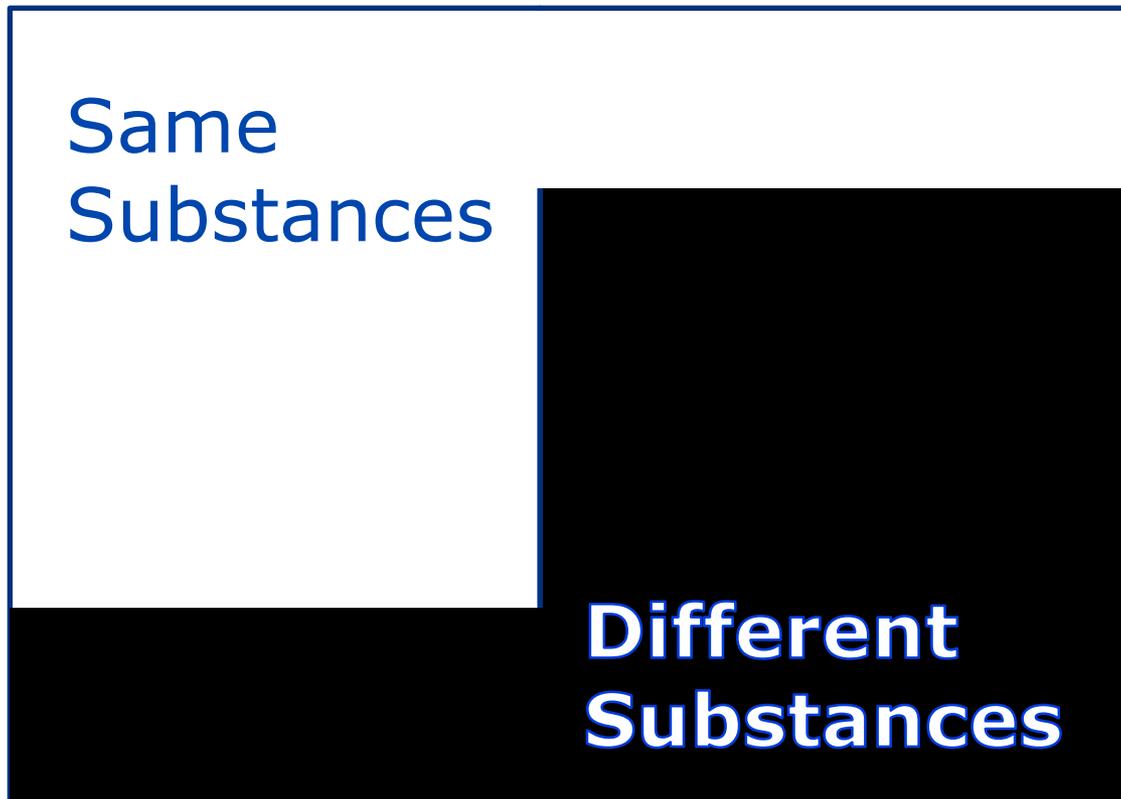
**Outside the
rules**



**Different
Substances**

SID – the early years

Trust the rules with their foreseen exceptions



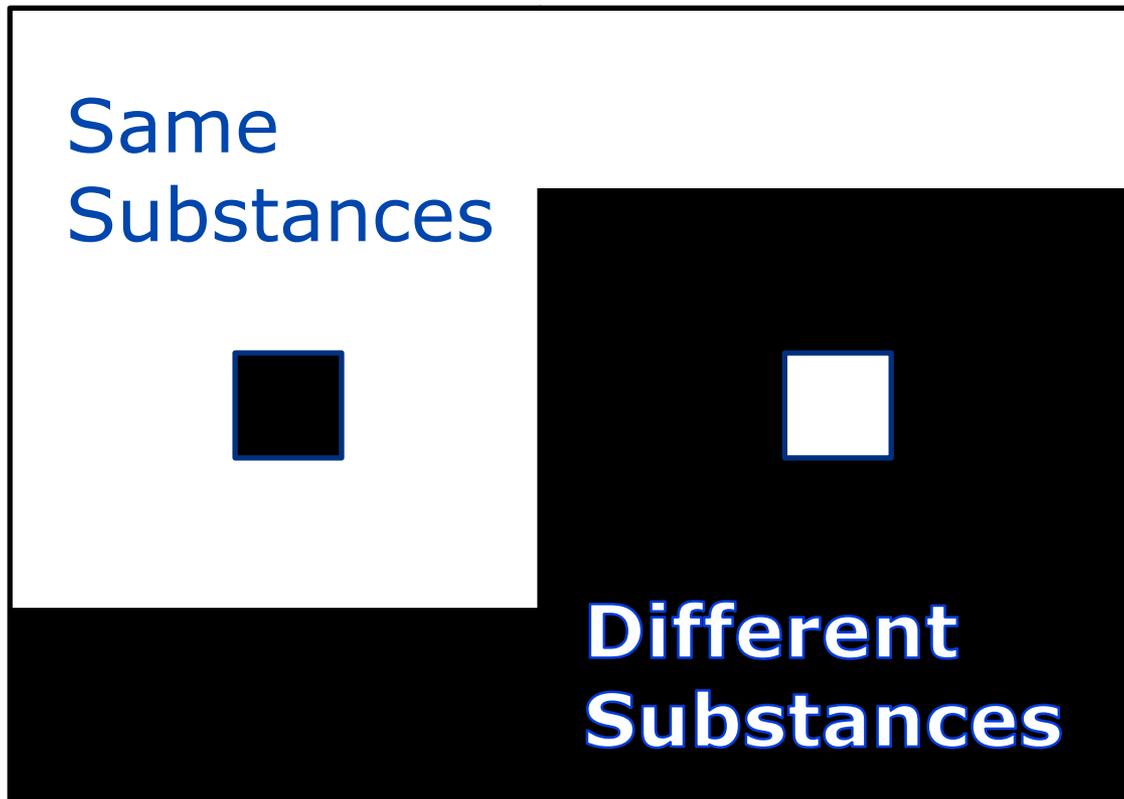
SID in a few dates

2010-2012 the coming of age

- End 2010 - Backlog of over 350 inquiry dossiers
 - Substance identification serves a purpose
- 2010-2012 – Trouble cases: complex UVCBs under Dossier Evaluation, crystalline phases, nano discussions (RIPoN1)
 - Guidance can be inconclusive – registrant is responsible for the registration approach chosen

SID – the coming of age

Can the rules answer everything?



SID in a few dates

2013-2014

- Feb 2013 – Commission’s general report on REACH
 - Clarification is needed on sameness
- Feb 2013 – SID workshop ECHA-MSCA-COM
 - Challenging concepts in the guidance
 - Substances can be broad – not fuzzy
- March 2014 – OECD SID guidance on oleochemicals UVCBs

Shades of SID

PRESUMPTION ZONE

**Compliance with all
accepted rules
(e.g. Guidance,
FAQs, manual of
decisions under
NONS, Q&As)**

→ Same substances

**Presumption that
substances are the
same**

Shades of SID

PRESUMPTION ZONE

Compliance with all accepted rules (e.g. Guidance, FAQs, manual of decisions under NONS, Q&As)

→ Same substances

IMPOSSIBILITY ZONE

Breach of fundamental rules (e.g. Art. 3 or guidance examples)

→ Different substances

Presumption that substances are the same

Substances are different

Shades of SID

PRESUMPTION ZONE

Compliance with all accepted rules (e.g. Guidance, FAQs, manual of decisions under NONS, Q&As)

→ Same substances

Presumption that substances are the same

PLAUSIBILITY ZONE

- No breach of fundamental rules**
- But other rules not applicable or not conclusive**



Possibly same substances but ...

Substances can be considered same, conditional on appropriate argumentation

IMPOSSIBILITY ZONE

Breach of fundamental rules (e.g. Art. 3 or guidance examples)

→ Different substances

Substances are different

Challenges ahead



SID: Registration challenges ahead

For registrants

- ~50000 New dossiers in 2018 → new joint submission members
- ~20000 New substances in 2018 → new SIEFs

For authorities

- ~200-400s Dossier evaluation per year, every year
- ~50s Substance evaluation per year, every year

Objectives for today and tomorrow



Objectives of the workshop

- A smaller grey zone?
- A lighter shade of grey?
- How to navigate the grey zone?



Thank you!

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