

# Rights and obligations resulting from SID considerations

## SID Workshop

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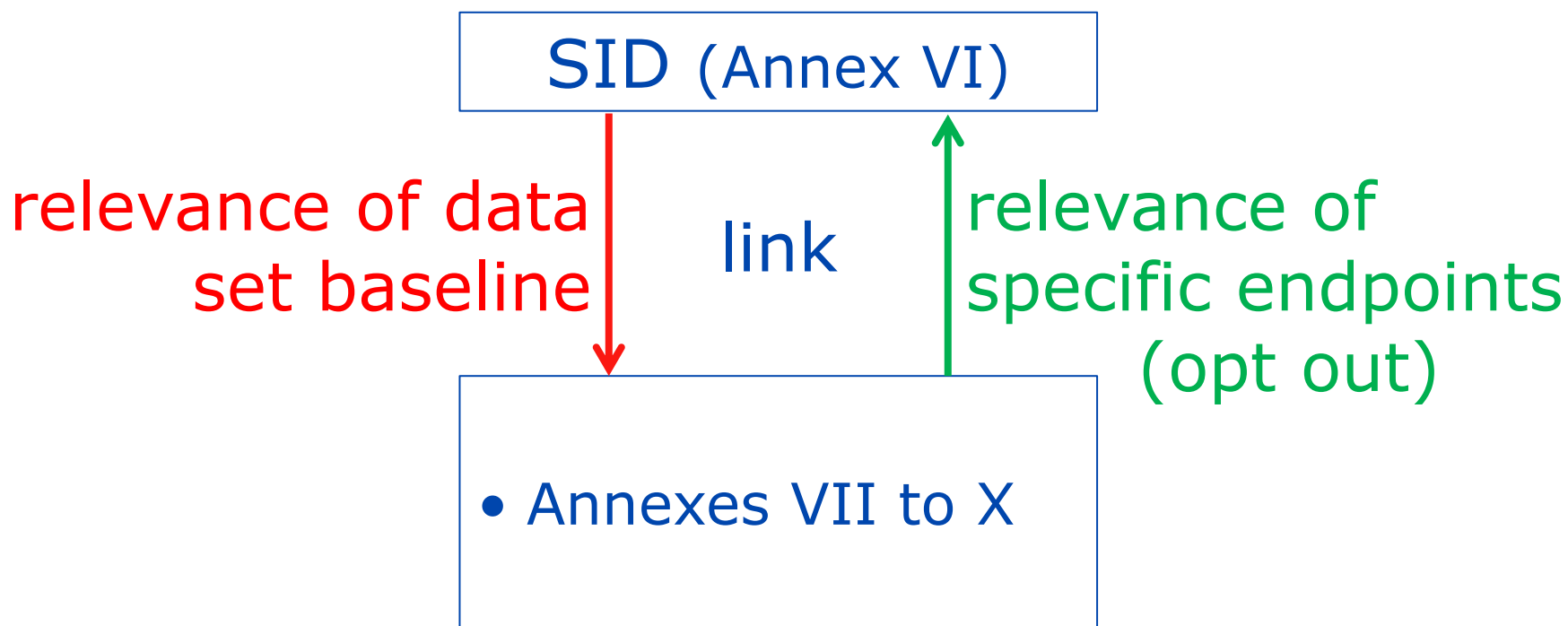
# Legal and scientific dimensions

- Regulatory rules have two aspects:
  - scientific aspect (basis determining rights and obligations)
  - legal aspect (rights and obligations)
- The concept of “sameness”
  - From the scientific standpoint  
Refers to the similarity between two or more compositions
  - From a legal standpoint  
Concerns the extent to which registrants can refer to the same set of information on hazards (data set baseline) for various compositions  
Remarks:
    - determining this is critical for registration, data sharing, evaluation, authorisation and restrictions
    - distinction joint submission obligation / data sharing obligation

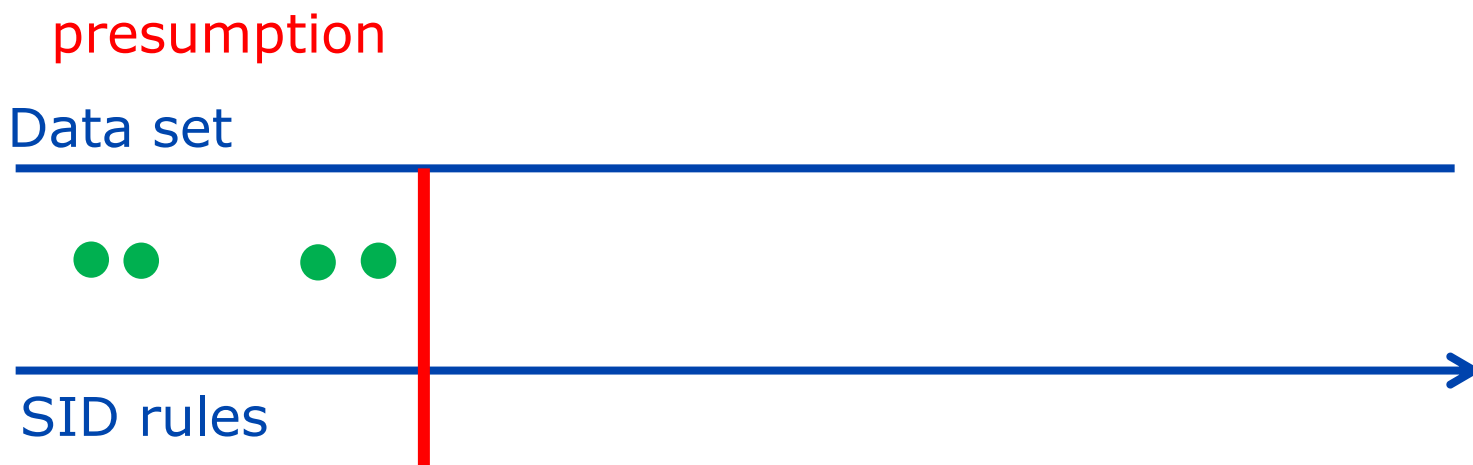
## Objective of Registration

- Objective pursued by the registration obligation:  
« *All available and relevant information on substances [...] should be collected to assist identifying hazardous properties* » (Recital17)
- Proportionality principle commends ECHA to not go beyond what is suitable and necessary to achieve this objective
- Clear SID/sameness is an essential element to achieve this objective but it is not *per se* the objective of registration
- SID/sameness considerations must be made with the aim of identifying the hazardous properties of the composition(s) concerned

# Structure of Registration dossiers

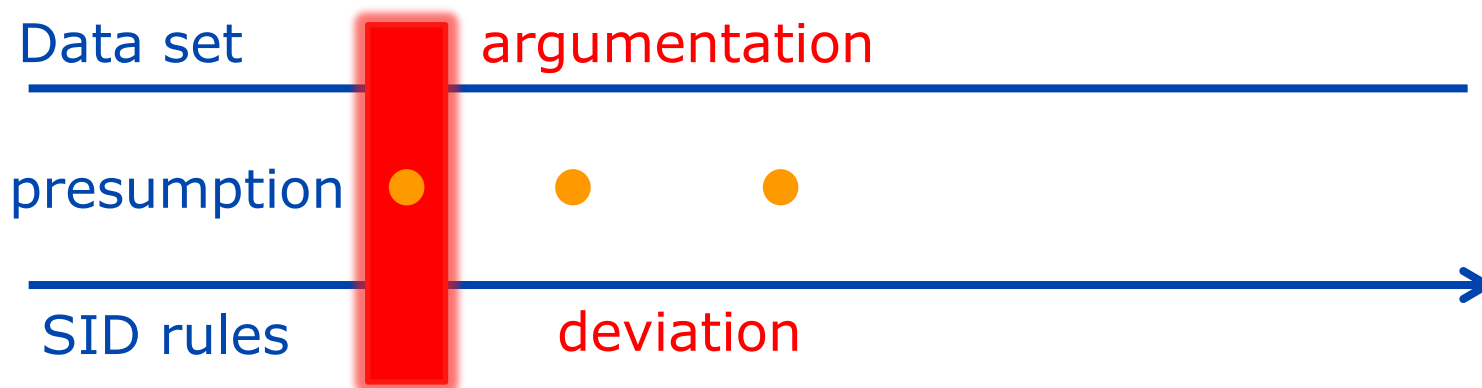


## When SID rules apply



Agreed SID rules (guidance, authorities' practices) are setting the level up to which there is a presumption that different compositions may refer to the same data set baseline

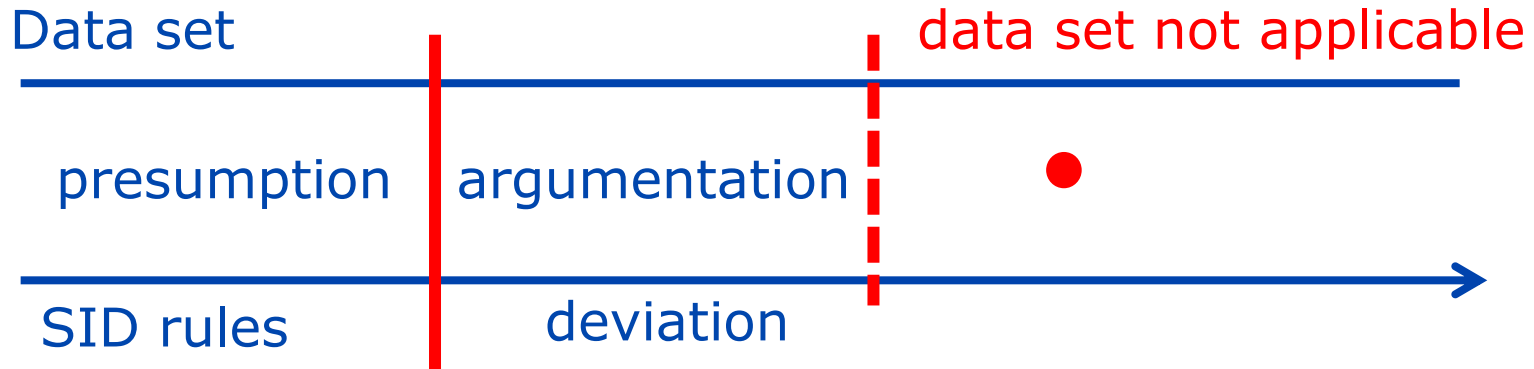
## In case of deviation from SID rules



Ambiguous or insufficient composition similarity as a result of a deviation from an established substance ID rule.

Registrant may exceptionally refer to the same data set baseline if he provides a valid justification that the data set baseline is relevant for that composition (registrant's responsibility)

## In case of deviation from SID rules



Registrant cannot benefit from the data set baseline:

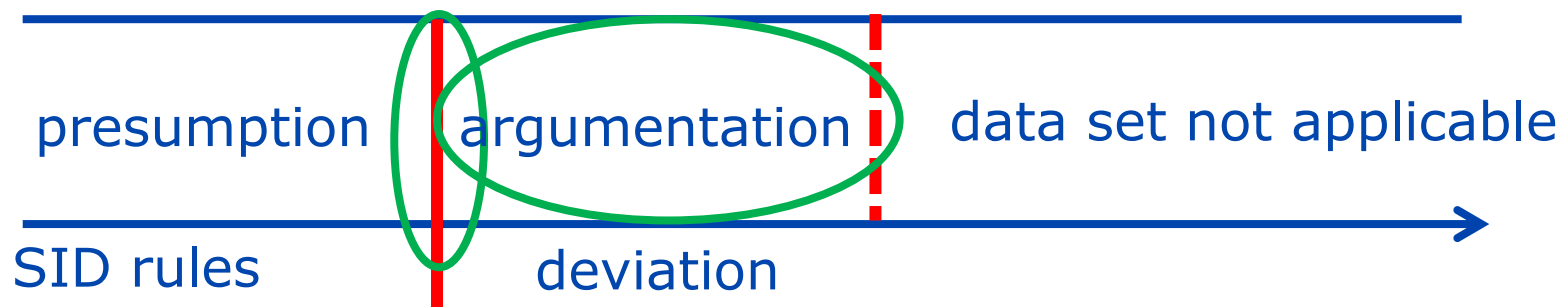
→ deviation from established ID rule not justified;  
and

→ deviation from ID rule possible but no valid  
justification of relevance of data set is provided

Registrant shall submit another data set separately,  
but may include read-across arguments

## Legal aspects to be resolved

Test data and CSR



1. The extent to which multiple registrants may benefit from the presumption that a data set baseline applies to all
2. The nature/level of argumentation required to ensure that a registrant can refer to data set baseline jointly submitted in spite of variation of its composition(s)



## Few advices

Terms are essential for a common understanding

### Be mindful

- Ensure that the persons you are speaking to shares/understand the prospect from which you are approaching the issue
- Try to qualify the meaning of generic terms

# Thank you!

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