Strengthening the OSOR principle

Information session on the updated registration process

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This presentation

- Implementing Regulation on joint submission of data and data sharing
- OSOR, principle and implementation
- Substance Identity Profile

Implementing Regulation

IR: what is it about (1/2)

- Transparency
  - Itemisation
  - cost-sharing model
  - documentation

- One substance, one registration
  - All registrants of same substance in one registration
  - ECHA to ensure
  - Full opt out possible

IR: what is it about (2/2)

- Fairness and non-discrimination
  - Reimbursement mechanism
  - Equal rights to all members
- Dispute resolution
  - Access to joint registration
  - Efforts to come to an agreement

A closer look at the OSOR principle and its implementation

OSOR
One Substance – One Registration

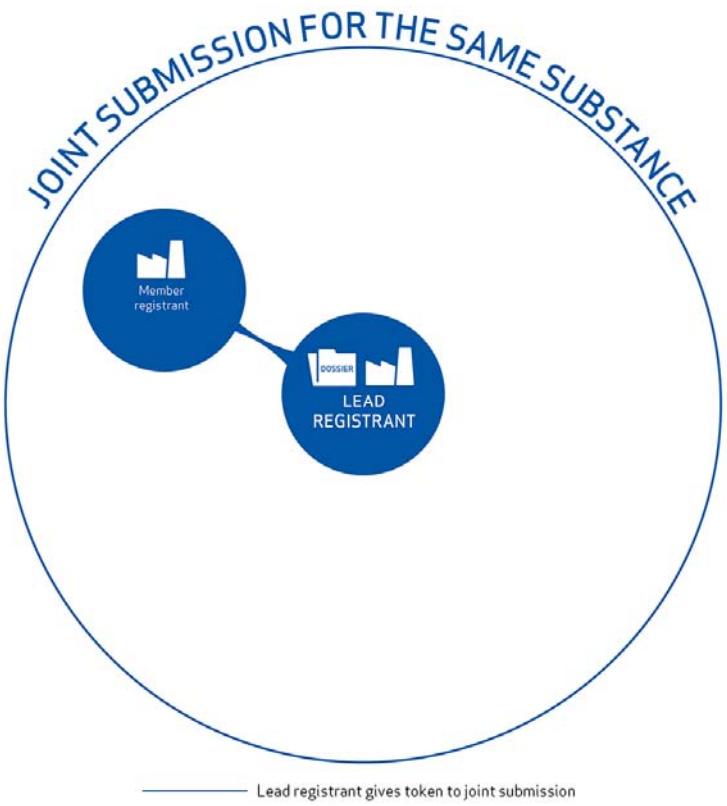
same substance

same information

Typical joint submission

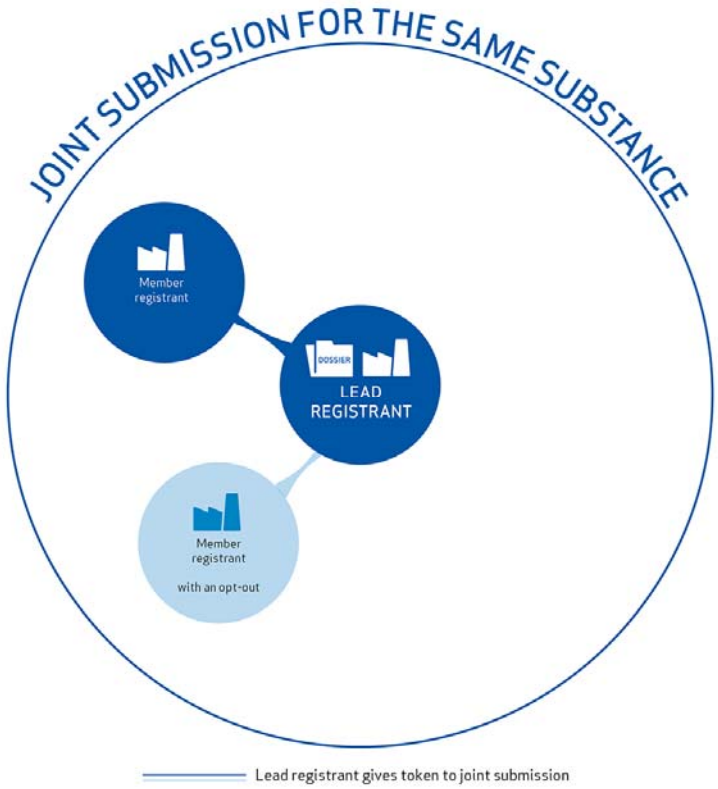
- Lead dossier
- Member dossiers
- Same information

- Lead provides token



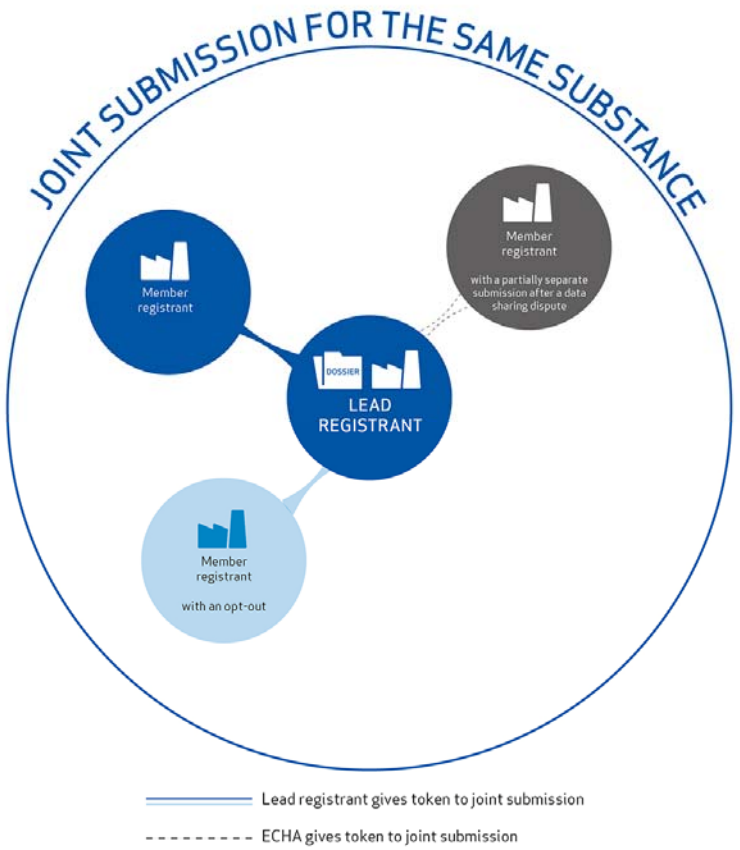
Joint submission, opt out

- Member opts out for part of the data
- Lead provides token



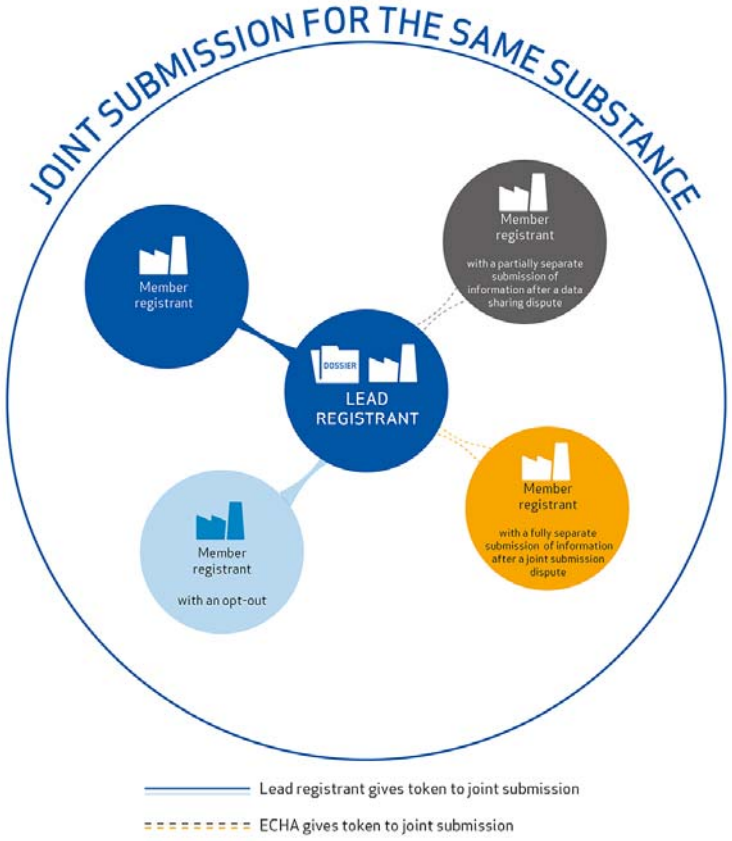
Data sharing dispute

- Partially separate submission after dispute
- Full opt out with all data is possible
- Dispute remains last resort



No data to share

- Normally lead registrant provides token
- Echa may provide token
- Dispute is last resort



Main aim with the implementation

- Try to ensure that all registrants of the same substance (for the same registration type) are brought together.

- Limit the “easy way out” of submitting individually instead of dealing with the data sharing and the SIEF process.

- Ensure that there is a proportionate way forward for the registrants who are blocked.

Creation of a joint submission

Rule #1: Only one joint submission can be created for the same substance and same registration type (Full (11), Intermediate (19)) combination (i.e. for a substance there can be two joint submissions)

Reasoning:

- *The articles are separated in the regulation and due to the difference in data requirements between Full and Intermediate it would be disproportionate to "force" both types together.*

Creation of a joint submission

Rule #2: A joint submission is considered 'existing' when the Joint submission object is created, regardless if the lead dossier has been submitted or not

Reasoning:

- *Blocking creation after a dossier submission (or successful lead registration) would allow a time window for creating multiple joint submissions*

Creation of a joint submission

Rule #3: The creation of a joint submission is always allowed unless another one 'exist': the presence of individual submissions will not block the creation of a joint submission

Reasoning:

- *Allowing existing individual to fully block the second submitter would be disproportionate*
- *Data sharing solution is not appropriate as there is no joint submission to give access to*

Submission of initial dossier

Rule #4: Initial submission of individual dossier is allowed unless i) a JS exists or ii) another individual dossier exists for the same registration type

Reasoning:

- *The main aim of the implementation is to eventually have all the Registrants submitting together*
- *Avoiding as much as possible the "easy way out" of individual submissions..*
- *..still maintaining some flexibility (individual submissions still possible if no JS or other individual exists)*

Submission of update dossier

Rule #4bis: Update submission of individual dossier is allowed until a JS exists and the LR has successfully submitted the lead dossier (passed BR)

Reasoning:

- *Individual submission still possible if LR has not passed BR: would be disproportionate to delay the submission of update due to a non 'fully functioning' joint submission*

Submission of a dossier

- Rule #5: Lead and members of a Joint submission are always allowed to submit both initial and update dossiers.

Reasoning:

- *The safety guard is on the non-duplicate creation of a joint submission*

Legacy data

Multiple existing joint submissions

- Cases handled individually and over time
- Updates allowed according to Rule #5
- Eventually only 1 joint submission

Multiple existing individuals

- Multiple existing individuals will be allowed to update until a JS is created and the Lead dossier is submitted according to Rule #4bis
- Eventually only 1 joint submission

Substance Identity Profile

Reporting the boundaries of the substance of the registration

Elements of the SIP

- “Boundary composition(s)” define the substance sameness criteria agreed by all members
- Registrants relying on the information jointly submitted should be within the scope of the SIP
- SIP essentially defined in terms of identity of constituents and their concentration ranges
- SIP may also include additional identifiers
- Not all possible compositions for one substance
- Could evolve over time

Why a SIP

- To implement OSOR requires transparency on what has been considered as the “one substance” registered
  - “scope of the registered substance”
  - Framed by the sameness criteria defined by registrants
  - Data submitted covers the compositions that are within SIP

Implementation

- All parties intending to register compositions within scope will need to register these compositions as “**one** substance” in **one** joint submission

Transparency

- Having this information available in IUCLID dossiers

Why a SIP

- Facilitates SIEFs to report transparently their sameness criteria in their dossier
- Disagreements focused on SID should not materialise into data sharing – joint submission disputes
- Enables member registrants to ensure their composition is within scope of the registered substance
- Transparency on scope of “letter of access” for parties joining an existing registration

More benefits

- Facilitates inquiries for new registrants
- Will facilitate specific compositions to be bridged more clearly with submitted data
- Facilitates assessment of information submitted jointly for complex substances

Not a new concept, nor ECHA idea

- "SIP" introduced by Cefic in their Guidance to Lead Registrants
  - "*can be used to support the substance sameness discussions in SIEFs*"
  - "*can then be shared with the SIEF members in order to facilitate the agreement of substance sameness*"
  - A joint submission implicitly entails a SIP
  - Used extensively by many consortia (available on REACHcentrum)

Example of SIP published by industry

SIPTemplate-Mono full version

Version	SFF / LR for:	SUBSTANCE IDENTIFICATION PROFILE (SIP)
v.1	CHDM	
[date]	SIEF Formation Facilitator	
Jun-09	Eastman Chemical	

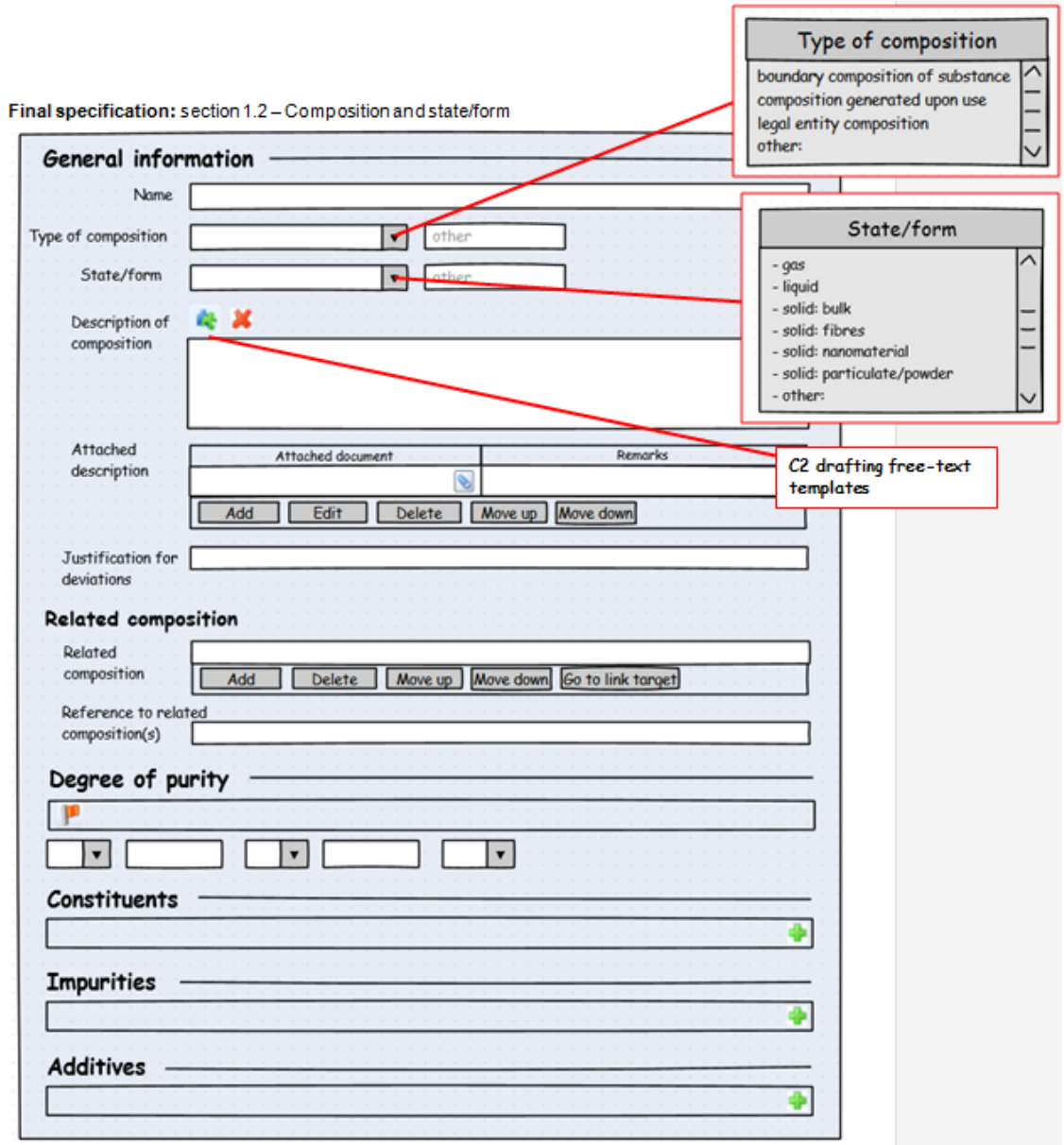
No	1.1. Chemical Name	1.2. EC Number	1.3. CAS Number	1.4. Composition Type
	Cyclohex-1,4-ylenedimethanol	203-268-9	105-08-8	Mono-Constituent Substance

This Substance Identification Profile (SIP) is developed to represent the Identification parameters of the Substance described in line with the Substance Identification requirements of REACH Annex VI and relevant Guidances for the purpose to identify the substance sufficiently to meet the REACH Registration requirements under the same Joint Submission.

The content of this SIP is developed by Eastman Chemical, discussed and agreed upon within the SIEF Leadership Team to the best of their knowledge to be used for the purpose of substance identification and sameness checking process in the (pre-)SIEF and as base for being part of the same Joint Registration Dossier under REACH

Reference	Substance Identification Parameter	Value	Remark / Justification
2.1.A	Name or other Identifiers of the substance		
2.1.1.a	IUPAC Name	1,4-Cyclohexanedimethanol	
2.1.1.b	Other International chemical name	1,4-Bis(hydroxymethyl)cyclohexane, 1,4-Cyclohexamethylenebis methylol, 1,4-Dimethylolcyclohexane, 1,4-Cyclohexanedimethanol	
2.1.2.a	Chemical Name	Cyclohex-1,4-ylenedimethanol	
2.1.2.b	Abbreviation	CHDM	
2.1.3.a	EC Number	203-268-9	
2.1.4.a	CAS Number	105-08-8	
2.2	Information related to molecular and structural formula of the substance		
2.2.1.a	Molecular Formula	C8H16O2	
2.2.2.b	Typical ratio of (stereo) isomers	30% wt cis-isomer	by GC
2.2.3.a	Molecular Weight	144.21	
2.3	Chemical Composition of the substance		
2.3.1	Main Constituent		
2.3.1.a	Name -Main Constituent	1,4-cyclohexanedimethanol	
2.3.1.b	CAS Number -Main Constituent	105-08-8	
2.3.1.c	EC Number -Main Constituent	203-268-9	
2.3.1.d	Concentration range -Main Constituent - Lower value	80%	
2.3.1.e	Concentration range -Main Constituent - Upper value	100%	

SIP in IUCLID 6.1



Conclusions

- Implementing regulation
  - Transparency and non-discrimination
  - Ensuring the OSOR principle
- One substance, one registration
  - Blocking multiple joint submissions
  - Opting out remains possible
  - ECHA to resolve disputes
- Substance identity profile
  - clarity on scope of registered substance
  - clear benefits

Thank you!

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