



Substance Identification & Sameness checking approach

Lead Registrant Workshop

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Turning our REACH expertise into practical help for industry

 **reachcentrum**[®]

Agenda

- **Why carry out the Substance Identification Process**
- **Substance Identification & Sameness checking in practice**
- **Suggestion how to move ahead**

Accurate Substance Identification needed - WHY?

- **Accurate Substance Identification in pre-Registration was important**
 - Accurate & justifiable EC Number was important to justify 'Phase In' Status.
 - The EC#, CAS# and name determined in which pre-SIEF the substance would start.
 - During the pre-SIEF process the SIEF members need to agree upon the substance sameness.
 - Unprepared this can have consequences!!

Agenda

- **Why carry out the Substance Identification Process**

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Issues that have arisen

- **Some Issues experienced**
 - The composition of the substance
 - Reluctance to include impurities
 - Worries about Classification and Labeling

- **Solutions**
 - Creating a Substance Identification Profile
 - Fill in the SIP Excel sheet with as much detail as is necessary
 - Consideration for SIEF splitting or merging

Substance Sameness Checking in Practice

Potential Registrants (<-> SIEF/Consortium)

Consortium / SIEF Leadership Team Members

Pre-Registration

Preparing for Pre-Registration & for Sameness Check in pre-SIEF
 Interpretation Guidance Substance Type SI under REACH
 •EC nr, EC Name, CAS nr, Other Identifiers

Pre-SIEF

1. Define Substance Identification Profile (SIP) & procedures for agreement

a) Approved EC, CAS, Name & Other Identifiers

b) Extra SI needed (linked to Subst. Type & Industry experiences) to sufficiently Identify the Substance for purpose

c) Verification Process

SIP

2. Substance sameness checking process

- Guided process to define & agree upon Substance sameness checking process (drafting & using SIP's)
- Agree upon the same substances in the Consortium (existing and new Members)
- Agree on role in sameness checking process in SIEF
- Alignment with the sameness checking in SIEF

3. Maintenance of the Annex 1

- Adding, changing substances covered by the Consortium
- Maintenance of the Substance Identification Profiles (SIP) per Substance
- Archiving of the SIP's per existing & new Member

SIEF

2. Acceptance process to form a SIEF

Other SIEF?

No

Accepted?

Yes

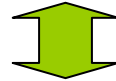
SIEF

Registration

3. Company specific Substance Identification for Registration

Substance Identification in a Consortium

- **The definition of a Substance in the CA (art I.1) refers to Annex 1**
 - Overview of the substances covered under the Consortium Agreement
 - Define the Identity of each Substance (Category) as clearly as possible



- **Key for the Purpose and Objectives of the Consortium (Art II.1):**
 - Agreement on the identity and sameness of the Annex 1 listed Substances and its regulatory status AND on Substances for which available information might be relevant;
 - Development of the Core data for the Substances
- **Key for Membership acceptance (Art III)**
- **Key for use of Information (Art V)**
- **Key for all Substance related activities conducted under the CA**



Clear process needed how to setup the Annex 1, maintain and align with the (pre-)SIEF Sameness Checking Process

Substance Identification in a SIEF

- **The definition of a Substance by the SIEF Leadership Team (if any)**
 - Define the Identity of the Substance as clearly as possible
 - Fill in as much detail as possible that is generic and accepted by all



- **Key for the Purpose and Objectives of the Substance Identification Profile (SIP) :**
 - Development of the Core data for the Substances
- **Identify the process for preparing the SIP**
- **Identify how the SIEF Membership can accept**
- **Identify where the SIP has been stored as Information for newcomers to the SIEF**

Substance Sameness Checking in Practice

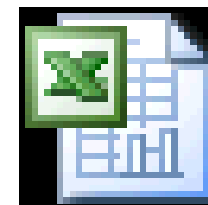
Microsoft Excel - P-I182 SIP - Citric Acid and Citrates - 26-01-2009.xls

File Edit View Insert Format Tools Data Window Help Adobe PDF Type a question for help

D95

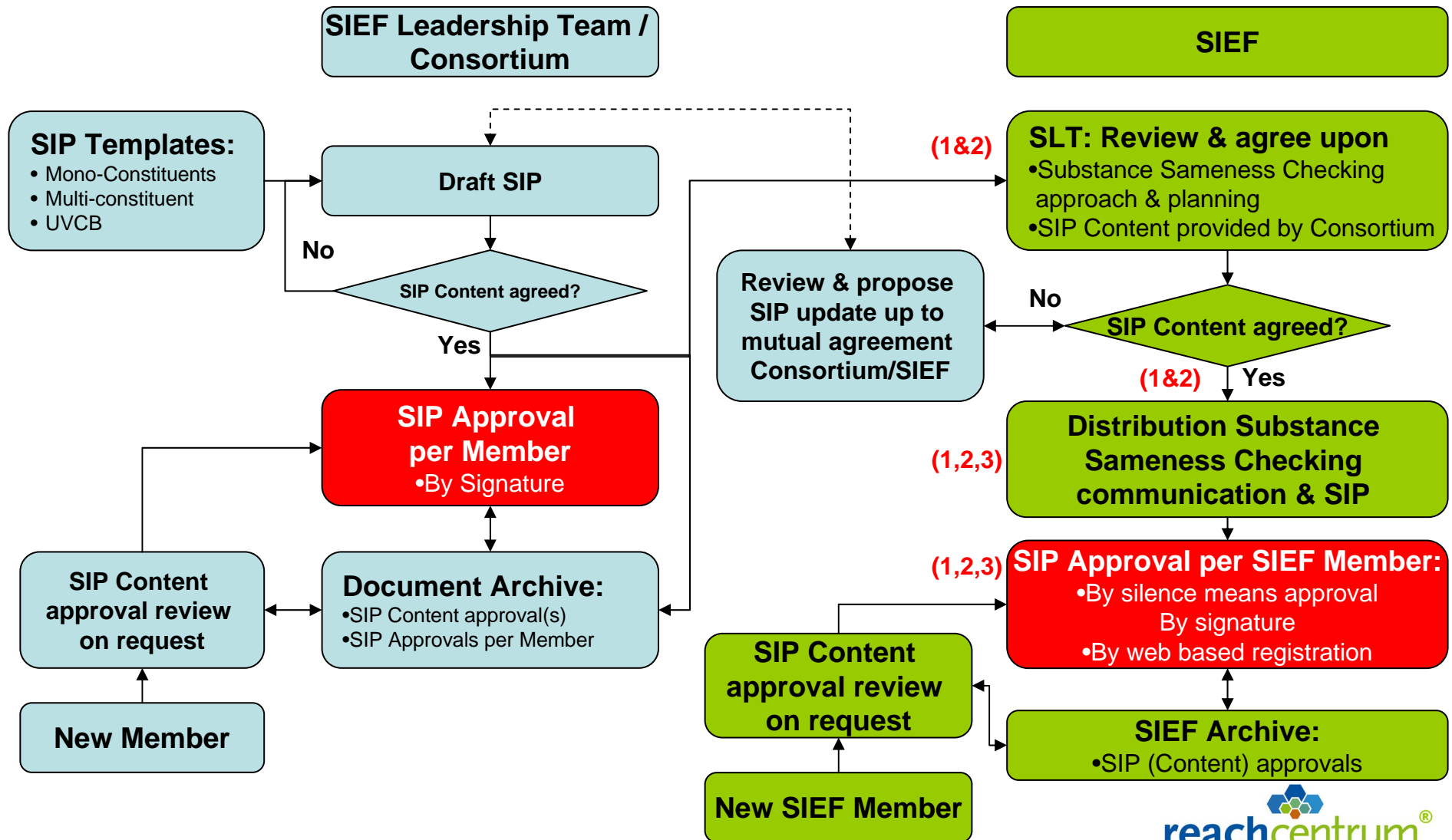
Version	Company	SUBSTANCE IDENTIFICATION PROFILE (SIP)			
v.1	XXX REACH Consortium & SIEF				
[date]	[Name Company]				
No	1.1. Chemical Name	1.2. EC Number	1.3. CAS Number	1.4. Composition Type	
				Mono-Constituent	
<p><i>This Substance Identification Profile (SIP) is developed to represent the identification parameters of the Substance described in line with the Substance Identification requirements of REACH Annex VI and relevant Guidelines for the purpose of identifying the Substance sufficiently and non-discriminatory to meet the REACH requirements for Registration under the same joint submission.</i></p> <p><i>The SIP is developed by the [XXX REACH Consortium] to the best of their knowledge to be used to agree upon being the same substance for the purpose of the Consortium and for the Substance Sameness checking process in the [pre-]SIEF.</i></p>					
Referenc	SI Parameter	Value / Not necessary / Not for SIP	Remark / Justification		
2.1.A	Name or other identifiers of the substance				
2.1.1.a	IUPAC Name				
2.1.1.b	Other International chemical name				
2.1.2.a	Chemical Name				
2.1.2.b	Abbreviation				
2.1.2.c	Other names				
2.1.3.a	EC Number				
2.1.3.b	EC Name				
2.1.3.c	EC Description				
2.1.4.a	CAS Number				
2.1.4.b	CAS Name				
2.1.4.c	CAS Description				
2.1.5.a	IUBMB Number				
2.1.5.b	INCI Number				
2.1.5.c	Other Catalogue identifiers				
2.1.B	Substances (with core identifiers) also falling under this substance (with justification)				
2.1.6.a	Chemical Name				
2.1.6.b	EC Number				
2.1.6.c	CAS Number				
2.1.7.a	Chemical Name				
2.1.7.b	EC Number				
2.1.7.c	CAS Number				
2.2	Information related to molecular and structural formula of the substance				
2.2.1.a	Molecular Formula				
2.2.1.b	Structural Formula				
2.2.1.c	Smiles notation				
2.2.2.a	Optical activity				
2.2.2.b	Typical ratio of (stereo) isomers				
2.2.3.a	Molecular Weight				
2.2.3.b	Molecular Weight range				
2.3	Chemical Composition of the substance				
2.3.1	Main Constituent				
2.3.1.a	Name -Main Constituent				
2.3.1.b	CAS Number -Main Constituent				
2.3.1.c	EC Number -Main Constituent				
2.3.1.d	Concentration range -Main Constituent - Lower value	80%			
2.3.1.e	Concentration range -Main Constituent - Upper value	100%			
2.3.1.f	Typical concentration -Main Constituent (= Degree of purity)				
2.3.2	Impurity / Impurities (above 1% or lower if contributing to the hazard or PTB profile)				
2.3.2.a	Agreed strategy for Impurity profile on SIP				
2.3.3	Additive(s) (above 1% or lower if contributing to the hazard)				
2.3.3.a	Agreed strategy for Additives profile on SIP				
2.4	Substance sameness checking procedure				

SIP Template SIP Template 2 SIP Citric Acid



Microsoft Excel
Worksheet

Substance Sameness Checking in Practice



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- **Suggestion how to move ahead**

Suggestion how to move ahead - Cefic Website

- Visit the Cefic website
 - Download a copy of the SIP
 - Fill the short version or the full version



The screenshot shows the Cefic website header with the logo and navigation menu. The main content area is titled "REACH documents and tools" and features a search bar and a list of themes. The "REACH" menu item is highlighted in orange. The "Substance Identification Profile (SIP) template" section is visible, including a date, a description, and a download link.

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THEMES

ES/CSA/CSR (7) | OR & Imports (1) | Polymers (1) | SIEFs (13) |

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1 2 3 next ▶

Substance Identification Profile (SIP) template

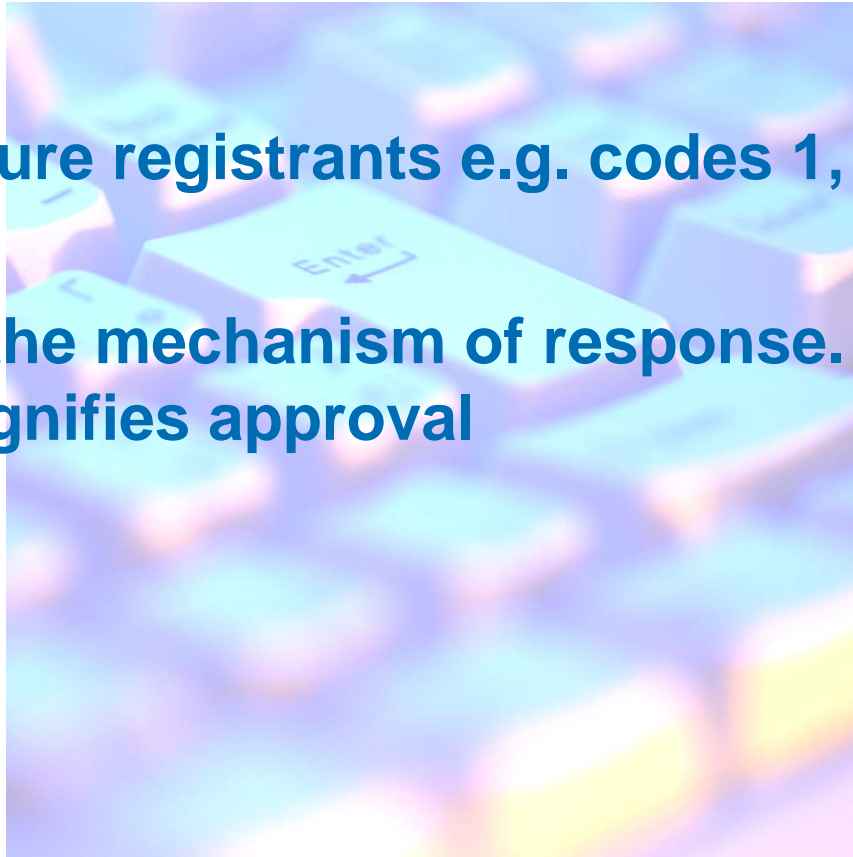
18/08/2009

This Substance Identification Profile (SIP) template can be used to support the substance sameness discussions in SIEFs. The intention is to use this template by the SFF, consortium or Lead Registrant to describe the substance to the best of their knowledge. The full template can be too complicated, therefore a short version is also provided. The SIP template has been developed by ReachCentrum and can be used for free.

download (62 Kb)

Suggestion how to move ahead - Survey

- Use an electronic tool to send out the survey
- Contact future registrants e.g. codes 1, 2 and 3
- Decide on the mechanism of response.
No reply signifies approval



Suggestion how to move ahead - SIEFreach

The screenshot displays the SIEFreach website. On the left is a navigation menu with a 'pre-SIEF Info' section containing items like 'Public Study Availability', 'Study Availability', 'SFF Designation', 'SIEF Designation', 'Sameness', 'Operating Rules', 'Classification & Labelling', 'Data Gaps', 'Cost Sharing', 'Testing Proposals', 'SIEF Status Page', 'Breakout Pages', 'Tools', and 'SIEF Members'. A red circle highlights 'Sameness' in this menu, with a red arrow pointing to a similar 'Sameness' item in a sub-menu on the right. This sub-menu also has a red circle around 'Sameness Docs'. A text box below the arrow states: 'The SIP can be loaded here'. The main content area shows the 'pre-SIEF & SIEF (Substance Information Exchange Forum)' for 'formaldehyde'. It includes a breadcrumb 'You are in: formaldehyde >- Sameness', the title 'Sameness', and a notice: 'This is checked out for editing by: bin wang (29/12/2008 11:21:22)'. Below this is a 'More Actions' button. A text box at the bottom right explains: 'This area can be used to announce the summary for active members. For 3 / 4 (passive/dormant) they should see results in the public domain'.



Thank you



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