

Pre-registration of Substances and Information Exchange Fora

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Overview

- What is pre-registration?
- Who should pre-register?
- What substances should be pre-registered?
- Why pre-register?
- When to pre-register?
- How to pre-register and what information is needed?
- What happens after pre-registration?
- What is a pre-SIEF?
- What is a SIEF?

What Is Pre-registration?



Pre-registration is a duty under REACH for potential registrants of phase-in substances taking place during the pre-registration period, granting them extended deadlines for registration.

Who Should Pre-register?



- Potential registrants =
 - EU manufacturers and importers of substances on their own or in preparations
 - EU producers and importers of articles
(meeting criteria of Article 7(1))
 - EU-based “only representatives” appointed by a manufacturer, formulator or article producer
outside the EU to fulfil the registration obligations of importers

What to Pre-register?

- **Phase-in** substances subject to registration
 - substances listed in EINECS
 - manufactured, but not placed on the market in the EU at least once since 1 June 1992
 - no longer polymer
- All types of substances:
 - mono-constituent substance
 - multi-constituent substance (“covered” by EINECS if all main constituents are listed in EINECS)
 - UVCB substance

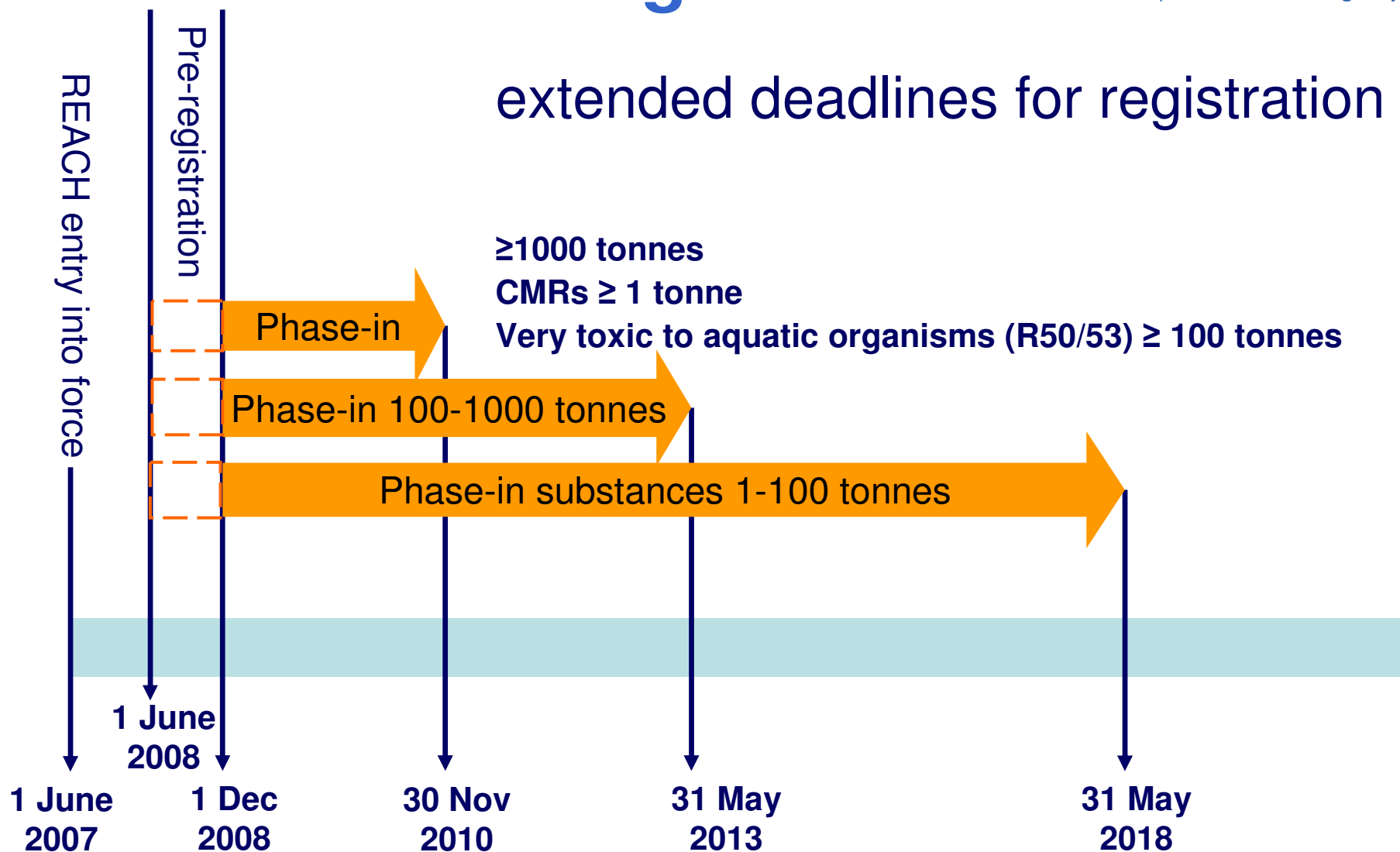
Why Pre-register?

- Pre-registration is not an obligation, but...
 - for companies who do not pre-register, the obligation to register applies from 1 June 2008 (even if companies may pre-register until 1 December 2008)
 - companies who do not pre-register have to interrupt manufacture, placing on the market and use from 1 June 2008 until their registration is completed (inquiry + submission of registration + completeness check by ECHA)
 - companies are still bound by joint submission and data sharing obligations → registration update may be necessary

Why Pre-register?

- For business continuity reasons and to benefit from the extended deadlines for registration
- Pre-registration brings companies together to share data, thereby reducing duplicate testing and costs
- Pre-registration is free of charge

When to Pre-register?



When to Pre-register?

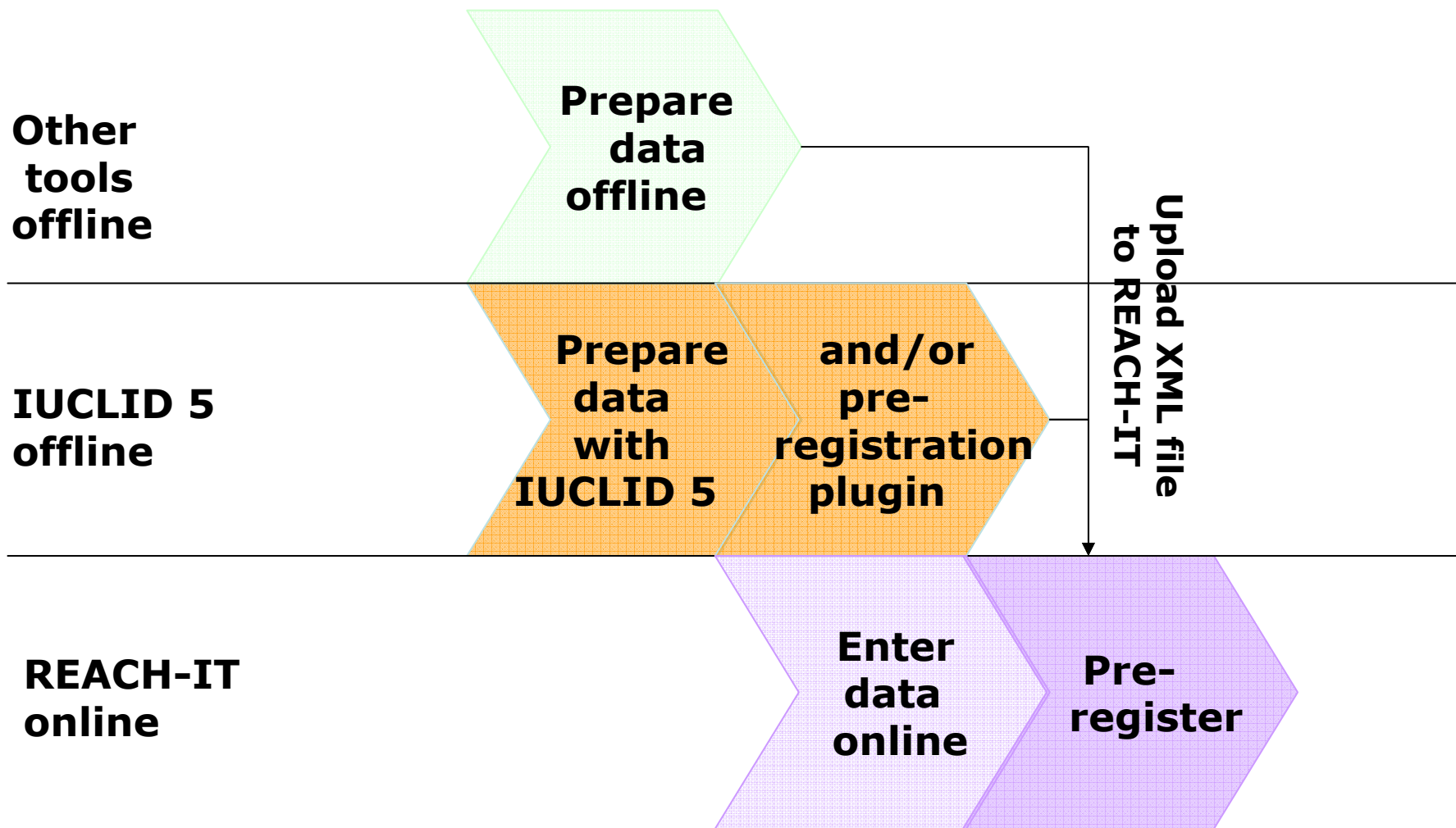
- Pre-registration period is from **1 June 2008 - 1 December 2008**
- As a first-time manufacturer or importer, you can pre-register after the pre-registration period, but:
 - at the latest 6 months after manufacturing or importing exceeds the 1 tonne threshold; and
 - at least 12 months before the relevant transitional deadline for registration.

How to Pre-register?



- Each legal entity must pre-register separately.
- Only representative: submit one **individual** pre-registration per substance and per non-EU-manufacturer represented, with the tonnage band and the envisaged deadline for registration

What Tools to Use?



What Tools to Use?

- **REACH-IT:** available on ECHA website on 1 June 2008 for on-line pre-registration
 - to create a pre-registration
 - to **submit** pre-registrations (mandatory)
 - to modify a pre-registration
 - to have an overview of all your pre-registrations
 - to access the pre-SIEF
- **IUCLID 5:** pre-registration plug-in allows to create “bulk”-pre-registration files containing information for a large number of substances with EINECS numbers.

What Information Is Needed?



- Substance name
- Similar substances (optional): substances which can be used for QSAR, grouping or read-across
- Envisaged tonnage band + registration deadline (pick-list)
- Contact person details (optional)
- Third party representative contact details (optional): if you have concerns about confidentiality, you can appoint a third party representative to deal with data-sharing on your behalf
- Remarks about the substance (optional)

What Information Is Needed?



- Substance name for a substance that has an EINECS number, using REACH-IT:
 - specify the EINECS number, or the EINECS name, or the CAS number, or the molecular formula.
 - REACH-IT retrieves the substance from the EC inventory.
 - confirm / select from the presented options the substance you want to pre-register.
 - for a multi-constituent substance: specify the main constituents one by one, using the button “add more constituents”.

What Information Is Needed?



- substance name for a substance that does not have an EINECS number, using REACH-IT:
 - specify
 - the CAS number and name(s), or
 - the chemical name(s).
 - REACH-IT then checks the EC inventory and all previously pre-registered substances
 - if REACH-IT finds a match, you confirm whether or not (one of) the presented option(s) is the substance you want to pre-register.

What Happens after Submission



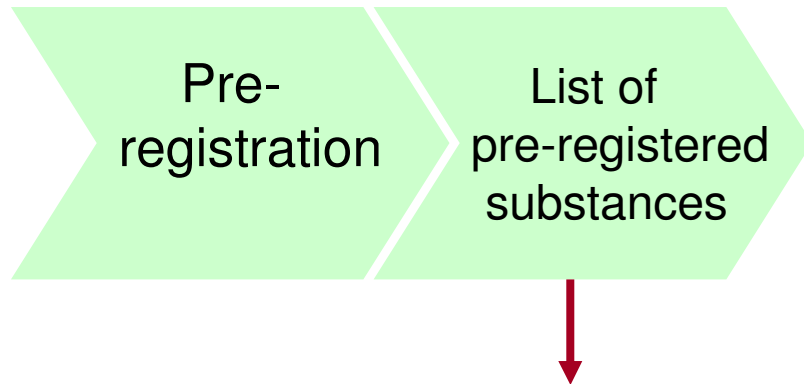
- You will receive a submission number after validation.
- You will receive a message in your REACH-IT message box, containing:
 - a link to the submission report (pdf format) and
 - the pre-registration number.
- You will have access to the pre-SIEF webpage.
- You can view / modify your pre-registrations.
- For “bulk” pre-registration files: REACH-IT will verify the file format, structure and content of the file, and will reject it if it is not conform.

How to Update a Pre-registration?



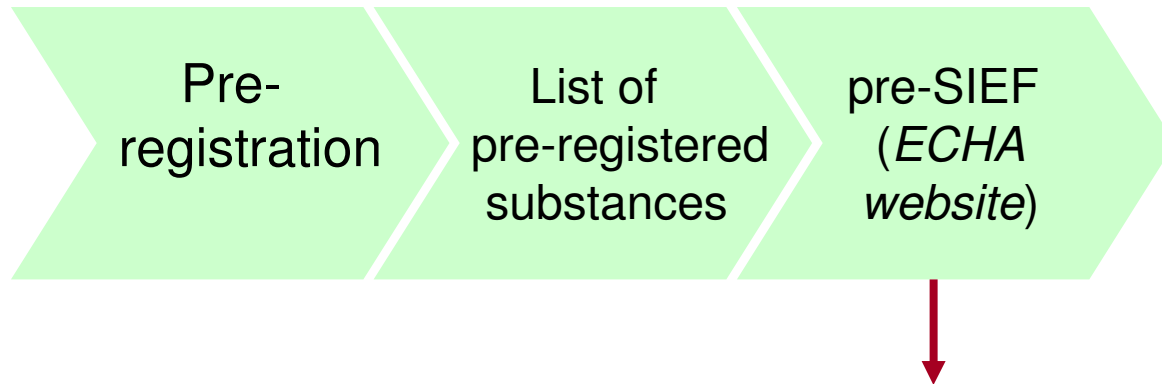
- A pre-registration can at any time be updated in REACH-IT, independently from the way it was submitted (on-line pre-registration or upload of bulk pre-registration).
- All fields can be updated, except the substance identity.
- The information in the pre-SIEF will be updated accordingly.
- A pre-registration cannot be deleted. If a potential registrant is no longer interested in a substance, he can “deactivate” his participation in the pre-SIEF, but he remains visible.

What Happens after Pre-registration?



- ECHA publishes the list of pre-registered substances by 1 January 2009
- Data holders (downstream users, universities, NGOs, ...) may indicate that they have relevant data on pre-registered substances, using REACH-IT

What Happens after Pre-registration?



- REACH-IT brings submitters of the same identifier together in a “pre-SIEF” webpage
- Can see contact details of:
 - other pre-registrants
 - early registrants, substances regarded as registered
 - data holders after 1 January 2009

What is a Pre-SIEF?



- After pre-registration, a substance pre-SIEF webpage will be formed for each EINECS n° CAS n° other identity code
- All potential registrants will be able to see:
 - each others contact details + contact details from data holders
 - identified read-across possibilities
 - remarks about the substance
- It is possible to navigate to the pre-SIEF webpages of the substances identified for read-across (to and from)
- If you have concerns on confidentiality, use a third party representative during pre-registration

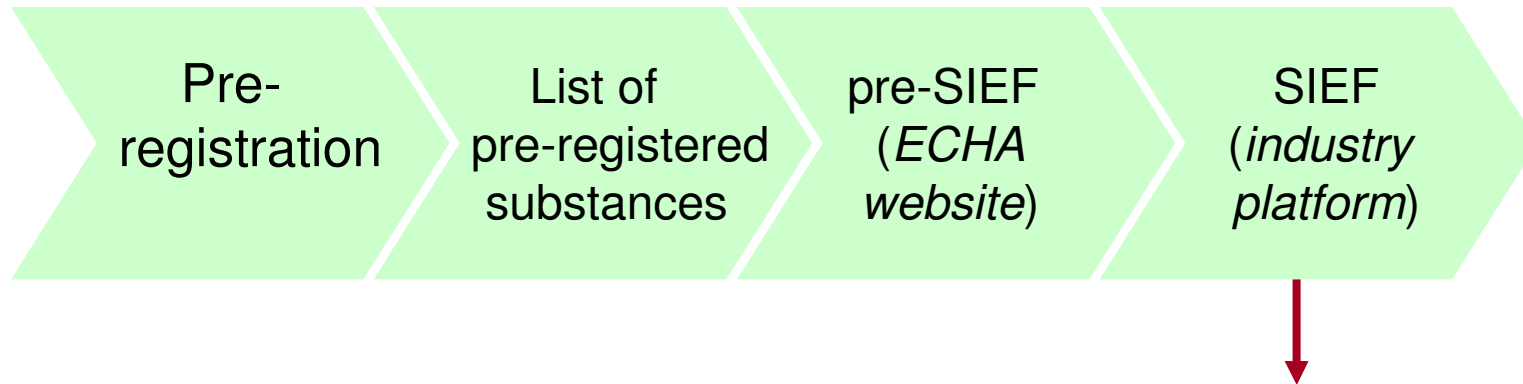
SIEF Formation Facilitator



To initiate discussions after pre-registration a “SIEF formation facilitator” can be identified on the pre-SIEF webpage:

- Only potential registrants can volunteer to become SIEF formation facilitator, on a first-come first-serve basis.
- Not legally binding, no additional obligations.
- Can post information to the other participants in a separate text box on the pre-SIEF webpage, e.g. on further communication tools to be used.

What Happens after Pre-registration?



- Industry needs to agree on SIEF formation and share data and costs within the SIEF

What Is a SIEF?



- Obligatory platform to:
 - share data among potential registrants of the same phase-in substances and data holders + avoid unnecessary testing
 - agree on classification and labelling
- Suitable platform to organise the mandatory joint submission of data
- Potential registrants within a pre-SIEF must discuss whether their substances are the same
- If agreement on the sameness: SIEF is ‘born’ (Article 29)

SIEF Formation – Key Issues



- Industry must assess the sameness (see guidance on substance identity)
No confirmation by ECHA!
- SIEF participants are free to organize themselves as they see fit
 - Consortium is one possible form of co-operation
 - Co-operation and collective approaches highly encouraged

SIEF Formation – Key Issues

- In many cases EINECS = SIEF, but:
 - substances within one EINECS number may, after detailed examination, turn out to be so different in terms of composition that data from one substance may not be relevant to describe the profile of the other substance: several SIEFs may be formed
 - different EINECS numbers may reflect the same substance: one SIEF may be formed

Data sharing obligations must be respected!
(it is not allowed to form 2 SIEFs for the same substance)

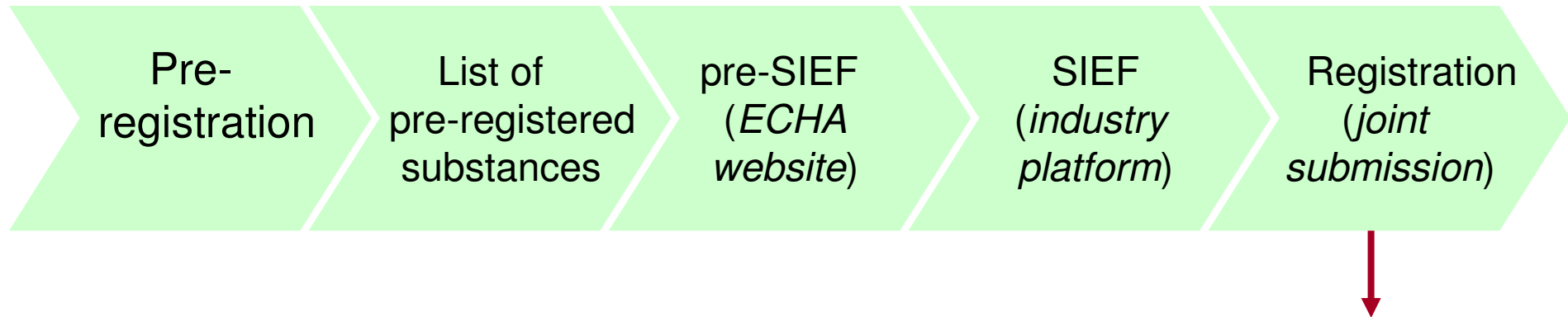
SIEF Formation – Key Issues



Cost sharing (see guidance on data sharing)

- Costs must only be shared for information:
 - that a registrant is required to submit
 - at the time when a registrant is required to submit the information
- Costs must be shared in a fair, transparent and non-discriminatory way
- If SIEF participants cannot reach an agreement, costs shall be shared equally

What Happens after Pre-registration?



- Industry needs to jointly submit data to ECHA via REACH-IT

Thank you for your attention