Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

Towards a successful implementation of REACH:

What should downstream users do now?

14 April 2008

A.I.S.E.

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Presentation outline

PART A. Definition of Downstream User (DU)

PART B. What should DUs do now?

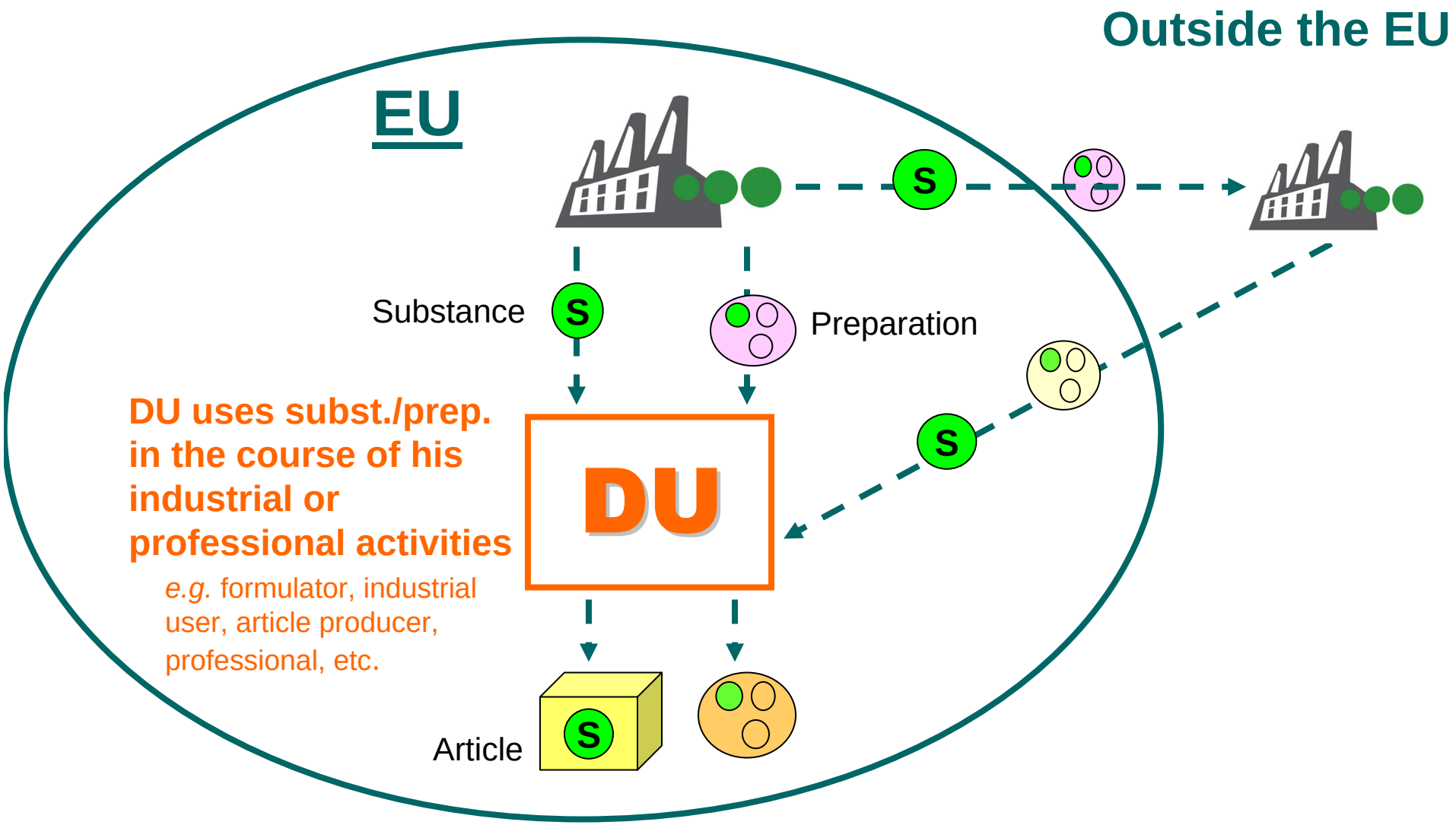
B.1. Pre-registration / Registration

B.2. Communication on safe use up and down in the supply chain

PART C. Challenges faced by DUs

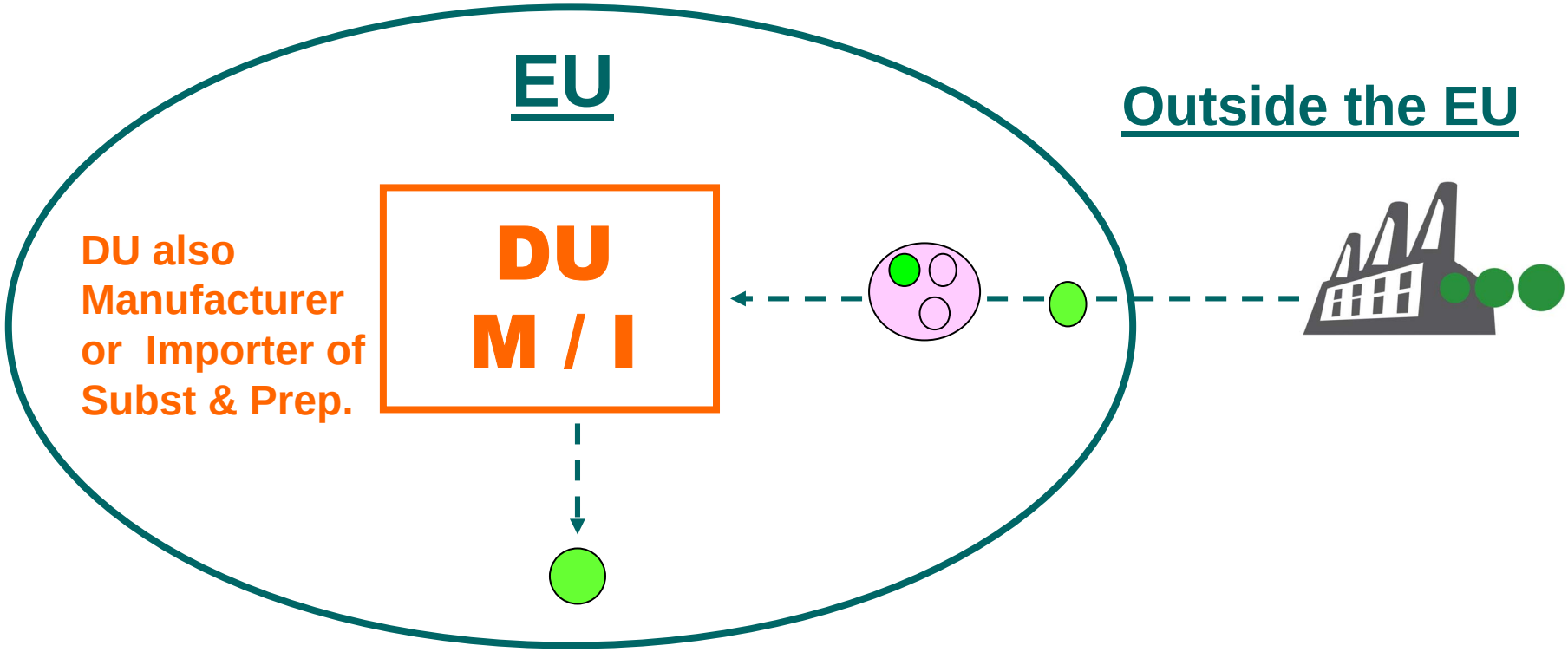
PART D. Summary

PART A. Definition of Downstream User



***Note*: A distributor or a consumer is not a downstream user**

….but a company can be DU and manuf. or importer of substances or preparations



In this case, he will have to fulfill duties of manufacturer or importer in addition to DU duties

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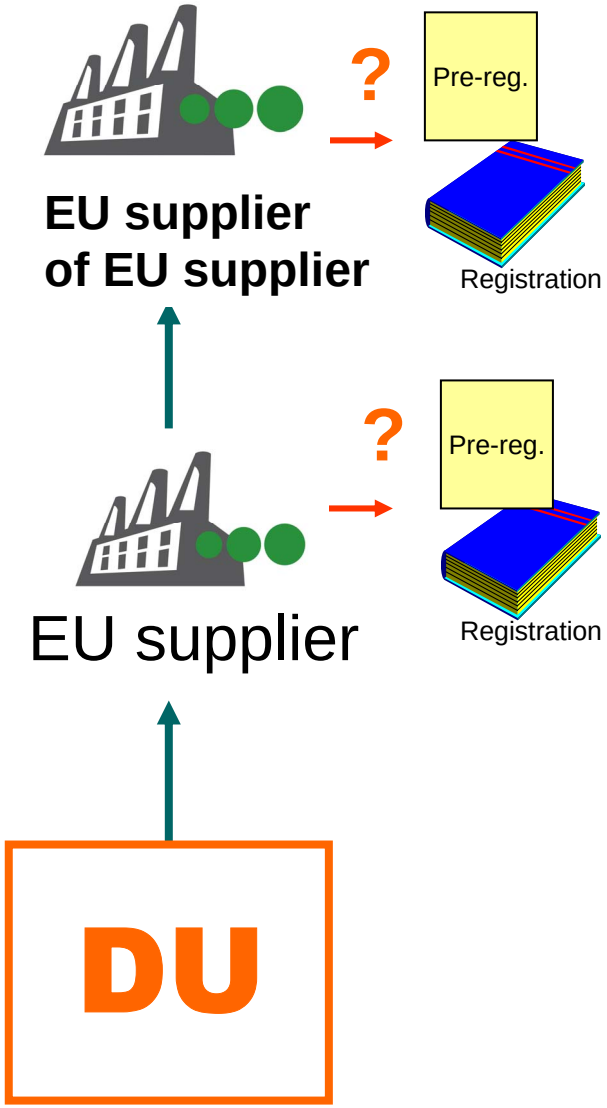
PART B.1.
If you use substances or preparations

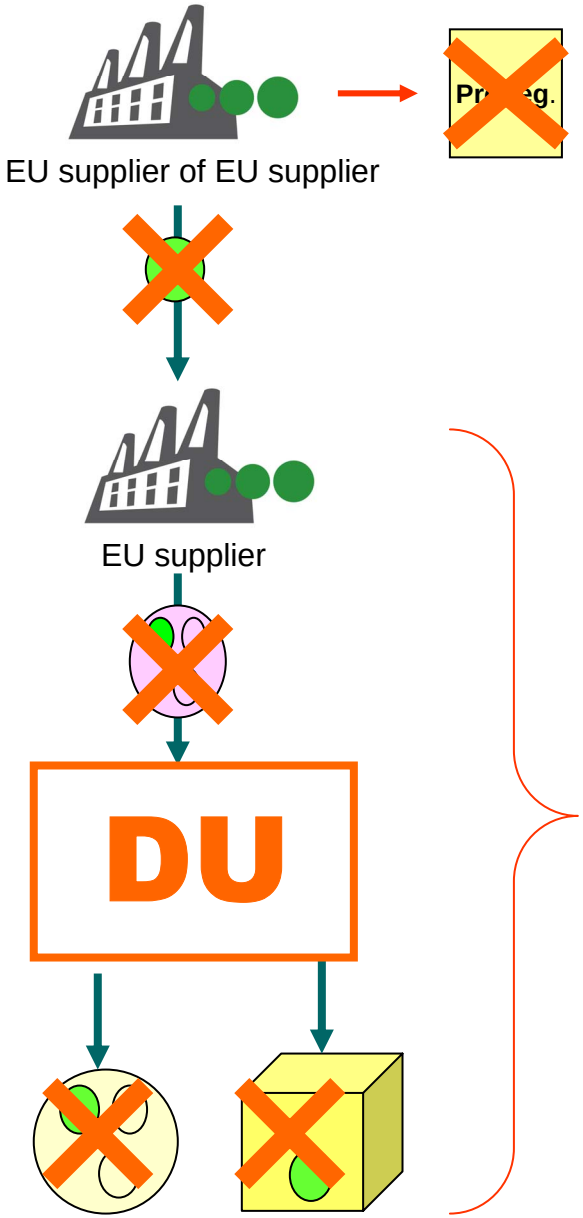


➲❶ **Recommendation:**
Check that your suppliers will pre-register and register the substances supplied to you
(when applicable)

⇨ **Ask your suppliers to do the same up the supply chain**
(when applicable)

***Note**:* This is not mandatory but vital to guarantee supply continuity through the whole supply chain…

…because



No pre-registration between June 1, 2008 & December 1, 2008 **means**….

➔ No manufacture/import of substance after Dec. 1, 2008!

➔ No manufacture of preparation(s) or article(s) with this substance after Dec. 1, 2008 through the whole supply chain!

PART B.1.
What should DUs do with their suppliers?

Practical approach

First option:

⇨ Obtain confirmation from your supplier that he will pre-register and register the substance

Second option:

⇨ Obtain confirmation from your supplier that he will pre-register the substance and

⇨ Reconvene before the registration deadline to confirm intent to register or not

Third option:

⇨ Consider alternative EU supplier or become importer

Remember:

- *Pre-registration is easy*
- *Pre-registration is not a commitment to register the substance!*

PART B.1.
What should DUs do to further increase supply certainty?

Be aware of the late pre-registration option

DU has the possibility to pre-register, if he imports a substance for the 1st time after December 1, 2008 (>1t/y)

- provided he submits the pre-registration within 6 months of first import and 12 months before the registration deadline
- in this case, the DU becomes an importer *i.e.* a registrant

***Notes**:*

⇨ *Pre-registration by DU cannot replace supplier pre-registration*

⇨ *In addition, if your substance is not on the pre-registration list in Jan. 2009, the Agency can provide support on request in finding a new supplier*

PART B.1.
What should DUs do to further increase supply certainty?

Should a DU pre-register the substances he purchases, during the pre-registration period (as a potential M/I)?

⇨ Maybe (probably exceptionally) if:

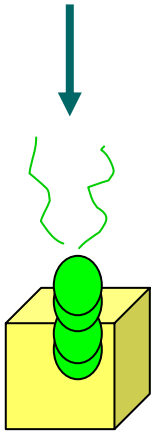
* the substance is critical for the business and/or
* no supplier commitment has been obtained and/or
* DU does not want to rely on late pre-registration

⇨ **Entails participation in SIEF with corresponding rights and duties**

Note: *Other considerations may lead a DU to pre-register (e.g. role in SIEF if he is "data rich")*

PART B.1.
If you produce articles

DU



ARTICLES

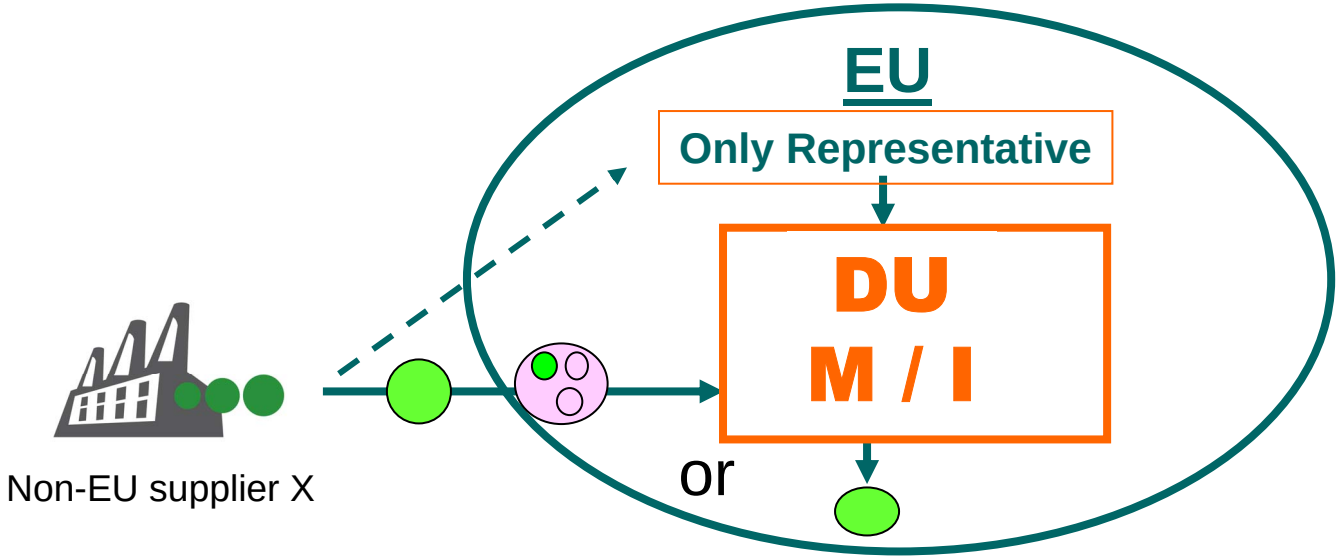
➲ ❷ **<u>Recommendation / legal duty</u>:**

Pre-register substances which are intended to be released from article(s)

(>1t/y)

***<u>Note</u>**: Registration is not required for substances which have already been registered for that specific use (e.g. by your supplier), but this is unknown at the time of pre-registration (June 1 – December 1, 2008)*

PART B.1.
If you are <u>also</u> a manufacturer or importer



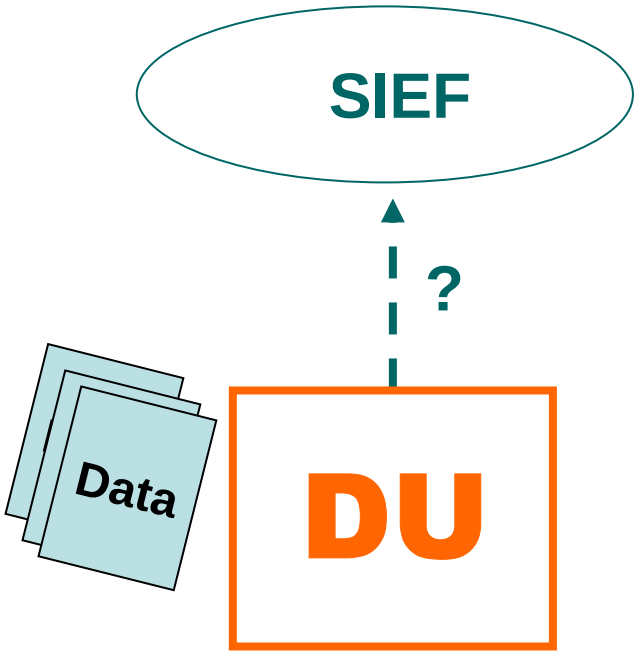
➲❸ <u>Legal duty</u>:

Pre-register all the substances that you manufacture or import at >1t/y per legal entity

⇨ **in case of import.. unless your non-EU supplier pre-registers through an Only Representative: you will become DU**

<u>Note:</u> *when you pre-register as (potential) M/I, you will have to carry M/I duties in addition to DU duties*

PART B.1.
If you own data



➲❹ **Recommendation:**

Review the data you own and determine if you want to participate in SIEF as data holder

***Note**: Applies as per January 2009*

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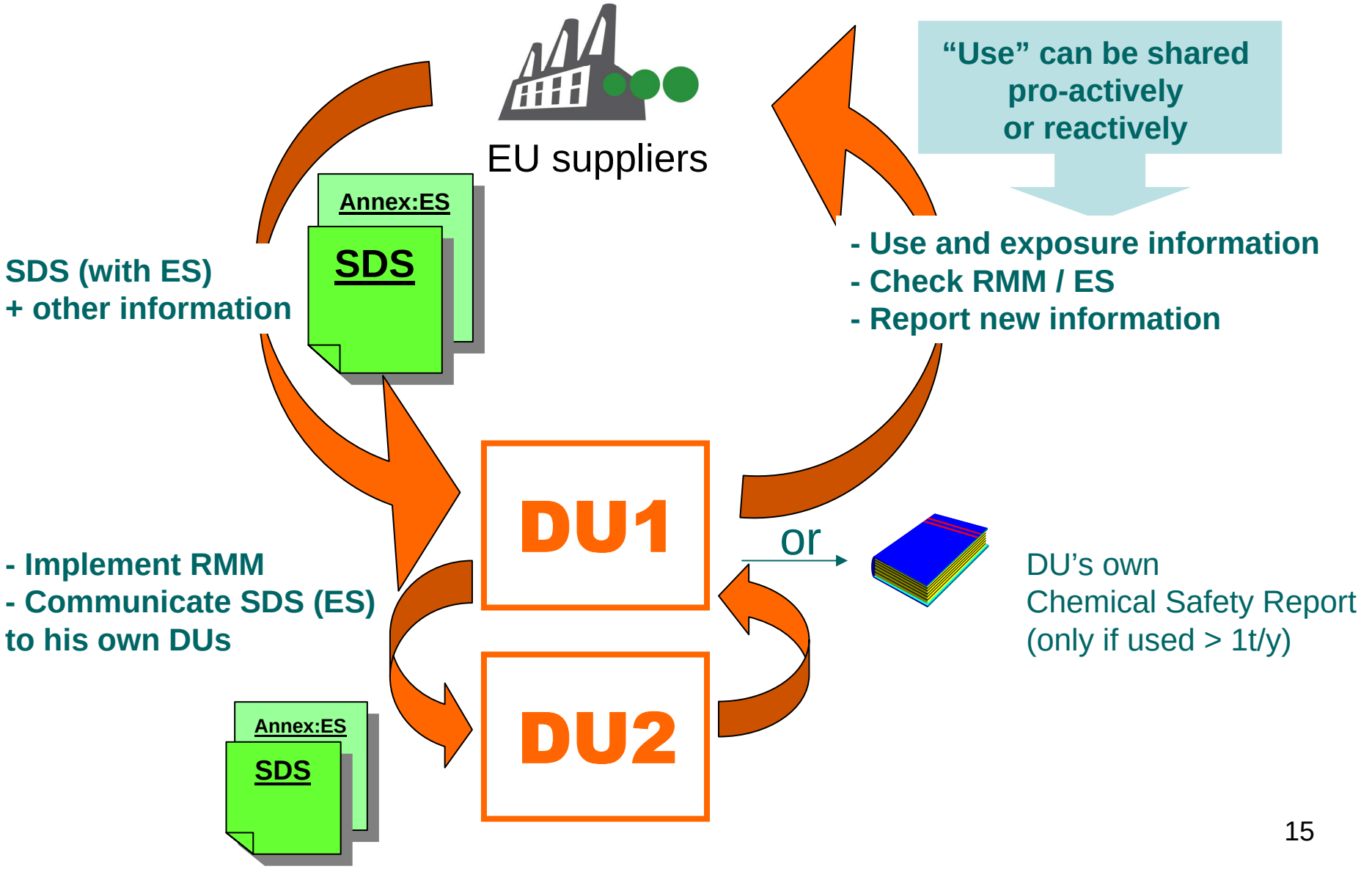
PART B.2.
DU rights and duties on safe use communication



PART B.2.
Communication on safe use down the supply chain

What are the criteria driving to ES development?

⇨ Your supplier will only perform ES if all the following conditions are met:

1. Substance is manufactured/imported at >10t/y and
2. Substance is classified as dangerous or is PBT/vPvB and
3. Substance is present in preparation above a certain concentration level (Art 14 (2))

Notes:

- The criteria driving ES requirements are different from criteria driving SDS requirements

- No action on ES is required by the DU if no ES is provided in your supplier's SDS

When will DU receive SDS with ES?

⇨ In theory, as per June 1, 2008…In practice, later on (for most substances)

When must DU comply with RMMs communicated via SDS as part of ES?

⇨ Within 12 months of receiving SDS of supplier with registration # and ES

PART B.2.
Making your use identified

➲❺ **Recommendation:**

Decide if you want to share your use pro-actively with your suppliers but to do it, wait for harmonised IT tools/questionnaire

⇨ Pro-active use reporting should be done one year before registration deadline, *i.e.* there is still time

⇨ RIP 3.2-2 covering use and Exposure Scenario has just been finalized

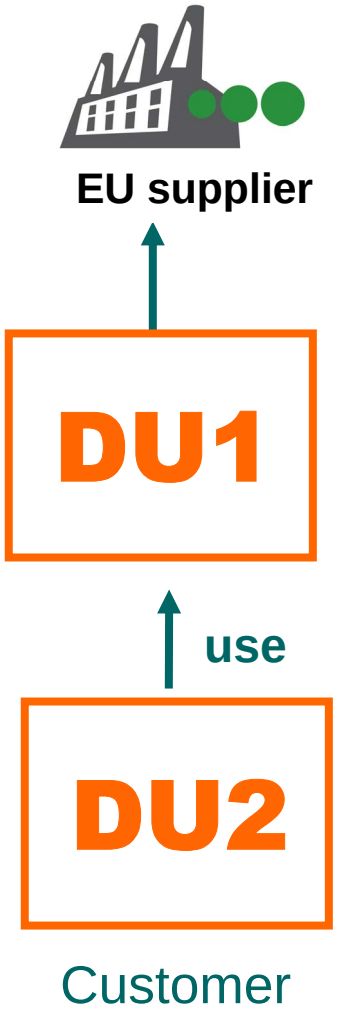
⇨ Use Industry IT-tools/questionnaire once available (currently under development by CEFIC, expected soon)

⇨ Use standard terminology

e.g. use descriptor system from RIP 3.2-2

e.g. standard RMM (under development)

PART B.2.
If you receive use information from your own customers



➲❻ **Recommendation:**

Pass it up in the supply chain

Please wait for the harmonised industry IT-Tools

Or perform the CSR and include ES in SDS (if applicable)

There is more to do for DUs

➲❼ Additional recommendations:

⇨ Read Guidance for Downstream User
http://reach.jrc.it/docs/guidance_document/du_en.htm

⇨ Work with your trade association on sector-specific or industry-wide approaches to facilitate communication

⇨ Prepare use information for your suppliers

⇨ Answer to your customers (show awareness)

⇨ Keep an eye on candidate list of Substances of Very High Concern for authorisation

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PART C.
Challenges faced by DUs

- Reliance on suppliers both for pre-registration/registration and coverage of identified use
  → even greater challenge for SME's
- REACH requirements change frequently in innovative companies
- Uncertainties of (pre-)registration scope *e.g.* Annexes IV-V
- Manage flow of communication effectively
- Understand how to generate Exposure Scenarios for preparations
- Delays in TGD publication (e.g. RIP 3.2-2 and 3.8) and IT Tools development

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PART D. What should DUs do now
In summary

Understand your roles and responsibilities under REACH

➲❶ Talk to your suppliers to ensure pre-registration and registration of your substances

→ Define business critical substances and assess options in case supplier is not responsive or decides not to register

➲❷ Pre-register substances which are intentionally released from articles

➲❸ If you are also manufacturer or importer, pre-register your substances

➲❹ If you own data, determine if you want to participate in SIEF as data holder

➲❺❻ Get prepared for communication up and down the supply chain (but wait for standardised IT-tools and questionnaires currently being developed to communicate)

➲❼ Read, understand and work via your Trade Association wherever appropriate

Let’s work together !

BACK-UPs

What should DUs do at a later stage?

DU will also have to do …but at a later stage

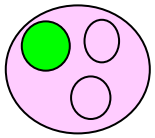
Timing	Duty	Action required	Ref.
As per June 1, 2007 (in practice: from 1 June 2008, but in most cases in 2009-2010)	Must do	-> comply with risk management measures (RMM) and with any restrictions which are applicable to your use communicated in SDS -> if RMM of your use are not appropriate , communicate it to your supplier -> if your use is not covered , either report it to your supplier or perform your own CSR and notify ECHA * Timing: Should be performed within 1 year of receiving SDS except for notification to ECHA which needs to performed within 6 months -> Be aware that your supplier can refuse your use…	Guidance for DU (chapter 5)
As per June 1, 2007	Must do	if you have new information on the hazard of the substance, communicate it to your supplier	Guidance for DU (chapter 10)
As per June 1, 2007 (in practice: from 1 June 2008, but in most cases in 2009-2010)	Must do	Provide your customers with SDS and potentially exposure scenario, if needed	Guidance for DU
As per June 1, 2007 (in most cases later on)	Must do	If no SDS is provided, comply with information provided by the supplier related to RMM, Authorization and Restriction (Art 32)	Guidance for DU
As per June 1, 08	Must do	Report to the Chemical Agency if your classification of substance is different to that of your supplier	Guidance for DU
As per Jan 1, 2009	May do	if you have information on substances e.g. test data, you may want to share them within SIEF as data holder	Guidance on Data sharing
As per Jan 1, 2009	May do	If your substance that you use is not on the Pre-registration list published by ECHA, you can ask ECHA to publish the name of your substance on its website. This could help you to find a potential registrant for the substance.	Guidance for DU (Chapter 3.3)

DU will also have to do …but at a later stage

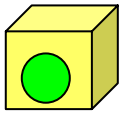
Timing	Duty	Action required	Ref.
As per when candidate list of SVHC will be published (end 2008)	Must do	If you manuf. or import an article which contains SVHC from the candidate list of SVHC at >0.1% (w/w), provide information to enable safe use of your article to your customers and if requested to your consumers and in this last case you need to reply within 45 days of request	Guidance on articles
As per June 1, 2009	Must do	Authorisation a) Check if your substance is part of substances recommended to be included in Annex XIV. If so, contact your supplier b) if the use of your substance is not covered by your supplier 's Authorisation, and you want to continue this use, you will have to apply for an authorisation for your own use and potentially your customer's use	a) Guidance for DU (chapter 12) + Guidance on authorisation (RIP 3.7)
As per June 1, 2009	Must do	Comply with Restriction, if relevant to your substance	Guidance for DU (chapter 13)
By Dec 2010, June 2013 or June 2018	Must do	Register subst. intentionally released from your articles at >1t/y, or >100 t/y or > 1000 t/y if not already registered by somebody in the same or different supply chain for that use	Guidance on articles
As per June 1, 2011	Must do	If you manuf./import an article containing a SVHC from the candidate list of SVHC at >0.1% (w/w) and which is >1t/y and which has not been registered for that use, you need to submit a notification to ECHA	Guidance on articles

Legend of symbols

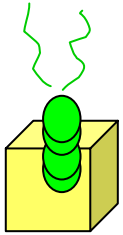
Substance



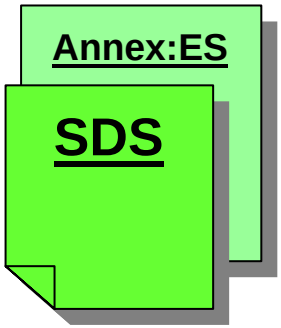
Preparation containing several substances



Article containing a substance



Article containing a substance intended to be released



Safety Data Sheet, with exposure scenarios annexed to it