

EFEO-Workshop REACH 4 June 2007, Grasse.

Obligations of Downstream Users (DUs)

***by : Jean-François GOURSOT Technical
Director
PRODAROM***

REACH

- Registration
- Evaluation
- Authorisation
& restrictions
of
- Chemicals

COVERS :

1. *AIM & SCOPE*
2. *REGISTRATION OF SUBSTANCES*
3. *DATA SHARING TO AVOID TESTING*
4. *INFORMATION IN THE SUPPLY CHAIN*
5. ***DOWNSTREAM USERS***
6. *EVALUATION OF PROPERTIES & USE*
7. *AUTHORISATION*
8. *RESTRICTIONS ON PRODUCTION & USE*
9. *FEES AND CHARGES*
10. *CLASSIFICATION & LABELLING (GHS)*
11. *EU-AGENCY & MEMBER STATES*
12. *ENFORCEMENT*

- **Downstream user**: means any natural or legal person established within the Community, other than the manufacturer or the importer, **who uses a substance, either on its own or in a preparation**, in the course of his industrial or professional activities. **A distributor or a consumer is not a downstream user**. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;

- **Use:** means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
- **Distributor:** means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;

WHO ?

USER OF SUBSTANCES
(AS SUCH OR IN PREPARATIONS)
WITHOUT PRODUCING OR IMPORTING THEM

EXAMPLE : FORMULATOR OF A PREPARATION
CONTAINING ESSENTIAL OILS or END USER
OF A PREPARATION...

YOU, YOURS SUPPLIERS, YOUR CUSTOMERS,
ALMOST EVERYONE

RELIEF OR WORRY ?

CLEARLY WITHIN REACH,
MAIN TASK (REGISTRATION) IS ON THE
SHOULDERS OF PRODUCERS AND
IMPORTERS

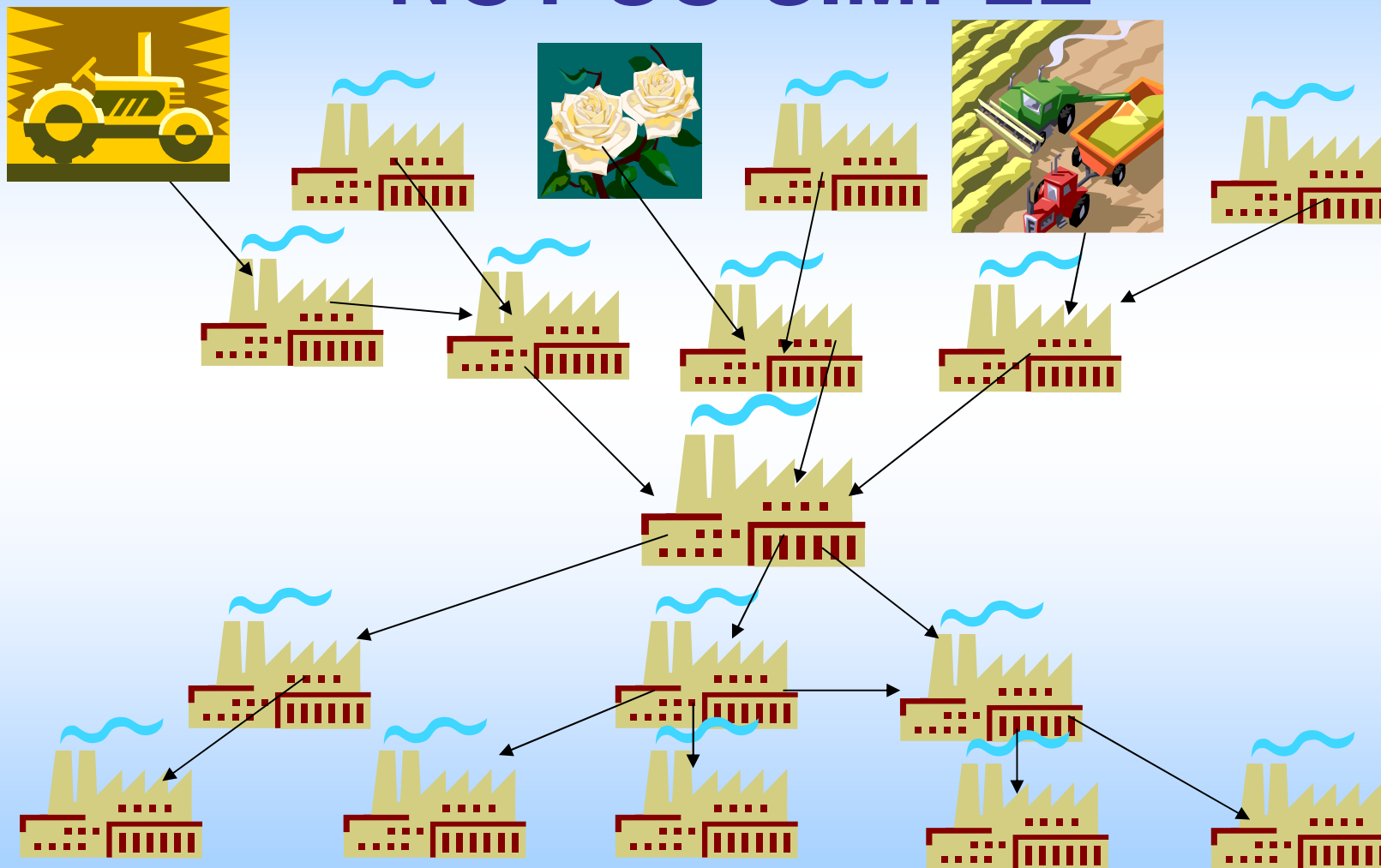
BUT...

THE MAIN TARGET FOR DUs

SECURE

ITS SUPPLY IN RAW MATERIALS IN
ORDER TO SECURE ITS SALES !

THE SUPPLY CHAIN : NOT SO SIMPLE



**However Communication
up & down
the Supply Chain
will be
of highest importance**

WHY ?

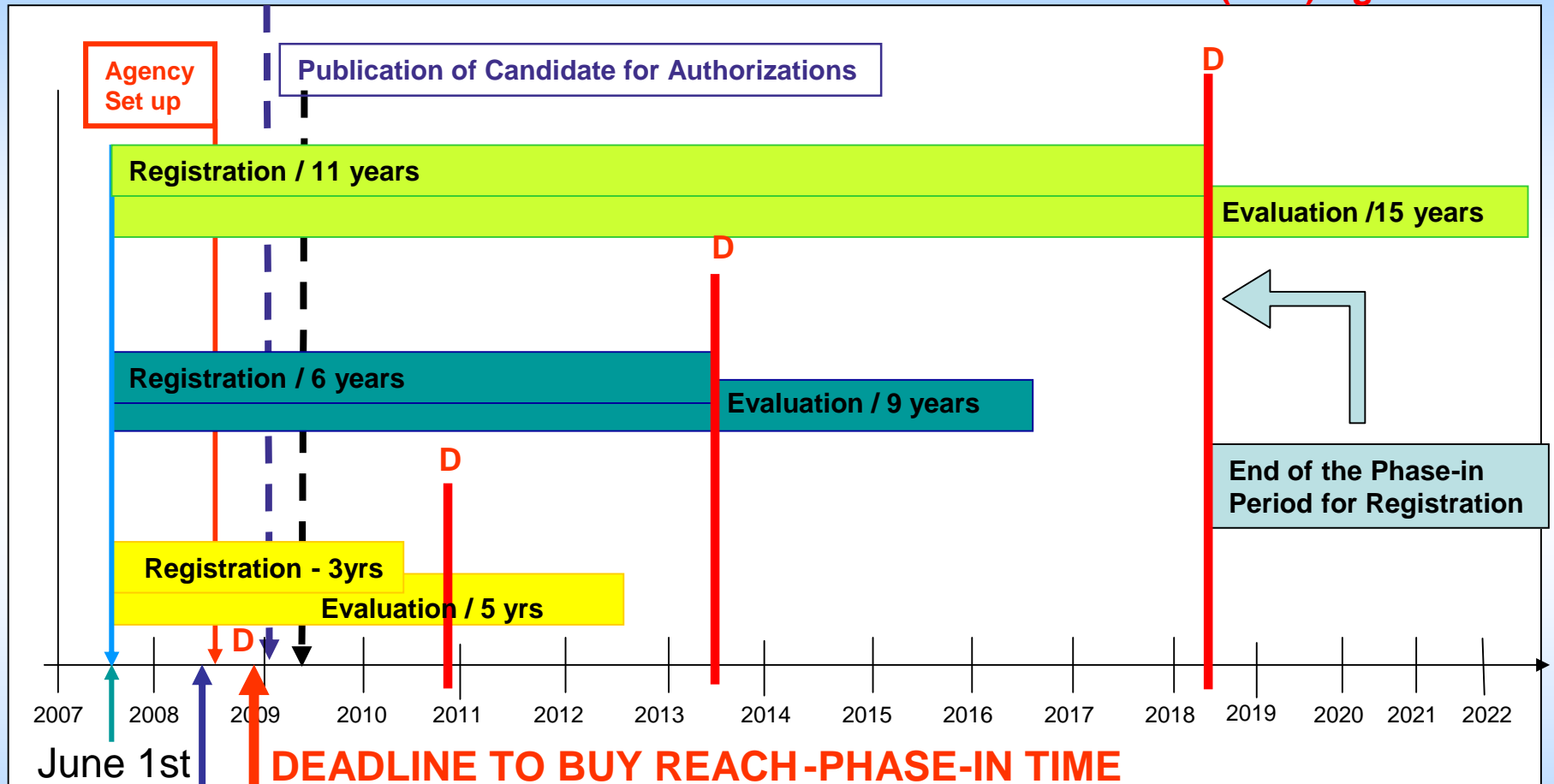
DOWNSTREAM USERS DEPEND ON UPSTREAM SUPPLIERS (= PRODUCERS or IMPORTER OF SUBSTANCE) FOR REGISTRATION

1. the Substance
2. the EU-based Producer or Importer (as legal entity)
3. the Identified Use(s)
4. the Hazard Properties
5. the Exposure due to the Use in Supply Chain:
 - Workers
 - Consumers
 - Environment
6. the Risk Characterisation
7. the Risk Management Measures for Safe Use
8. the Communication up & down the Supply Chain

REACH: REMEMBER Phase-In

Jan 1, 2009: List of Pre-registered substances

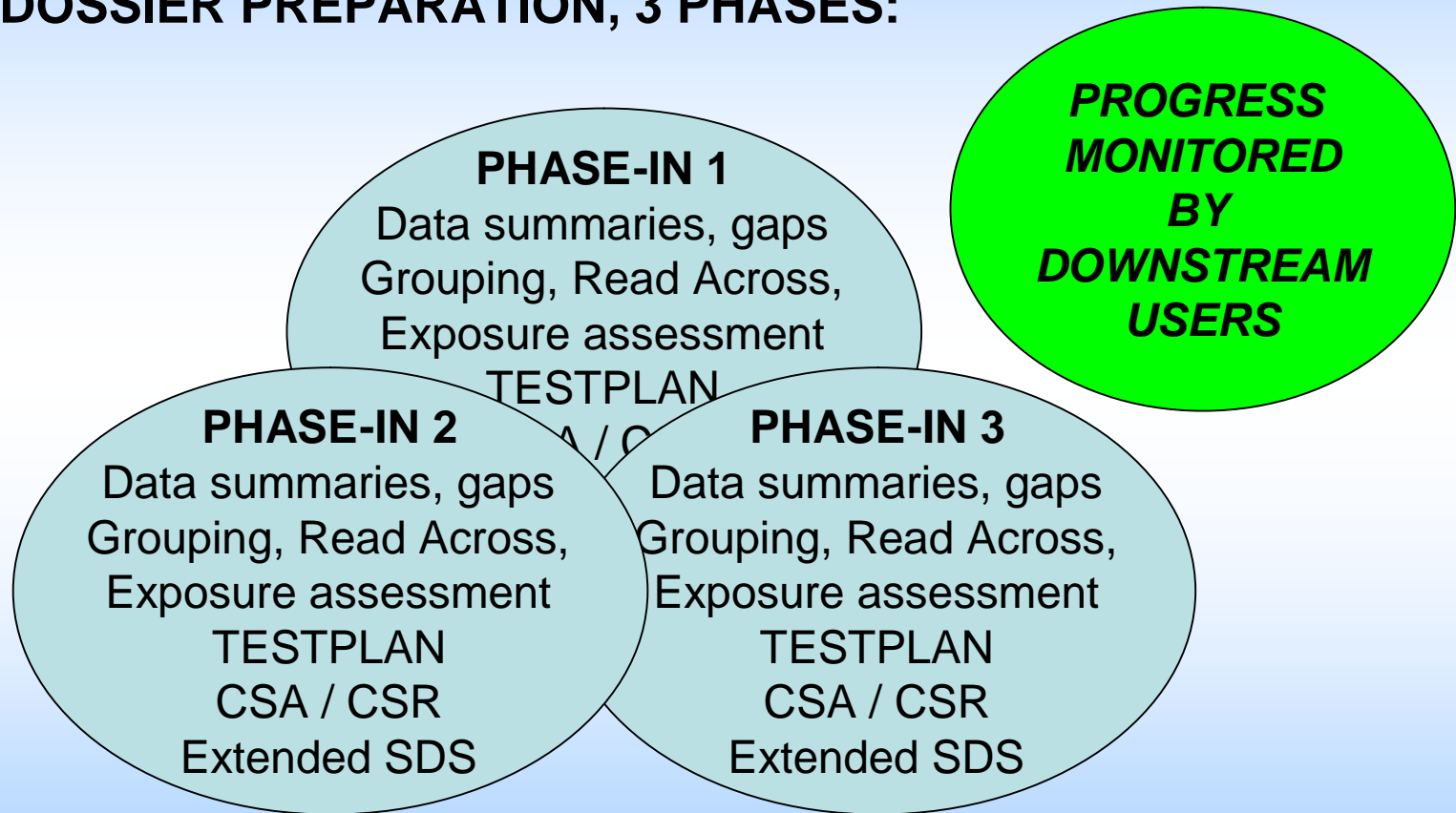
D=Deadline for (Pre-)registration



6 months for Pre-registration	> 1 t/year	> 100 t/year	> 1000 t/year + R50-53 > 100tons/y + CMR 1+2 (> 1 t/year)
-------------------------------	------------	--------------	---

REGISTRATION: by PRODUCER/IMPORTER

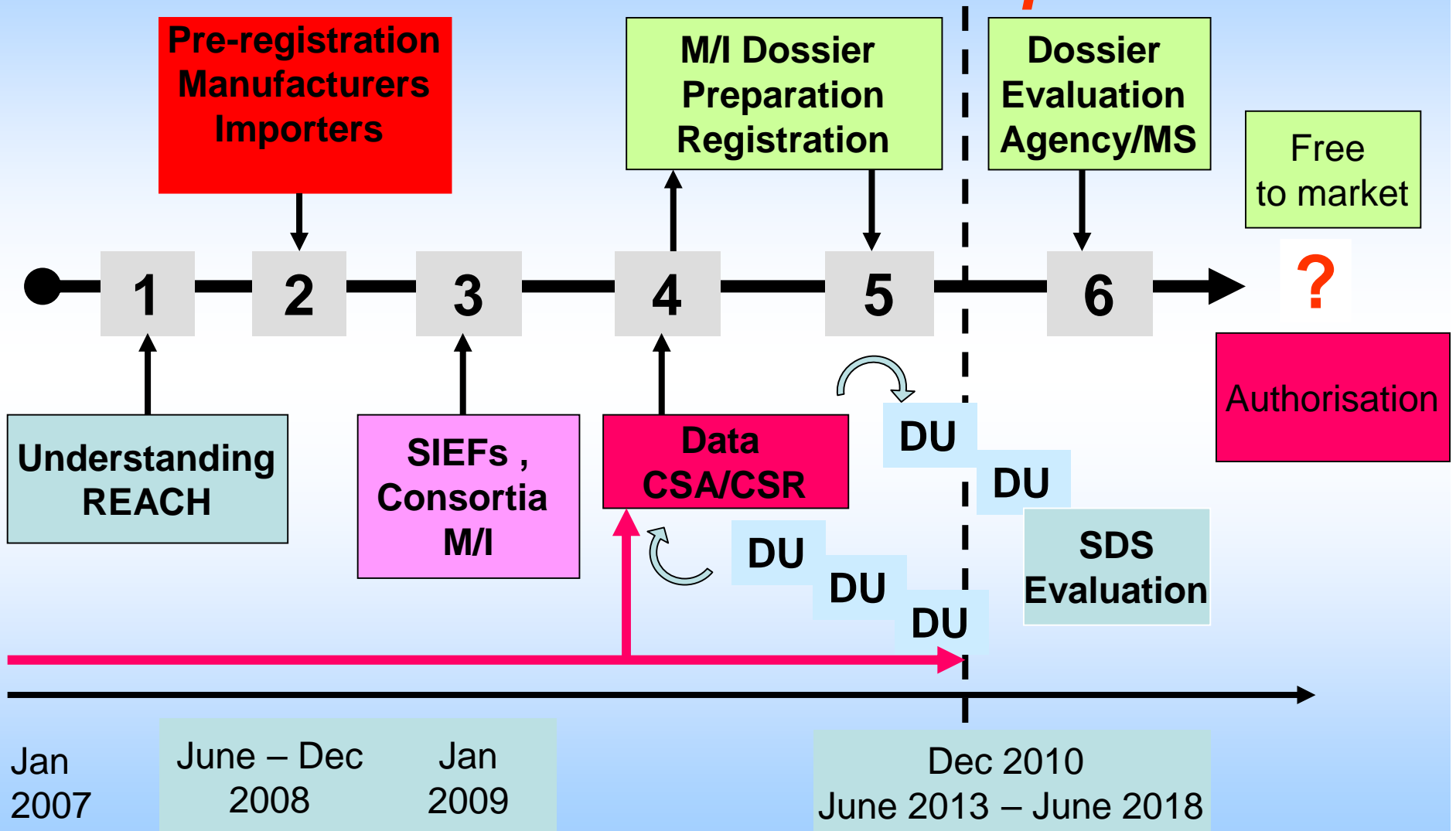
➤ DOSSIER PREPARATION, 3 PHASES:



➤ DOSSIER COMPLETION & SUBMISSION

REACH: THE REGISTRATION PROCESS

Downstream User Participation



CRITICAL PHASE :
REACH
PRE-REGISTRATION:

a ***MUST***

to Produce & Market
after December 1st, 2008
until actual Registration

& USE

REACH PRE-REGISTRATION: WHEN?

- **Substances Can Only Be Pre-registered**
BETWEEN JUNE 1ST and DECEMBER 1ST 2008
- *late pre-registrations are possible, but **only** for companies producing or importing a phase-in substance **for the first time** since the past 15 years*
- Consequences : if a substance has not been pre-registered, only “new producers/importers” could postulate for phase-in status.

No Volume Threshold for Pre-Registration

REACH PREREGISTRATION and THEN?

- **January 1st, 2009:**
 - List of preregistered substances
 - Names of substances
 - EINECS and CAS number or other ID -code
 - First envisaged registration deadline
 - **NO names of Companies (SUPPLIERS)**

DOWNSTREAM USERS TO CHECK IF USED SUBSTANCES ARE LISTED

YES

NO

OK for PHASE-IN

SIEF:

Downstream Users can submit Data to EU Agency and participate in SIEF

1. Register as NEW
2. Seek alternative supplier & file late Pre-registration
3. Import & (pre)register
4. STOP use



LATE PRE REGISTRATION

1. Register as NEW
2. **Seek alternative supplier & file late Pre-registration**
3. Import & (pre)register
4. STOP use

Late pre-registration :

within 6 months of first manufacturing or importing in quantities of 1 t/y or more but no later than 12 months before the relevant phase-in deadline for registration (art. 28.6).

Inform Agency about interest for one substance not on the list

and provide name of actual supplier

Agency must publish on its website name of the substance

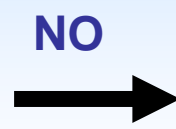
On demand Agency will provide name of DU to potential interested supplier for late pre-registration

The Chemical Safety Assessment and Report (CSA / CSR)

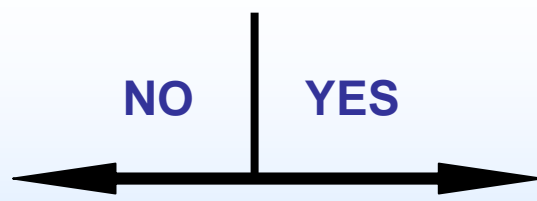
SUBSTANCE NEEDS REACH REGISTRATION?



IDENTIFIED USE (DOWNSTREAM)
IS IN SCOPE OF REACH?



HAZARDOUS SUBSTANCE?

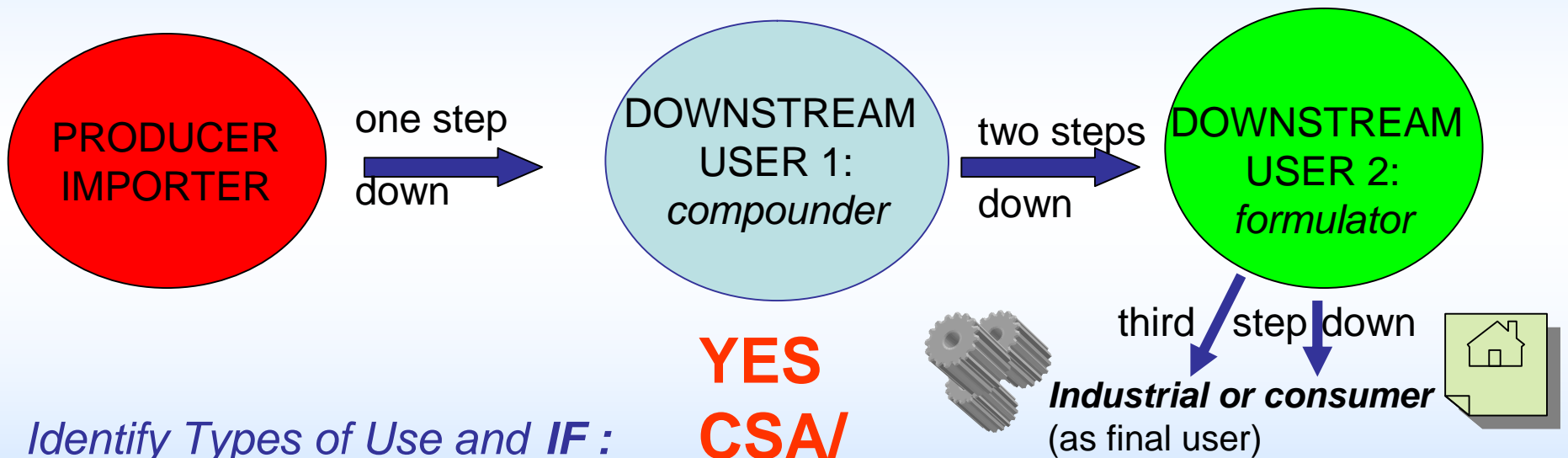


- Mixed Situations:**
- substance needs registration
 - use A needs CSR
 - use B needs no CSR
 - use C needs part of CSR



FRAGRANCE SUBSTANCES & DOWNSTREAM USER SITUATIONS

1. Production / Import &
2. Use: Incorporation Products
3. Final user (consumer or industry)



Identify Types of Use and **IF** :

1) volume > 10 t/y

2) substance classifies as hazardous

YES
CSA/
CSR

Art. 10 Registration
with CSA and CSR
by Producer/Importer

HOWEVER

DOWNSTREAM USE OF FRAGRANCE SUBSTANCES

USE & REACH	PRE-REGISTER & REGISTER	CHEMICAL SAFETY REPORT <i>if > 10 t/y per Legal Entity</i>			
		SUBSTANCE SAFETY ASSESSMENT and if ... SUBSTANCE CLASSIFIES AS HAZARDOUS then ALSO Exposure Assessments for :		
			CONSUMERS	WORKERS	ENVIRONMENT
COSMETICS (Dir. 76/768/EEC)	always	always	NO , except YES for indirect exposure via environment	YES , for ALL: production & compounding & formulation	YES , for ALL: production & compounding & formulation & FINAL FATE
NON-COSMETICS 1. Household cleaners 2. Airfresheners 3. Articles, e.g. candles	always always always	always always always	YES , for ALL: direct & indirect exposures	YES , for ALL: production & compounding & formulation	YES , for ALL: production & compounding & formulation & FINAL FATE
FLAVORS 1. For Food/Feed 2. For Oral Care (= cosmetics)	NO always	NO always	NO YES , as for Cosmetics	NO YES , as for Cosmetics	NO YES , as for Cosmetics

DUTIES OF DOWNSTREAM USERS

1. *Implement Safe Use Recommendations of Supplier*

2. **WHAT IF DOWNSTREAM USE OF SUBSTANCE IS CONFIDENTIAL or NOT COVERED BY REGISTRANT**

- Prepare CSR for Use
 - Report this Use to the Agency with:
 - Substance identify
 - Identity of Downstream User
 - Identity of Supplier(s)
 - Description of Use
 - Proposal for additional testing if needed
- BUT....**

DUTIES OF DOWNSTREAM USERS

- A downstream user need not prepare such a CSR in any of the following cases:
 - (a) no safety data sheet required
 - (b) CSR not required to be completed by his supplier
 - (c) the downstream user uses the substance or preparation in a total quantity of less than 1 tonne per year;

DUTIES OF DOWNSTREAM USERS

- (d) the downstream user implements or recommends an exposure scenario communicated to him in the safety data sheet;
- (e) the substance is present in a preparation in a concentration lower than any of the concentrations set out in Article 14(2);
- (f) the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled

DOWNSTREAM USE AUTHORISATION & RESTRICTIONS (1)

- **Substances subject to Authorisation (Annex XIV):**
 - CMR category 1 & 2
 - PBT & vPvB
 - “*equivalent concern*”: probable serious effects to human health or environment
- **Procedure starts June 1, 2009 with:**
 - First Candidate list by Agency
 - Priority to high volume, wide spread use, PBT/ vPvB
 - Member States can propose Additions
 - “Interested Parties” can comment on proposal

DOWNSTREAM USE AUTHORISATION & RESTRICTIONS (2)

- **Request for Authorisations for a Use(Annex XIV):**
 - by producer, importer or **DOWNSTREAM USER**
 - For a specified use with
 - a CSR
 - analysis of alternatives
 - a substitution plan
 - if appropriate: a socio-economic analysis for substitution
- **A granted Authorisation:**
 - is time limited
 - may be reviewed at any time
 - will be reconsidered in light of new data

DOWNSTREAM USERS (EU-based):

2 Key Questions

1. **WHAT IS THE REACH-STATUS OF YOUR *INCOMING SUBSTANCES AND PREPARATIONS (mixtures)***

.....

2. **WILL YOUR *EU-BASED UPSTREAM SUPPLIER PRE-REGISTER & REGISTER***

..... review your portfolio, obtain confirmation upstream

ASSURE YOUR REACH-STATUS NOW!

DOWNSTREAM USERS (EU-based): Possibilities

- 1. You can change your status from IMPORTER to DOWNSTREAM USER if the non EU producer decides to appoint an ONLY REPRESENTATIVE (you continue to import but you become DU within REACH)***
- 2. You can choose to IMPORT or to PRODUCE if you think that your supply chain is endangered (with pre - registration or not).***

HOW TO PREPARE ?

- Assess your portfolio of substances
- Inform your suppliers about your uses
- Monitor carefully pre-registration / registration / authorization /
- Be ready for possible own CSA/CSR
- Global review of your **supply chain**.

FOR HELP : COMING GUIDANCE

The **RIP 3.5** (RIP = Reach Implementation project)
“**GUIDANCE DOCUMENT ON DOWSTREAM -USER
REQUIREMENTS**”

SHALL PROVIDE DUs WITH CLEAR GUIDANCE.

The draft TGD available in september 2007

More info on www.ecb/jrc/reach/rip/

...

EFEQ-Workshop REACH

4 June 2007, Grasse .

Obligations of Downstream Users

**With thanks to EFFA and Hans van
Bergen for this input**