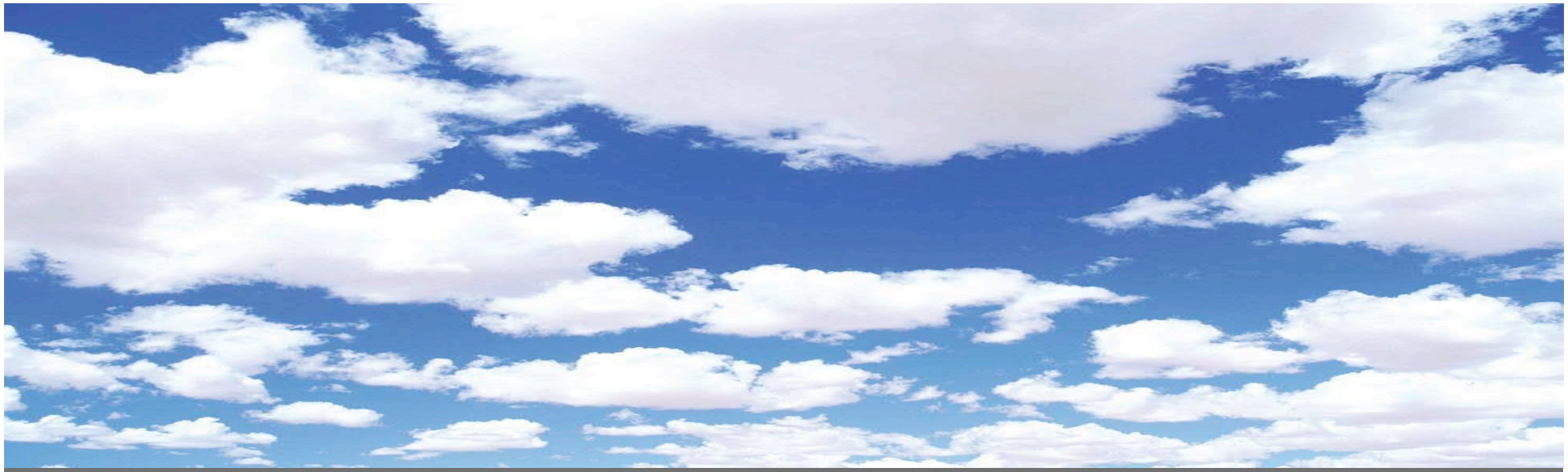


REACH challenge: can ECHA deal with it?

ecopa

29 November Brussel

Dr. Erwin Annys

REACH

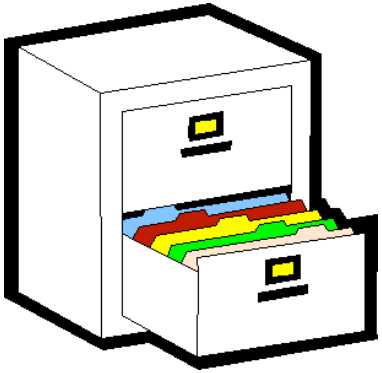
Registration

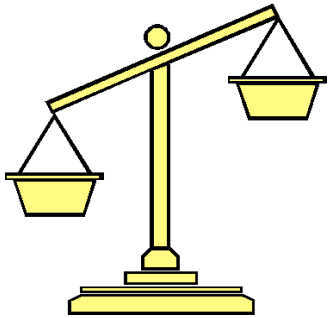
Evaluation

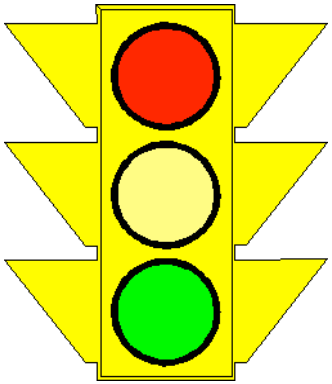
Authorisation and Restriction

of

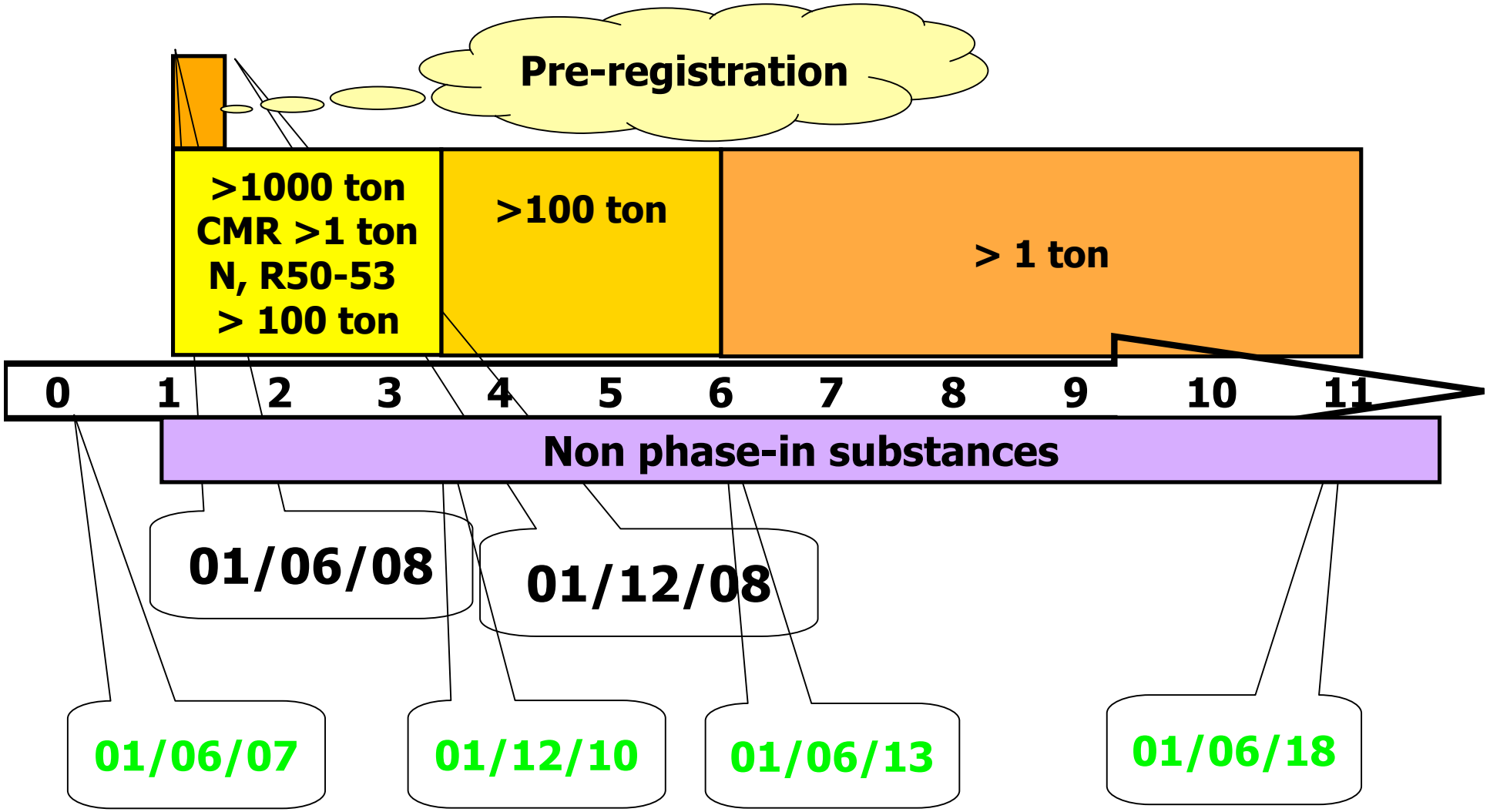
Chemical substances







Registration

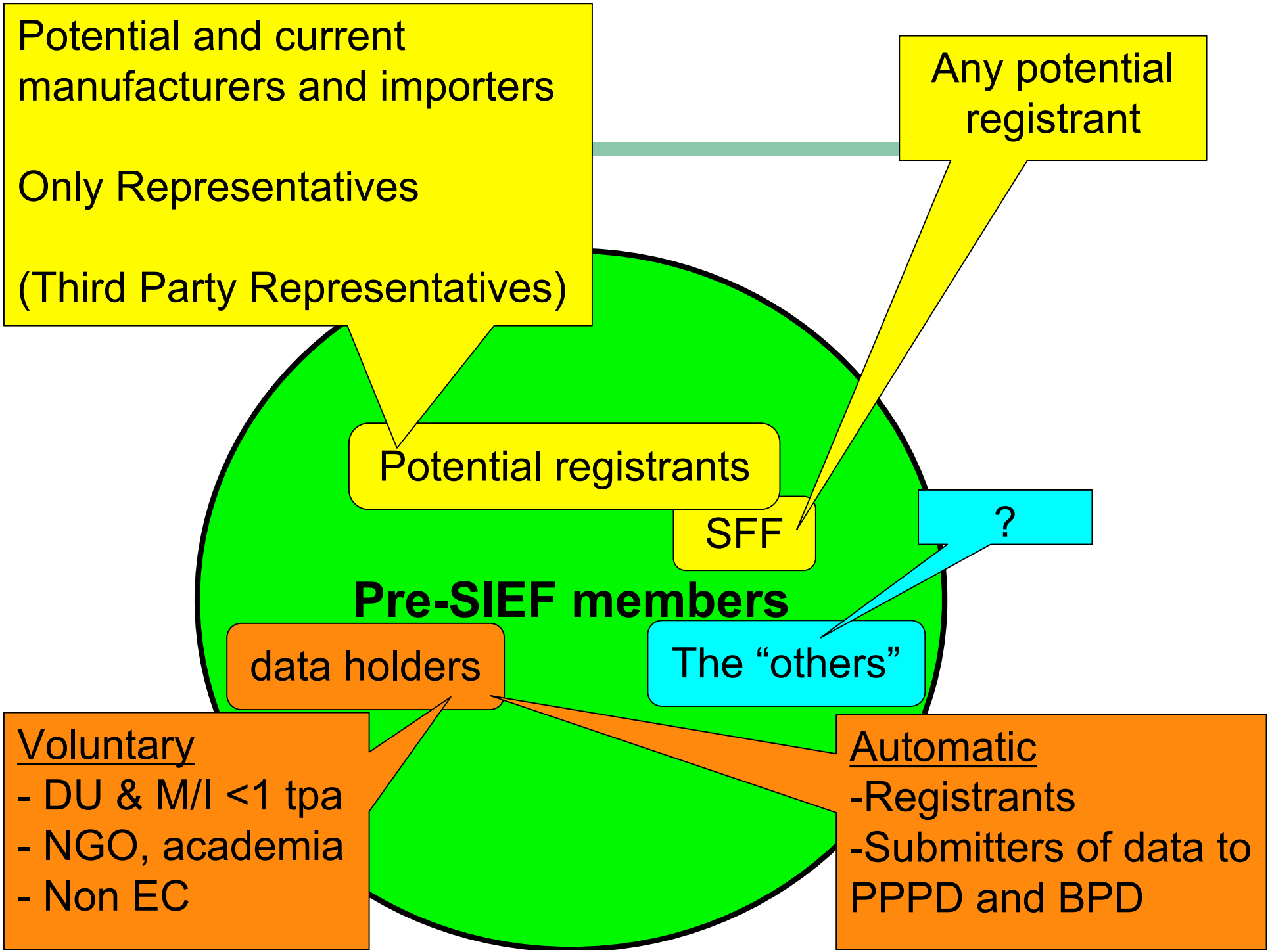


Estimations

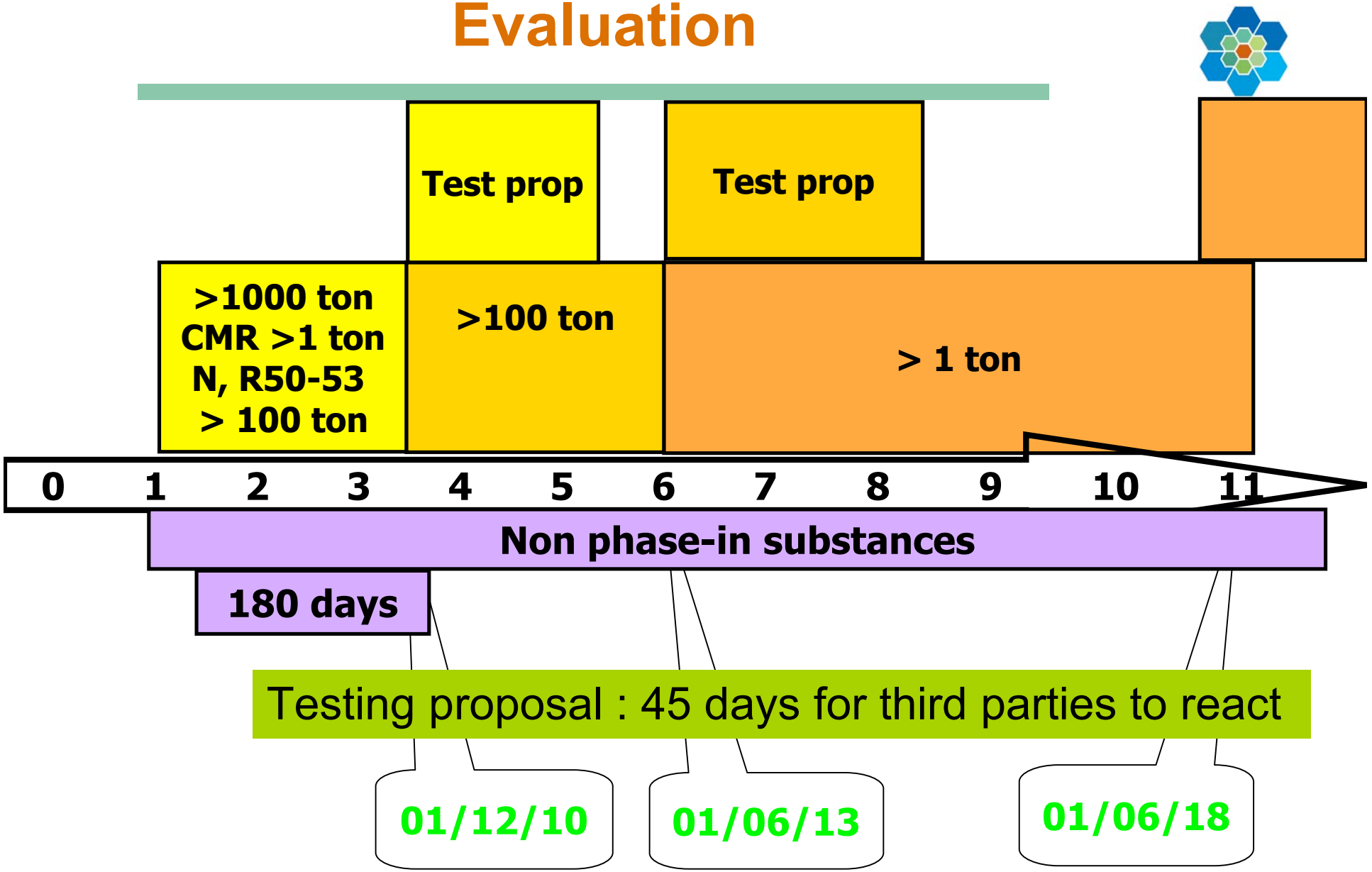
- 30.000 substances
- Average of 5 manufacturers/importers per substance
- 180.000 to 200.000 pre-registrations were expected by Commission and ECHA

Reality

- Status 28/11/08 12h
  - > 2.000.000 pre-registrations
  - > 50.000 substances
  - > 47.000 legal entities
  - 3400 bulk files in queue
  - 100.000 pre-registrations on 26/11
  - 3600 new legal entities signed up on 26/11


Potential and current manufacturers and importers
Only Representatives
(Third Party Representatives)
Any potential registrant
Potential registrants
SFF
?
Pre-SIEF members
data holders
The “others”
Voluntary
- DU & M/I <1 tpa
- NGO, academia
- Non EC
Automatic
-Registrants
-Submitters of data to PPPD and BPD

Evaluation


Test prop
Test prop
>1000 ton
CMR >1 ton
N, R50-53
> 100 ton
>100 ton
> 1 ton
0
1
2
3
4
5
6
7
8
9
10
11
Non phase-in substances
180 days
Testing proposal : 45 days for third parties to react
01/12/10
01/06/13
01/06/18

Annex XI

- General rules for adaptation of the standard testing regime set out in Annexes VII to X
  - Exposure based waiving
    - Footnote in the text presented for Comitology procedure
    - Without prejudice to column 2 of Section 8.7 of annexes IX and X, a *DNEL derived from a screening test for reproductive/developmental toxicity shall normally not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study*. Without prejudice to column 2 of Section 8.6 of annexes IX and X, a *DNEL derived form a 28 days repeated dose toxicity study shall normally not be considered appropriate to omit 90 days repeated dose toxicity study*.

Guidance documents

Reproductive/developmental toxicity: ECHA Guidance R7a describes under R.7.6.4.1 that at Annex VIII level a negative result of a screening assay can provide a basis for a DNEL in relation to reproductive toxicity derived from the highest dose level used in the study (Page 359 in the paragraph Reproduction/Developmental Toxicity Screening Test (OECD TDs 421 und 422): *"…However, a negative result can provide the basis for a DNEL in relation to reproductive toxicity derived from the highest dose level used in the study and using an assessment factor that takes into account of the limitations of this study".*

Guidance documents

28day/90 day study: *Guidance Document R8 defines default assessment factors for differences in exposure duration, including extrapolation from subacute to sub-chronic and subacute to chronic (see table 8-5 and 8-6).* Therefore is it generally accepted to perform such extrapolations. This is confirmed by guidance document R7. In chapter R.7.5.2 it is mentioned on page 312, that e.g. under Annex IX "a sub-chronic repeated dose toxicity study (90-days) is usually required, in one species (90-day study; rodent)…and a short-term repeated dose toxicity study (28 days) is the minimum requirement…".

PBT criteria

- PBT criteria double role
  - Authorisation
  - Evaluation
    - Chemical Safety Assessment for substances above 10 ton/year
      - Evaluation human health hazard
      - Evaluation physicochemical hazard impact on human health
      - Evaluation environmental hazard
      - PBT and vPvB evaluation

Guidance documents

Type of data	Criterion	Screening assignment	See section
Persistence			
Ready biodegradability test	readily biodegradable	Not P and not vP	
Enhanced ready biodegradability test	readily biodegradable	Not P and not vP	
Specified tests on inherent biodegradability Zahn-Wellens (OECD 302B) MITI II test (OECD 302C)	≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum ≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P Not P	R.R.11.1.3.1
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) **or** Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability < 0.5)[1] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2) **or** Does not biodegrade fast (probability < 0.5)[1] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2)	P P	

Guidance documents

Bioaccumulation			
Convincing evidence that a substance can biomagnify in the food chain (e.g. field data [1])	e.g. BMF > 1	B or vB, definitive assignment possible	R.R.11.1.3.2
Octanol-water partitioning coefficient (experimentally determined or estimated by valid QSAR)	Log Kow ≤ 4.5	Not B and not vB	
Toxicity			R.R.11.1.3.3
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.01 mg/L	T, criterion considered to be definitely fulfilled	
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.1 mg/L	T	
Avian toxicity (subchronic or chronic toxicity or toxic for reproduction)	NOEC < 30 mg/kg food	T	

Thanks for your attention