

REACH

A challenge for the future of stabilisers

Dr. Norbert Rohde

BÆRLOCHER



we add character to plastics

content

■ REACH

- past milestones
- pre-registration
- SIEF formation
- communication in the supply chain
- registration

■ stabilisers in PVC

- general overview
- influence of REACH
 - availability
 - authorisation



REACH – past milestones

- **01.06.07** **entry into force**
target: registration dossiers of all chemicals
on the market until 2018 to be prepared by
manufacturers/importers
- **until 01.06.08** **establishing of the new European Chemicals**
Agency (ECHA) in Helsinki
- **01.06.-01.12.08** **pre-registration of phase-in substances**



REACH – pre-registration

- **expectation by EC Commission and ECHA:
approx. 150,000 pre-registrations**
 - **on 19.12.08 ECHA published the result:
about 2.75 million pre-registrations for about 150,000
substances
done by 65,000 companies**
- ⇒ **major challenge for the ECHA IT-system**

REACH – pre-registration – some reasons

- unclear situation with exempted substances
- recyclers were forced to pre-register
- re-imports needed pre-registration
- strategic considerations (e.g. downstream users)
- misinterpretation of the regulation
- market more complex than expected

REACH – pre-registration – some examples

■ calcium distearate	694
■ zinc distearate	866
■ lead distearate	148
■ dibutyltin ethylhexyl thioglycolate	149
■ barium p.tert.butylbenzoate	137
■ bisphenol A	2038

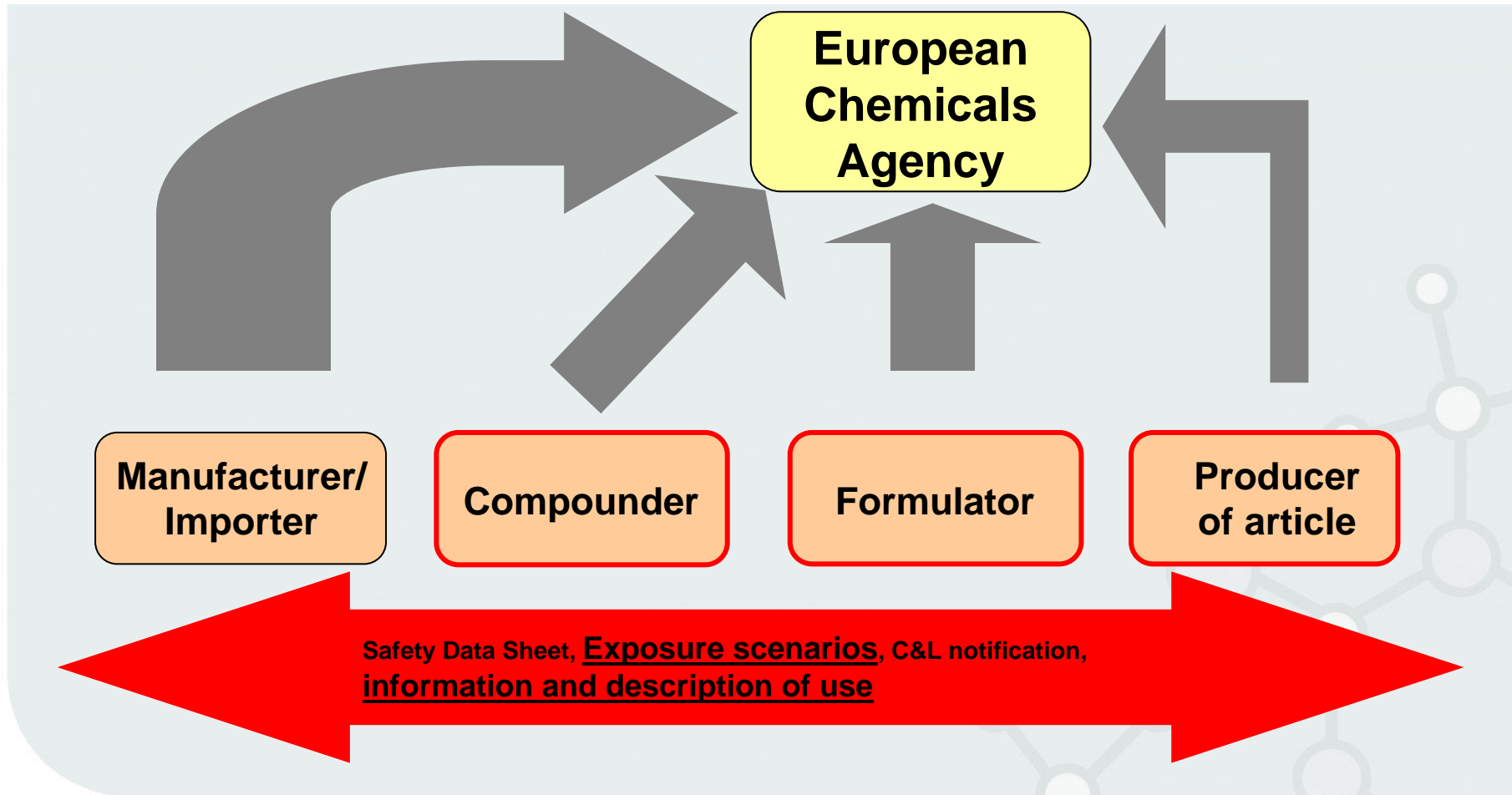


REACH – SIEF formation

- **tasks in the Substance Information Exchange Forum (SIEF)**
 - **sameness check of pre-registered substances**
 - **exchange information about available (animal) studies**
 - **collectively identify needs for further studies**
 - **agree classification and labelling**
- **SIEF Formation Facilitator recommended;
reimbursement foreseen**
- **industry is responsible for this step;
details are not given in the REACH regulation**

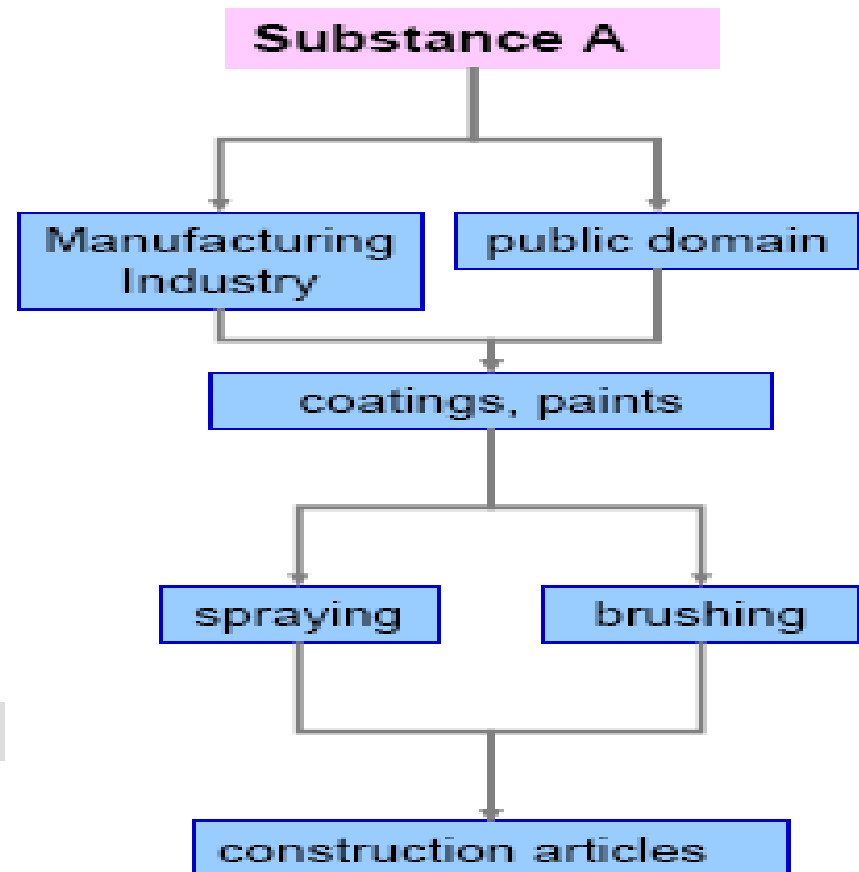
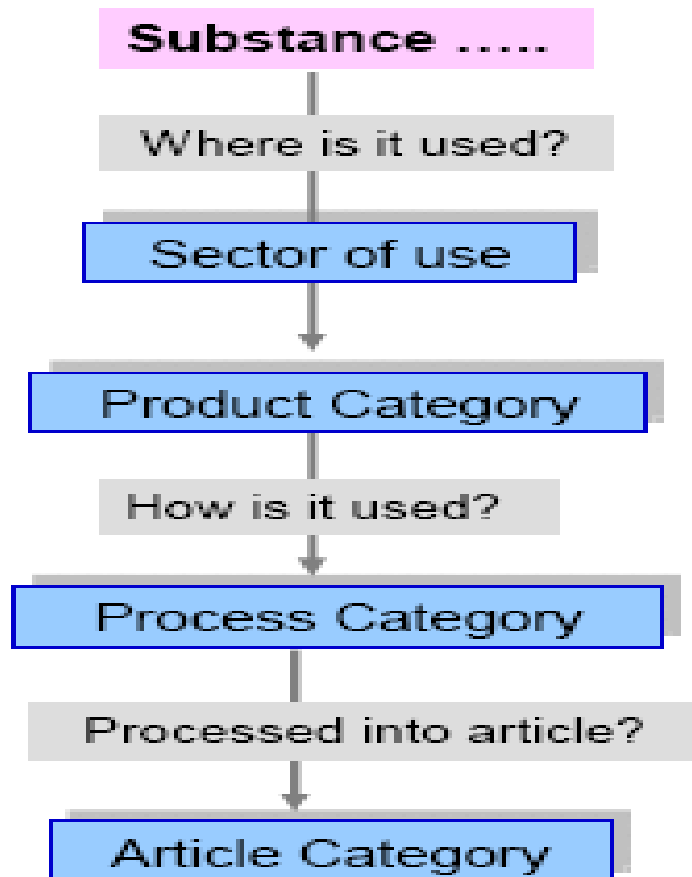


REACH - Communication in Supply Chain



Presentation X • Date • Author • page 8

REACH – communication – descriptor system



Presentation X • Date • Author • page 9

REACH – typical descriptors PVC

■ Process categories (PROC)

PROC 5 **Mixing or blending in batch processes for formulation of preparations and articles**

PROC 6 **Calendering operations**

PROC 14 **Production of preparations or articles by tableting, compression, extrusion, pelettisation**

■ Article categories (AC)

C18.1 **Constructional articles / building material f. indoor use**

C18.2 **Constructional articles / building material f. outdoor use**

C19 **Commercial / consumer plastic products**



REACH – typical descriptors PVC

- **Sector of use categories (SU)**

**SU12 Manufacture of plastics products, including
 compounding and conversion**

- **Product categories (PC)**

PC32 Polymer preparations and compounds

**Each category will be combined with typical exposure data to
enable the chemical safety assessment (CSA).**

**Further details are described in the Technical Guidance Document
on Information requirements and CSA (chapter R.12)**



REACH – registration deadlines

- **Registration until 1st Dec.2010 for substances:**

- ⇒ **manufactured/imported >1000 t/y**

- ⇒ **cmr cat. 1 and 2 (>1 t/y)**

- (carcinogenic, mutagenic, toxic to reproduction)

- ⇒ **classified with R50/53 (>100 t/y)**

- (very toxic to aquatic organisms)

- **Registration until 1st June 2013 for substances:**

- ⇒ **manufactured/imported >100 t/y**

- **Registration until 1st June 2018 for substances:**

- ⇒ **manufactured/imported >1 t/y**

stabilisers in PVC – general overview

- For the time being approx. 300 substances are used as additives in the PVC industry
- Up to 50% of these substances are pre-registered with a registration deadline Dec. 2010
- Consortia are already established (or will start very soon) for these substances with the early deadline, e.g.
 - lead stabilisers
 - zinc salts of fatty acids
 - organotin stabilisers
 - organophosphites



stabilisers – influence of REACH - availability

- **Not all pre-registrations will be followed up by registrations.**
- **Critical issues:**
 - **costs (consortia/consultancy fees, tests)**
 - **availability of consultants and test facilities**
 - **complex supply chains**



stabilisers – influence of REACH - authorisation

■ How and when will a substance fall under authorisation?

1. Proposal by a member state or the commission
2. Addition to the candidate list after complex discussions between member states, commission and ECHA.
3. Submission of comments by all interested parties
4. Inclusion in the list of substances to authorisation with definition of sunset dates (first time: 29.05.2009).

⇒ **Sunset dates will be fixed within the period of 36 to 42 months (first possible sunset date: 01.06.2012).**



REACH authorisation – first candidate list

- approx.1500 substances are expected to fulfil the criteria
- 30.06.08 Publication of 16 substances proposed by member states for candidate list:

Benzyl butyl phthalate

Dibutyl phthalate

Bis (2-ethyl(hexyl)phthalate)

Diarsenic trioxide

Diarsenic pentaoxide

Lead hydrogen arsenate

Triethyl arsenate

Bis(tributyltin)oxide

Anthracene

4,4'- Diaminodiphenylmethane

5-t-butyl-2,4,6-trinitro-m-xylene

Sodium dichromate, dihydrate

Cobalt dichloride

Alkanes, C10-13, chloro

Hexabromocyclododecane



REACH authorisation – outlook

- **Except some plasticisers the PVC industry is not influenced by the first candidate list.**
- **Proposals for the candidate list can be made continuously; review of list of substances subject to authorisation (annex XIV) at least every 2 years.**
- **Some of the presently used stabilisers fulfil the criteria to be included in annex XIV – unknown when they will be proposed.**



stabilisers – under consideration - lead

- **Most of the existing lead stabilisers will be registered by 2010.**
- **A consortium has already started its work.**
- **Lead stabilisers are classified as cmr class 1 substances**
 - hence fulfilling the criteria for annex XIV
 - unknown when will appear on candidate list
- **BUT according to VINYL2010 lead stabilisers will be phased-out by 2015 in the EU.**



stabilisers – under consideration - tin

- Butyltin stabilisers fulfil the criteria for annex XIV.
- Risk assessment showed no concern in rigid PVC applications.
- EU Scientific Committee on Health and Environmental Risks (SCHER) confirmed the safe use of the majority of tin stabilisers except for several specific applications including printed t-shirts, wall covering and flooring (Dec 2006).
- For the time being the EU Commission/member states are considering restrictions/use bans for certain applications.



stabilisers – under consideration - others

- **Salts of p-tert. butylbenzoic acid**

The acid recently has been classified as reprotoxic cat 2.
Salts probably have the same properties (although not yet tested)

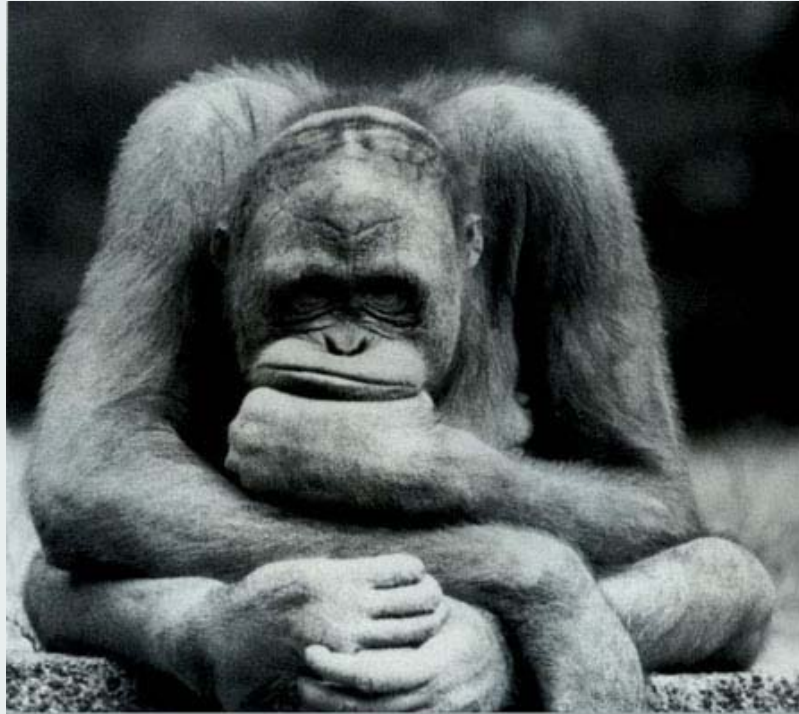
– hence fulfilling the criteria for annex XIV.

- **Nonylphenol derivatives**

Nonylphenol under discussion as possible endocrine disruptor since many years.

Endocrine disruptors (although scientific definition is still missing) may fall under authorisation as well.

REACH – will keep us busy during the next years



Oh what to do, what to dooo?

- Thank you for your attention -

Presentation X • Date • Author • page 21

BÆRLOCHER



we add character to plastics