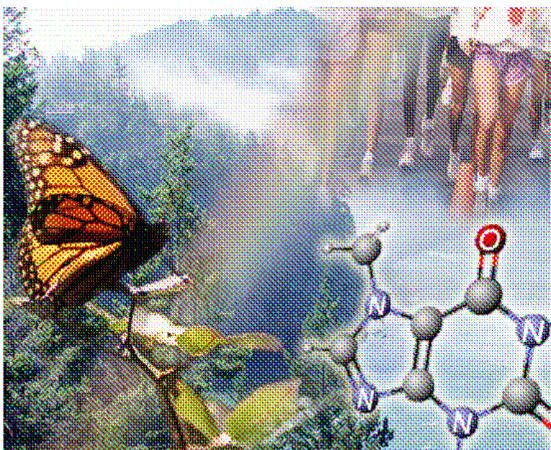


Identification and Naming of Substances under REACH RIP 3.10

RECHA

Guidance for identification and
naming of substances under
REACH



June 2007

Guidance for the implementation of REACH



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Energizing Chemistry

Substance identity is essential for

- **Pre – registration**
- **Formation of SIEF's**
- **Registration and formation of consortia**
- **Data sharing**
- **Grouping of substances**
- **Classification & Labelling**
- **other EU- and national legislation**
- **International Trade**

Activities since the first TGD draft was published in 2006

- 1. 19th April 2006** **Informal meeting with the ECB in ISPRA:** Participants: Cefic and ECB representatives, VCI delegation: BASF, Cognis and LANXESS
- 2. September 2006** **Participation on Internet Consultation:** Comments from 13 German companies and 13 European and German associations
- 3. 14th March 2007** **Meeting with the DG Environment** Participants: DG ENVI, Cefic, ECB, BDI and VCI delegation (BASF, LANXESS)
- 4. 23rd May 2007** **Cefic Awareness workshop**
- 5. 01. June 2007** **Guidance for identification and naming of substances under REACH (RIP 3.10) was published unchanged**
- 6. August 2007** Establishment of a 'core group' with members of Cefic, VCI and other European associations, i.e. CIA, to identify 'add ons' of RIP-Guidance Documents

Participants on Internet consultation September 2006

REACH Alliance:

BIBM
CEMBUREAU
CEPI
CERAME- UNIE
CPIV
ERMCO
EuLA
EUROALLIAGE
EUROFER
EUROGYPSUM
EUROMETAUX
EUROMINES
IMA-Europe

VCI- Membership companies:

Albemarle Europe
(Martinswerk)
Baerlocher
BASF
Bayer
Berzelius Metall GmbH
Chemetall GmbH
Clariant
Cognis
Degussa
Henkel
K+S- Aktiengesellschaft
Sasol GmbH
LANXESS

Associations:

Bv. dt. Kalkindustrie e.V.
Bv. Baustoffe, Steine und
Erden
Bv. der Gipsindustrie e.V.
Bv. Keram. Rohstoffe e.V.
Iv. Chemiefaser e.V. (IVC)
Vb. Mineralfarbenindustrie
Vb. Kali- und Salzindustrie
Wv. Bergbau e.V.

Bv. Bundesverband
Iv. Industrievereinigung
Vb. Verband
Wv. Wirtschaftsvereinigung

Definitions of 'Substance' and 'Preparation' according to article 3.1 + 3.2

REACH (VO 1907/2006) is a substance-related regulation.



Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Preparation: means a mixture or solution composed of two or more substances;

Basic Principles

- TGD is not legally binding
- No obligations beyond the legal Reach text
- Decision on how to describe the **identity of a substance** is within the responsibility of the registrant and not of authorities (paradigm shift under REACH)

Consequences of changing current EINECS nomenclature to TGD

- No re-definition of substances with existing CAS No. or EINECS No. (1)
- Would lead to a lot of additional substances currently dealt with under one common description
- Would cause doubts about the phase-in status of currently marketed substances
- Would create tremendous work to adapt current databases in industry as well as in authorities
- Would cause adjustment and re-evaluation of lots of existing study reports to new descriptors
- Would endanger the validity of hazard, exposure, and risk assessments done under EU, OECD, ICCA HPV, etc. as reference substances are no longer existing or valid
- Would cause lots of new substance notifications outside the EU as the legal basis of substance descriptions got lost

Current priority issues

The main current priority issues of industry discussions with regard to the RIP 3.10 guidance are:

- Naming rules
- Mixtures
- Reaction mass
- Impurities (% limit)
- Phase-in status

Definitions of 'substance' and 'preparation' acc. to REACH

The common reaction of



results in C + D with small amounts of raw materials, solvent, by-products (so called "crude product").

In line with REACH C+D will normally be regarded as a **preparation!**

But according to the EINECS [Manual of Decisions, ***Criteria for reporting substances for EINECS*** (ECB web-site)] there are other options:

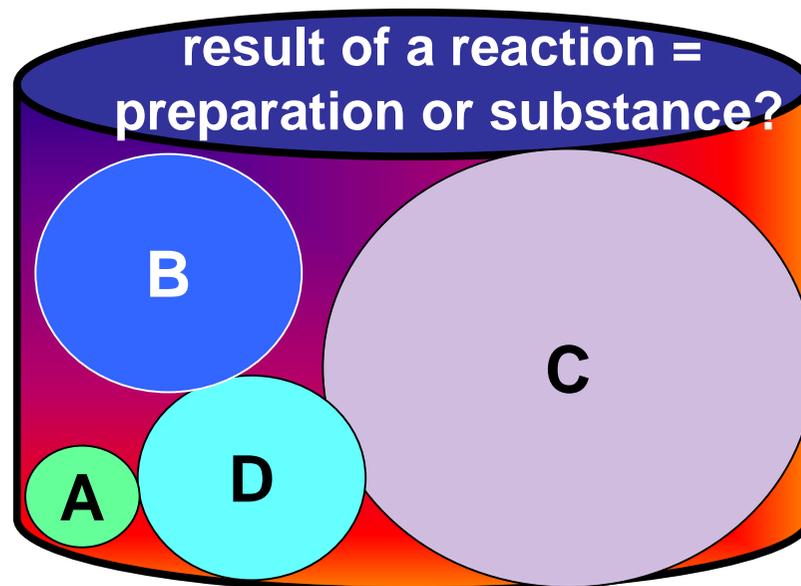
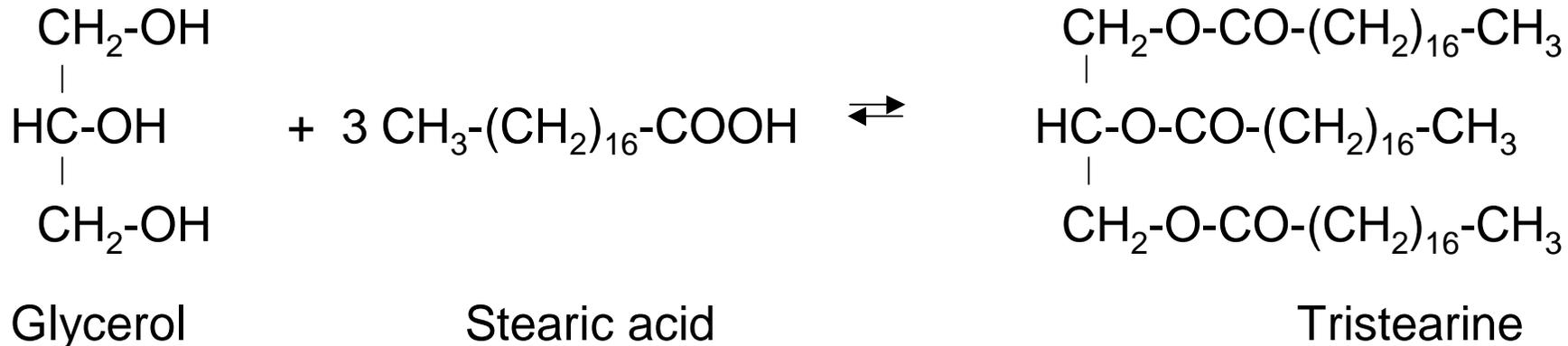
Different options which may be regarded in practice II

- There are the following options for identification and naming:
 - a) as UVCB* substance - e. g. by listing of raw materials
 - b) as substance C - with impurity D
 - c) as substance D - with impurity C
 - d) as reaction product C + D

* Substances of **U**nknown or **V**ariable Composition, **C**omplex reaction products or **B**iological materials

- In these 4 cases the tonnage band for registration will be the total amount of the result of the reaction
- The assessment must be based on the substance data but it should be allowed of the data of the components as well

Esterification of Glycerol with Stearic acid



- A = Stearic acid
- B = Diester
- D = Monoester
- C = Triester
- Remainder: Glycerol

LANXESS - Examples of 'preparations'

- **Dichlorination of benzene results in the isomeric mixture of crude dichlorobenzene. The composition of the preparation is:**
about **40%** 1,2-, **5%** 1,3- and about **55%** 1,4-dichlorobenzene
- **Chlorination of toluene produces the preparation crude chlorotoluene, consisting of:**
about **40%** 1,2- and about **60%** 1,4-chlorotoluene
- **Nitration of toluene produces the preparation crude nitrotoluene, consisting of about **60%** 1,2-, about **5%** 1,3- and about **35%** 1,4- nitrotoluene**
- **Nitration of chlorobenzene produces a preparation with:**
about **38%** 1,2-, **2%** 1,3-, and about **60%** 1,4- chloronitrobenzene

Different options which may be regarded in practice

We as LANXESS retain the common practice for identification and naming of substances based on EINECS. We need flexibility and will decide case by case:
Is the result of the reaction



a preparation: We are going to register the different substances C and D. Each substance will be registered in its tonnage band

or is it

a substance with impurities.

Multi-constituent substances?

- We as LANXESS do not intend to use the multi-constituent substance approach
- If we intend to produce C + D as the result of a manufacturing process:



e. g. : C + D : sum 12 t/a, C = 8 t/a and D = 4 t/a

- for the registration of C + D, we will submit a dataset for each of C and D, each < 10 t/a **and not > 10t/a as it is requested by the TGD RIP 3.10 !**
- We are not going to register C+D with data set > 10 t/a.

Many Questions to be asked - but not yet answered to Industry I

- Where does the REACH Regulation describe 'multi-constituents' and 'reaction masses' and require their (pre-)registration?
- How does the REACH Regulation describe a 'preparation' and distinguish this from other 'mixtures'?
- If constituents of a reaction mass must be registered separately, how many additional registrations would be needed? – And what implications does this have on costs and animal testing?
- How can phase-in status be managed for different substances that fall under the same EINECS entry?

Many Questions to be asked - but not yet answered to Industry II

- How should reaction masses be named if containing different products as a result of different concentrations of reaction materials and/or products?
- For instance:
 - (a) would there need to rename the substance for a change of concentration?
 - (b) how can CBI be protected in such instances?
 - (c) does a change in reaction conditions/ mixture concentrations imply a need to register immediately?
- What are the consequence of changing any naming schemes with regards to other legislation?

Possible impacts of TGD RIP 3.10 for industry I

We are worrying about ...

- **Re-naming of many substances with consequences that they are not in line with CAS, IUPAC, EINECS and common practice**
- **being no longer in the “Phase-in status“ because “Mixture of ...” was not EINECS-listed**
- **by applying the 80/20 rule or the other terms of the TGD Draft that the real substance according to EINECS will be not covered**
- **Consistent application of the 80/20 rule will dilute the substance definition**

Possible impacts of TGD RIP 3.10 for industry II

We are worrying ...

- **By making a reference to this rule, it will be easier for “free-riders“ to demonstrate the identity of a substance without any obligation to prove it**
- **According to the results available so far, the number of multi-constituent substances with all components < 80%, which have until now been EINECS listed, will exceed by many times the number of phase-in substances to be registered under REACH**
- **According to estimates available so far the expected number of substances to be registred would be much higher than the number of phase-in substances!**

Conclusion



Consistent interpretation of the terms 'Substance' and 'Preparation' within the meaning of REACH results in fewer registrations than the strict implementation of the TGD- RIP 3.10-requirements!

Our goals:

- No differentiation between mono- und multi- constituent substances,
- No 80:20 Rule
- Largely retain the present arrangements
- Open for ongoing improvements
- More flexibility for company decisions

**Many Thanks for
Your Attention.**

Any Questions?

