

Science For A Better Life

Ninth ECHA Stakeholders' Day

How industry is preparing to REACH 2018

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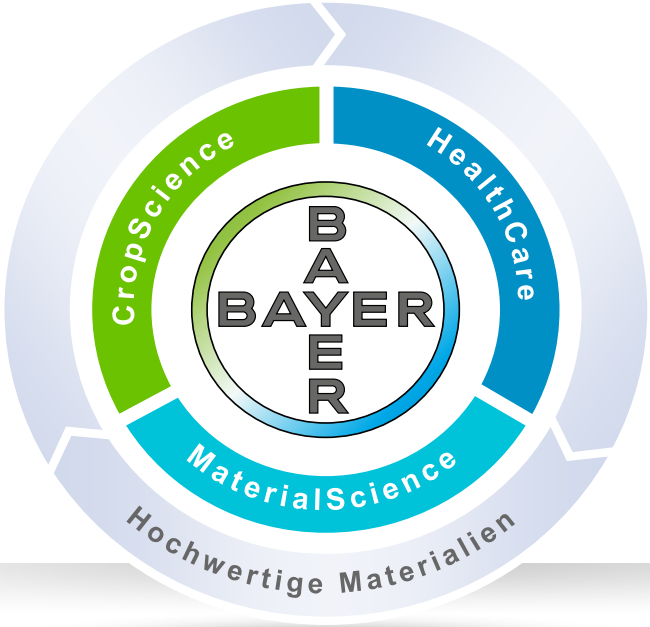

113.200 employees

Full year sales: € 40,2 billion

291 subsidiaries

R&D expenditures €3,19 billion

Status: 31st December 2013

Agenda

1. Registration
2. Comparison of Deadlines
3. Registration 2018 - First Steps
4. Next steps - Analysis of the status
5. Registration - Decision making process
6. Challenges

1. Registration

Bayer

2010: 125 substances

2013: 150 substances

2018: 200 - 300 substances?

in addition non-phase-in and

PPORD notification

Far away?
NO!!!
Registration is a continuous process, no shutdown!

2. Comparison of Deadlines

2010
Short time frame, but well known substances
Huge amount of data, often big consortia

2013
3 years timeframe, high number of substances
Less competitors, but still consortia or LoA

2018
Longer timeframe, higher number of substances
Due to changes in portfolio early identification of substances difficult
Less data, but also less competitors or no LoA
little support by suppliers / no registration

3. Registration 2018 - First Steps

Inventory

- Identification of substances between 1 and 100 t per year
- Differentiation between own production and purchased substances
- Identification of exact volume
- For purchased substances/products - contact with suppliers
- Check of existing/new SIEFs
- For imported products:
- Existing OR or own registration as an importer?

4. Next steps - Analysis of the status

Own registration

- Data gap analysis – most important task
- Check of existing SIEFS
- Data sharing
- Check of uses – contact with supply chain/customers

Purchased substance

- Contact with supplier- registration intended? guaranteed?
- Registration not intended?
- Support of supplier's registration, own registration, cease or substitution?

Imported substances

- OR appointed or foreseen?
- EU supplier as an alternative available?
- Own registration needed?

5. Registration - Decision making process

Does a consortia exist or will a new one start?

Can a Letter of Access (LoA) be bought?

Cost sharing is vital! Costs depend dramatically on number of registrants

Are cost too high (cost may be a knock-out criterion)?

Cost-benefit-analysis crucial – costs of registration, testing etc. in relation to realized profit

5. Registration - Decision making process

Do we really need a registration for substances > 10 t or could a registration < 10 t be sufficient?

Cost differences up to 300 000 €/substance (repeated dose and reproductive toxicity

Registration of a substance slightly above 10 t/year will be reviewed!

But: If a substance is used for the preparation or in the production process of pharmaceuticals or pesticides neither a waive of registration nor a change of supplier is possible!

5. Registration - Decision making process

Which kind of registration?

1 -10 t/year / 10 – 100 t/ intermediate or full registration (Relevant data for substances > 1 t/year available - Germany's Voluntary Action Programme of Substances > 1 t/year) ; more flexibility by full registration

Can or should we support all uses? Exposure triggers testing!

Analysis of all uses indispensable

Check of intrinsic properties: Criteria for inclusion in candidate list fulfilled ? Inclusion likely?

Labelling with e.g. skulls and crossbones – accepted by customers?

Registration of these substances has to be considered.

6. Challenges

- Data sharing possible?
- Volume tracking – slight inaccuracy can cause a registration in an upper volume range
- Uncertainties
  - Decision of supplier to register can be revised shortly before deadline
  - Unexpected volume increase during the next years can request more data
  - Registration/identification of nano materials
  - Change of portfolio – not foreseeable now

Portfolio analysis is much more triggered by REACH than in the past
The smaller a substance the more difficult the decision!

6. Challenges

Registration is not the only REACH business

- Monitoring of Substance Evaluation
- Authorisation processes started (e.g. aprotic solvents)
- Update of existing dossiers as a continuous duty – every change of a tonnage band or update of tox studies requires an update of the whole dossier (new guidance, new IUCLID system…)

Registration 2018 started in June 2013
An internal deadline was set by end of 2016
BUT: Volumes, uses, decision on registration will be revised again in 2017
Contracts with suppliers have to be checked

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Thank you!