Application for Authorisation

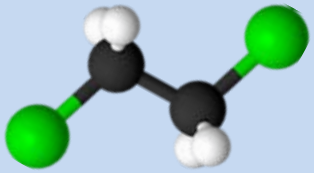
Stock-taking Conference on the Implementation of REACH Authorisation

13-14 November 2017 at ECHA, Helsinki

emp Biotech GmbH • Robert-Rössle-Strasse 10 • D-13125 Berlin • Germany

excellence – made possible

We can do it alone – The application process of a small enterprise



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What is *emp* Biotech?

Privately held chemical company

- **established in 1993**
- **33 employees**
- **<3 Mio EUR in sales**
- **ISO 9001:2008 accredited manufacturer**
- **ASiG system for work and health safety**

Corporate Headquarters at Science Campus in Berlin-Buch

Manufacturing site in Berlin-Tempelhof

Business Fields

Bio and fine chemicals

- Fluorophores and redoxmarkers
- Protein labeling kits
- Transfection reagents
- Haptens, moisture trap and buffers

Contract synthesis and research

Synthesis reagents for automated oligonucleotide syntheses

Biochromatography – at any scale

- Zetadex - Dextran based purification resins for size exclusion chromatography
- Ion Exchange resins
- Material for affinity chromatography

Zetadex production flow - EDC is used

Supply Purchasing

Sugar (Dextran)
Origin: China and Japan

Chemicals Solvents
Origin: UK, D

Plastic parts
Origin: USA, UK, D

Polymer production

Steps involving EDC

- EDC purification
- Cross-linking reaction (Polymerisation)
- Disposal
- Hydrolysis
- Filtration and washing
- Drying
- Surface modification

Final product finishing

- Bead fractionation
- Packaging
  Bulk material

Zetadex™-end products

- Column and plate filling

- Packaging
  Box units

CentriPure™-, ZetaSep™-end products

Sales

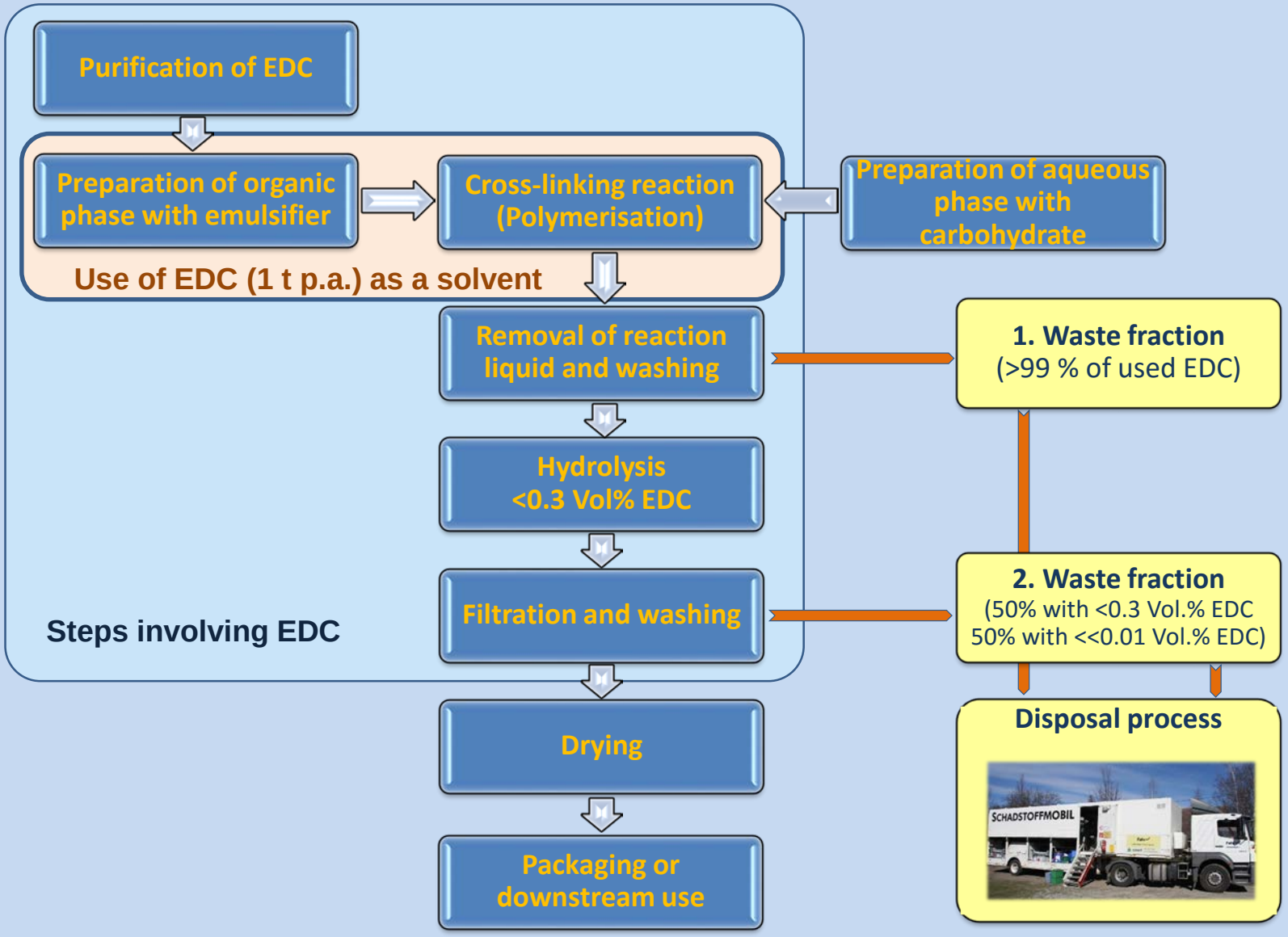
- Shipping
- Distribution
  International sales and distributor network

End users

- Applications
  Purification
  Separation
  Diagnostic

Use of EDC as a solvent

Matrix manufacturing process – AfA required



AfA process initialisation

September 11th, 2015

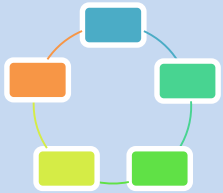
Kick-off

Call of our supplier → EDC is in Annex XIV of REACH

Entry No. **26**

Problem

Need for authorisation → No REACH team!

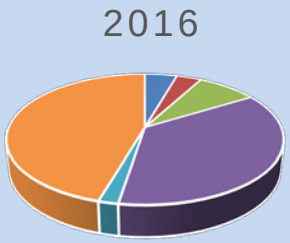


Latest Application Date
22.05.2016

Motivation

Zetadex - Dextran based products accounted for 45% of total sales

High risk of bankruptcy!



AfA process – first challenges

September / October 2015

Initial information procurement and training

Internet, ECHA, BG RCI → Need of consultation!

National Helpdesk (BauA Dortmund)

Personal Consultation (October 25th, 2015) → CSR, SEA, AoA

Search for external help

No efficient experiences or
too expensive (about 300,000 EUR from EDC consortium in Brussels)

We try to do it by ourselves!

AfA process begins

November / December 2015

Data collection

By use of our own network

- Production team
- Service partner for analysis
- Financial consultant

Calculation and writing

- Official REACH guidelines are too complicated
- Some tools are too complicate and oriented to large industrial use only (e.g. ECOTOC TG spreadsheet)
- Most helpful tools: ECHA templates and similar published applications

PSIS at ECHA (March 16th, 2016)

Best thing we could do! → Helpful comments, hints, corrections.

↓

Application for Authorisation on 02 May 2016!

AfA influenced development at emp Biotech

Disadvantages and additional problems

- High financial cost for a SME
- Publication of relevant information for competitors (Market size, production volume, internal processes)
- Additional costs lead to higher product prices

SME fee: € 24.345
(turnover ≤ € 2 Mio)

LIO fee: € 54.100
(turnover ≥ € 50 Mio)

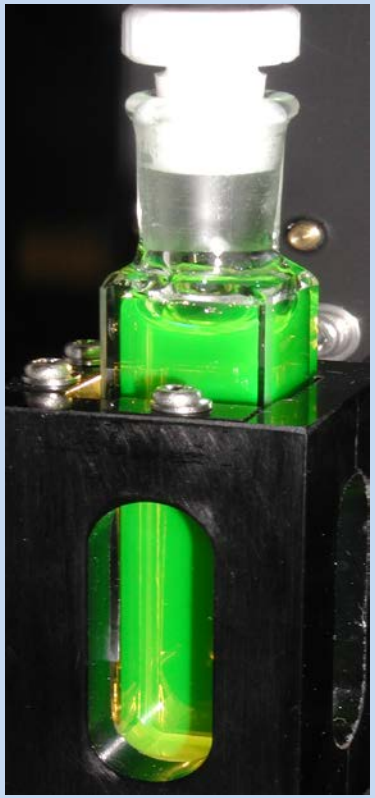
New Challenges

- Research program for search of alternatives

Benefits

- Continuous control of EDC excess
- Improvement of the production process, incl. technical equipment
- Better protection of employees and environment by additional RMM‘s
- Increased awareness of management and employees to REACH

*REACH – **R**egulates **E**very **A**ctivity of **CH**emists*



Thank you !