Assistance to start a REACH project

Ewald Langenohl,
Managing Director TÜV Rheinland BioTech

EUROPEAN CHEMICAL REGIONS NETWORK

REACH regulation –
The burden of proof and the work for experts and expert communities

Chamber of Commerce and Industry Aachen
22.11. - 23.11.2007

TÜV Rheinland Group – Facts 2006

Sales revenues (Mio. €)	**900**
Employees worldwide	**10,400**
- Germany	5,600
- international	4,800
Locations worldwide	**340**

The TÜV Rheinland Group is a leading international technical service provider. Our mission is the long-term development of safety and quality in the interaction between man, technology and the environment.

TÜV Rheinland BioTech was founded 2005 to establish and provide REACH services in the international market.

How to start a REACH-project (I)

Our assistance in preparing companies for pre-registration:

1. An in-house workshop to raise awareness among all the different players (sourcing, marketing, sales, product safety, …)
2. Inventorying of all manufactured and imported substances
3. Check of the IT-Environment (product list, sourcing list) to check-over the inventory (to be done international)
   (very useful in international companies with many subsidiaries)
4. Check of the applicable registration requirements under REACH (Filtering)
5. Check-over the real constituents of a preparation
6. Investigating the specification (of a assortment) of the imported substances

How to start a REACH-project (II)

7. Full inventory of required and available data Drafting a REACH project plan
8. Missing data and cost analysis (SimREACH®)
9. Training of “REACH compliance managers”
10. Impact assessment to prepare for entrepreneurial decisions (profitability of the product portfolio, amortization of the registration, etc…)
11. (We are counterpart for the entrepreneurial decisions involved in registering substances)
12. Assessing the personal and financial capacities
13. Setting up a budget

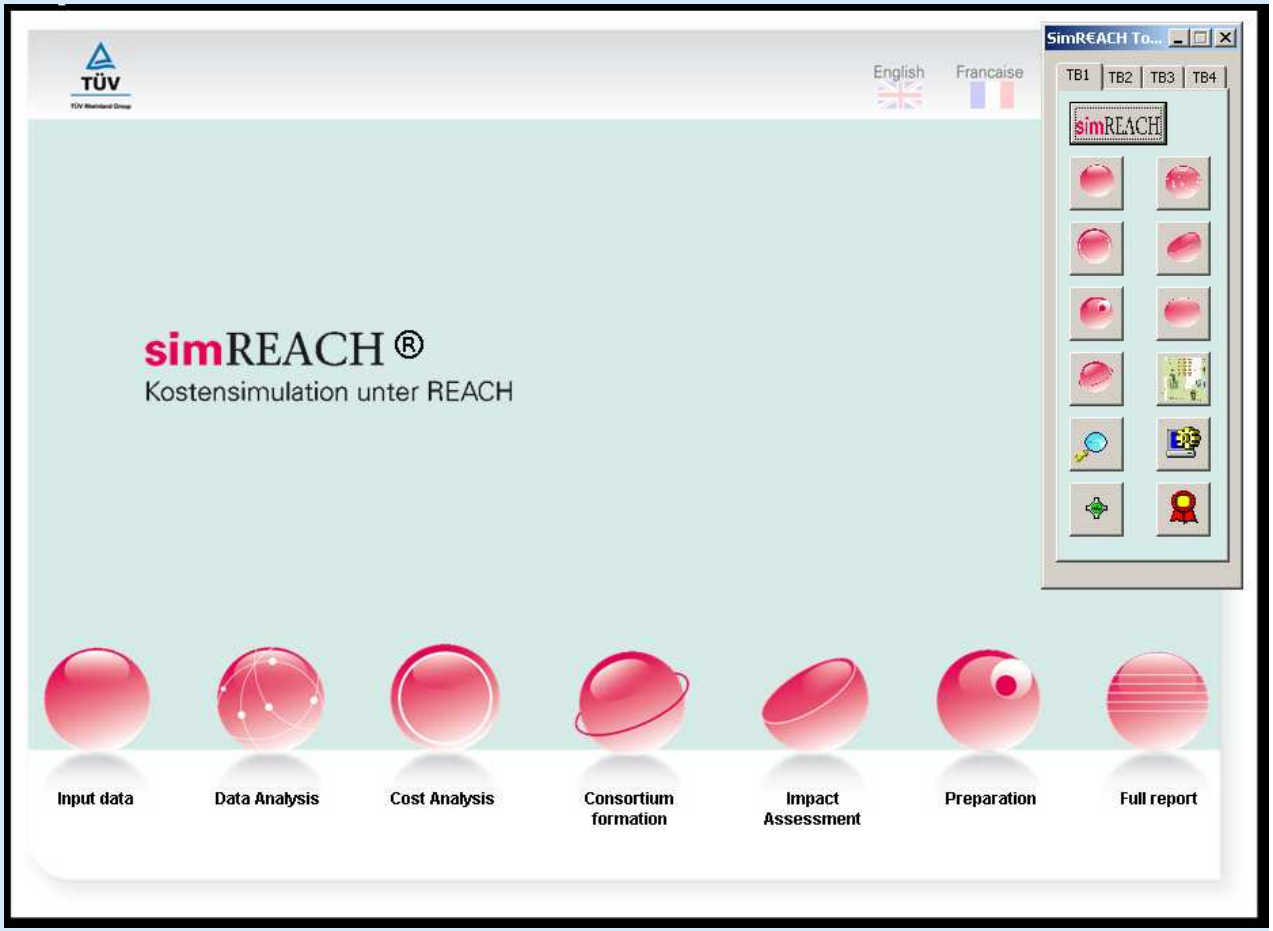
How to start a REACH-project (III)

14. Setting up a budget
15. Deciding on the focus of the registration process.
16. Setting up a plan for communicating with customers and suppliers
17. Preparing an action plan for SIEF/consortia
18. Checking pre-consortia situations/contracts
19. Drawing up a laboratory timetable

The preparation for pre-registrationis very important, complex and extremely time-consuming.

Our Expert system SimREACH® :

Simulates the new chemical directive by translating the entire directive into calculations.



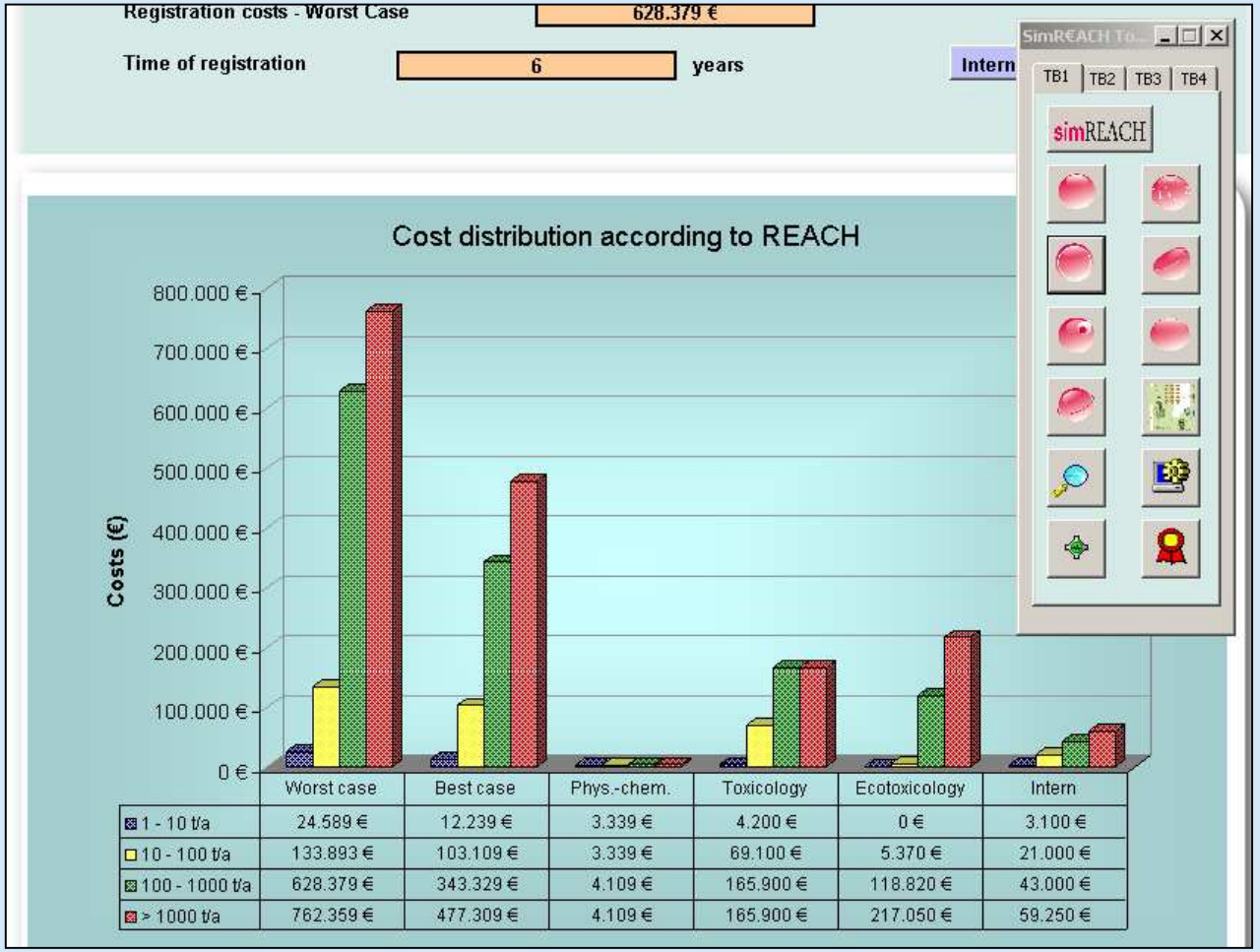
Our Expert system SimREACH® :

Provides a
data gap analysis.

OECD 112	Dissociation constant	The study shall be proposed.
	Toxicological Data	
OECD 402	Acute toxicity by dermal route	The study does need to be conducted.
OECD 401/ 420	Acute toxicity by oral route	The data is available
OECD 403	Acute toxicity by inhalation	The exposition of the substance by inhalation being unlikely, the study does not need to be conducted.
OECD 404/ 428	Skin irritation or skin corrosion	An in-vivo skin irritation test being available, the study does not need to be conducted.
OECD 427	in vivo skin irritation	The data is available
OECD 405	Eye irritation	An in-vivo eye irritation test being available, the study does not need to be conducted.
-	In vivo eye irritation	The data is available
OECD 406/ 429	Skin sensitisation	The study does need to be conducted.
OECD 410	Short-term repeated dose toxicity studie / by dermal route (28-days)	The study does need to be conducted.
OECD 412	Short-term repeated dose toxicity studie / by inhalation (28-days)	The short-term repeated dose toxicity study by dermal route being to be conducted for the susbtance, the study of the toxicity by inhalation does not need to be conducted.
OECD 411	Sub-chronic toxicity study dermal (90-days)	The study shall be proposed.
OECD 413	Sub-chronic toxicity study by ihalation (90-days)	The sub-chronic toxicity study by dermal route being to be conducted for the susbtance, the study of the toxicity by inhalation does not need to be conducted.
OECD 452	Long-term repeated toxicity study (>= 12 months)	Nonnecessary for this band of tonnage
OECD	In vitro gene mutation study in bacteria	The study does need to be conducted. Further mutagenicity

Our Expert system SimREACH® :

Provides a cost estimation.

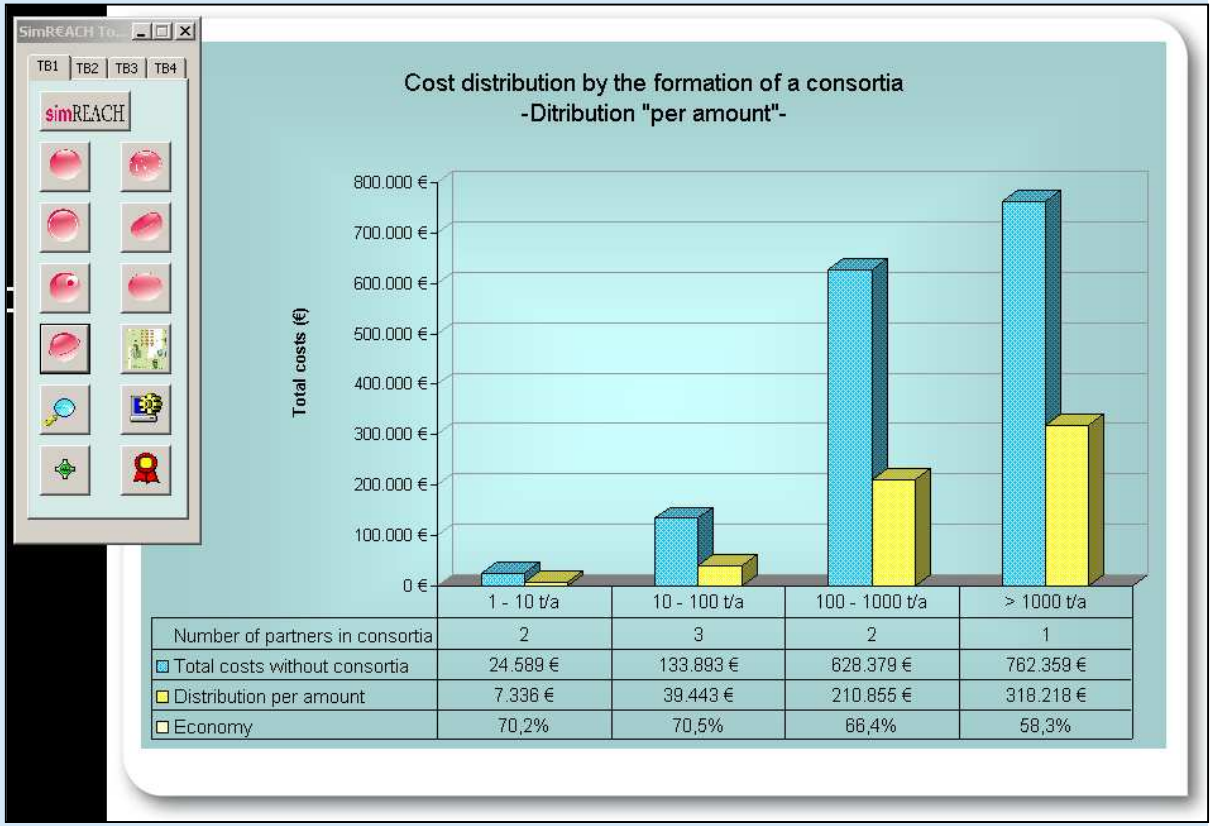


	Worst case	Best case	Phys.-chem.	Toxicology	Ecotoxicology	Intern
1 - 10 t/a	24.589 €	12.239 €	3.339 €	4.200 €	0 €	3.100 €
10 - 100 t/a	133.893 €	103.109 €	3.339 €	69.100 €	5.370 €	21.000 €
100 - 1000 t/a	628.379 €	343.329 €	4.109 €	165.900 €	118.820 €	43.000 €
> 1000 t/a	762.359 €	477.309 €	4.109 €	165.900 €	217.050 €	59.250 €

Our Expert system SimREACH® :

Evaluates all the key economic aspects:

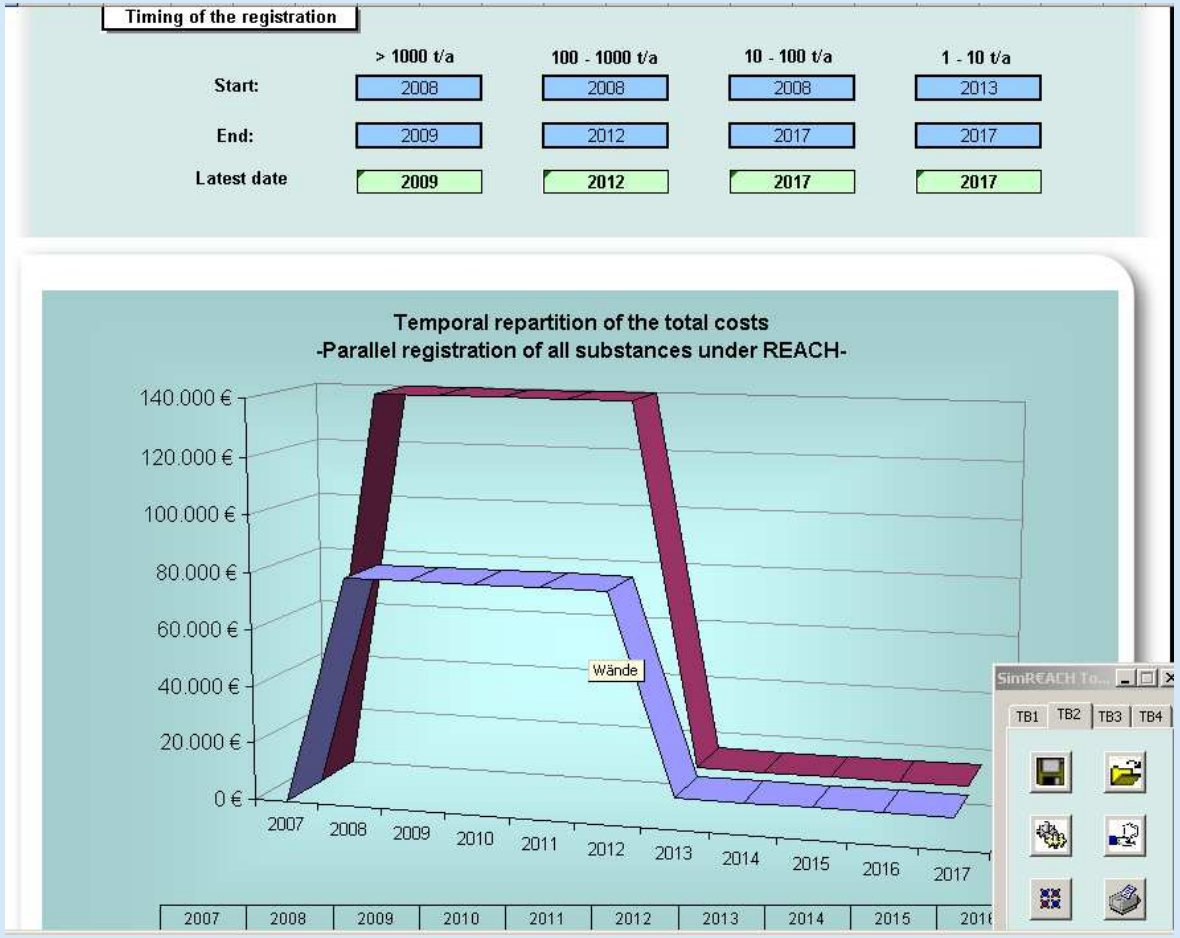
- the profitability of the product portfolio,
- Optimal consortia line-ups,
- Financial requirements in years-to-come
- Amortization of the registration.



	1 - 10 t/a	10 - 100 t/a	100 - 1000 t/a	> 1000 t/a
Number of partners in consortia	2	3	2	1
Total costs without consortia	24.589 €	133.893 €	628.379 €	762.359 €
Distribution per amount	7.336 €	39.443 €	210.855 €	318.218 €
Economy	70,2%	70,5%	66,4%	58,3%

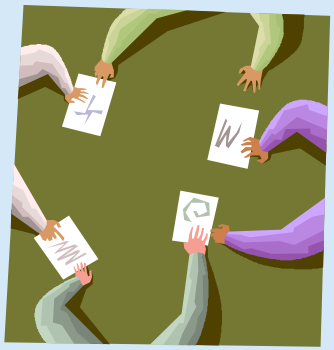
Our Expert system SimREACH® :

SimREACH® allows to check if the strategic decisions do still make sense within the framework of the new legislation.



TÜVRheinland®
Genau. Richtig.

REACH-Experiences



Our experience in assisting
the companies:

1. Small and medium sized chemical companies start(ed) their REACH preparation very late.
2. Chemical trading/distribution companies have the biggest challenge to be compliant with REACH.
   Reason: No personal capacities, no experience with notification of chemicals, IT-Systems are not prepared: no overview about the amount of constituents in preparations, no IUPAC-name or CAS-Nr., different languages, no own toxicological studies, …
3. The impact of REACH towards the business of SMEs is unknown for them
4. It´s not clear for downstream-users/importers, if non-EU-companies will really register their products. Their exist a real fear for missing essential chemicals.

REACH-Experiences

5. Article producers/trader have no idea, if they are affected by REACH.
6. Article trader have no idea how to deal with SVHC-substance-information towards the endconsumer.

Our conclusion:

We have to assist companies to understand the way, REACH will affect their business. On this way we´ll prepare the companies towards the SIEF-Entrance.

This could only work with highly trained and motivated employees.

TÜV Rheinland BioTech

We offer all necessary REACH-services - worldwide

Contact

Ewald Langenohl

- Telefon: + 49 221 690 589 14
- Telefax: + 49 221 690 589 13
- e–mail: Ewald.Langenohl@de.tuv.com
- TÜV Rheinland BioTech GmbH
  Nattermannallee 1
  50826 Köln