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Chemical Solutions at the Speed of the Market



A Manufacturer's Perspective

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Reach – A Manufacturer's Perspective



- ◆ About McIntyre
- ◆ Practical Aspects
 - Know Your Enemy.
 - Know your Friends.
 - Know Yourself.
 - Don't just sit there.....
- ◆ Issues & Concerns.
- ◆ Conclusion.



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About McIntyre

- ◆ Privately owned.
- ◆ US based.
- ◆ Manufacturing in US & UK
- ◆ Service locations Brazil & Singapore
- ◆ UK subsidiary is young (2000)
 - Excellent Growth.
 - Good Logistics to Far East.
 - Strong support from US parent.



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About McIntyre

◆ Products

- Surfactants & Cosmetic Preservatives.
- Global, Regional & Local customers.
- > 400 products.
- ~ 130 substances manufactured.

◆ People

- UK Headcount ~ 50.
- Technical staff - 8



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About McIntyre

◆ REACH Strategy

- Understand the requirements.
- Comply Globally.
- Retain the maximum number of substances post REACH.
 - Business viability.
- Work Directly with customers.

◆ REACH being driven from UK.



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Practical Aspects

- ◆ REACH came into effect 1st June 2007.
- ◆ Know Your Enemy.
- ◆ Know your Friends.
- ◆ Know Yourself.
- ◆ Don't just sit there.....



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Know Your Enemy.

- ◆ “I don’t have to do anything because cosmetics are exempt from REACH”
- ◆ “My processes are low impact for IPPC, so I will be exempt from REACH as well.....surely.”
- ◆ “What is REACH?”
 - From a trader based in Switzerland, sourcing in Asia, and selling into Europe.



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Know Your Enemy.

◆ EU Regulation 1907/ 2006.

◆ Text Available on

http://reach.jrc.it/legislation_en.htm

or via

http://ec.europa.eu/echa/home_en.html

Have you read it?



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Know Your Enemy

- ◆ The guidance documents (RIPS) will be published on the ECHA website.
- ◆ Not all are available
 - Including guidance on pre- registration*
- ◆ Have not always been well received.

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

*at 06/12/07



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Know Your Enemy

- ◆ You need to know what REACH requires.
- ◆ You need to read the text.
 - Or have someone else read it, and explain it to you!
- ◆ Read the RIPS
 - Advice only!



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Know your Enemy

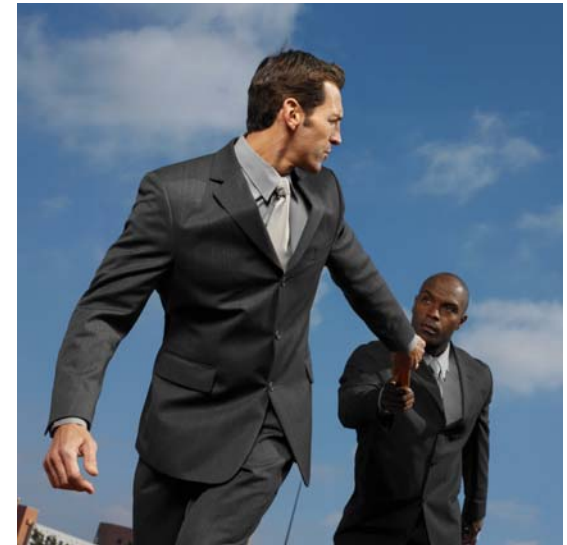
- ◆ REACH is very young, and requires some interpretation to apply it to your business.
- ◆ You (or someone in your organisation) are best placed to do this.
- ◆ **LEARN THE LANGUAGE OF REACH.**



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Know Your Friends

- ◆ REACH is a HUGE task.
- ◆ You will need some help.
- ◆ You are very likely to need to work co-operatively
 - Regulators
 - Suppliers
 - Customers





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Know Your Friends

- ◆ Where to get Help?
 - Regulators – HSE helpdesk.
 - Trade Associations
 - CIA Reach Ready
 - BACS
 - CTPA, UKCPI
 - Many, many consultants.
 - REMEMBER – no-one knows your business as well as you do!



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Know Yourself

- ◆ How EXACTLY does REACH impact your business?
 - Manufacturer?
 - Importer?
 - Downstream User?
 - All Three??



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Know Yourself

◆ Substances

- What substances do you make/ use?
 - SUBSTANCES not products.
- How much of each substance?
 - On 100% active basis.
 - Look at a number of years.
- Which are the strategic substances
 - Especially those you buy.



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Don't Just Sit There!

- ◆ McIntyre has already
 - Broken down all Products into Substances.
 - Identified all substances by CAS/ EINECS, or confirmed polymer status.
 - Considered product grouping and read-across
 - Identified volume for 2005 & 2006. 2007 volume will be added when books close.
 - Identified strategic RM's
 - Started to collect data.



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Know Yourself

- ◆ McIntyre Group has already
 - Joined (and used) REACH Ready
 - Attended as many REACH functions as possible
 - Had IUCLID5 training.
 - Identified & monitored consortium formation.
 - Worked with Trade Associations.
 - Communicated with Suppliers and customers.



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Issues & Concerns

◆ Where to begin?

- ❑ Cost
- ❑ Resource
- ❑ Cost
- ❑ Uncertainty
- ❑ Cost
- ❑ Time Demands
- ❑ Cost
- ❑ Loss of products
- ❑ Cost
- ❑ Real World Complexity
- ❑ Cost
- ❑ Loss of RM's
- ❑ Cost
- ❑ Animal Testing
- ❑ Cost
- ❑ Adverse consumer reaction
- ❑ Cost



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COST

- ◆ The biggest impact of REACH on any business.
 - Not really an issue for >1000Te with multiple suppliers. – pence per kilo.
 - Smaller volume specialties most affected.
 - Current ELINCS data cost for 1-10Te – £40,000
 - Most McIntyre products sell at <£1000 per Te
 - Do the Maths!



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COST

- ◆ Estimated registration costs for 130 substances
 - ~ €1 million.
- ◆ Data Costs?????
 - Lowest estimate - €2 million
 - Scary estimate - €10 million
- ◆ Admin costs
 - Travel, legal, salary, consultant etc etc?
 - Who knows?



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Cost

◆ Data Requirements – End Points

Band	Physico-chemical	Toxicity	Ecotoxicity
1-10	14	6	3
10-100	14	14	7
100-1000	17	17	21
>1000	17	20	27



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COST

- ◆ Cost to business over phase in period
 - Best Case? - €4- 8 million.
 - Worst Case? - €10 – 20 million

This will allow the business to continue to sell the same volumes of the same products.

Several million Euro's of spend to stand still.



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Resource

- ◆ Huge resource required to form, participate and manage consortia work.
- ◆ At least same resource needed for solo registration.
- ◆ Resource needed to –
 - manage IUCLID
 - Manage Data
 - Manage Consortium work
 - Manage business!



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Resource

- ◆ Test Labs?
- ◆ Regulators?
 - ECHA
 - CA's
- ◆ Will we get a “level playing field?”
 - HSE will enforce UK REACH during site visits (?)
 - What about imported goods?



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Uncertainty

- ◆ Who is a REACH expert?
 - No case law
 - Missing Guidance
 - Interpretation is “developing.”
 - REACH still subject to legal challenge.
- ◆ We need to start “doing” REACH in 6 months.



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Uncertainty

- ◆ I know that some products will be withdrawn
 - Will be on ECONOMIC grounds
 - NOT “to protect human health & environment”
- ◆ I don't know WHICH products.
- ◆ Neither will I until the consortium meets.



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Uncertainty

- ◆ Why can't we say which products will “die”.
 - We sell 110 Te of product X into Europe, but hold little data, because the product is EINECS and data is generally available.
 - After Pre- registration we find that we are the only producer. Total cost of registration - €587,000.
 - After Pre- registration we find several other producers/ importers, some of whom have data. McIntyre total registration costs as part of the consortium with data sharing- €87,000.
- We don't know the cost until after consortium formation, and initial exchange of data!



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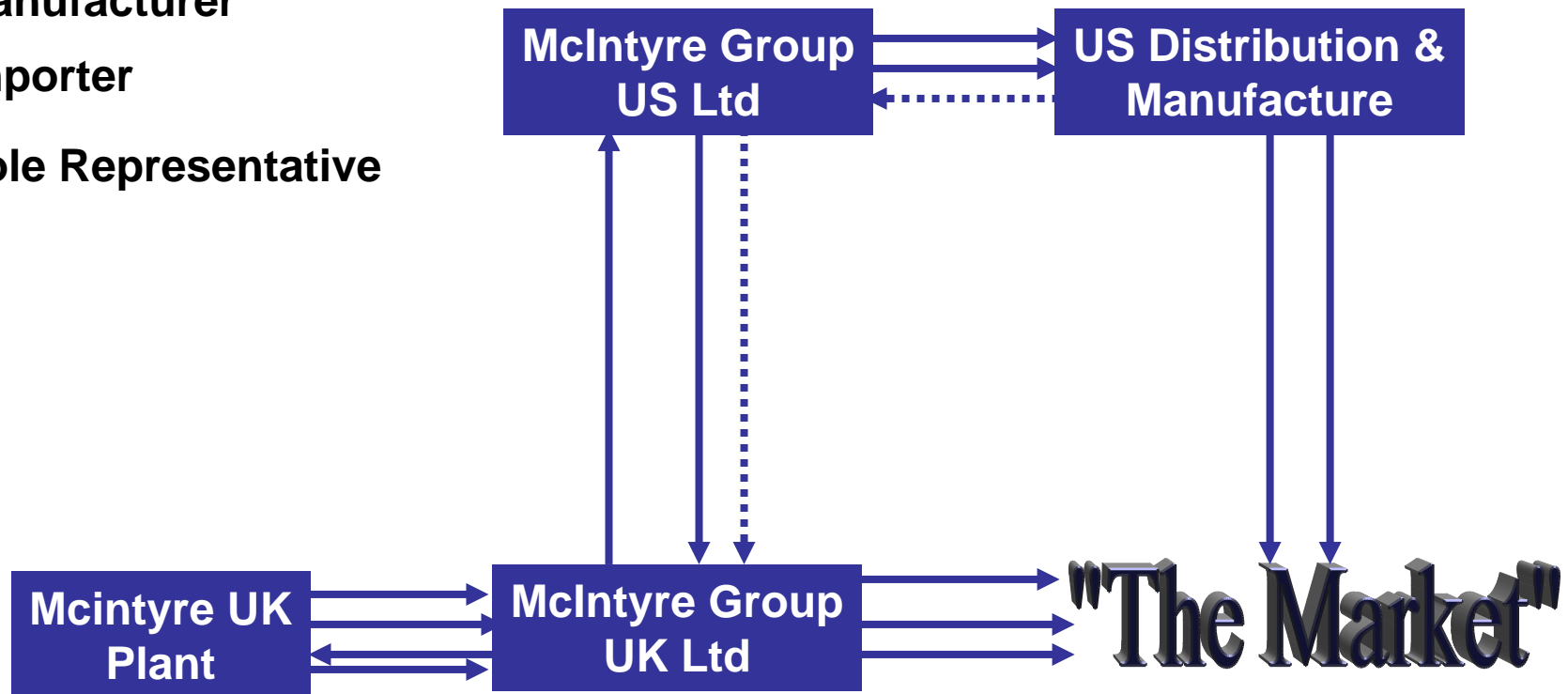
Real World Complexity

McIntyre UK is a

Manufacturer

Importer

Sole Representative





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Animal Testing

- ◆ Much (UK) business requires “not tested on animals”.
- ◆ REACH requires data from animal testing.
- ◆ Many products used in cosmetics.
- ◆ REACH does not require animal tests for cosmetic ingredients.
- ◆ So that’s OK isn’t it?



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Animal Testing

- ◆ **Cosmetics Directive**
 - Ingredients tested on animals after 2009 may not be used.
 - Tested Anywhere, for any purpose.
- ◆ **Great majority of products have multiple uses.**
 - Non- cosmetic uses may need animal data.
- ◆ **Political hot- potato!**
- ◆ **Brinksmanship?**



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Conclusion

- ◆ Some Good will come from REACH.
 - Boom time for consultants!
 - Fantastic prospects for Toxicologists!
 - Salad days for Lawyers!
 - Should become favourable to produce in EU (?)
 - Protectionism?
 - Some additional controls will be imposed on potentially harmful substances.



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Conclusions

- ◆ REACH will have an impact on McIntyre, and the whole chemical industry.
 - Increased costs
 - Reduced portfolio
 - Restriction on growth and innovation
 - Cash drain.
 - Resource drain.
 - Adverse impact on customer relationships.



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Conclusion

- ◆ REACH will change the supply and use of chemicals into (and out of) Europe.
- ◆ The VAST majority of decisions on substances will be ECONOMIC.
- ◆ SME's will be worst affected
 - Vital part of industry.
- ◆ Look at the effects of the Biocidal Products Directive.



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Conclusion

“The Purpose of [REACH] is to ensure a high level of protection of health and the environment, as well as the free movement of substances.....whilst enhancing competitiveness and innovation....with the goal of achieving sustainable development.

Will it?