



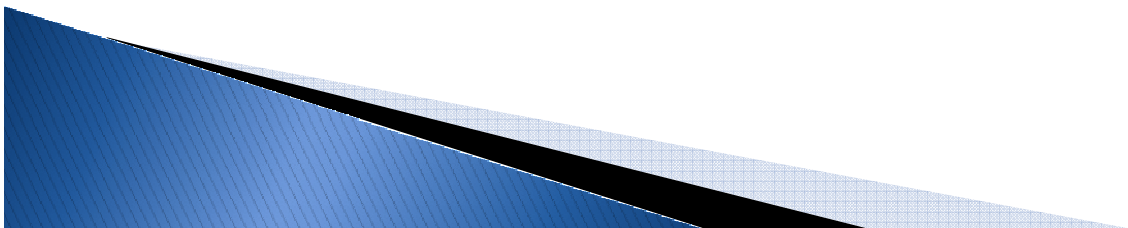
Centre for  
**Strategy & Evaluation  
Services**

## **Interim Evaluation: The European chemical market after the introduction of REACH**

- Impact on Competitiveness and the operation of  
the Single Market**
  - Impact on Innovation**
- 

**REACH Survey and interviews: Main findings and conclusions  
Milano**

**15 December 2011**

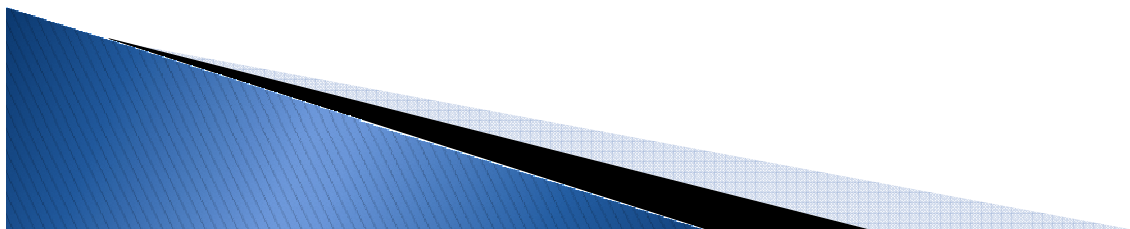




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# **Impact on competitiveness and the operation of the single market**

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# Structure of presentation

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- ❖ Objectives
- ❖ Method and research tools
- ❖ Main findings
- ❖ Conclusions

# Objectives of the study

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- ❖ Part of the Commission's REACH review
- ❖ Evaluate impact of the REACH Regulation on the market of chemical substances and the competitiveness of the EU chemicals industry
- ❖ Particular focus on SMEs
- ❖ Identify strengths and weaknesses of REACH implementation in terms of market dynamics, consumer choice and prosperity, costs of compliance and administrative procedures
- ❖ Provide recommendations

# Method

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- ❖ General Commission evaluation framework
  - Relevance, Effectiveness, Efficiency, Utility, Sustainability
  - Additional issues examined : coherence, acceptability
- ❖ Competitiveness framework
  - Inputs (e.g. labour, materials, capital and R&D investment)
  - Industry structure (e.g. concentration, role of SMEs)
  - Processes (e.g. production process, supply chain linkages)
  - Outcomes (production, productivity, profit margins, sales)
  - Framework conditions (regulation, access to finance, market openness, technological progress, demand etc.)

# Research tools

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## ❖ Interviews

- Industry associations, MSs authorities/helpdesks, trade unions and NGOs, individual firms, experts (90 in total)

## ❖ Desk research

- Analysis of documents and sources (professional/academic journals)

## ❖ Business survey

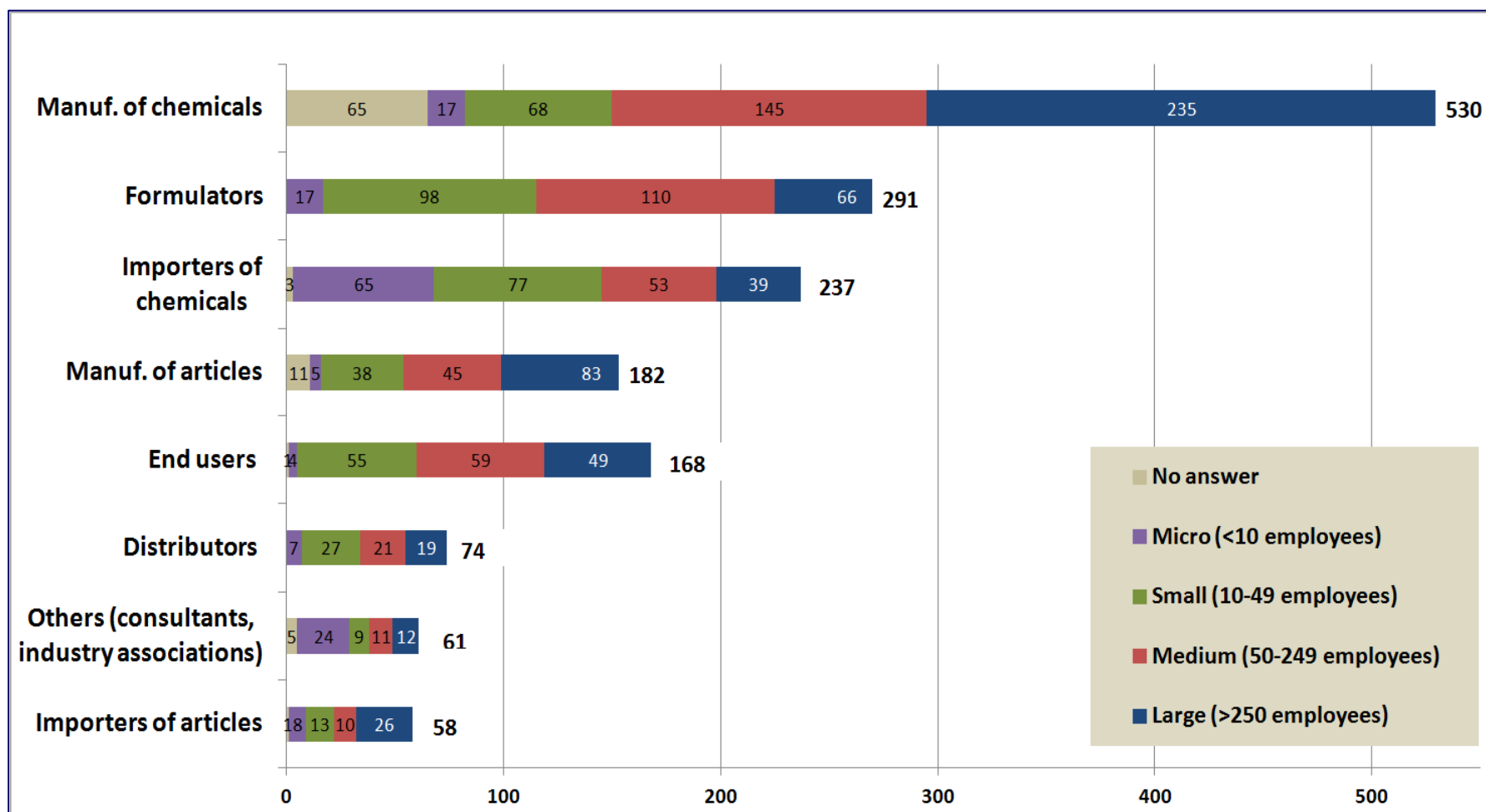
- Cover all roles in the supply chain
- 1601 responses received in total

## ❖ Case studies

- Focus on specific issues identified as important

# Business survey – Respondent Profile (I)

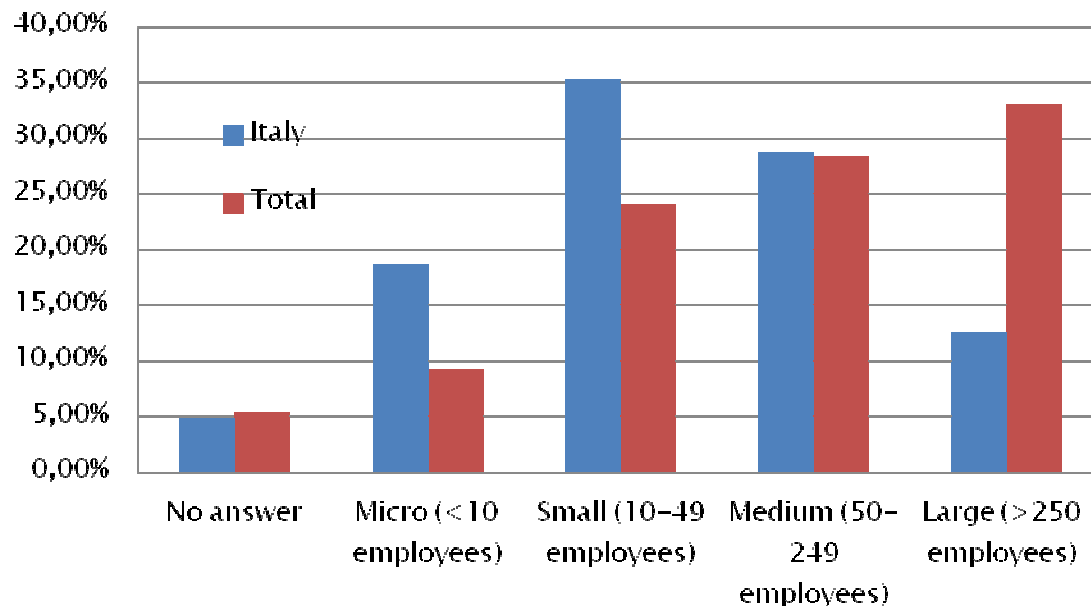
## Main role stated (Total=1601)



# Business survey – Respondent Profile (Italy)

## Main role stated (Total=1601) & Firm sizes

### Percentage share of respondents by firm size



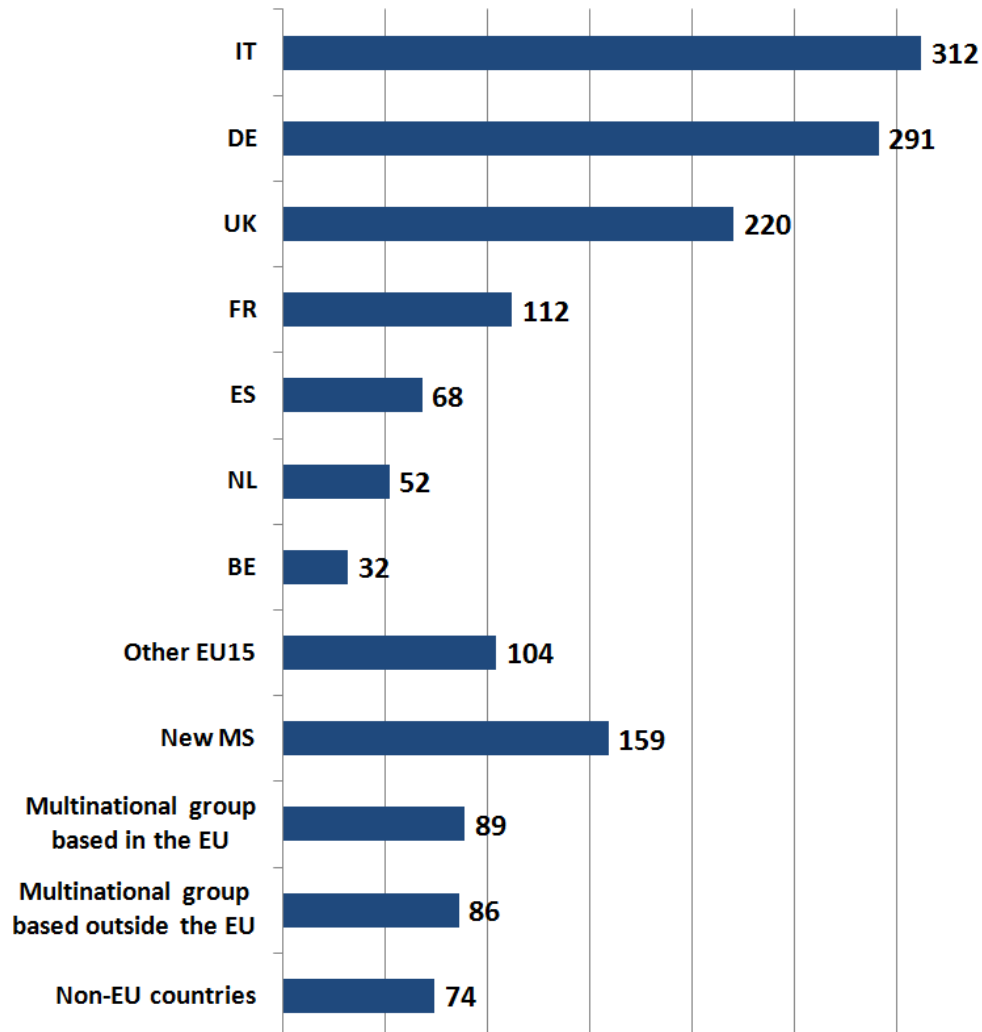
### Distribution by role:

- Slightly less manufacturers (26% vs 33%)
- Slightly more importers (20% vs 15%)



# Business survey – Profile (II)

## Country of origin



## Ownership type

- ❖ 46% (*Italy 64%*) single site independent firms
- ❖ 15.7% unit of multi-site firm operating in one country
- ❖ 12.6% (*Italy 5.5%*) REACH unit
- ❖ 10.5% unit of an EU group
- ❖ 5.7% unit of a non-EU group

# Findings – Main issues considered

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- ❖ Costs of REACH and cost drivers
- ❖ REACH processes and mechanisms
  - SIEFs and consortia
  - Supply chain communication and (e)SDS
  - ECHA and national helpdesks
- ❖ Business responses
- ❖ Utility of REACH – new knowledge
- ❖ Impact on prices of chemicals and products
- ❖ Operation of single market – surveillance and enforcement
- ❖ Impact on intra-EU trade, imports and exports


# Costs of compliance with REACH

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- ❖ Main aspects identified
  - Costs of registration
  - Supply chain communication - (e)SDS
  - Human resources – consultants (horizontal)
- ❖ Limited experience/information
  - Authorisation and restriction – firms preparing
  - Notification for articles
  - Chemical safety reports for downstream users
  - Production changes costs (anecdotal data)

# Registration costs

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- ❖ Total cost per registration: most common value of €50k-€100k, average about €139k 
- ❖ ECHA fees, Access to data-studies/Letters of Access and Human resources most often stated as the main cost drivers
- ❖ Wide distribution - type of substance and SIEFs size are main factors
- ❖ Estimated total costs from registration, so far: €1.3-2.6 billion (26,000 registration dossiers for €50-100k/dossier)
- ❖ Share of registration costs to annual turnover : <0.5% for 60%
- ❖ Difficult to estimate future registration costs for the total period
  - based on survey input we expect increase in registrations but ECHA data indicate otherwise
  - while data requirements will decrease, availability of information is also expected to increase → more tests?



## Average cost for single registration (all costs incurred)

Value in €s	Importers of chemicals		Manufacturers of chemicals		Total	
	Number	%	Number	%	Number	%
0-10,000	7	7.6%	11	4.3%	21	5.6%
<b>10,001-25,000</b>	<b>18</b>	<b>19.6%</b>	20	7.9%	41	11.0%
<b>25,000-50,000</b>	<b>22</b>	<b>23.9%</b>	<b>51</b>	<b>20.2%</b>	<b>80</b>	<b>21.4%</b>
<b>50,001-100,000</b>	<b>24</b>	<b>26.1%</b>	<b>74</b>	<b>29.2%</b>	<b>106</b>	<b>28.4%</b>
<b>100,001-250,000</b>	<b>19</b>	<b>20.7%</b>	<b>57</b>	<b>22.5%</b>	<b>80</b>	<b>21.4%</b>
250,001-500,000	2	2.2%	24	9.5%	28	7.5%
500,001-1,000,000		0.0%	7	2.8%	8	2.1%
>1,000,000		0.0%	9	3.6%	9	2.4%
<b>Total</b>	<b>92</b>	<b>100%</b>	<b>253</b>	<b>100%</b>	<b>345</b>	<b>100%</b>

- Lead registrants generally indicate higher costs
- Larger firms average costs also skewed towards higher values
- In the case of intermediates, costs are typically around €10k



## Distribution of average registration costs

### Distribution of average registration costs

In general: cost is widely distributed and skewed to the left. Mean is around €139,000 but median is around €70,000. In the case of Italy mean is around €71,000 and median €42,500 but the number of responses provided was rather small. Still, it follows expected pattern given the much greater share of small firms.

Euros/registration/firm	Italy		Total	
	Number	%	Number	%
0-10,000	5	11.9%	21	5.6%
10,001-25,000	9	21.4%	41	11.0%
25,001-50,000	10	23.8%	80	21.4%
50,001-100,000	9	21.4%	106	28.4%
100,000-250,000	8	19.0%	80	21.4%
250,001-500,000	1	2.4%	28	7.5%
500,001-1,000,000		0.0%	8	2.1%
>1,000,000		0.0%	9	2.4%
<b>Grand Total</b>	42	100.0%	373	100.0%
<b>Median cost</b>	€42,500		€139,000	
<b>Mean</b>	€71,500		€70,000	



# Supply chain costs

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## ❖ REACH has introduced supply chain communication costs

- Human resources
- IT systems (specialised or part of ERPs)
- Supply chain communication time (low awareness, mainly small DUs) users
- Easier for sectors with more integrated supply chain structure (e.g. automotive vs. engineering)
- Total cost estimates difficult
- Typically around 1 FTE plus IT system installation and maintenance

## ❖ Not clear whether costs will increase over time

- Clarification of procedures and communication tools, experience should mainstream processes and time required
- But, more and smaller firms entering the system

# Human resources

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- ❖ One out of two respondents have created REACH units
  - >60% of large firms, <40% of small and micro
- ❖ Typical value of <2 FTE dedicated - inside or outside REACH unit (70% of respondents)
  - Manufacturers of chemicals most often referred to 2-5 FTE
  - Large enterprises often have central REACH unit plus 1 full or part time in each unit
  - For SMEs REACH staff often add some 5% to salary costs
- ❖ Use consultants - often in addition to the above internal costs



# Business response to REACH costs

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- ❖ Wide range of responses
- ❖ Typically (50-60% of firms): try absorb costs rather than increase prices - reduce profit margins
- ❖ Depends on type of substance and market competition – differences between basic/ specialty/consumer chemicals
- ❖ Reduction of production volume to avoid costs – wait for 2<sup>nd</sup> registration
- ❖ Withdrawal/consolidation of product portfolio less common (16% of manufacturers, 37% of importers of chemicals stated adopting this approach sometimes or frequently)
- ❖ Limited evidence of production relocation so far – multiple parameters of which REACH is not the most crucial

## Impact on prices (producer and final)

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- ❖ Around 50% of manufacturers and importers of chemicals state that they never/seldom increased prices
- ❖ 50% of downstream/end users referred to an increase in the costs of substances used
- ❖ Some 50% consider that REACH led to increase of their prices in comparison to non-EU firms
- ❖ Non-EU firms also refer to important REACH costs and impact on trading in the EU
- ❖ We conclude that producer prices have been affected - different levels and strategy depending on sector
- ❖ **Final consumers' prices**: No evidence of impact to this point – increases mainly upstream
- ❖ Further down supply chain impact is diluted

# Withdrawal of substances

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- ❖ Does take place - mainly in the form of reduction of number of suppliers
- ❖ 35% of all firms already experienced – 21% expect to happen in future
- ❖ In Italy, 42% withdrew products from EU market vs 28% average
- ❖ Main drivers:
  - Registration costs – full withdrawal or waiting for second stage
  - Candidate list and large retailers/producers requiring that suppliers do not use certain chemicals (sin list)
- ❖ Main response: substitution of chemicals or change of suppliers
- ❖ Limited evidence of general problems in the market so far
  - Sector variation: e.g. DUs in automotive and aerospace sector consider it quite problematic due to replacement procedures and requirements

# Impact on trade

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- ❖ No apparent impact on level of intra-EU trade
  - In many sectors high levels of trade already in place
  - REACH rarely seen as providing an incentive to enter other markets
  - Suggestions of possible shift of importers to intra-EU suppliers to avoid registration costs – no specific evidence
- ❖ No evidence available on intra-EU trade shifts
  - Fear from countries dominated by small firms
- ❖ Trade data do not provide evidence on impact of imports
  - References by some non-EU industry representatives of difficulty of following REACH requirements
- ❖ But, the above does not mean that REACH is irrelevant – possibility of multiple national regulation unwelcome for many
- ❖ The differences among MSs in definition of articles in relation to SVHCs seen as a possible danger to internal market

# Benefits from REACH so far

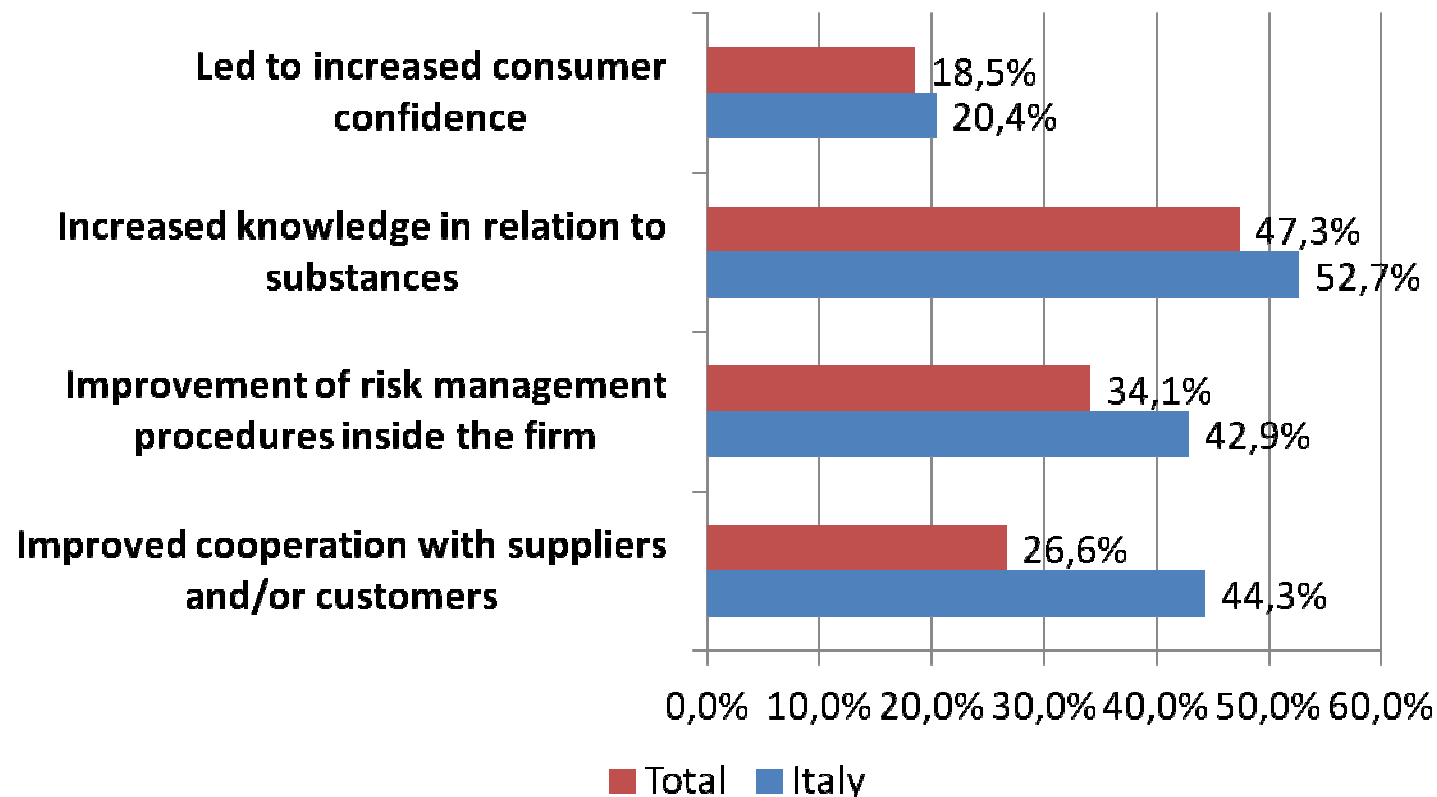
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- ❖ So far, benefits of new knowledge on substances and their uses for firms appear limited
  - 1<sup>st</sup> registration focused on well known substances – limited added value for innovation according to great majority (80-90%)
  - 25% referred to benefits concerning risk management practices but more expected in future
- ❖ Despite costs, supply chain integration and communication generally considered a positive aspect
- ❖ Little impact on consumer confidence: limited awareness
- ❖ Job creation
  - Related to administrative aspects – much less so on business opportunities
  - Mainly consulting and other support services
  - Fears for activity relocation outside EU, but little evidence so far

# Benefits from REACH so far - Italy

## *Benefits of REACH*

Percentage of firms stating that the REACH has brought the above benefits moderately, very extremely (in all cases the moderately represents the greatest share)



# Role of REACH structures and mechanisms (I)

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- ❖ SIEFs operation and effectiveness varies a lot
  - Generally effective in reducing costs of registration
  - Problems with communication and coordination
  - Drivers: SIEFs size and capacity of managers/lead registrants
  - **Consortia** has most often a positive role
  - Unclear pricing for LoA's – impact on SMEs often linked to potential exit from market
- ❖ Concerns but no evidence of breach of competition rules or abuse of dominant position related to SIEFs
  - High costs of LoAs for small firms; no evidence of abuse – mainly issue of transparency of charges
  - Industry largely aware of competition regulation issues
  - Concerns in relation to business intelligence appear inherent to the whole process : who produces what and at what level already quite important

# Role of REACH structures and mechanisms (II)

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## ❖ SDSs development problematic

- No consistent/common format of (e)SDSs used
- Long documents, difficult to handle leading, loss of relevant information
- A major issue in Italy is language
- Varying familiarity with processes/mechanisms among firms
- But, work in progress ; support of associations and learning curve

## ❖ Role of ECHA and national structures moderately positive

- ECHA tools (IT, guidance documents) - moderately effective and improving
- National help-desks' contribution varies – expectations of firms often go beyond their remit – still some of them do aim to address them
- Industry associations or consultants often fill gaps
- SMEs tend to make less use of ECHA and more of national structures

## ❖ Market surveillance

- Early stage - 45% of firms stated no own experience
- Firms with some experience were rather positive (>50% fair or better)
- But, differences in approaches (inspection requirements, penalties, role of customs) and lack of resources in some MSs
- Tools for coordination in place (enforcement projects, RIPE, forum)

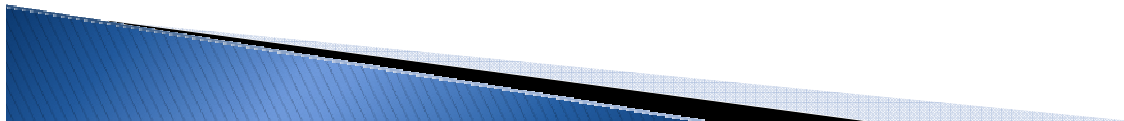
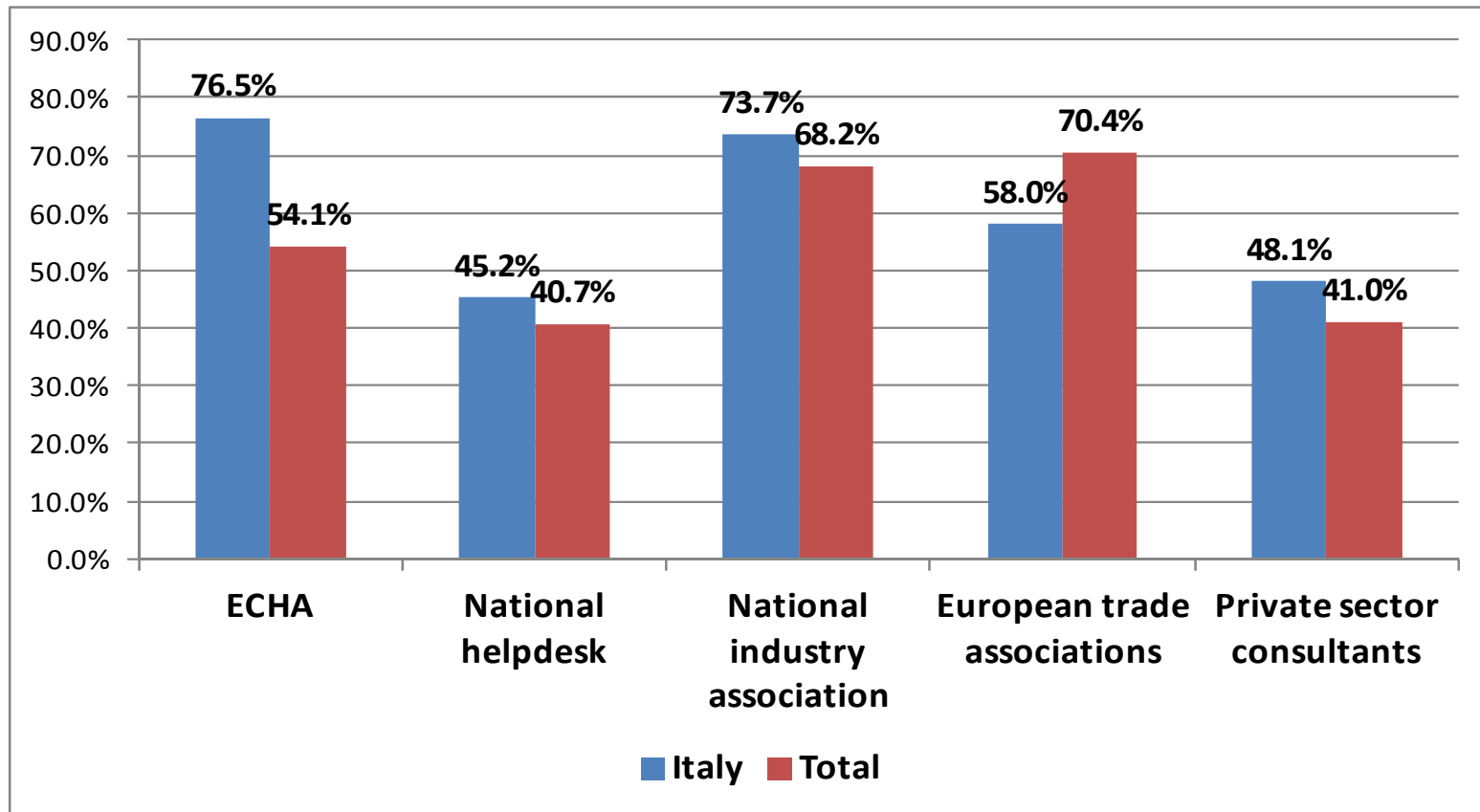


# REACH structures and mechanisms (Italy)

## Satisfaction with the REACH structures and help

Share of firms stating that structures are quite, very or extremely helpful

The results reflect also the level of use made meaning that less IT firms stated no use of ECHA, helpdesks of national associations while more stated no use of European trade



# Role of REACH structures and mechanisms (III)

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## ❖ Only representatives

- Overall positive contribution in de-codifying REACH for non-EU firms and reducing costs for importers
- Quite extensive use of ORs (responsible for 19% of registrations)
- Supply of ORs diverse – range from individuals to large firms
- Concerns on quality of services often raised
- Practical issues on the communication and sharing of information with clients and importers
- Unclear aspects on expected role and obligations in terms of communication in supply chain and in authorisation

**❖ Overall, no evidence indicating critical failure of any part of the mechanisms, structures or processes**

**❖ But, certain problematic areas or implementation aspects that may cause confusion, duplication of efforts and costs for firms**

# Conclusions - Impacts on competitiveness

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- ❖ Cost implications, particularly for SMEs
- ❖ Direct impact on short term availability for intermediate inputs for some DUs sectors – replacement not always easy
- ❖ Increase in costs/prices against non-EU competitors present but not widespread
- ❖ Profit margins generally affected, at least in the short term although level appears rather limited
- ❖ No evidence indicating loss of markets due to REACH so far
- ❖ Positive role in promoting cooperation with customers/suppliers, supply chain integration – possible long term benefits
- ❖ Benefits from new knowledge are not expected to materialise and provide competitive advantage in the short term
- ❖ Regulatory framework: current period characterised by certain level of uncertainty that may continue until 2018

# Conclusions - Impact on single market

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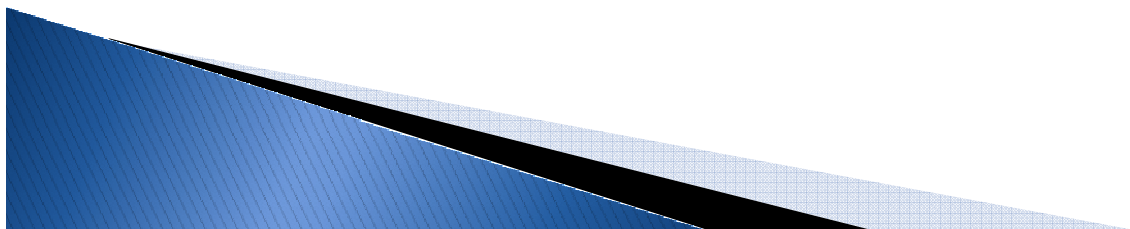
- ❖ Single Regulation importance generally served
- ❖ But, no evident impact on trade at this stage
- ❖ Role of market surveillance and unified approach
  - Still work in progress
- ❖ Specific issues
  - interpretation on the definition of 0.1% of SVHCs in articles often stated as a negative indication – not practical experience to this point



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## **Impact on Innovation**

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# Structure of presentation

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- ❖ Objectives of the study
- ❖ Methodology and research tools
- ❖ Presentation of main findings
- ❖ Conclusions

# Objectives of the study

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- ❖ Evaluate impact of REACH on the innovativeness of the EU chemicals industry
  
- ❖ Considers the role of REACH in terms of:
  - Creating new knowledge
  - Guiding the direction of the research process
  - Supplying resources – human as well as financial
  - Facilitating the creation of positive external economies (e.g. in terms of information exchange, knowledge and visions); and,
  - Facilitating the formation of markets

# Methodology

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## ❖ General evaluation framework

- Relevance, Effectiveness, Efficiency, Utility
- Also - Consistency, Costs and Benefits

## ❖ Innovativeness framework - European Innovation Scoreboard

- Enablers (HR, research systems, and finance)
- Activities (investment and intellectual assets)
- Outputs (innovators and economic effects)



# Research tools

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## ❖ Interviews

- Industry associations, MSs authorities/helpdesks, trade unions and NGOs, individual firms, Clusters, innovation-related organisations, experts , ECHA and the Commission
- >80 in total

## ❖ Desk research

- Analysis of documents and sources (professional/academic journals)

## ❖ Business survey

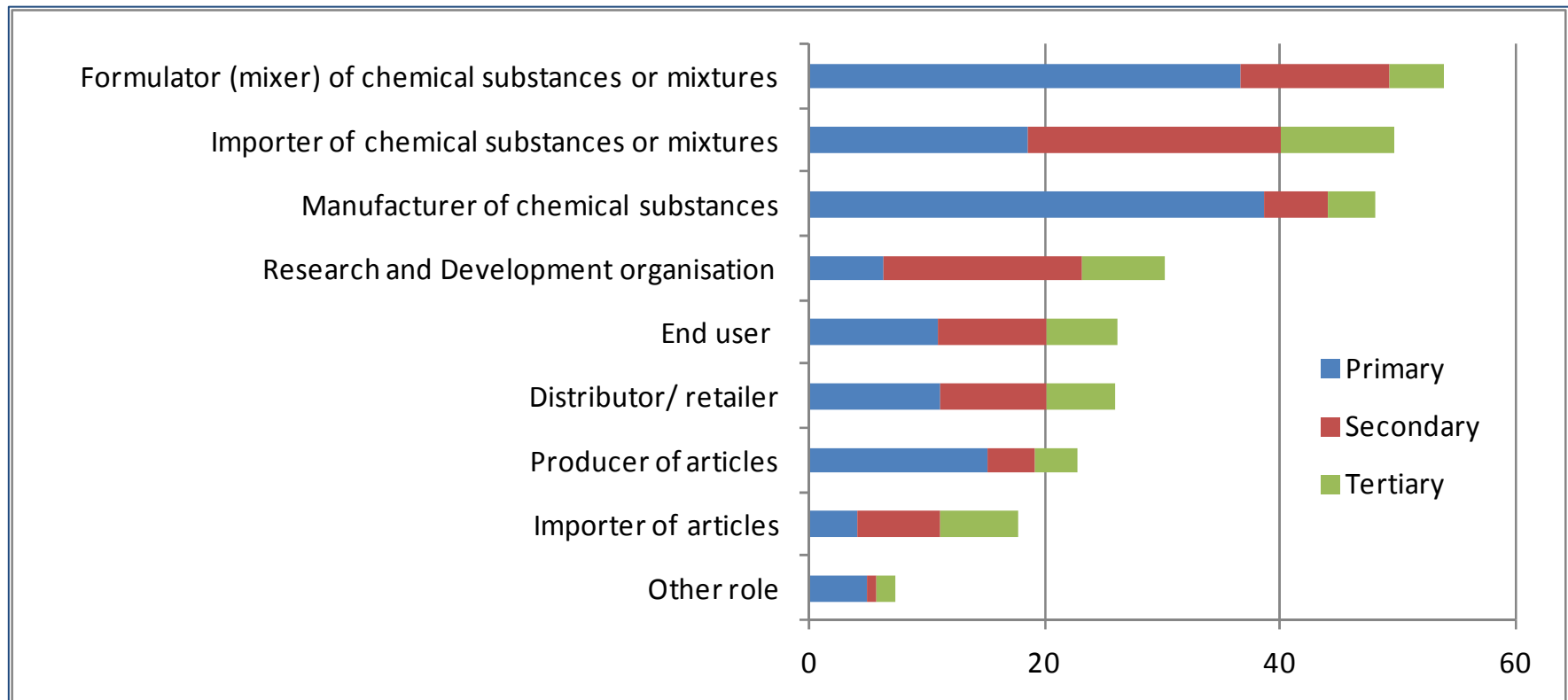
- Cover all roles in the supply chain
- 577 responses received

## ❖ Case studies

- Focus on specific issues identified as important (PPORD, IP, etc.)

# Business survey – Profile (I)

## Main role stated % (Total=577)



In the Italian responses, some 30% indicated their main role as formulators; 24% as manufacturers.

# Business survey – Profile (II)

## Country of origin

Country	Answers	Share
Germany	119	21%
Italy	91	16%
UK	47	8%
Netherlands	42	7%
Spain	39	7%
France	33	6%
Belgium	26	5%
USA	20	4%
Other (EU)	103	18%
Other (non-EU)	13	2%
No response	37	6%
<b>Total</b>	<b>570</b>	

- The majority (46.6%) of respondents were units of a multi-site, multi-country enterprise group (Italy 14%)
- Single-site independent firms make up the second largest category (40.8%) – (Italy 66%)
- Some 70% of Italian respondents were SMEs

# Effectiveness in encouraging innovation

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## ❖ The innovation process – three stages

- Conception and initial evaluation of innovative ideas
- Implementation – further research, development, piloting
- Marketing – production and launch

## Effectiveness – Conception Stage

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- ❖ Much data has been created/ captured through the different REACH mechanisms (Registration, SDS, CSR...)
- ❖ Data does not necessarily lead to conception of new ideas and innovative activity – but some has been reported
- ❖ Data is owned by SIEF or consortia secretariats and the member companies
- ❖ 60% of respondents indicated that REACH had diverted resources from ‘truly innovative’ research activities to compliance or regulatory ones (*in Italy the response was 50%*) but R&D expenditure often rose
- ❖ First registration deadline dealt with generally well-known substances – not much gap-filling. The next deadlines might lead to more new knowledge.

# Effectiveness – Implementation Stage (I)

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- ❖ Additional cost of testing existing substances was seen as a disincentive to innovation (30% Italian respondents said yes it was) – the situation has changed now (but not completely)
- ❖ Too early to assess the balance of research interest between new uses for existing substances & new substance development
- ❖ Research indicates that there are still many factors against research on new substances
- ❖ Relatively few applicants for PPORD – but seems useful for innovation (Italy 50/719 – 7%)
- ❖ Other Measures to support innovation:
  - **Volume exemption often too low for the testing and piloting required**
  - **Exemption on isolated intermediaries does not contribute greatly**
  - **Exemption for polymers does not contribute greatly to increased innovation**

## Effectiveness – Implementation Stage (II)

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- ❖ 50% of respondents stated that there has been a reduction in the need or cost of testing at their firms (18% in Italy)
- ❖ There does not appear to be a reduction in animal testing
- ❖ Nearly half of firms using external laboratories indicate that they had experienced delays in access to laboratories due to capacity constraints at such laboratories due to REACH-related testing
- ❖ Over a third of respondents stated that REACH had reduced the expected rate of return on innovation
- ❖ Nearly half of respondents indicated that risks and uncertainty related to innovation had increased as a result of REACH
  - **The main areas of uncertainty as regards innovation relate to testing and other registration costs, time delays in registration, lack of clarity in the Regulation and supply chain robustness**

# Effectiveness – Marketing Stage

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- ❖ REACH has important effects in terms of direct costs – impacts on innovation funding
- ❖ Can costs be recovered through additional revenues – market structures?
- ❖ Time to market (compared to pre-REACH):
  - **Over 40% of firms considered there had been an increase in time to market, about a third no change and just over 10% a reduction**
- ❖ Lack of awareness of REACH in the general public
- ❖ Lack of understanding in customers
- ❖ In the case of start-ups/ spin-offs, it is probable that the costs of doing business will increase, and market entry costs will be higher



## Efficiency – costs vs outputs

- ❖ Important amount of data generated and captured
- ❖ Cost of implementation of REACH
- ❖ At this early stage, data generation has not led to substantial increase in innovation. This may happen after the next two registration deadlines
- ❖ Has REACH signalled a direction for R&D or other innovative practices related to health, safety and environmental protection that would not otherwise have taken place in your firm? (Italy 12%, 38% - yes, 31% no).

Options	Nº	%
Yes – there has been a fundamental reappraisal of our research orientation towards more safety and environmental protection.	19	5.1
Yes – partly	136	36.8
No	199	53.8
Do not know	16	4.3
<b>Total</b>	<b>370</b>	<b>100.0</b>

# How useful are the “innovation drivers”

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- ❖ *Substitution mechanisms* are considered key innovation drivers
- ❖ **Registration**: some barriers to new substance registration remain; issues around costs of registration for smaller tonnages
- ❖ Placing of substances of the **candidate list** had knock-on impacts:
  - **Withdrawal**
  - **Blacklisting of substance by DU**
  - **Substitution**
  - **Pressures on users & producers of those substances**
- ❖ **Authorisation** process aims at encouraging substitution – early days
- ❖ **Restriction**: not attracting much discussion at this point
- ❖ Projects being set-up to encourage substitution (FIT-REACH, VEGE-REACH, Axelera project on modelling processes)

# REACH, CLP and Intellectual Property

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- ❖ Chemical industry is a knowledge intensive industry
- ❖ Areas of concern regarding the protection of IP; critical information and know-how being available in some documents (CSR...) and disseminated world wide
- ❖ 74% of survey respondents did not believe that the flow of information in the supply chain was in conflict with the protection of their IP
- ❖ As regards patenting, the situation is not yet fully clarified and resolved

# Distribution of benefits and costs

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- ❖ The general principle seems to be that REACH raises overall costs
- ❖ In general, larger firms, with more scope to specialise in recruitment strategies, access to funding, and power in markets, might be able to deal with such cost increases more easily than SMEs
- ❖ Some sectors also are more affected (e.g. inks, dyes, metal plating, coatings)

# Conclusions – Impacts on innovativeness

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## Impacts on inputs/ enablers

### ❖ Human resources:

- Redirection of R&D/ innovation personnel to compliance work (permanent).
- Increase in expenditure on R&D and innovative activities.

### ❖ Open research systems

- Much data created, captured and disseminated
- How much of this has been truly new?

❖ **Links with universities and networks** developed by companies focus on the compliance/ regulatory elements of REACH.

### ❖ Finance and support

- No new funds, increased uncertainty & risk
- Few examples of support. (FIT-REACH/ Subsport)

# Conclusions – Impacts on innovativeness

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## Impact on firm activities

### ❖ Firm investments/ activities

- Some long term shift in the orientation of R&D
- Widening in the scope of innovative activities (incl new)
- Registration costs/ the candidate list are major drivers, authorisation has had a similar effect/ restriction has not been very active to date
- Volume exemption too low, not many use PPORD.

### ❖ Linkages and entrepreneurship

Increased supply chain collaboration and linkages with DUs, - some positive innovative results but a majority indicated no

### ❖ Intellectual assets

- Issues about IPP remain.

# Conclusions – Impacts on innovativeness

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## Impact on outputs.

### ❖ Innovations – *what is “innovation”?*

- Some has occurred – and is continuing
- The effect on innovation:
  - compared to the pre-REACH situation - 43% responded negative while 13% responded positive (Italian data similar);
  - more thought it would worsen in the future than improve.
  - Innovative SMEs: over 50% see the position as negative and 38% expect it to worsen.
  - 40% thought time to market increased compared to pre-REACH



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**Thank you for your attention!**

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**Questions, Comments?**

