

Cefic RIEF II
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EU Inspection Project “REACH – EN – FORCE 2” *Results and Lessons*

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Project REACH-EN-FORCE 2

Overview

- Coordinated enforcement activities by ECHA Forum
- Background on REACH-EN-FORCE-2
- Findings of the project REACH-EN-FORCE-2
- Conclusions

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Coordinated Enforcement of ECHA Forum

- ECHA Forum as a **network of Member State Enforcement Authorities** established under REACH and CLP
- All **Member States and EEA countries** (in total 31 countries) are represented
- One **major pillar** of Forum tasks is the coordination of enforcement in form of individual **enforcement actions** (projects)

Coordinated Enforcement of ECHA Forum

ECHA Forum enforcement activities:

- REACH-EN-FORCE projects (1, 2 and 3)
- Pilot projects
 - on specific **obligations** or rules (e.g. a specific restriction like PAH)
 - on specific **procedures** (e.g. communication interlinks)
- Enforcement cooperation with ECHA on “evaluation –type” activities such as:
 - REACH **evaluation decisions**
 - **intermediate** screening
 - **nano form** of registered chemicals
 - **revocation** of registration numbers

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Report on REACH-ENFORCE-2 „REF-2“



Forum REACH-EN-FORCE 2 Project Report

**Obligation of downstream users -
formulators of mixtures**

Report available (soon also with an update for additional details):

http://www.echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

General aim of REF-2

Companies having a role of a downstream user / formulator:

- REACH **registration** status of substances used ←
- CLP **notification** duty of substances used ←
- Implementation of **risk management measures** on-site
- **Information** down the supply chain (REACH Art 31 & 32) ←

General aim of REF-2

Information down the supply chain in Safety Data Sheets (SDS):

- **Management** and handling of own SDS ←
- Implementing **quality requirements** in own SDS ←
- **Quality of information** in own SDS ←

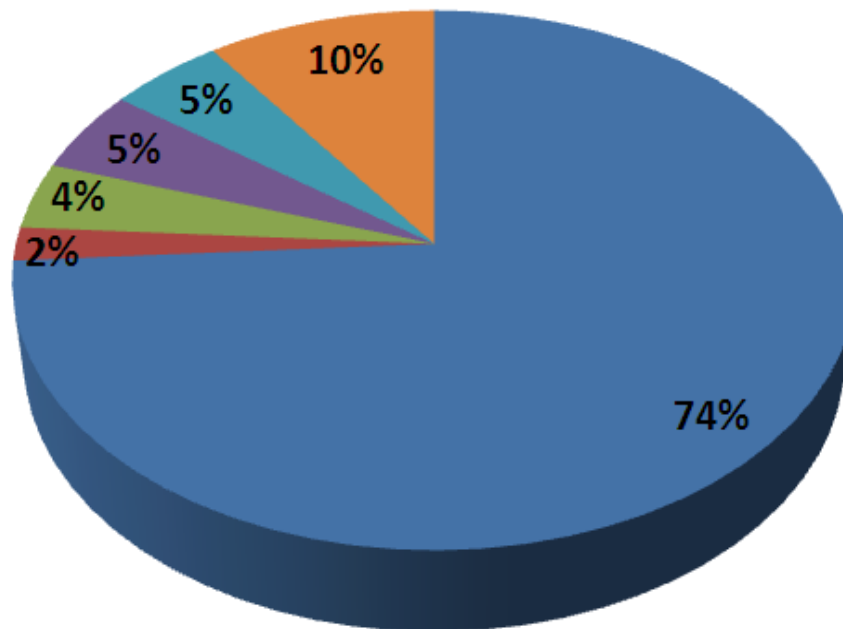
General information on REF-2

Inspections:	Mai 2011 – March 2012
Member states participating:	29 (from 30)*
Inspections conducted:	1181
Substances checked:	6907
Mixtures checked:	4484
SDSs checked:	4496

* Croatia at that time no Member State

Companies' economic activities

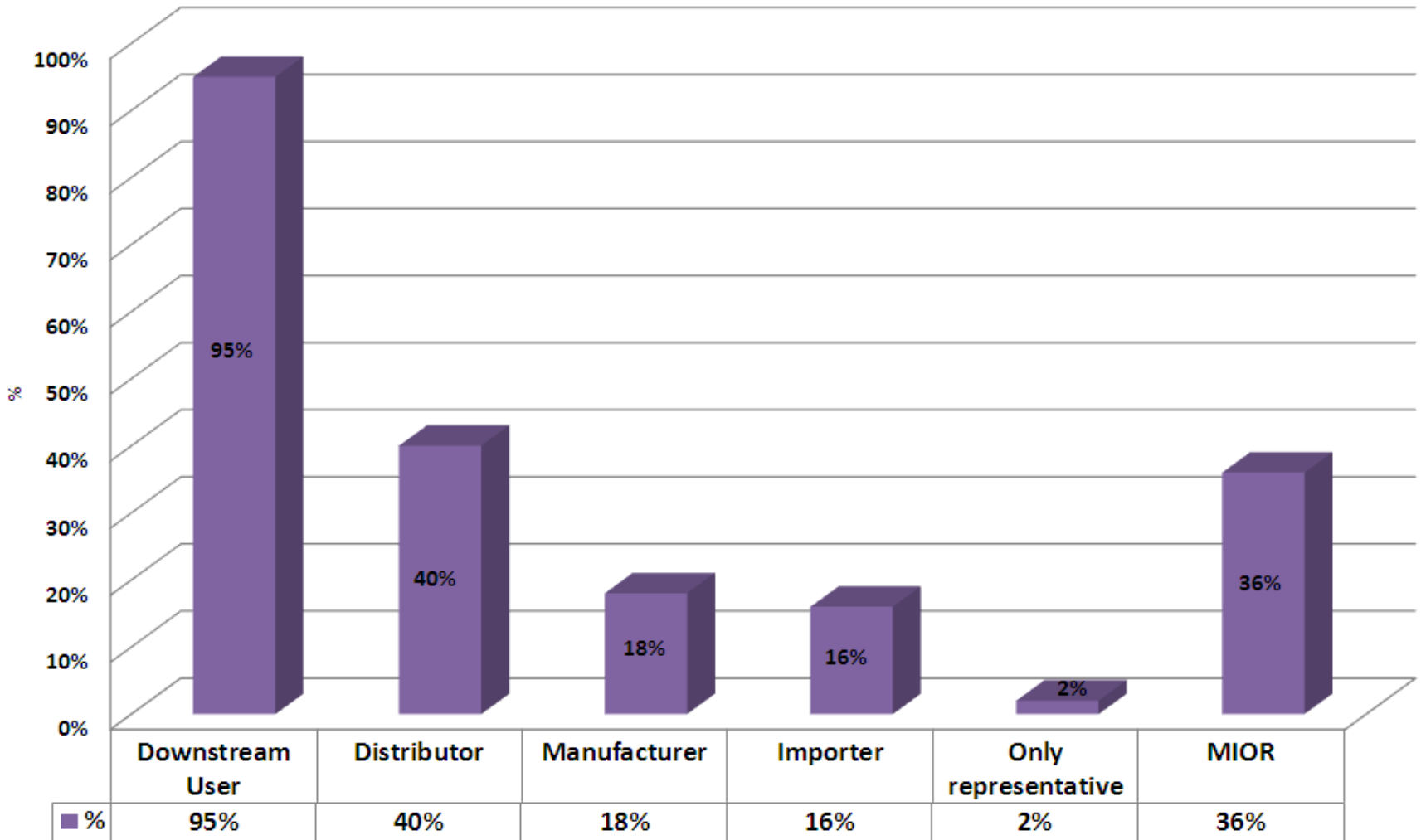
Checked companies according to the statistical classification of economic activities (NACE)



- NACE Division Number 20 - Manufacture of chemicals and chemical products (870)
- NACE Division Number 21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations (19)
- NACE Division Number 23 - Manufacture of other non-metallic mineral products (44)
- NACE Division Number 24 - Manufacture of basic metals (61)
- NACE Division Number 46 - Wholesale trade, except of motor vehicles and motorcycles (64)
- NACE Division Number - Others (123)

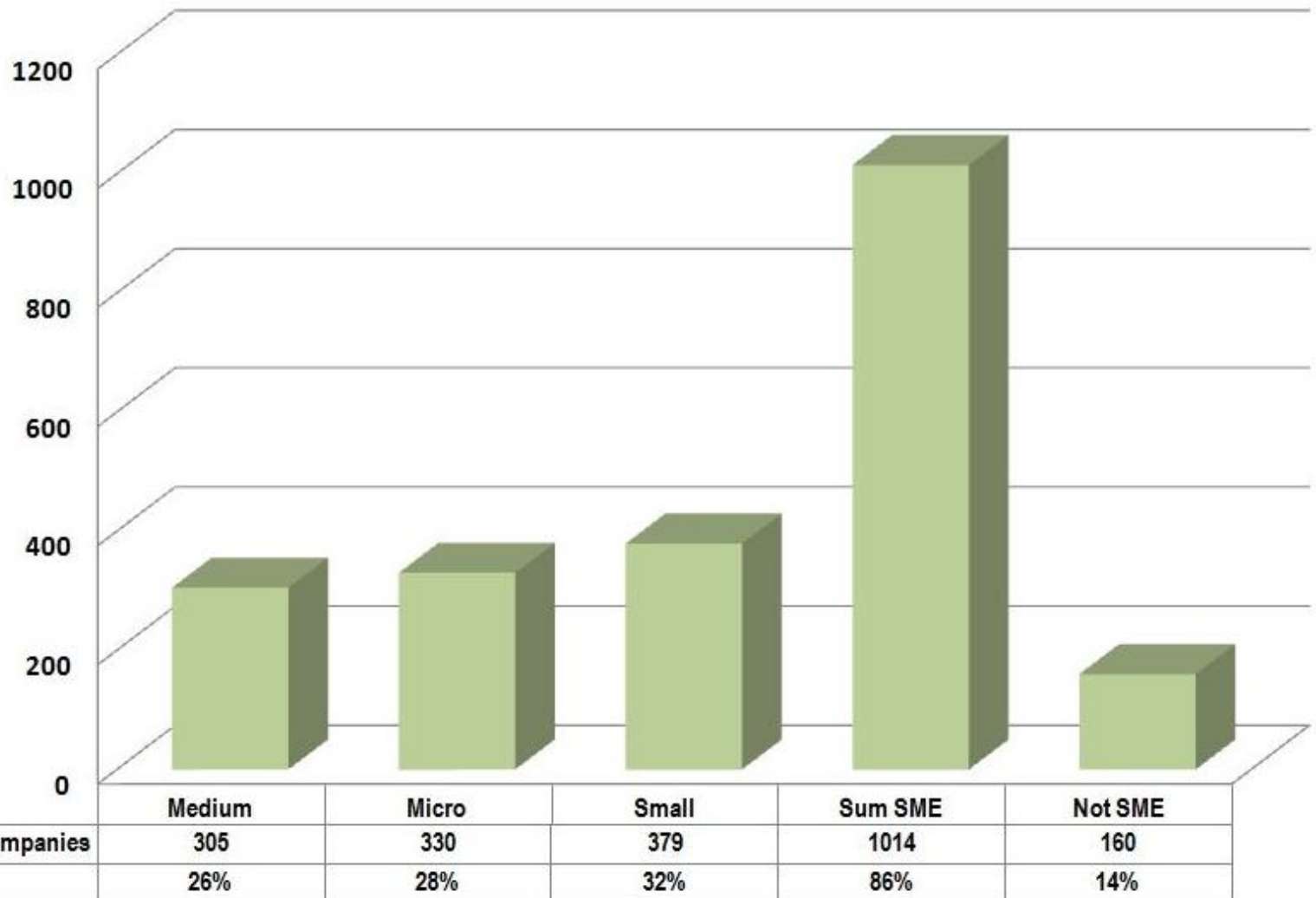
Proportion of REACH roles

Roles of the checked companies



Companies by size

Size of the checked companies



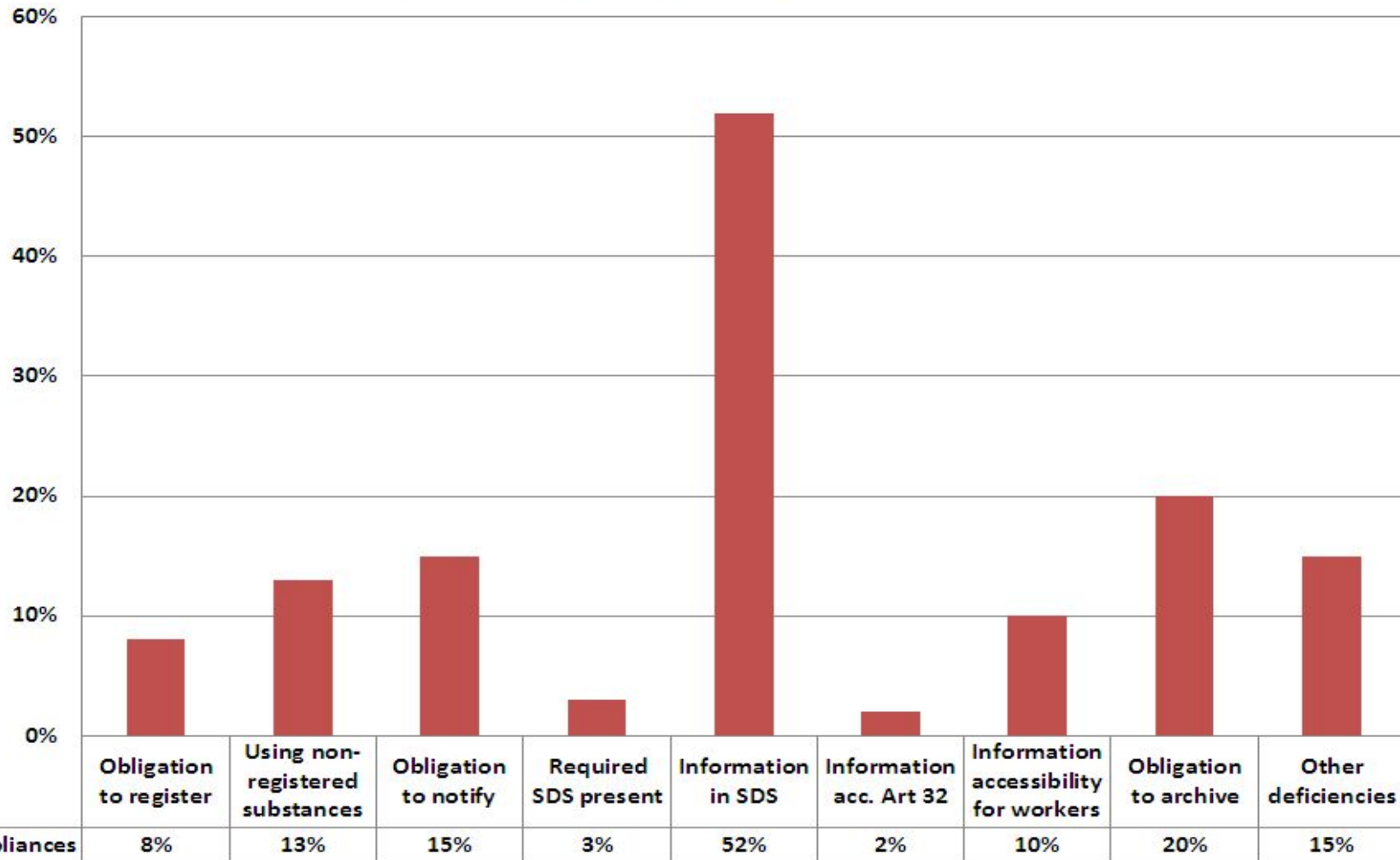
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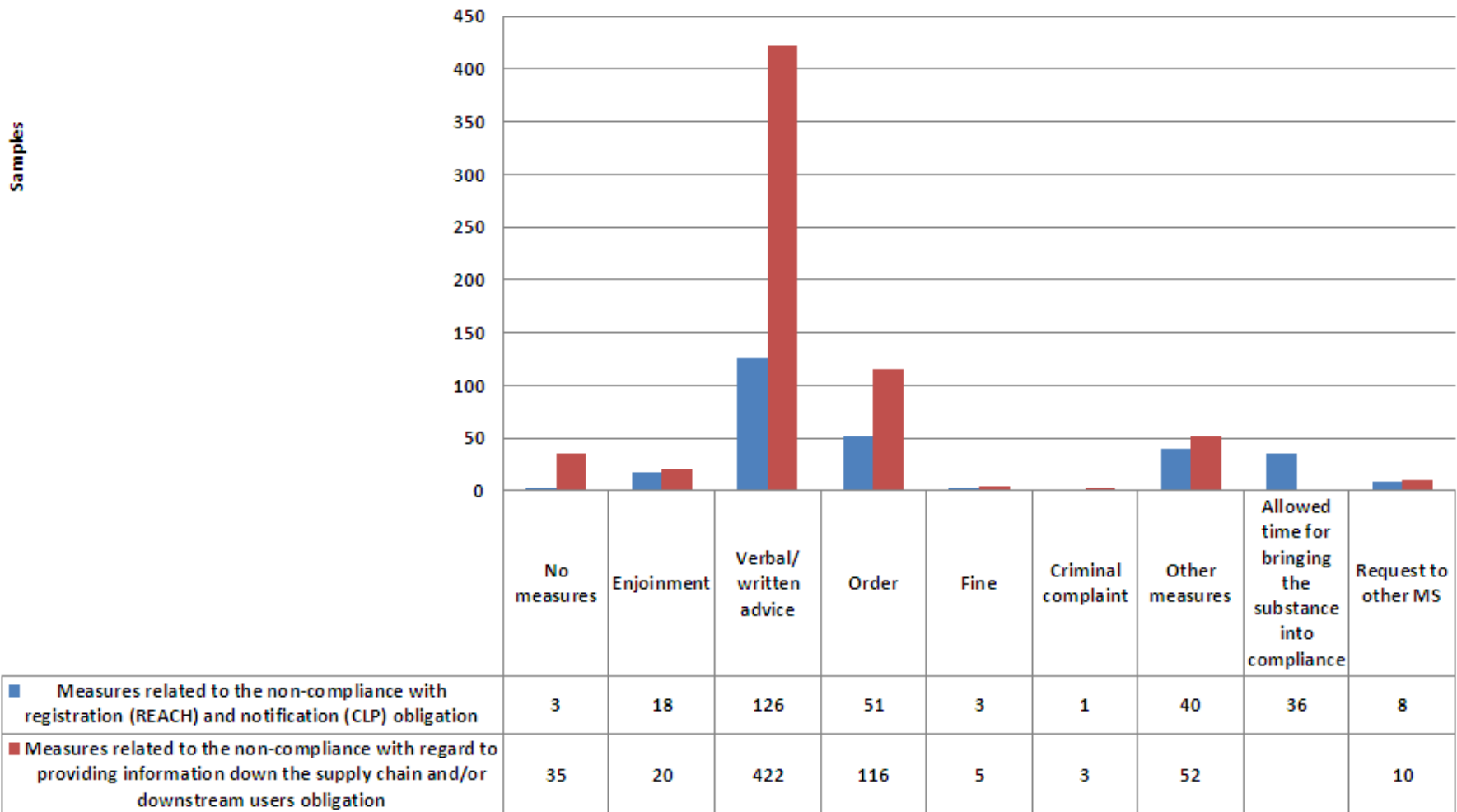
Proportion of non compliance detected (per inspected issue)

Non compliances detected



Measures taken as a result of non-compliance

Types of measures imposed by authorities on non-compliant companies



REACH registration duty

Registration related offenses (21 in total):

- **Failure to register**: 8% of the obliged companies
- Offense group is **57% non-SME**
- **Failure to register**: 12% of the obliged non-SME

REACH registration duty

	Registration duties			Registration offences		
	Cases re-reported	% of MIOR in size category	% of duty group	Cases reported	% of obliged MIOR in size category	% of offense group
Micro	18	62	7	2	11	10
Small	56	74	21	3	5	14
Medium	98	84	36	4	4	19
Not SME	97	91	36	12	12	57
	duty group	of MIOR group	of all comps	offense group	of duty group	of MIOR group
Over all	269	82	23	21	8	6

MIOR.... Manufacturer/Importer/Only Representative



CLP notification duty

CLP notification related offenses (21 in total):

- **Failure to notify**: 15% of the obliged companies
- Offense group is **14% non-SME**
- **Failure to notify**: 6% of the obliged non-SME

CLP notification duty

	Notification duties			Notification offences		
	Cases re-reported	% of MIOR in size category	% of duty group	Cases reported	% of obliged MIOR in size category	% of offense group
Micro	21	72	8	8	38	19
Small	58	76	21	17	29	40
Medium	93	80	34	11	12	26
Not SME	103	96	37	6	6	14
	duty group	of MIOR group	of all comps	offense group	of duty group	of MIOR group
Over all	275	85	23	42	15	13

MIOR.... Manufacturer/Importer/Only Representative

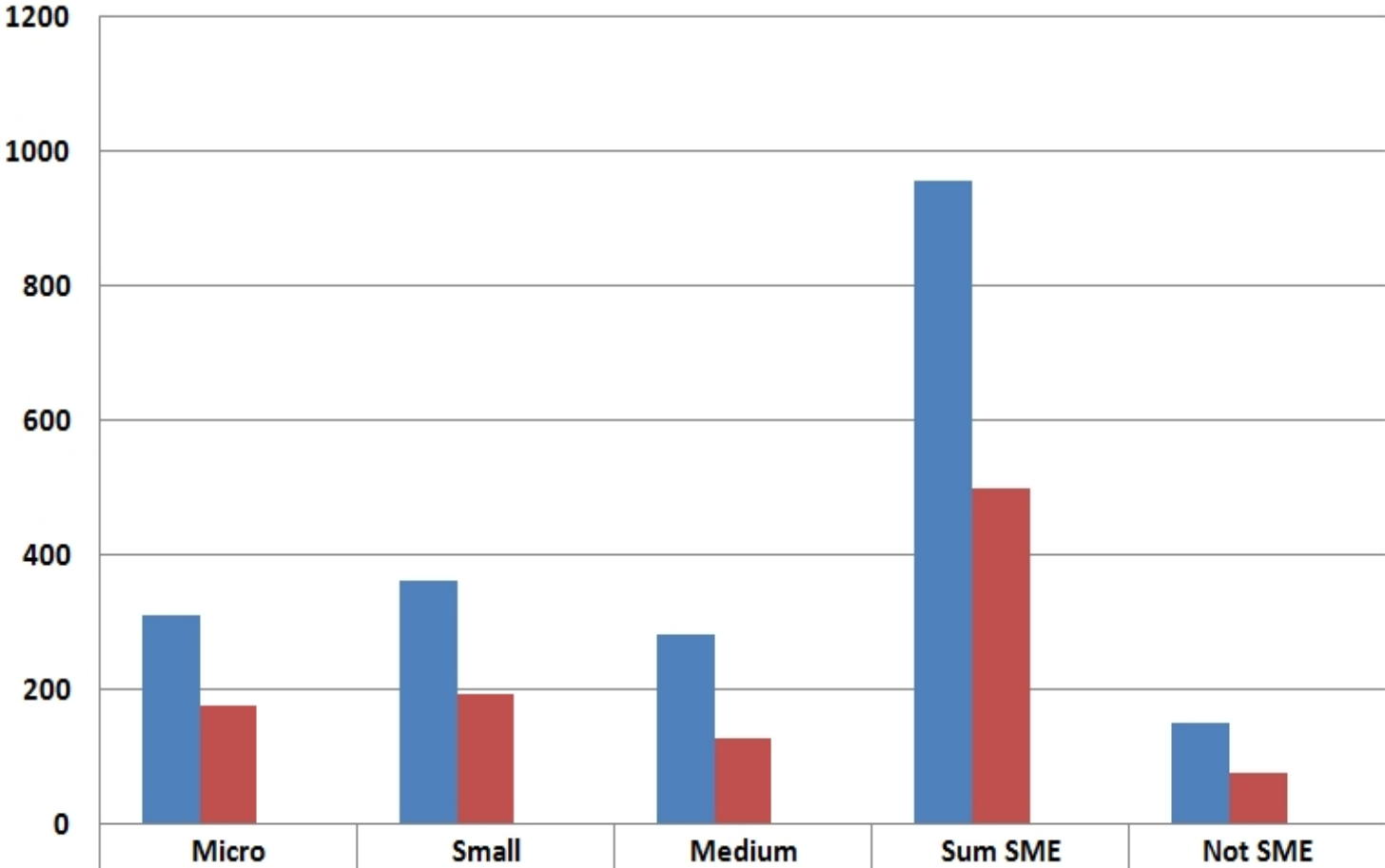
Information down the supply chain

SDS format and availability

- Failure to have **SDSs available**: 3%
(cf. 2010 (REF-1): 13%)
- Failure in **language** used and/or in **structure**: 14%
- 52% of companies prepare (already) SDSs according to the **new format** defined in Article 2 of Regulation 453/2010

Deficient information in SDS by company size

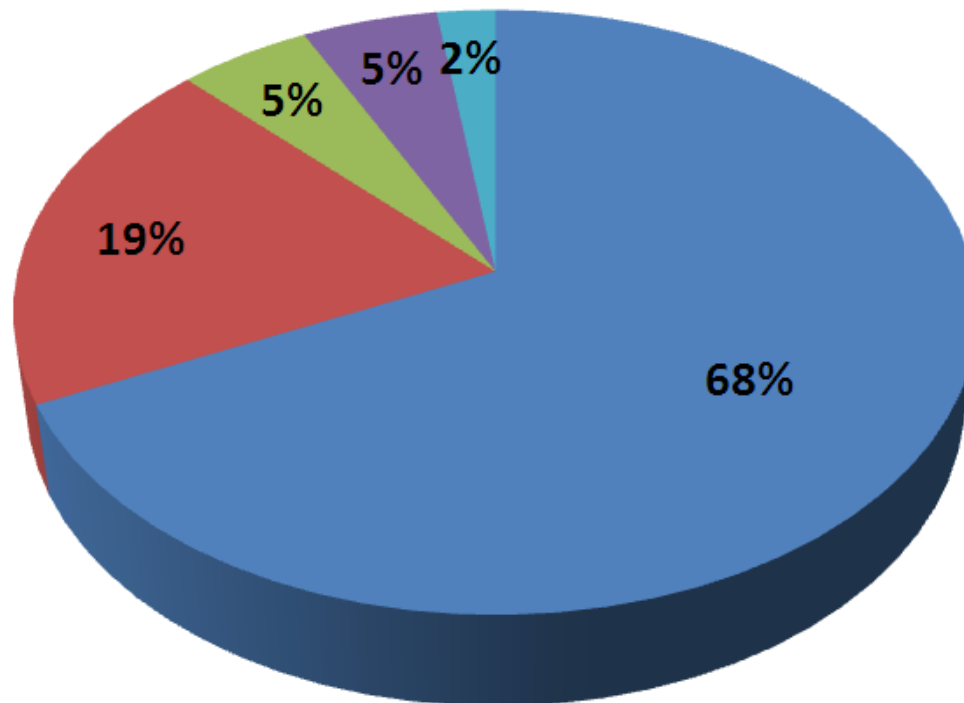
Deficient information in SDS by company size



■ Samples	311	362	282	955	150
■ Deficient information in SDS	177	193	128	498	77
■ %	57%	53%	45%	52%	51%

Existence of structures for SDSs preparation

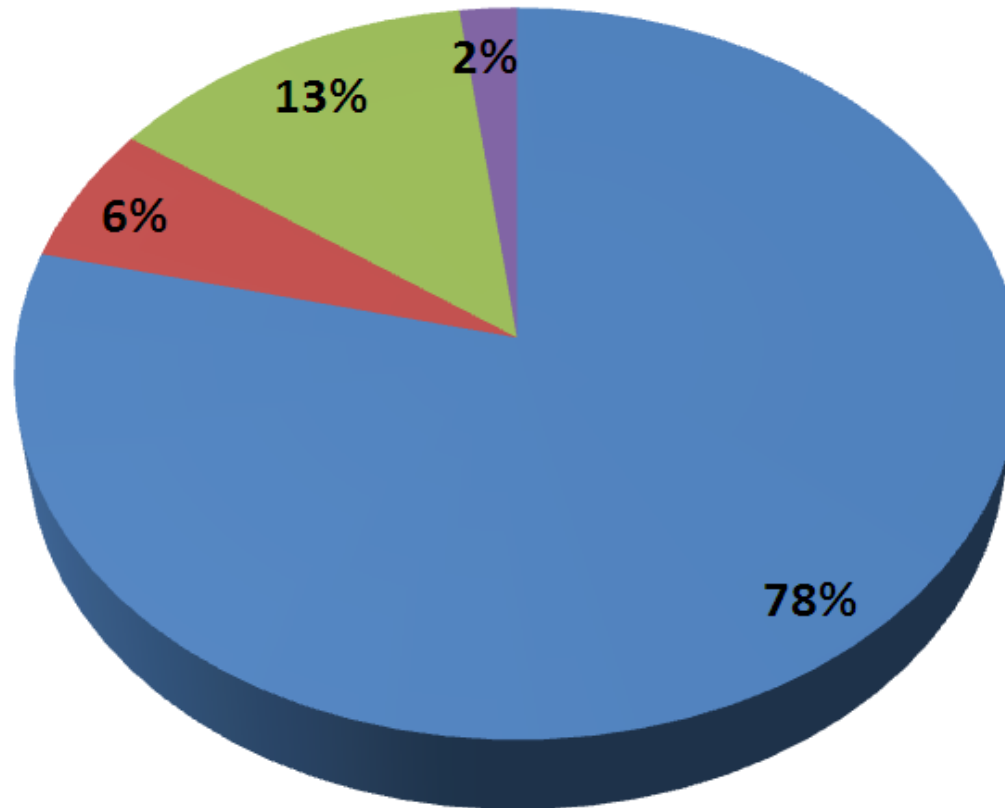
Existence of SDS preparation structures



■ yes, within the company ■ yes, commissioned contractors ■ no ■ partially ■ not required

Existence of structures for SDSs distribution

Existence of SDS distribution structures



■ yes

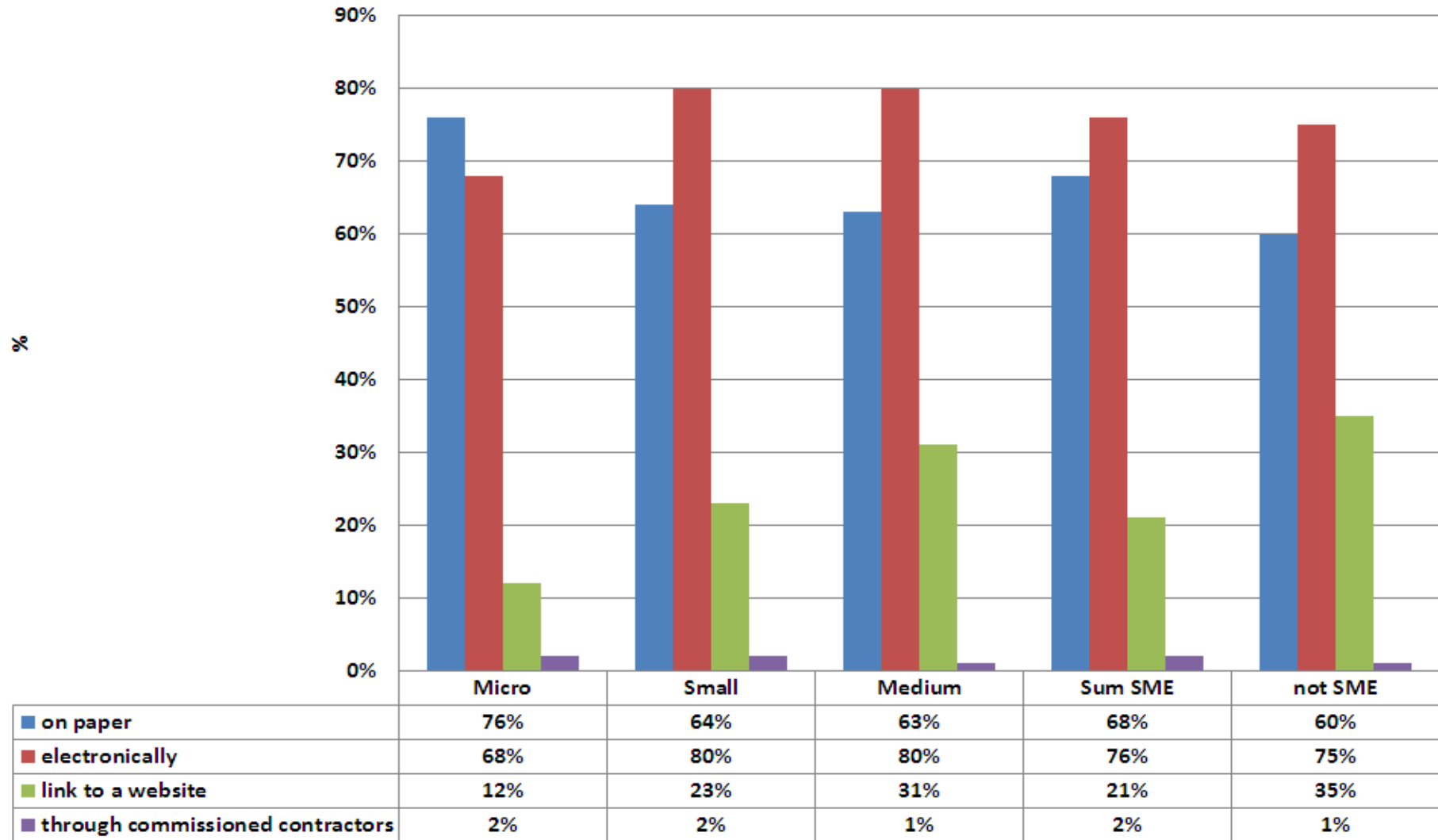
■ no

■ partially

■ not required

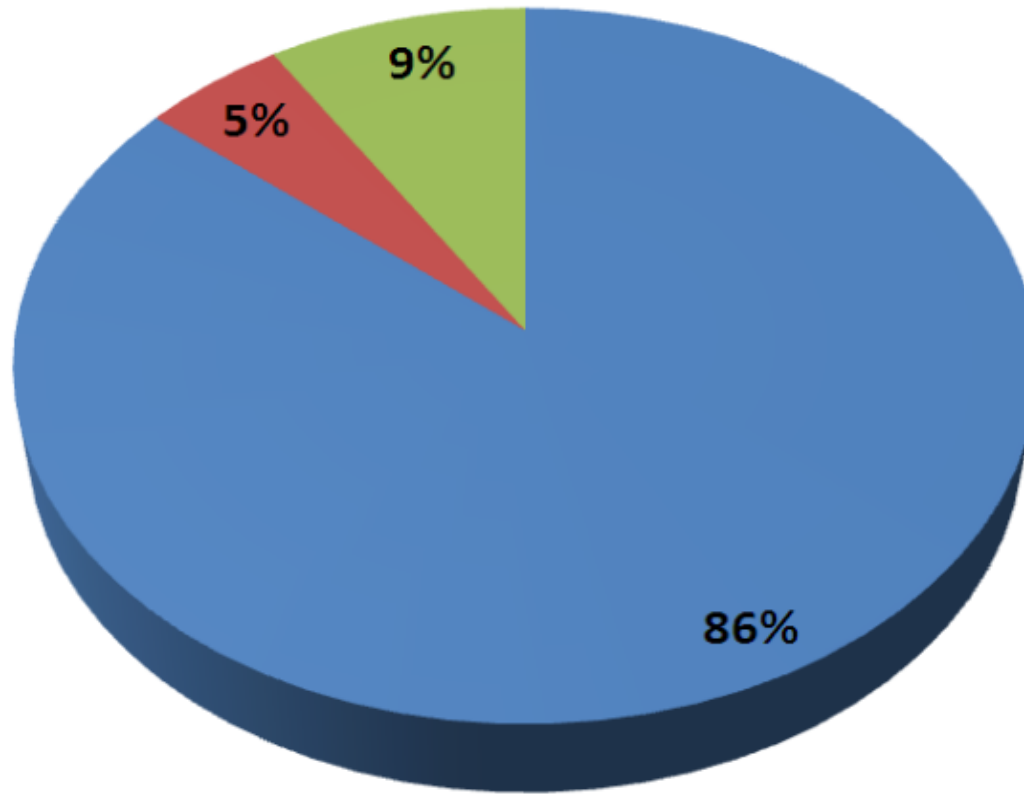
Means of SDS distribution by company size

Dominant means of SDS provision. Comparison of companies by size categories.



Compliance of SDS with REACH Articles 31.5 and 31.6

SDS comply with REACH article 31.5 and 31.6

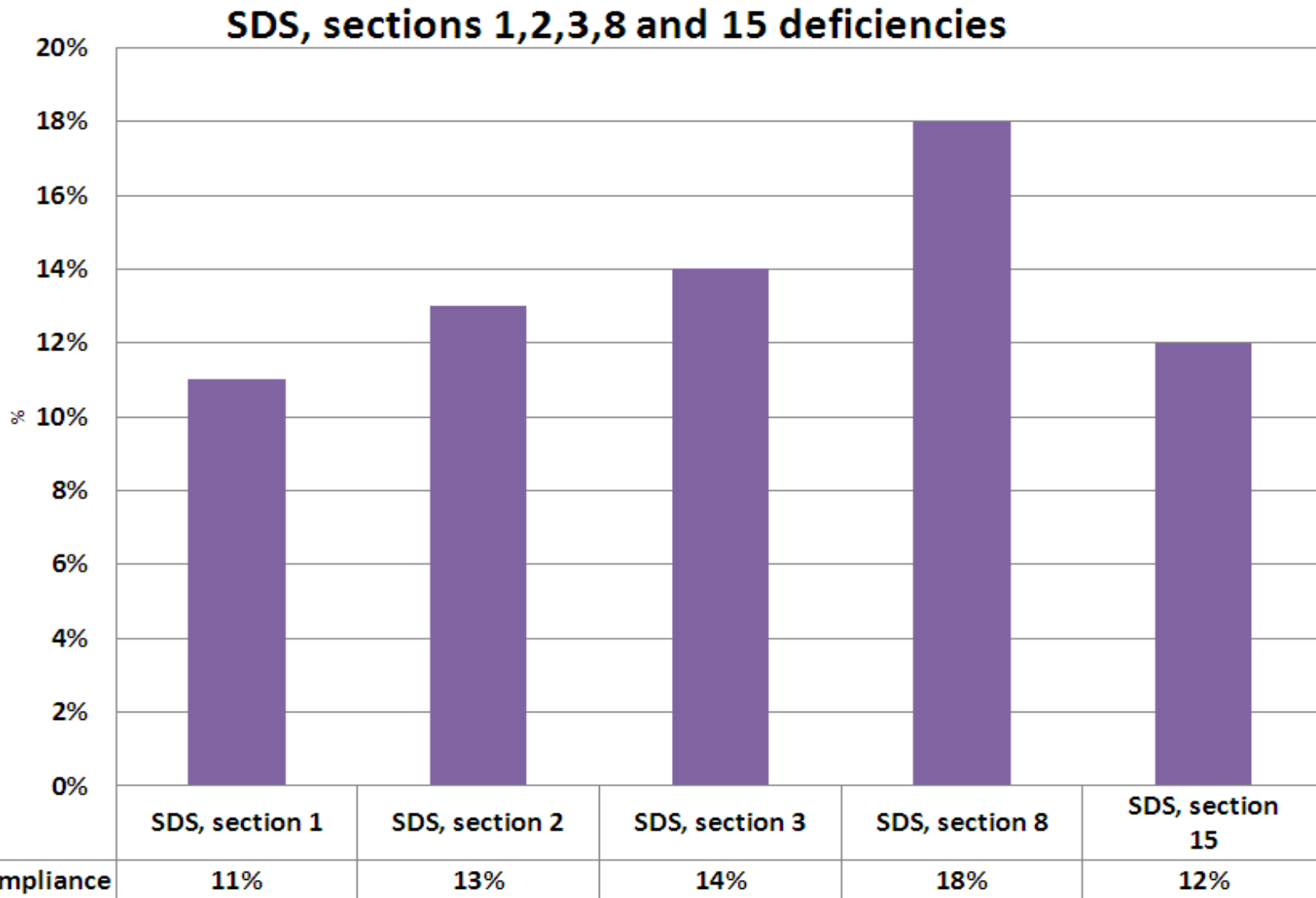


■ yes

■ no

■ partially

Deficiencies in individual Sections of SDS



Requirements under control in Section 1 of a SDS

Based on criteria defined in the ECHA Guidance:

- Name of the substance / mixture
- Use(s) of the substance / mixture
- Company identification: full address and telephone number within the EEA
- e-mail address of the competent person responsible for the SDS
- Emergency telephone number

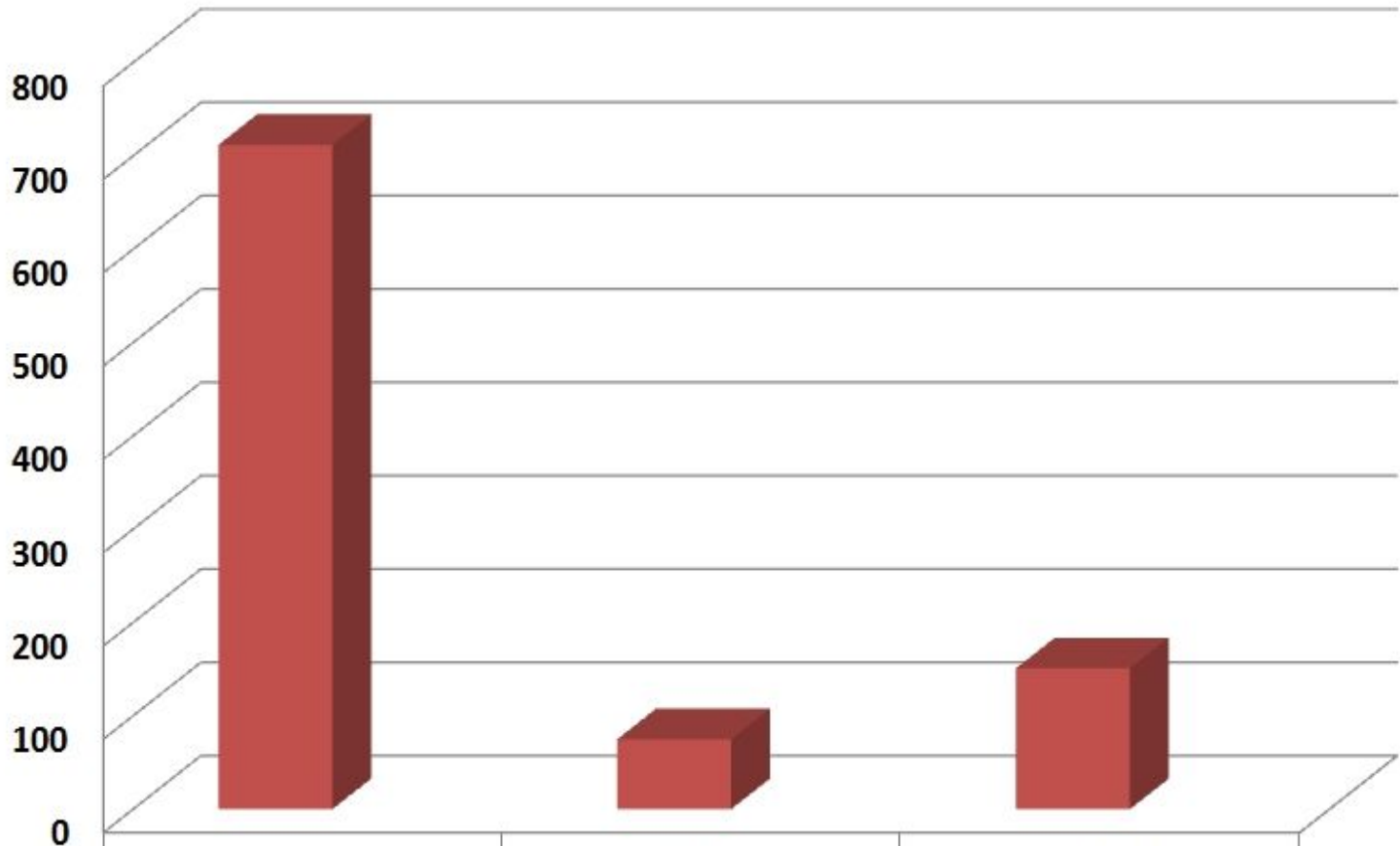
Requirements under control in Section 2 of a SDS

Based on criteria defined in the ECHA Guidance:

- Classification of the substance / mixture
- Description of the most important adverse physicochemical, human health and environmental effects
- Description of symptoms

Correspondence of Section 15 or 2 of SDS with the label

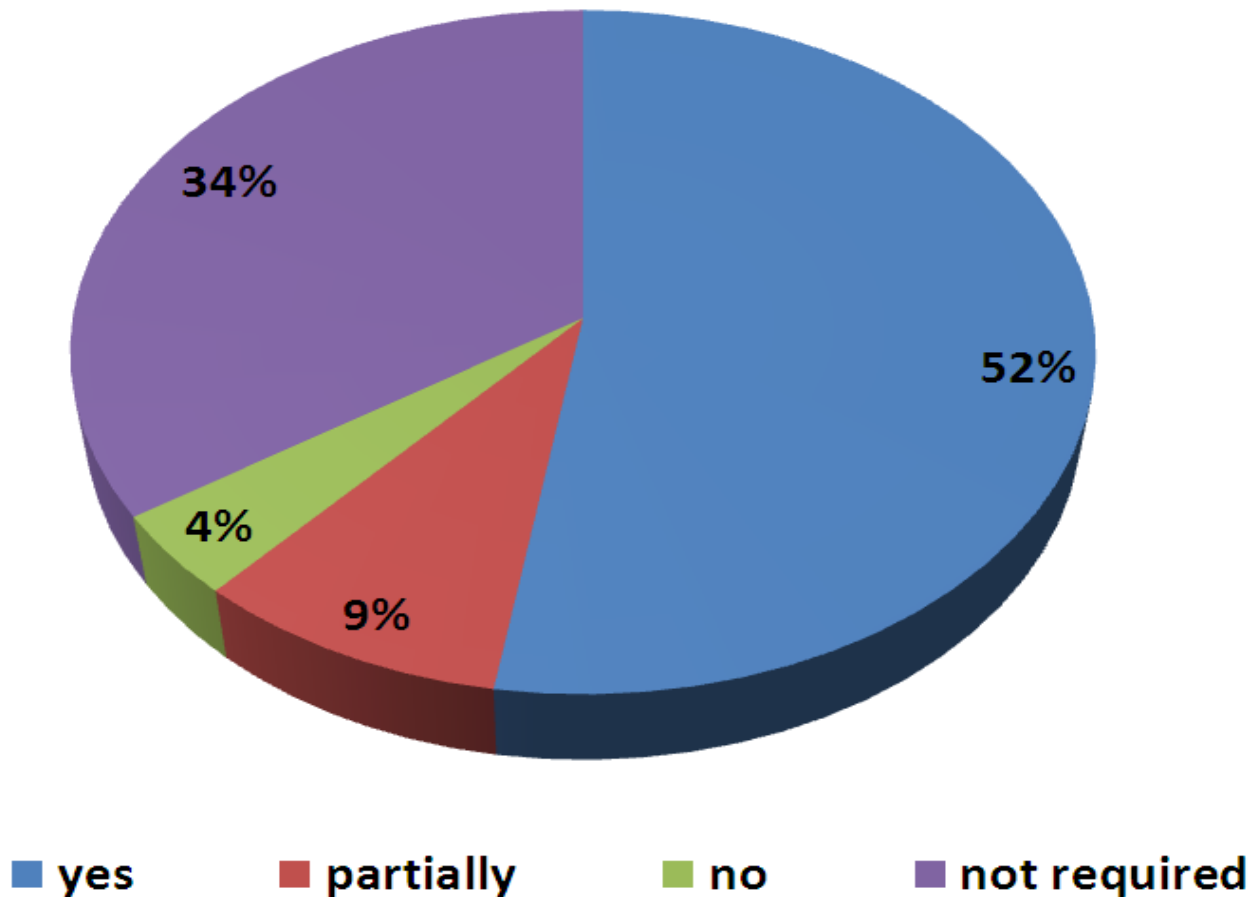
Correspondence S15 or S2 with labels



■ Number of companies	712	75	151
%	76%	8%	16%

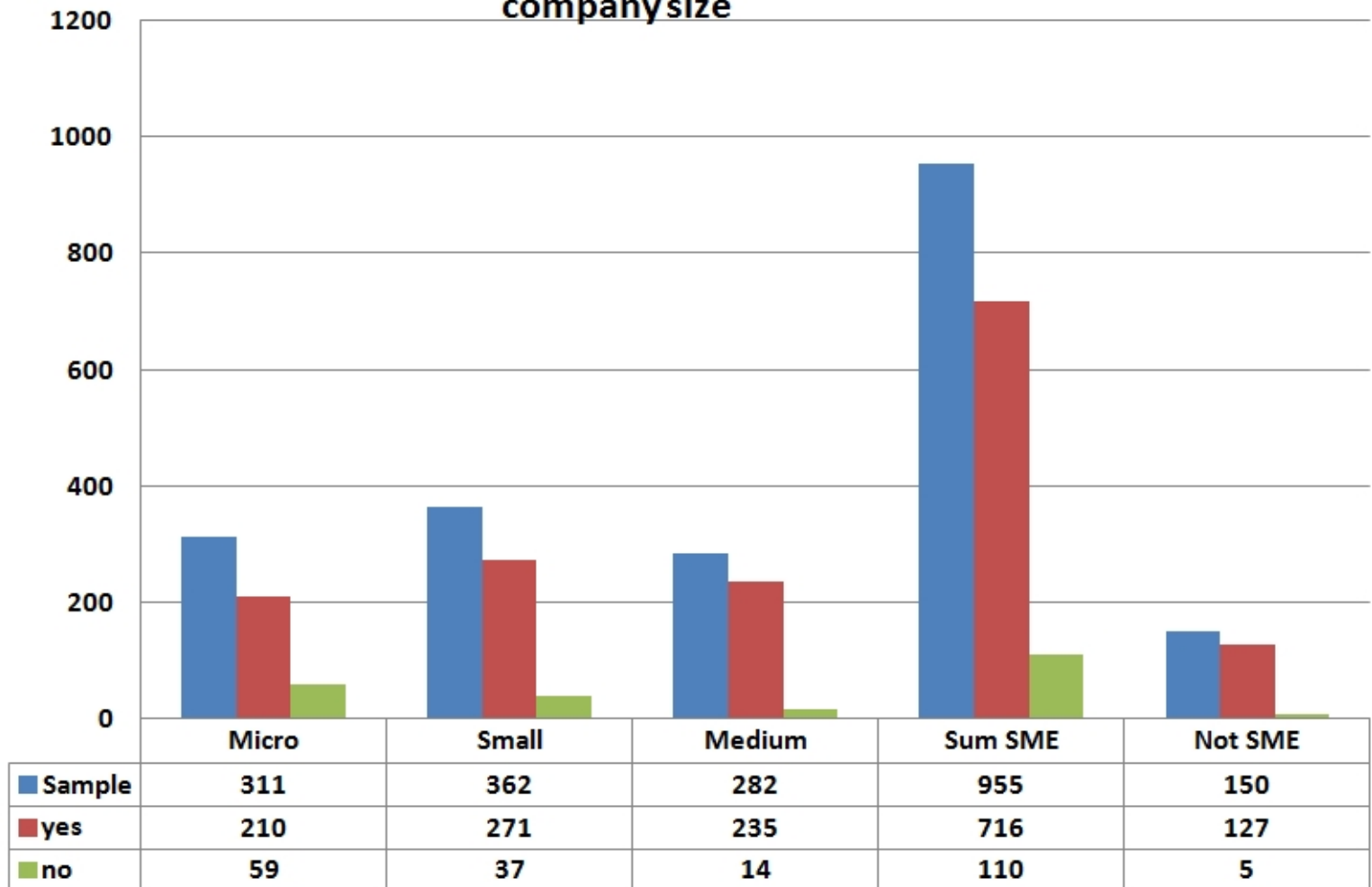
Use of the new format for substance SDS

New format of SDS for substances in the checked companies



Correspondence between information in the SDS and composition by company size

Verification of correspondence between information and composition by company size



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Conclusions from REF-2

- EU wide **coordinated enforcement** of relevant instruments of chemicals legislation is **in place**
- **Broad REF-2 participation** in the EU-EEA (29 from 30 countries), a large number of inspections carried out (1181)
- Still a **high level (52%) of non-compliant SDSs**
- SDS will certainly remain an area in the **focus of future inspections**

Conclusions from REF-2

- **Knowledge building** is still an issue (especially in SME)
- Need for awareness raising about **good SDS** in the supply chain being **vital** for having **Title IV of REACH** (information in the supply chain) functioning
- Industry must step up **SDS stewardship**
- Do we also have a basic **structural problem with compilation of SDSs** ?

Conclusions from REF-2

- **A level playing field** for duty holders in the EU is ensured with coordinated enforcement activities and with harmonised enforcement procedures
- You identify a specific **need for coordinated, EU-wide enforcement action**:
inform ECHA Forum via your stakeholder organisation

http://www.echa.europa.eu/documents/10162/13577/hep_submission_proposal_template_en.doc

EU Inspection Project

“REACH – EN – FORCE 2”

Results and Lessons

Thank you for your attention !