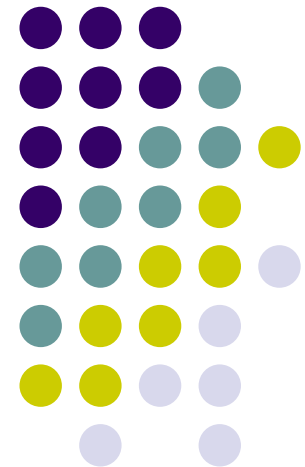


REACH 2009

Dott. Mariano Alessi
Ministero del lavoro, della salute e delle politiche sociali

Bologna 12 giugno 2009

La garanzia
della corretta attuazione del REACH
deve passare attraverso un
efficace sistema
di controllo e vigilanza



Attori nel contesto dell'Attuazione



Inspectors



ECHA / MSCA

On-site inspection

Verifying if dutyholders fulfilled their obligations

Enforcement authorities

- labour inspection
- health inspection
- environmental inspection
- trade inspection
- customs
- ...

Verification processes in REACH (outside the site)

Verifying content of Information submitted to ECHA

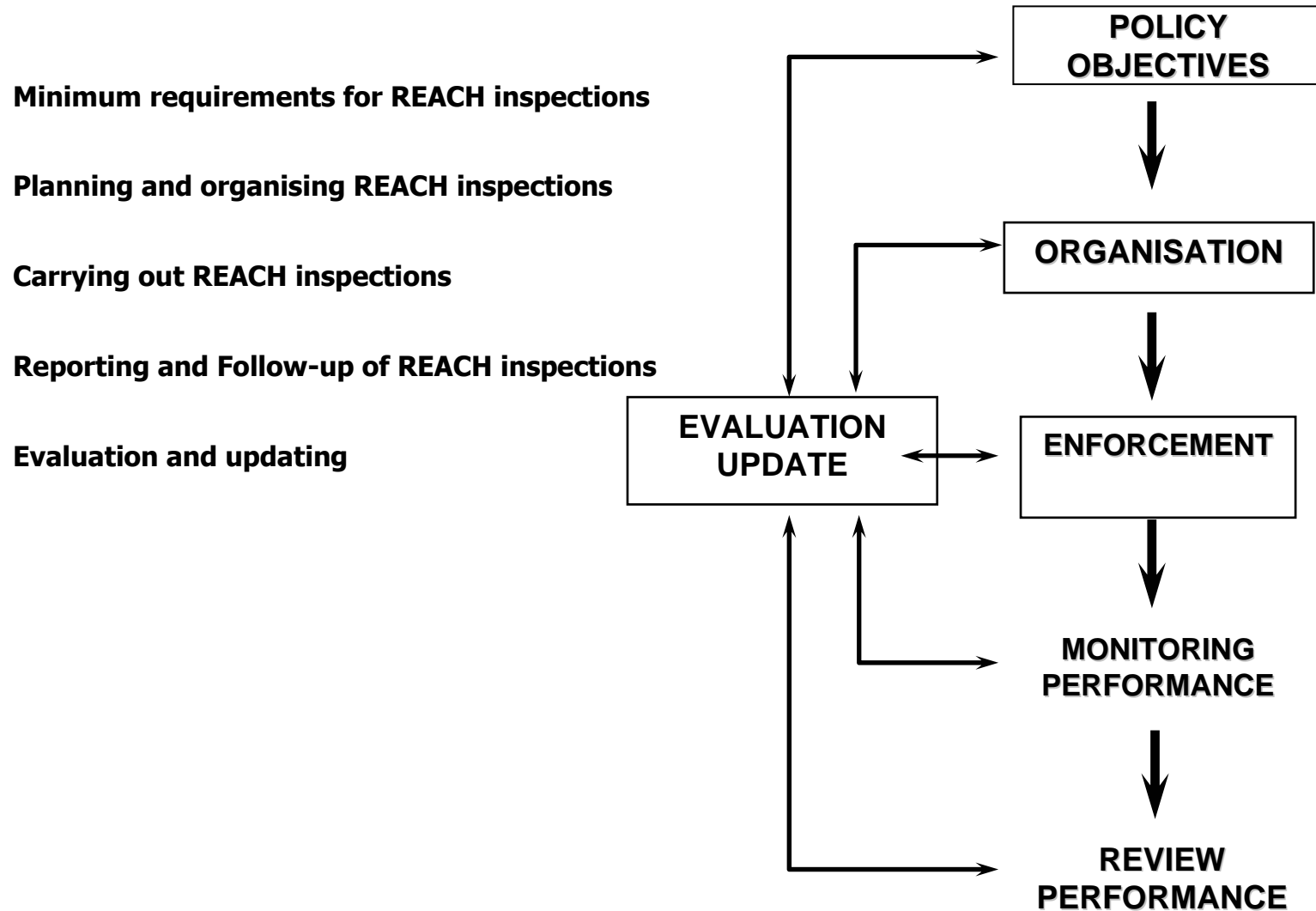
ECHA

Compliance check

MSCAs

Substance evaluation
(may include quality check of dossier if compliance check was not carried out)

*starter document on the Minimum criteria for Inspections
under the REACH Regulation*





Definitions

.....

‘enforcement’ refers to the range of actions an enforcing authority may take in order to secure a dutyholder’s compliance with REACH. By article 127, it is clear that enforcement should be given a wide interpretation, and includes not only formal enforcement but also inspection, investigation, monitoring and other measures taken in pursuance of articles 125 and 126.

‘inspection’ is a proactive , planned and routine process that involves collecting information to make an assessment of a dutyholder’s current level of compliance, by comparing their activities to the legal requirements and benchmark standards relevant to the activities in question. Information may be obtained by reviewing relevant documents held by the dutyholder, and/or interviewing people, and/or monitoring, and/or observing site conditions, standards or practices where activities subject to the requirements of REACH are carried out under the dutyholder's control. It follows that REACH inspection activity can occur at or away from a dutyholder’s premises.

‘investigation’ is a reactive, non-routine process which includes all those activities carried out in response to an accident, incident, or an occurrences of non-compliance or an identified instance of non-compliance, to gather and establish the facts, detect contraventions of REACH duties, identify immediate and underlying causes and the lessons to be learned, prevent recurrence, and take appropriate action, including formal enforcement.

‘monitoring’ means periodic or continuous surveillance, measurement, sampling, testing and/or analysis of various media, such as substances, preparations, articles, the environment (air, water, soil, vegetation, animals) and so on, to determine the level of compliance with statutory requirements.

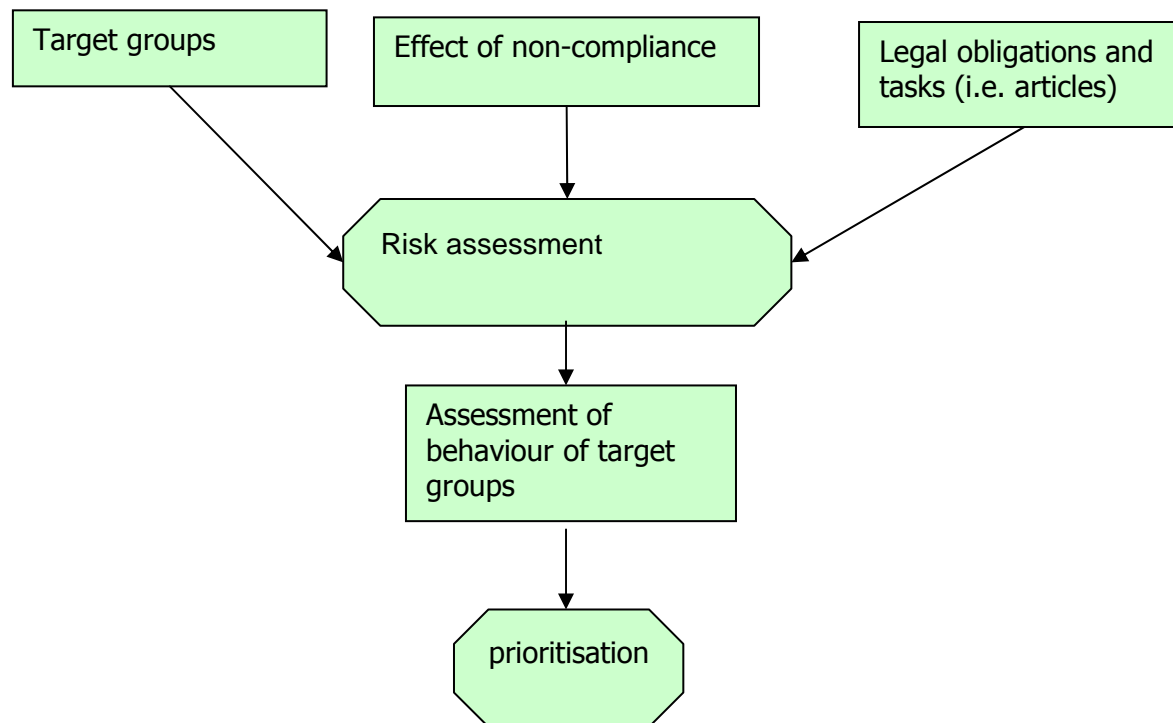


Diagram Risk assessment scheme for setting priorities for national Reach enforcement strategies



Definitions

-
- **‘Risk Analysis’** - Determination of the impact and the probability of non-compliance with the REACH requirements.
Probability could be assumed as a function of the level of awareness and knowledge and the level of acceptance of the legislation by the target groups,, the probability of being found in incompliance, the probability of sanctions to be imposed both by the enforcement authorities and the public (reaction to the bad image).
 - **‘Risk Assessment’** – Estimation of the acceptability of the risk, determined by the risk analysis. If the risk is unacceptable, preventive or correction measures have to be applied.
 - **‘Risk Recipient’** – any person or environment feature that are endangered as a result of incompliance of some of the dutyholders with the requirements of REACH. Such risk recipients are e.g. workers, consumers, surface or groundwater, etc.



Definitions

.....

- **‘Performance indicators’** are instruments that measure results achieved by compliance and enforcement programs.
Examples of such performance indicators are the number of inspections performed, number of inspectors per known target groups, number of enforcement notices issued, etc.
- **‘Compliance’** - The state of conformity with the obligations imposed by the REACH Regulation.
- **‘Complaint’** – An accusation against a dutyholder that they are in some way failing to meet one or more of the duties imposed upon them by the REACH Regulation.
- **‘Dutyholder’** - The generic term for a person (natural or legal) with responsibilities under the REACH Regulation. It is generally equivalent of a member of one of the target groups.
- **‘Target group’** is a group of entities which exercise a particular activity and have a characteristic set of obligations according to the REACH Regulation. Target groups under REACH are manufacturers, importers, distributors and downstream users.



Manual Forum Project on pre registration/registration of phase in substances and SDS in 2009

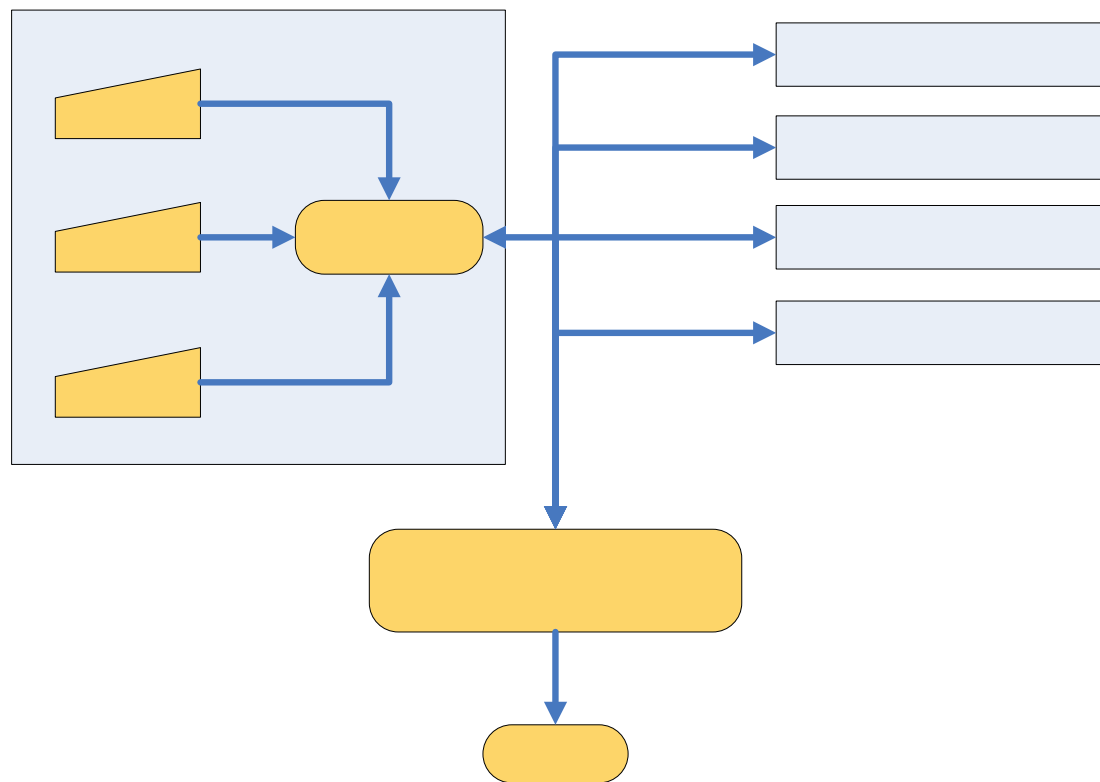


Fig: Relations between actors in the project

Participatin



Forum for Exchange of Information on Enforcement European Chemical Agency

14-15 May 2008

Traceability of Chemicals in the Customs Jungle



Hervé SCHEPERS - European Commission - TAXUD-B3

At the Customs office



→ The eight jungles

1st jungle: Customs Control

2nd jungle: chemicals

3rd jungle: names

4th jungle: numbers & identifiers

5th jungle: translation

6th jungle: databases

7th jungle: classification

8th jungle: fraud



Tapaamme Helsingissä

4th Conference of European Customs Chemists



Helsinki, Finland
June 2010

PROBLEMS OF ENFORCEMENT AUTHORITIES



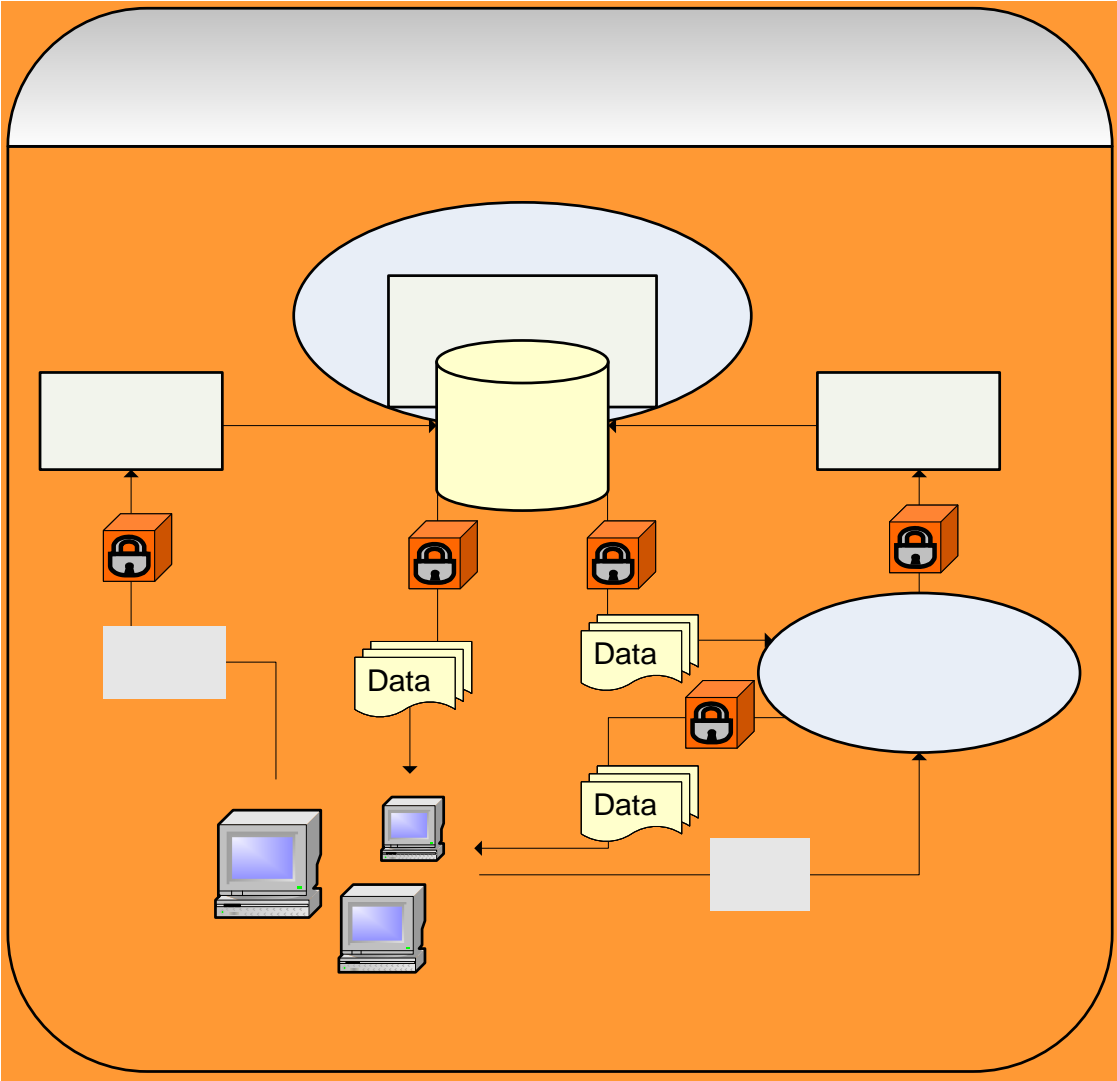
- REACH enforcement is a complex task for authorities
- Local enforcement authorities are lacking the means to interact and exchange important information quickly and in-time
- Currently enforcement authorities work REGIONALLY - while markets are organised INTERNATIONALLY and companies operate GLOBALLY



Enforcement authorities need CO-OPERATION !



Implementation of



REACH Int



Attività in esecuzione

- **Accordo Stato Regioni per il Regolamento REACH**
 - Definizioni
 - Obblighi generali
 - Autorità preposte alle attività di controllo
 - Gruppo tecnico di esperti a supporto Coordinamento Interregionale della Prevenzione
 - Personale che esegue i controlli
 - Programmazione controlli
 - Linee guida per l'attività di controllo
 - Attività di controllo
 - Campionamento e analisi
 - Rete dei laboratori a supporto attività di controllo
 - Sistema interattivo



La rete.....prende forma



Le regioni e le province autonome, nell'ambito della propria organizzazione e legislazione, **individuano l'Autorità per i controlli sul REACH,**



Le Regioni e le province ne danno comunicazione all' **Autorità competente nazionale**

19 Regioni + 2 province autonome →

21 Autorità per i controlli



individuano tra le strutture operative nell'ambito del territorio regionale o della provincia autonoma **le articolazioni organizzative territoriali che effettuano i controlli** di cui al presente Accordo

LIVELLO REGIONALE

L'AC nazionale è altresì responsabile dei controlli esplicitati attraverso le strutture direttamente da essa dipendenti :

USMAF, NAS, ISPESL corpo ispettivo di cui al decreto 27 gennaio 2006 del Ministro della salute

NOE..

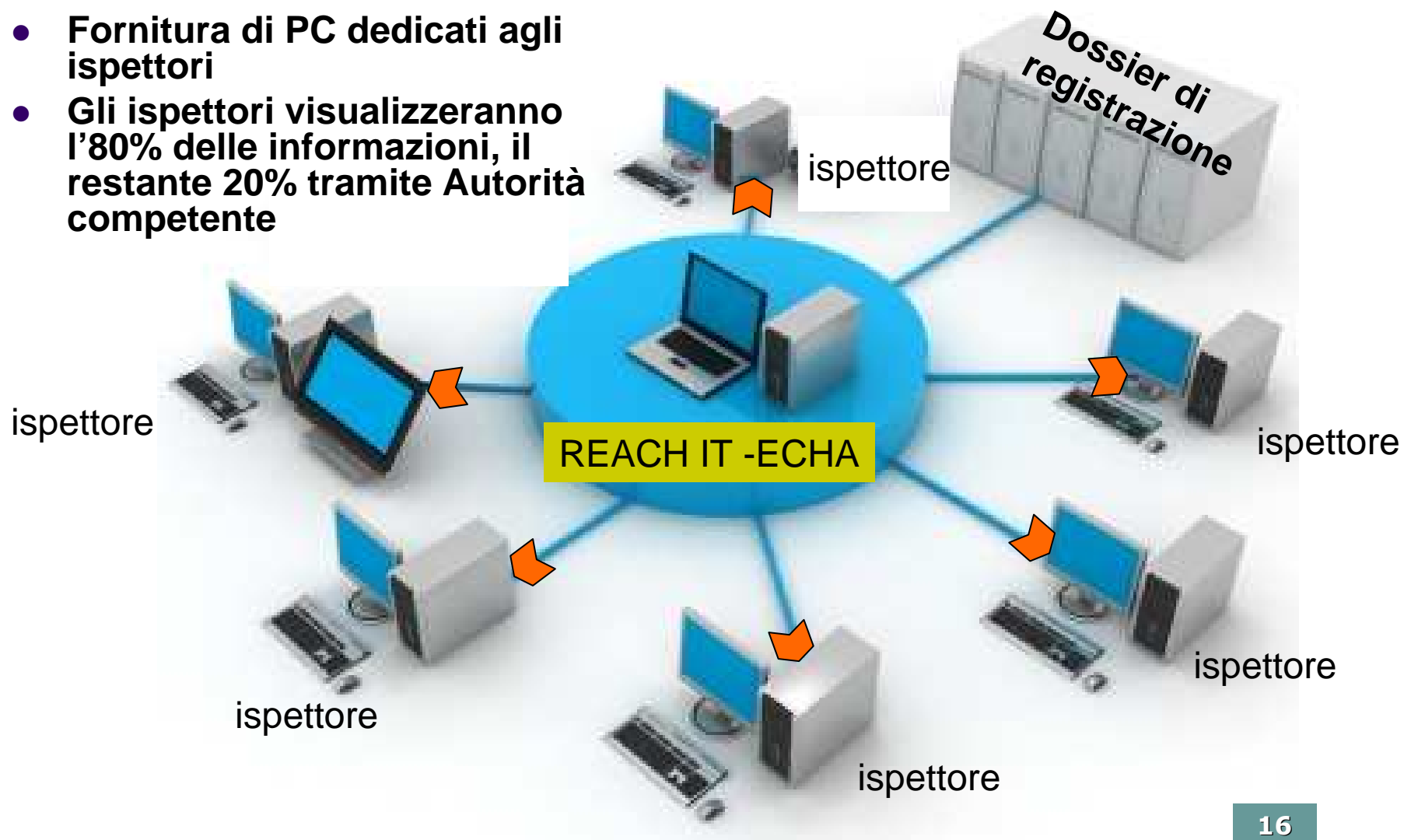
e l'Agenzia delle dogane.

LIVELLO NAZIONALE



Operatività degli ispettori

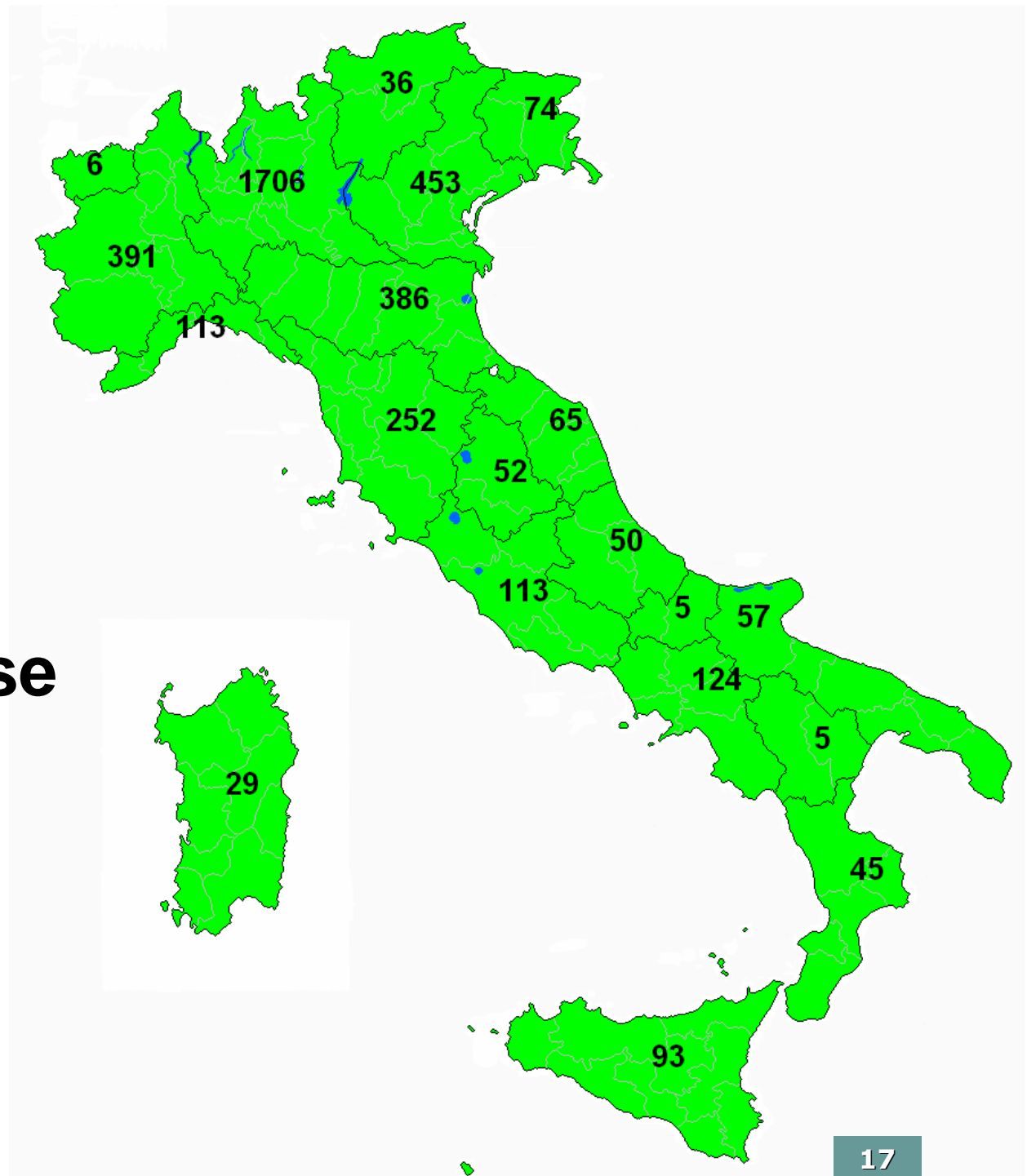
- Fornitura di PC dedicati agli ispettori
- Gli ispettori visualizzeranno l'80% delle informazioni, il restante 20% tramite Autorità competente



150.000
sostanze
pre-registrate

in Europa:
- 65.000 imprese

in Italia
- 4055 imprese



L'ECHA-FORUM E LA FORMAZIONE DEGLI ISPETTORI

FORUM-4 del 28-30 APRILE 2009



- Sono previsti altri due incontri per la fine dell'anno (Forum-5; Forum-6)
- Entro ottobre prima del Forum-6 un apposito WG elaborerà, su mandato, un programma armonizzato con il materiale per la formazione dei formatori
- in tempo utile, ciascun Membro del Forum potrà rendere disponibile i materiali utilizzati attualmente dalle proprie Autorità nazionali-territoriali per contribuire e rendere più uniformi le metodologie
- E' auspicabile, pertanto, che l'ACCORDO Stato-Regioni possa rapidamente dare una spinta propositiva al contributo italiano nell'ambito delle procedure minime armonizzate, alla migliore formalizzazione dei compiti e alla chiarezza nella realizzazione delle reti "gerarchiche" proposte dall'ECHA nell'attuazione del Regolamento.



In bocca al lupo Break a leg



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