



Strategies to Combat Counterfeit Activities in the EU

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What has the Commission done so far - Internal Market ?



- **Directive 2004/48/EC of the EP and the Council**
on the **enforcement of intellectual property rights**

What has the Commission done so far – **Customs** ?



- **Regulation No 1383/2003 of the Council**
concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights
- **Commission Regulation (EC) No 1891/2004**
laying down provisions for the implementation of **Council Regulation (EC) No 1383/2003** concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights

What has the Commission done so far - **Customs** ?



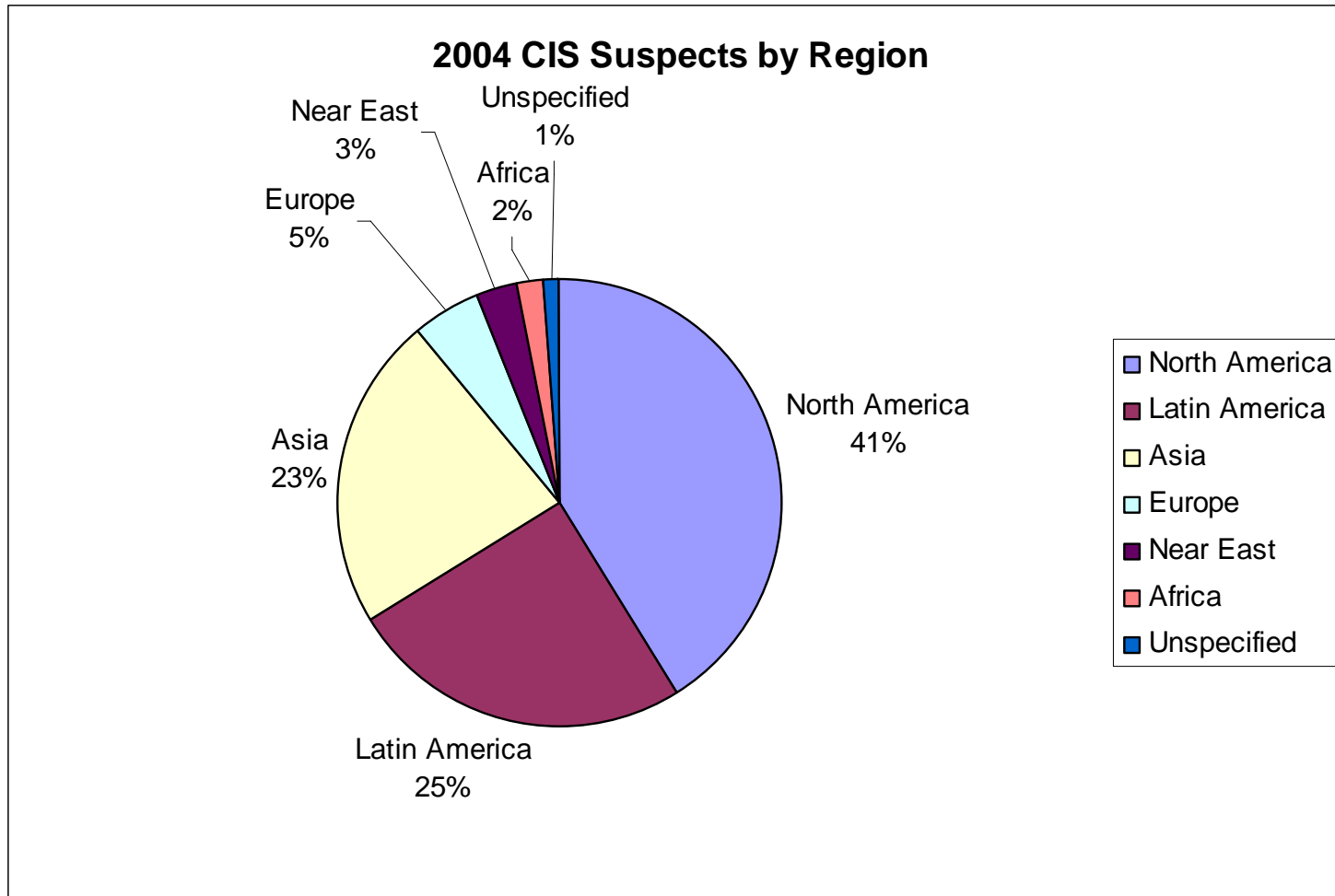
- **Communication** on a **customs response** to latest trends in **counterfeiting and piracy** and proposal for **action plan** (in preparation)

What has the Commission done so far - **Cooperation** ?



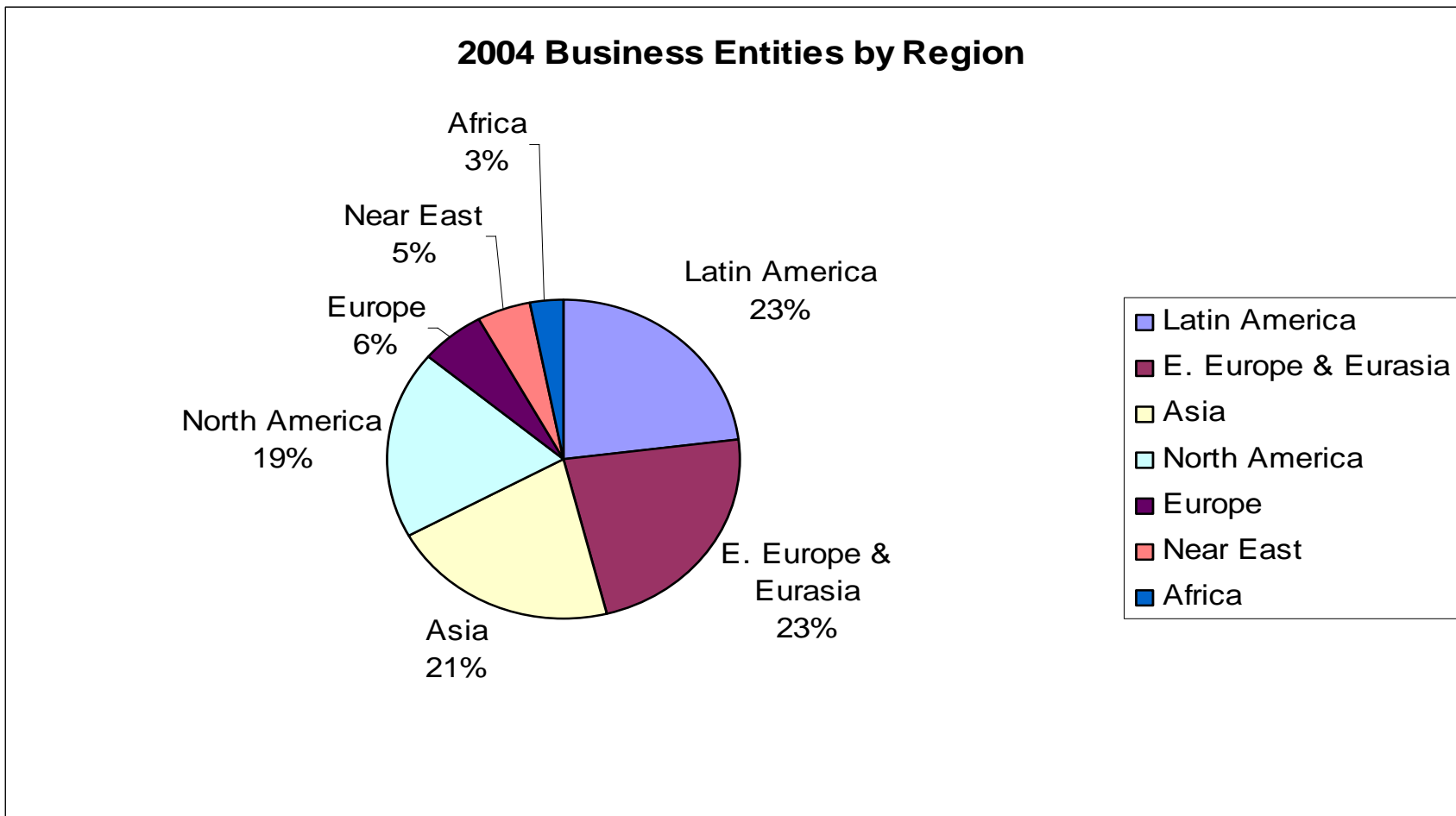
- **Regulation (EC) No 2006/2004 of the EP and Council**
on **cooperation between national authorities** responsible
for the enforcement of consumer protection laws
(the Regulation on consumer protection cooperation)

Counterfeit Activities: Suspects by Region*



**Source: Pharmaceutical Security Institute (2004),
Counterfeit Incident System (CIS)**

Counterfeit Activities: Business Entities by Region*



**Source: Pharmaceutical Security Institute (2004),
Counterfeit Incident System (CIS)**



...and concerning **pharmaceuticals**?

- **Guideline 94/C 63/03 on**
Good Distribution Practice (GDP)
- **Regulation No. 953/2003 of the Council**
to **avoid trade diversion** into the European Union
of certain key medicines



...and with the Review of the Pharma Directives ?

- Dir. 2001/83/EC and 2001/82/EC of EP and Council, as amended*
 - Legal provision to use only **active substances as starting materials** for a medicinal product, which have been manufactured in compliance with **GMP** (Part II) *(Article 46/ 50)*
 - Legal provisions for **inspections** at manufacturers of active substances used as starting materials and at MAH *(Article 111/ 80)*

* by Directives 2004/27/EC and 2004/28/EC

Additional Pharmaceutical Legislation in Preparation



- **Directive of the Commission on
Good Manufacturing Practice (GMP)
for certain excipients**

Legal provision in Directive 2001/83/EC, as
amended by Directive 2004/28/EC (Article 46)

Activities of the Member States



e.g.

- **legal definition** of counterfeit medicinal products and corresponding penalty legislation
- Establishment of **Intelligence Task Forces / Units** in the pharmaceutical sector in the Member States
- Co-ordinated **market survey activities** on specific products (EDQM/ EMEA)
- **Co-operation networks** through Heads of Medicines Agencies

EU Medicines Enforcement Officers (EMEEO)



- EMEEO installed by Heads of Medicines Agencies in 2004
- Representatives (enforcement officers) from Member States
- Observers from EMEA, COM
- Rotating management committee

July 2005: New Objectives for EMEO



- Surveying the extent of the counterfeit problem in the EU
- Developing an EU wide anti-counterfeiting strategy

Possible Future Initiatives through EMEO

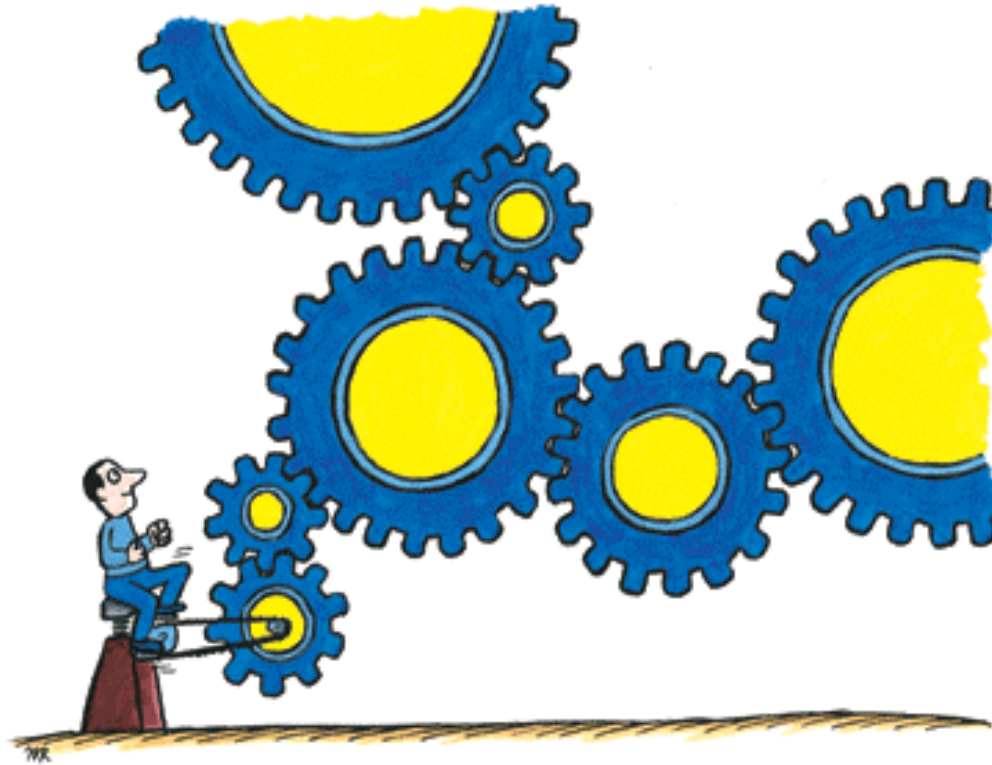


- Initiate/ conduct **research study**
- Make proposals for **medicines surveillance**
- Co-operate on **inspections**
- Prepare **trainings**/ educate on extent of problem
- Monitor and evaluate **technical developments**, e.g. feasibility study of passive and non-passive product and packaging security solutions

Future Activities of the Commission



- **Horizontal activities** on customs level (DG TAXUD)
- **Sectoral activities** at DG ENTR for pharmaceuticals, e.g.:
 - **Monitor the work of EMEO** and consider the results of the research study for possible legal implications
 - **Enforce Co-operation networks** with Non-EU countries through bilateral arrangements, e.g. with WHO and the Council of Europe
- **Public-Private partnerships?**



Thank you for your attention!