



European activities in the field of Human Substances - Organ Donation and Transplantation

Journalist Workshop 9 October 2012

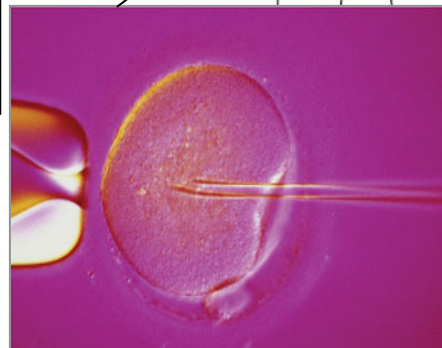
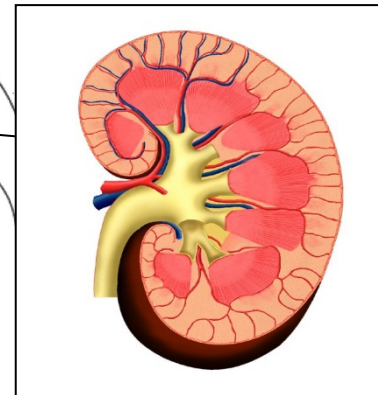
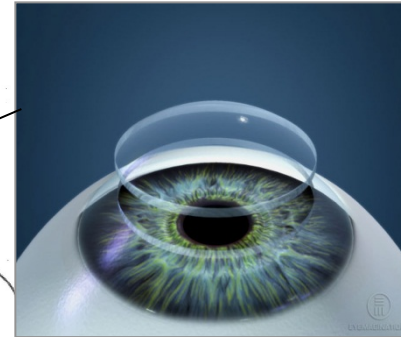
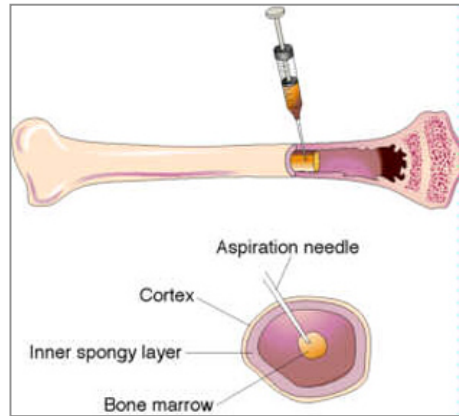
**Hélène Le Borgne, Policy Officer for Organ donation & transplantation,
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Health and Consumers Directorate General
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SUBSTANCES OF HUMAN ORIGIN (SoHO)



European
Commission



Health and
Consumers

ORGAN TRANSPLANTS IN THE EU - 2011



GODT Global Observatory on
Donation & Transplantation

In collaboration with
**World Health
Organization**



GODT African Americas Eastern Mediterranean Europe South-East Asia Western Pacific Search

EUROPEAN UNION DATA

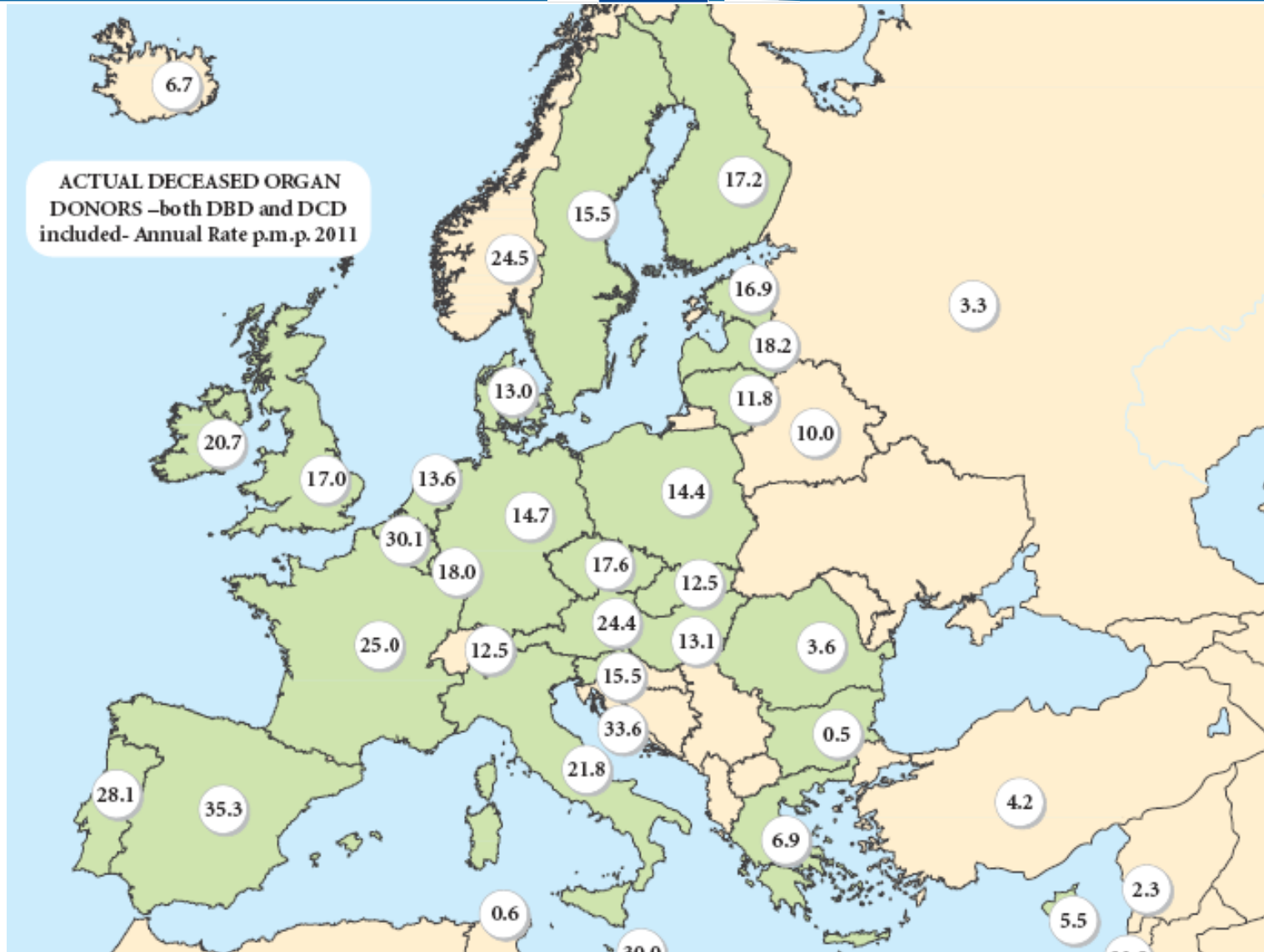
Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants	Small Bowel Transplants
18712 (20,6% LD)	7006 (3,5% LD)	1980	1677	859	56

9604 ACTUAL DECEASED ORGAN DONORS (both DBD and DCD included)

**2011 data*

N= 27 COUNTRIES (504,2 million inhabitants)

DECEASED ORGAN DONORS - 2011



Source: Council of Europe / ONT 2012 Newsletter

Health and Consumers



Article 168 of the Treaty:

“setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives”

■ **Directive 2010/53/EU** of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation

- Adopted on 7 July 2010
- To be transposed by Member States until 27 August 2012

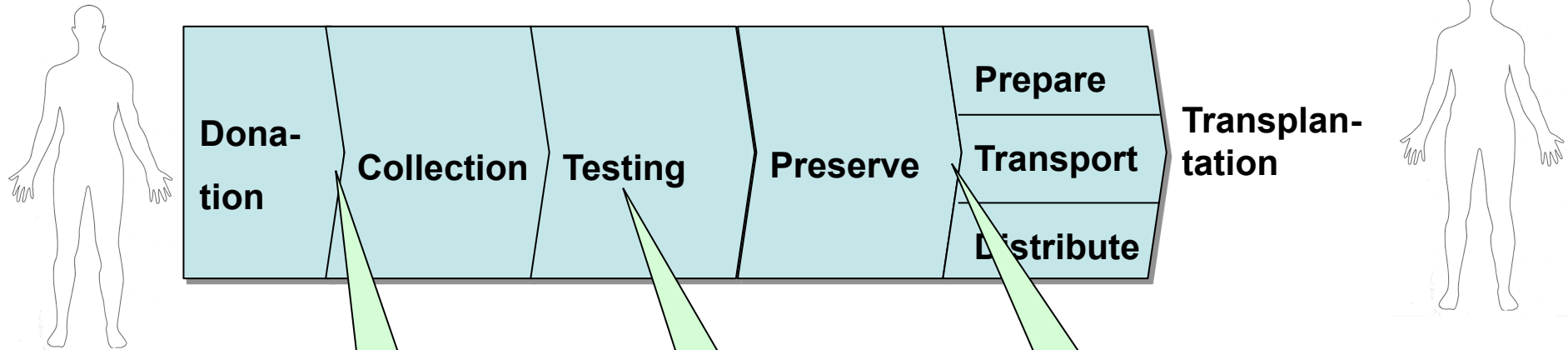
■ **Commission Implementing Directive** laying down information procedures for the exchange, between Member States, of human organs intended for transplantation

- Aligns communications on organ characterisation (offering), traceability and alerts
- Adopted Today (9 October 2012)



DIRECTIVE 2010/53/EU Key elements for quality and safety

- Chain from donation to transplantation, from donor to recipient



3 levels:

- 1 Procurement/transplant centres**
 - Selection, consent...
 - HIV, Hepatitis B, Hepatitis C...
 - Processing Quality requirements
- 2 National Competent Authorities**
 - Oversight: vigilance, traceability, accreditation, inspection...
- 3 European Commission**
 - Support tools: traceability, rapid alert system system...



- The following areas are **outside of the scope of the Directive:**

- Consent systems (opt-in / opt-out)

- Waiting lists

- Allocation criteria

- Legislation around brain death

→ The areas remain **national competence**

→ However, the Commission can encourage Member States to **share experiences through collaboration under the Action Plan** (voluntary tool)

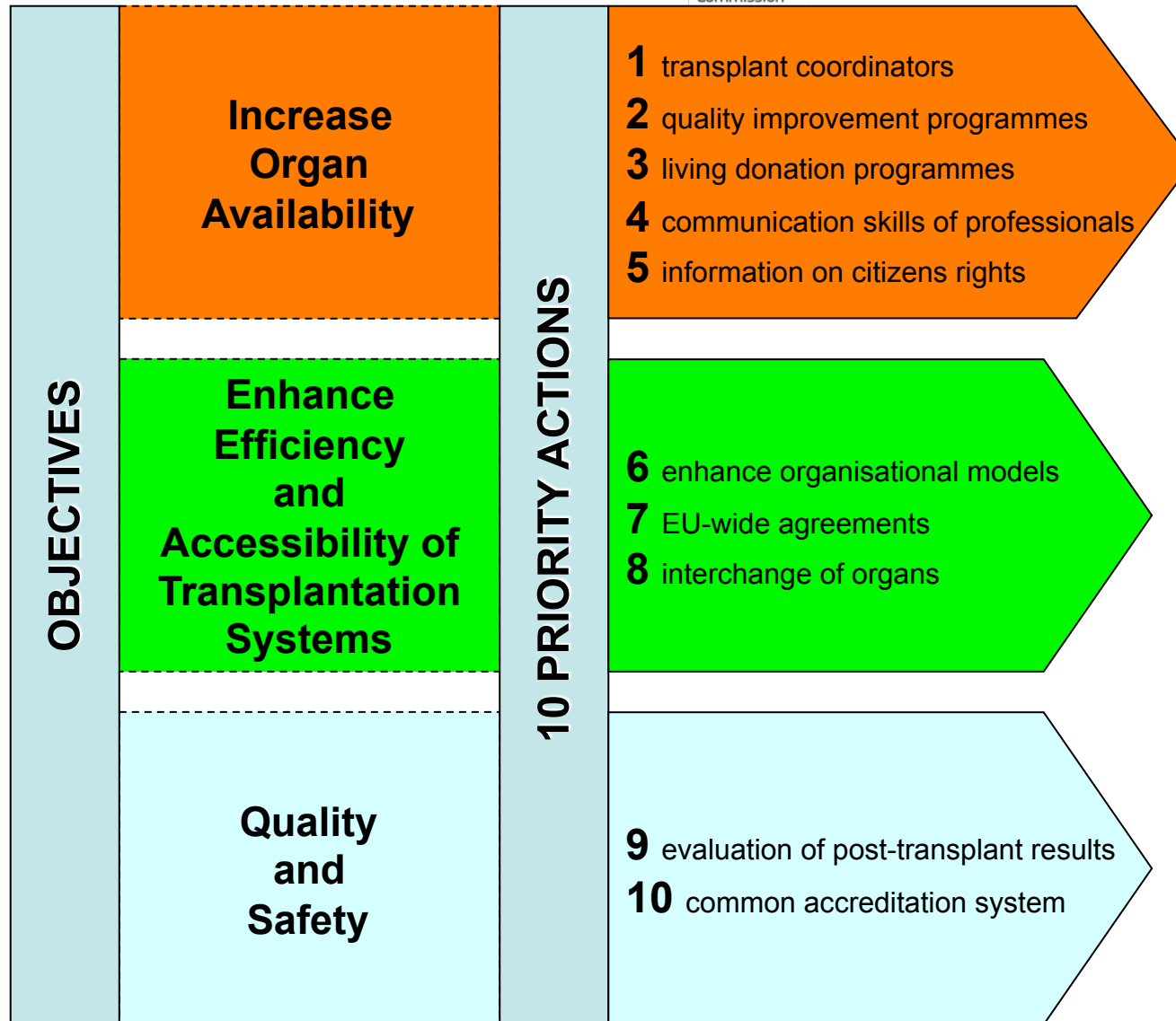


NON-LEGAL COMMISSION ACTIVITIES

- **International cooperation** (Council of Europe, WHO)
- Activities under the **Action Plan** – 3 main objectives:
 - increase organ availability
 - improve transplant systems (efficiency and accessibility)
 - improve quality and safety
- Halfway 2009-2015: Mid-term Review

Tools at disposal under the Action Plan:

- **Projects** funded under the **Public Health Programme**
- **Working groups**: living donation, indicators, transplant donor coordinators,
- **Journalists Workshops**



Consumers



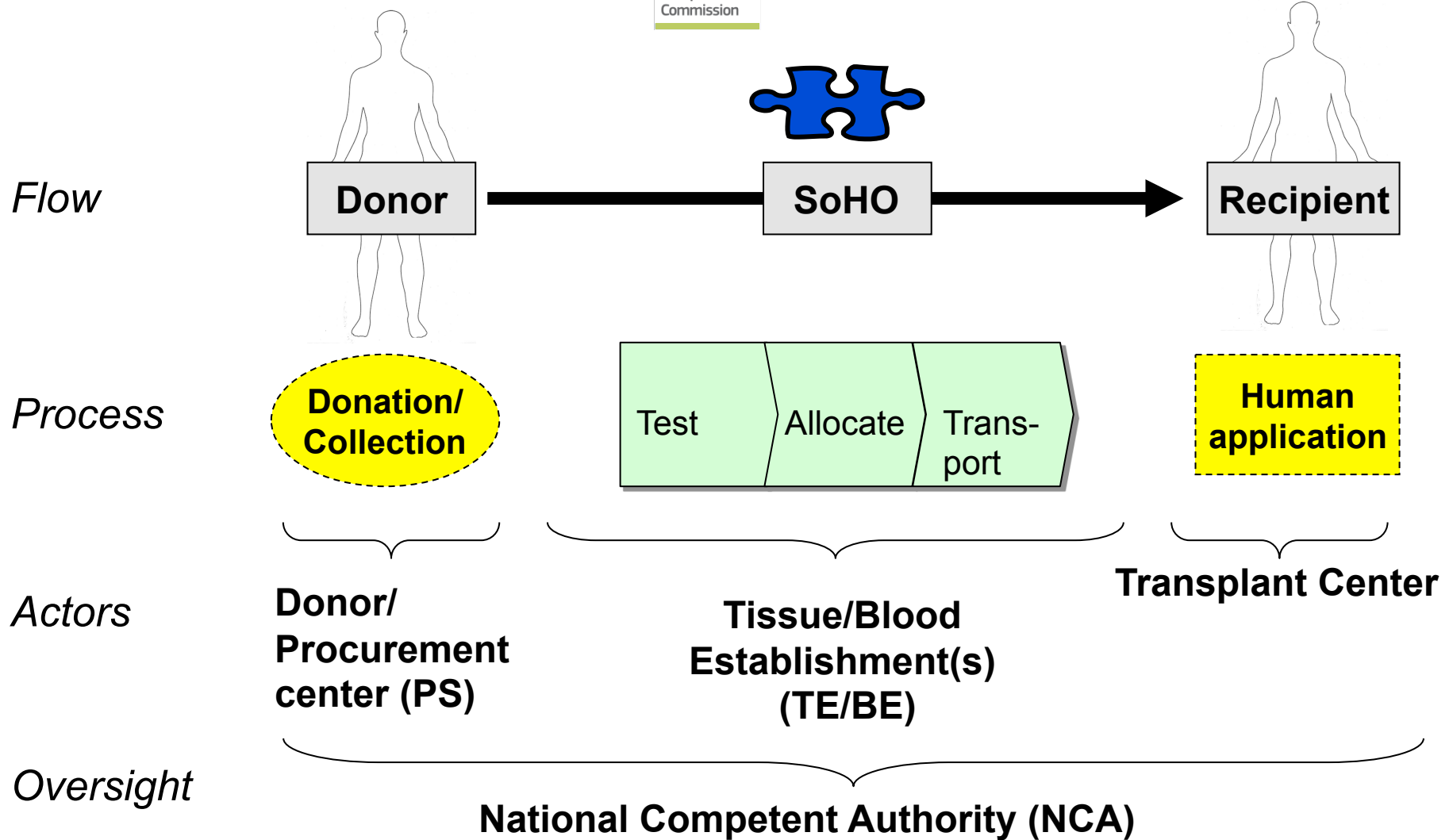
- Joint action 2011: **ACCORD – Assisting Member States in reaching the full potential of deceased and living donation**
 - Collaboration with ICU experts
 - Registers for living donors
 - Twinning programmes

- Project: “**Train the trainers in transplant donor coordination**”
 - for national/regional/local trainers (80 participants from all Europe)
 - to increase organ availability

- Project to support **cross-border exchanges: COORENOR**
 - develop an IT tool to offer cross-border organs which can not be used at national level
 - encourage cross-border agreements to facilitate organ exchanges
 - pilot project is set-up. Preparing for a roll-out (Joint Action)



TODAY'S DIFFERENT VIEWS ON TRANSPLANTS



OUR TEAM



http://ec.europa.eu/health/blood_tissues_organ/policy/index_en.htm

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THANK YOU !