



# Public Health Programme – Workplan 2005

## Substances of Human Origin

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Unit C6 Health Measures



## Article 152 Public Health

4 (a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining of introducing more stringent protective measures.



## **Safety of blood, tissues and cells, and organs. Legislation**

### **Blood**

- Directive 2002/98/EC on the quality and safety of blood
- Commission Directive 2004/33/EC on certain technical requirements

### **Tissues and cells**

- Directive 2004/23/EC on the quality and safety of human tissues and cells



## Projects Funded 2003

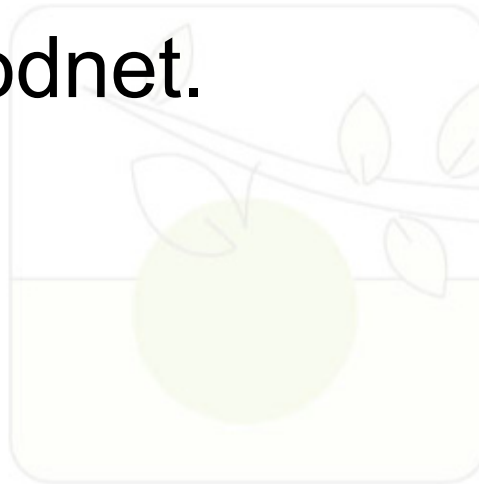
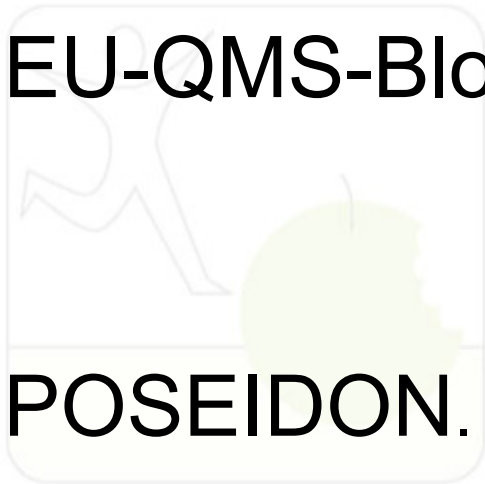
■ JACEI.

■ EUROPEAN QUALITY SYSTEM FOR TISSUE BANKING.

## Projects Funded 2004

■ EU-QMS-Bloodnet.

■ POSEIDON.





## Safety of blood, tissues and cells, and organs. 2005

- Aims to promote the quality, safety and availability of substances of human origin
- Minimize risks and ensuing threats to patients' health associated with their collection, processing, distribution and use.
- Activities should support implementation of existing EU legislation



## **BLOOD** Priorities 2005

### **Priority given to the development of tools**

- Practical guidelines on how to install and maintain quality systems in blood establishments
- Assist in the training of inspectors, using modern techniques
- Promote the optimal use of blood and blood components



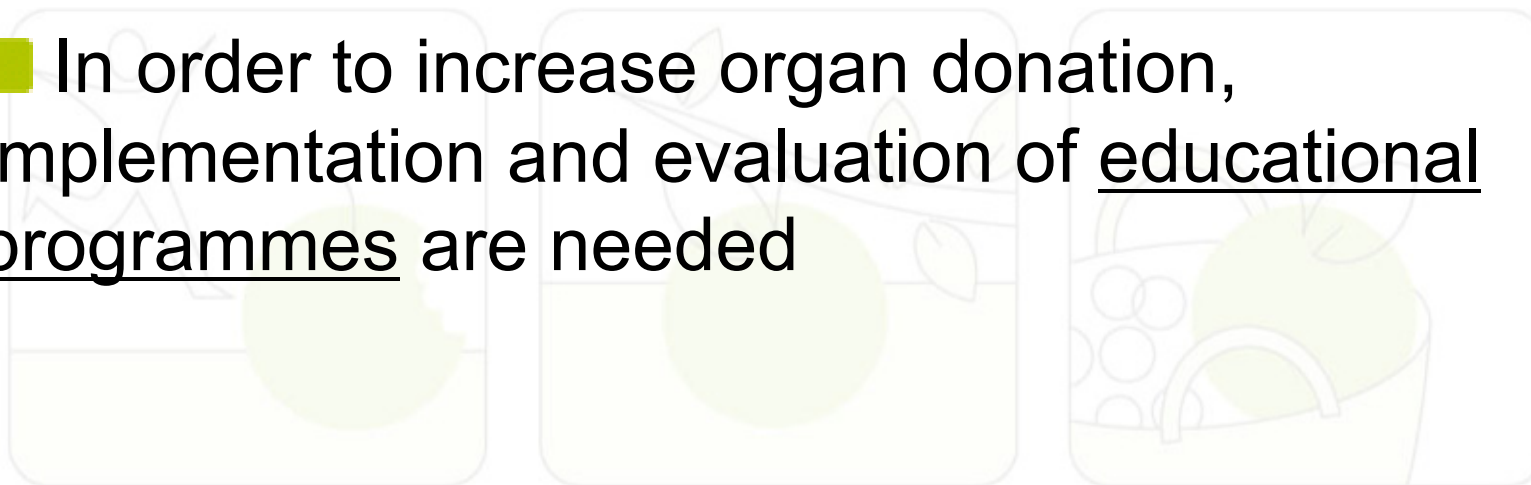
## TISSUES AND CELLS Priorities 2005

- Implementation of quality systems in tissue and cells establishments needs in particular to take into account the needs of the new Member States
- Work should be extended to inspection practices, through the preparation of guidelines concerning the conditions of the inspections and control measures and on the training and qualifications of the officials involved,
- and to serious adverse event reporting

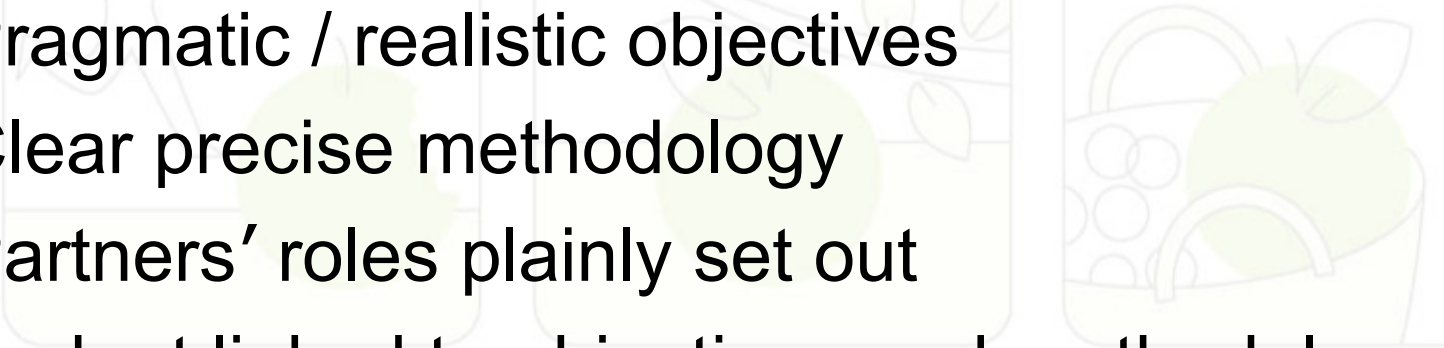


## ORGANS Priorities 2005

- In order to increase organ donation, implementation and evaluation of educational programmes are needed



## **Safety of blood, tissues and cells, and organs. 2005**

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- Pragmatic / realistic objectives
  - Clear precise methodology
  - Partners' roles plainly set out
  - Budget linked to objectives and methodology
  - Community-added value demonstrated
  - Concrete deliverables produced
  - Public health oriented