

Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010
on standards of quality and safety of human organs intended for transplantation

CHAPTER II

THE QUALITY AND SAFETY OF ORGANS

Article 4

Framework for quality and safety

1 Member States shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in this Directive.

2 The framework for quality and safety shall provide for the adoption and implementation of operating procedures for:

- a the verification of donor identity;
- b the verification of the details of the donor's or the donor's family's consent, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place;
- c the verification of the completion of the organ and donor characterisation in accordance with Article 7 and the Annex;
- d the procurement, preservation, packaging and labelling of organs in accordance with Articles 5, 6 and 8;
- e the transportation of organs in accordance with Article 8;
- f ensuring traceability, in accordance with Article 10, guaranteeing compliance with the Union and national provisions on the protection of personal data and confidentiality;
- g the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1);
- h the management of serious adverse events and reactions in accordance with Article 11(2).

The operating procedures referred to in points (f), (g) and (h) shall specify, inter alia, the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres.

3 In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.