# Standards of quality and safety of human organs intended for transplantation

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The Commission presents a report on the implementation of Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. The report is based on responses to a survey launched by the Commission in 2014, to which 29 countries replied (i.e. all Member States and Norway).

**Implementation of the Directive:** In general, the survey shows that the Member States have implemented EU legislation on bodies in an adequate way:

- all Member States have appointed **competent authorities at national level** and have established supervisory mechanisms to ensure standards of safety and quality of human organs;
- all countries reported having an **authorisation scheme** for organ procurement agencies;
- 26 Member States reported that **organ procurement teams** came from overseas on a regular or *ad hoc* basis. For 21 of these, these activities are carried out in a structured collaboration, most often with *Eurotransplant* (Germany, Austria, Belgium, Croatia, Hungary, Luxembourg, Netherlands and Slovenia) or *Scandiatransplant* (Denmark, Finland, Norway and Sweden) or within these organisations;
- **on-site checks, audits or inspections of procurement centres** were carried out in 22 countries. The frequency of such inspections varies from year to year every three to five years, but most frequently every two years (in seven countries);
- all Member States indicated that they applied at least one of these three approaches to assess the **competence of health personnel**: checking of qualifications at recruitment (23 countries), participation in regular training programmes (24 countries) or additional certification (11 countries);
- sixteen Member States and Norway have adopted a **system of tacit consent** at the national level for organ donation (consent is assumed unless declared otherwise before death). Seven Member States have established an **explicit consent system** (donors must expressly agree to organ donation), while four countries have a mixed system;
- most countries have a **register or records for living donors** (23 out of 29). The majority of countries (27 out of 29) monitor donors living after the donation. Sixteen countries offer a lifetime medical check-up, while seven have defined a limited duration for donor monitoring, ranging from one to thirty years;
- all Member States indicated that they have set up authorisation schemes for **transplant centres**.

**Additional efforts:** given the rather general nature of legal requirements in EU law, the structure of national organisations may be fragmented and vary considerably between countries. As a result, the report highlights the **importance of good coordination** within countries (by means of a strong and well-informed contact point) and between them.

The Commission also recommends that further efforts be made to **improve the monitoring carried out by the Member States**, both as regards recipients and living donors, as well as certain aspects of the quality and safety framework, for example procedures or authorisations.

Indeed, some countries have indicated that they do not have procedures in place to date, such as verifying the identity of the donor, verifying information on consent, or ensuring traceability.

Some of these efforts are already being deployed in the framework of work financed by the Commission. Upcoming implementation surveys and reports will be able to highlight the progress made by Member States.