

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

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The Commission presented a report on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells.

The report is based on the replies to questionnaires that the Commission sent to Member States in 2012 (verification of the completeness of transposition), 2013 (implementation survey) and 2014 (implementation of the voluntary and unpaid donation (VUD) principle) and follows up on the [Commission communication](#) published in January 2010 as well as the two reports on the application of the principle of VUD for tissues and cells issued in [2006](#) and [2011](#).

Overall application of the Directives: this Report reveals an overall **adequate application of the current quality and safety requirements** of the EU tissues and cells legislation in most of the responding EU Member States and EEA countries.

Significant progress has been made in many areas, also through the active support by Commission funded projects and other initiatives:

- since 2003, a number of projects have been funded under the multi-annual programmes for Union action in the field of health addressing the area of human tissue and cells for clinical application. These actions allowed for the **development of guidelines and manuals** in areas of common interest such as inspections and vigilance, included training courses for Member States Competent Authorities and their inspectors and **brought together professionals** in the tissue banking sector for the development of detailed technical guidance in line with the EU legal requirements;
- an additional support on training of tissue establishment personnel was given through EU-funded projects such as **European Quality System for Tissue Banking (EQSTB)** and **European Good Tissue Practices (EuroGTPs)**. Good practices developed by the EU-funded initiatives were also included by the Council of Europe in a dedicated Guide to the Quality and Safety of Tissues and Cells;
- as regards the **risk of transmission of communicable diseases** thorough tissues and cells, the collaboration with ECDC proved extremely valuable. In addition to providing regular updates during the bi-annual meeting of the tissue and cell expert sub-group on the epidemiological situation relevant to the tissue and cell sector, the development of risk assessments (e.g. for HTLV, malaria, dengue and chikungunya) and preparedness plans (e.g. for WNV outbreaks) provided a valuable contribution to policy and decision making in this sector at both national and EU level;
- the Commission developed - in close cooperation with Member States - a **Rapid Alert Platform for Tissues and Cells (RATC)** which facilitates web-based communications between Member States in case of alerts relating to human tissues or cells transferred across borders

However, the report points to some **gaps and difficulties** in relation to the application and enforcement of the existing provisions (e.g. definitions, requirements on the safety aspects regarding living donors, inspections framework), some of them owing to the different approaches taken by the Member States when transposing and implementing the current EU legislation and others due to the scientific and technologic developments since the adoption of the Directives.

Another important issue highlighted by some Member States was the **need to foster harmonisation of the inspection practices** in the Member States. Even though most of the Member States reported using the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments, there is no common agreement on the classification of shortcomings identified during inspections (e.g. classification of minor, major and critical deficiencies).

The Commission will **follow-up** with Member States to address situations where the legislation might not have been fully or correctly implemented.

Voluntary and unpaid donation (VUD) principle: as regards the implementation of the VUD principle, the Commission survey showed that Member States **overall comply with Article 12 of Directive 2004/23/EC** requiring them to take the necessary measures to encourage VUD. However, Member States interpretation of what is considered compensation and incentive vary.

Only 17 Member States reported having guiding principles regarding the possibility to compensate tissue and cell donors, but in many cases these principles were just a description of the practices allowed at national level. An important issue is how and by whom the decision concerning the value and form of compensations for tissue and cell donors is taken.

In conclusion, the gaps and difficulties identified suggest that a further in-depth evaluation might be useful. The Commission will consider the **need for an evaluation** in order to assess the relevance, effectiveness, efficiency, coherence and the EU added value of Directive 2004/23/EC and its implementing Directives.