Evaluation of the EU blood, tissue & cells legislation

On behalf of:
European Commission
DG Health and Food Safety (SANTE)
Unit B4/ Medical Products: Safety, Quality and Innovation

The Legislative Framework for Blood, Tissues and Cells

European Commission

Basic Acts

Directive 2004/23/EC

Scope: Tissues and cells intended for human applications

Directive 2002/98/EC

Scope: blood and blood components

Main Provisions:

- Designation of Competent Authorities;
- Authorisation and Inspection
- Traceability and incident notification systems;
- Principle of voluntary and unpaid donation;
- Consent and data protection
- Quality Management and Responsible persons

Technical Directives

4 Directives implementing technical requirements

4 Directives implementing technical requirements

Health

The original objectives of the intervention

The main objective of the Directives was to ensure a high level of human health protection in these sectors

Specific/operational Objectives:

- To define safety and quality requirements for all stages of the chain from donor to recipient;
- To ensure effective regulatory oversight of the blood, tissues and cells sectors;
- To achieve a degree of harmonisation of safety and quality at Union level which facilitates cross-border exchanges;
- To achieve Community (Now Union) sufficiency through the encouragement of voluntary and unpaid donation and a strong public sector.

2017-2018
Evaluation of the Legislation – the purpose

The purpose of the evaluation is to provide a comprehensive assessment of the directives, examining their **functioning across the EU**.

In particular the evaluation will assess the extent to which the Main Directives have **met their original objectives** and whether they remain fit for purpose assessing also the contribution of the Implementing Directives.

The evaluation is expected to provide a sound **evidence base** which will be used to consider the need for any changes to the legislation.

Roadmap

- Evaluation of Directives 2002/98/EC and 2004/23/EC and their technical directives

- Key elements

Roadmap consultation	Q1 2017 - completed
Public consultation	Q2-3 2017
External contract	Q2 2017 – Q2 2018
Draft final report	Q3 2018
Internal Commission consultation	Q4 2018
Final report publication	Q4 2018

Roadmap key sections

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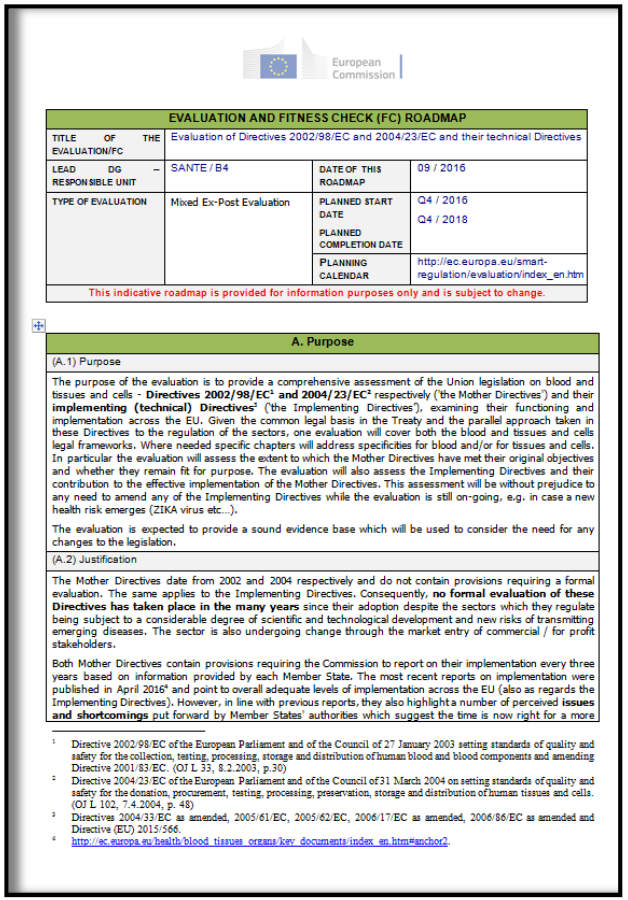
1. **The key drivers and original objectives of the intervention**
2. **The scope of the evaluation**
3. **Issues to be examined / assessment criteria/evaluation questions**
4. **Evidence base**
5. **Stakeholder consultation**
6. **External contract**



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EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Evaluation of Directives 2002/98/EC and 2004/23/EC and their technical Directives		
LEAD DG – RESPONSIBLE UNIT	SANTE / B4	DATE OF THIS ROADMAP	09 / 2016
TYPE OF EVALUATION	Mixed Ex-Post Evaluation	PLANNED START DATE PLANNED COMPLETION DATE	Q4 / 2016 Q4 / 2018
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm
This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose

(A.1) Purpose

The purpose of the evaluation is to provide a comprehensive assessment of the Union legislation on blood and tissues and cells - **Directives 2002/98/EC[1] and 2004/23/EC[2]** respectively ('the Mother Directives') and their **implementing (technical) Directives[3]** ('the Implementing Directives'), examining their functioning and implementation across the EU. Given the common legal basis in the Treaty and the parallel approach taken in these Directives to the regulation of the sectors, one evaluation will cover both the blood and tissues and cells legal frameworks. Where needed specific chapters will address specificities for blood and/or for tissues and cells. In particular the evaluation will assess the extent to which the Mother Directives have met their original objectives and whether they remain fit for purpose. The evaluation will also assess the Implementing Directives and their contribution to the effective implementation of the Mother Directives. This assessment will be without prejudice to any need to amend any of the Implementing Directives while the evaluation is still on-going, e.g. in case a new health risk emerges (ZIKA virus etc...).

The evaluation is expected to provide a sound evidence base which will be used to consider the need for any changes to the legislation.

(A.2) Justification

The Mother Directives date from 2002 and 2004 respectively and do not contain provisions requiring a formal evaluation. The same applies to the Implementing Directives. Consequently, **no formal evaluation of these Directives has taken place in the many years** since their adoption despite the sectors which they regulate being subject to a considerable degree of scientific and technological development and new risks of transmitting emerging diseases. The sector is also undergoing change through the market entry of commercial / for profit stakeholders.

Both Mother Directives contain provisions requiring the Commission to report on their implementation every three years based on information provided by each Member State. The most recent reports on implementation were published in April 2016[4] and point to overall adequate levels of implementation across the EU (also as regards the Implementing Directives). However, in line with previous reports, they also highlight a number of perceived **issues and shortcomings** put forward by Member States' authorities which suggest the time is now right for a more

[1] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. (OJ L 33, 8.2.2003, p.30)

[2] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. (OJ L 102, 7.4.2004, p. 48)

[3] Directives 2004/33/EC as amended, 2005/61/EC, 2005/62/EC, 2006/17/EC as amended, 2006/86/EC as amended and Directive (EU) 2015/566.

[4] http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor2.

http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm

Specific Assessment Criteria - I

1. Relevance
2. Effectiveness
3. Efficiency
4. Coherence
5. EU Added Value

Specific Assessment Criteria - II

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1. Relevance → Still up to date? (science, technology, epidemiology, commercialisation, new actors)?
2. Effectiveness → Increasing safety and quality? Negative side-effects or barriers?
3. Efficiency → Benefits and costs for establishments, clinicians, authorities
4. Coherence → Consistent with other legislation, any gaps and overlaps? With regulatory frameworks in third countries?
5. EU Added Value → Could the results be achieved better at national or global level?

Health

Evidence Base

1. Evidence from monitoring
2. Previous implementation reports
3. Issues arising from implementation (complaints, infringement procedures, interpretation/scope questions)
4. Open online **Stakeholder Consultation** – public and targeted – launch in May 2017 – 12 weeks
5. External contract for a study to support the evaluation (review of evidence and filling of gaps) – call completed – contractor to be appointed May 2017

Consultation activities - 2

- **Stakeholder Conference** to validate findings to date and to plug remaining information gaps
  - September 20th 2017
  - Brussels
  - Room capacity: 250
  - 'First-come-first-served' basis
  - Registration not yet open

Follow developments here…

https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

Evaluation of the EU blood and tissues and cells legislation

The Commission is currently carrying out an evaluation of the EU blood and tissues and cells legislation. This is the first formal evaluation of this legislation since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells). This evaluation is in line with the Commission's Better Regulation Package and aims to assess whether the legislation has achieved its original objectives and whether it is still fit for purpose. The evaluation will consist of several steps starting with a Roadmap and including a study by an external contractor and extensive consultation of stakeholders. The final evaluation report is expected to be published by the end of 2018.

Roadmap

The Commission has published a Roadmap on the evaluation of the EU blood and tissues and cells legislation. This Roadmap is a first step in the evaluation process and outlines the purpose, content and scope of the evaluation. Stakeholders are invited to submit comments on the Roadmap until 15 February 2017 via this link

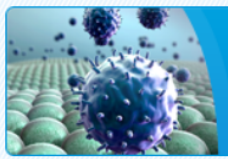
To view the feedback received, please click here.

External Contract

An external contractor will be commissioned to prepare a study that supports the evaluation. This study will be based on the documents and reports provided, the relevant published literature, documents developed by other bodies (like the European Parliament, the Council of Europe or the World Health Organisations) and possibly the results of the public and targeted consultation. Where information gaps remain, the contractor will be expected to find additional sources of information.

A request for services has been sent to the 4 eligible contractants who have signed a framework contract with DG SANTE on evaluation and impact assessment in public health.

State of Health in the EU >



e-newsletter Thu, 04/27/2017

European Solidarity Corps: Youth in Action for Health

Latest updates

Annual summary of activity - 2016 RAB (Rapid Alert


Thank you