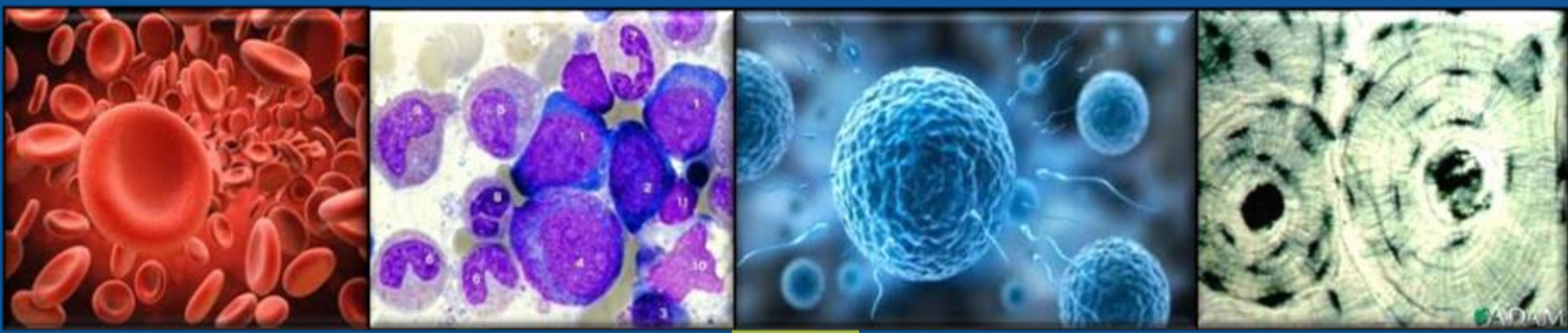


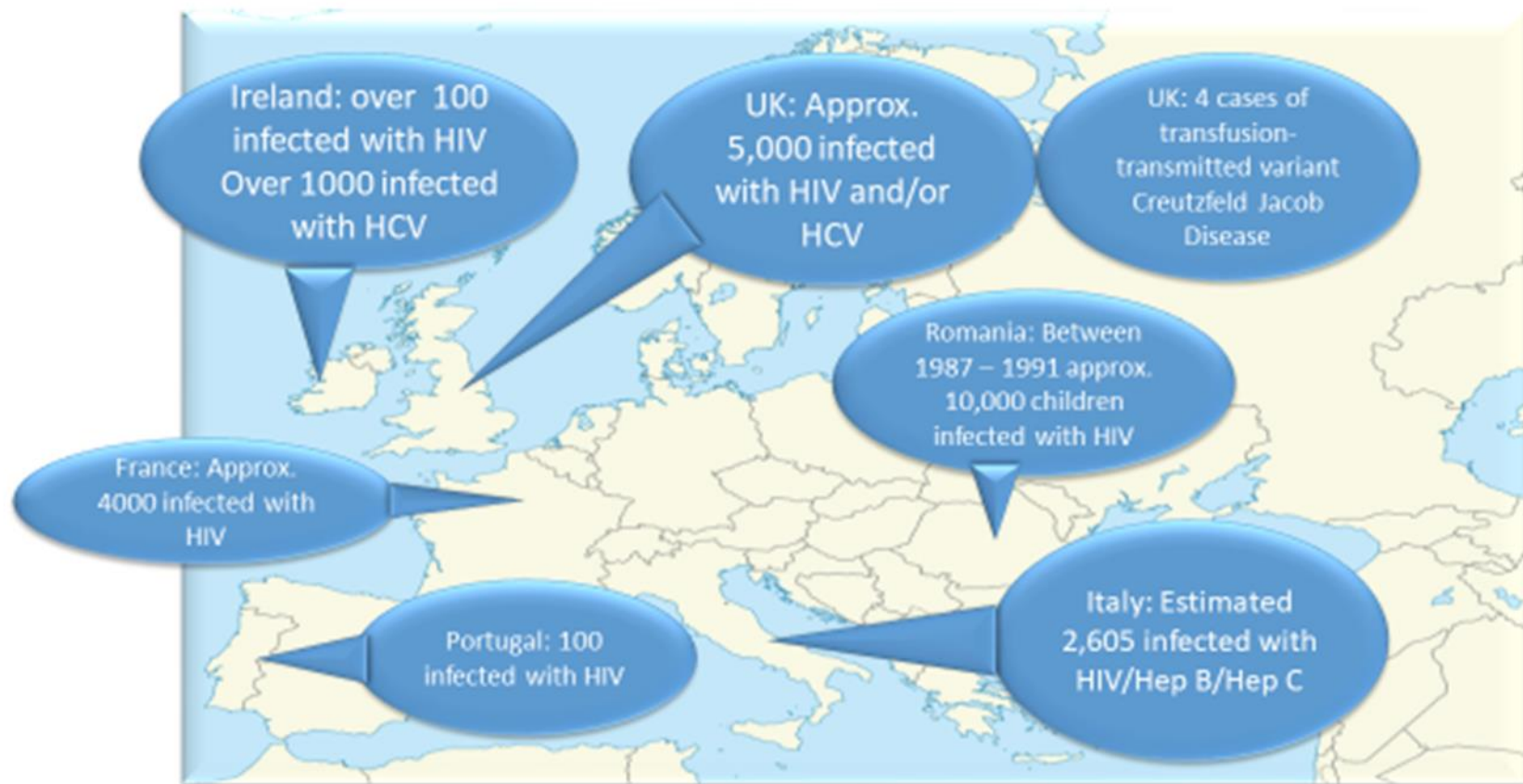
REVISION OF THE EU LEGISLATION ON BLOOD, TISSUES AND CELLS

16/3/2022

S. Van der Spiegel, MD, MBA
Substances of Human Origin
DG SANTE, European Commission

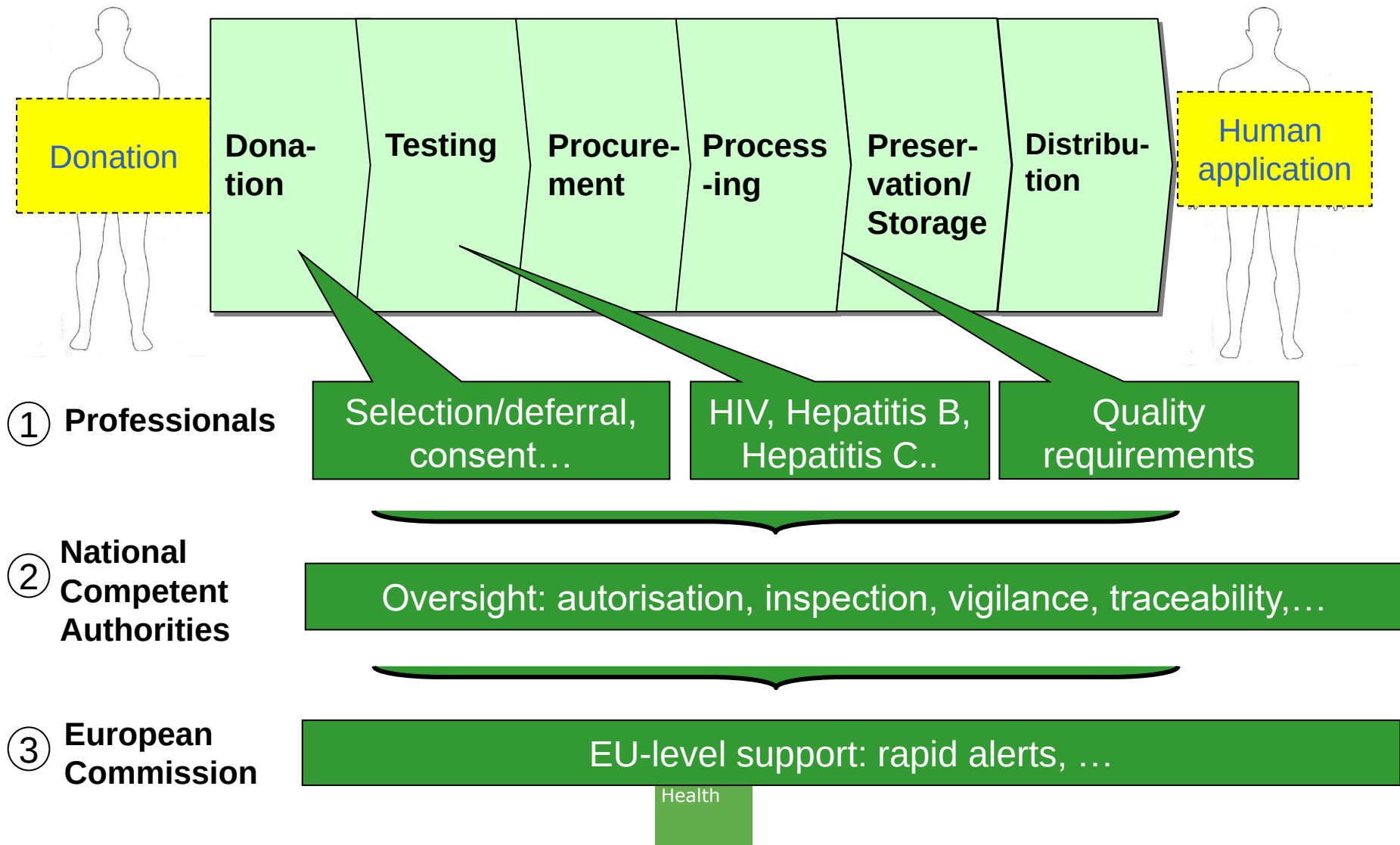


Why does the EU legislate SoHO?



Infectious disease transmissions of HIV and hepatitis C by blood transfusion and plasma derived medicinal products in the 80s and 90s

EU legal frameworks



Conclusions of the Evaluation - 2019

The legislation had increased the safety and quality of blood, tissues and cells across the EU. However, 5 gaps/shortcomings were identified:



1. Patients are not fully protected from avoidable risks

EU safety and quality requirements are incomplete and have failed to remain up to date with frequently changing scientific and epidemiological developments. The outdated provisions are technical in nature



2. Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos

Donor adverse reactions (including serious ones) are not systematically reported and the requirements for testing egg and sperm donors for genetic conditions are limited.



3. Divergent approaches to oversight cause unequal levels of safety and quality and barriers to the exchange of BTC across the EU

Lack of general principles, provisions for verification of effective implementation of inspection, authorisation, vigilance.



4. BTC legislation lags behind innovation

Limited clinical data on safety and efficacy of new ways of processing donations. Difficulties in defining the borderlines for novel BTC with other regulatory frameworks

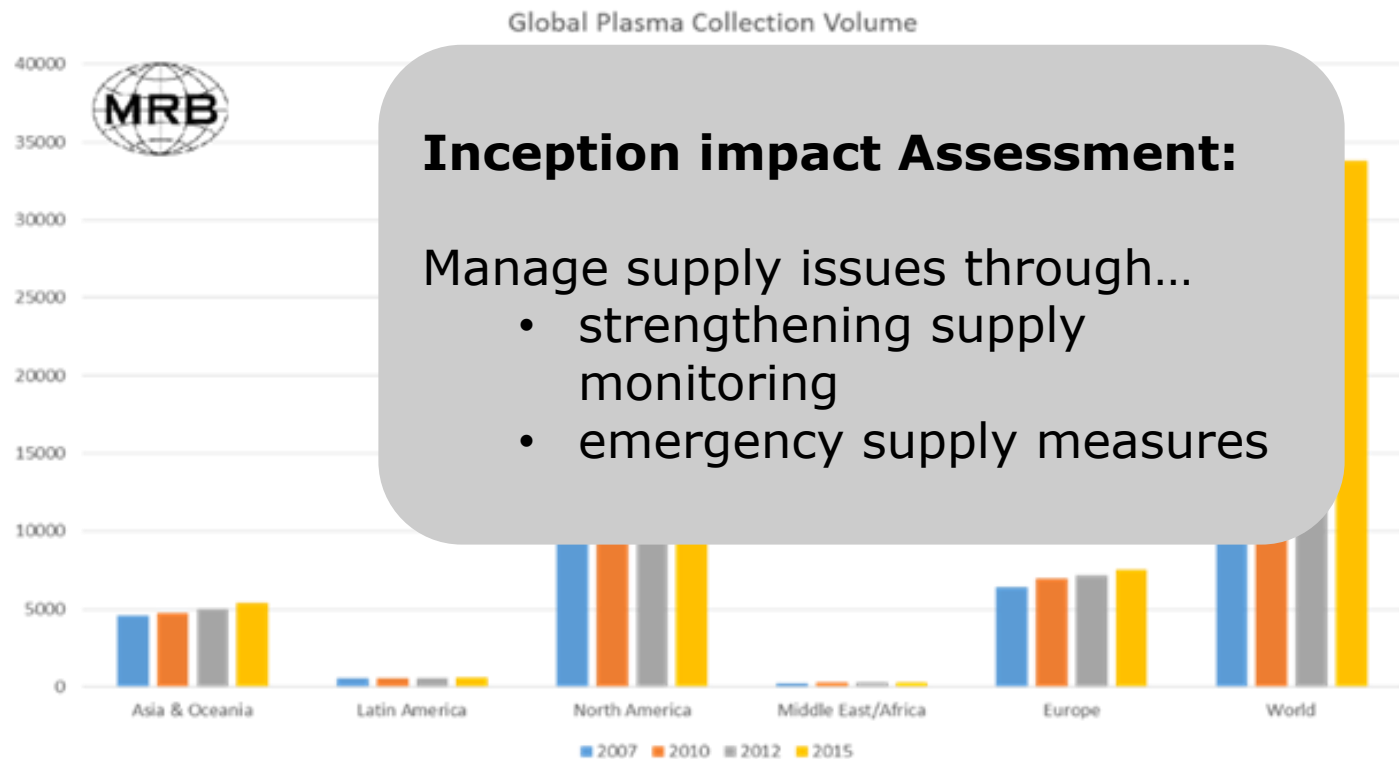


5. EU vulnerable to interruptions in supply of some BTC

High dependence on plasma import. Lack of supply monitoring for crisis management.

- Reliance on US for sufficient plasma for the manufacture of plasma-derived medicinal products

Global plasma supply is out of balance, dependent on one country/region – should we be concerned?





- European Commission
 - Donor protection and vigilance
 - Support collection (communication, awareness)
 - Support strategic independence (equitable access, access, free market)
 - **Optimize legal framework** (PMF, donation, GPG)
- EDQM (Council of Europe)
 - Data collection and reporting
 - Evidence based guidance
 - Networking and conferences (optimal use)
 - Awareness building, campaigns
- Member States/National Competent Authorities
 - National targets and support for collection
 - Monitoring and reporting on plasma and PDMP
 - Contingency plans and appropriate use
 - Donor vigilance



- Manufacturers
 - Collaboration on optimal use
 - Data and knowledge sharing (SARE, best practice, decision support)
- Blood Establishments
 - Increase collection (awareness, collect more and better)
 - Donor safety and recognition
 - Collaborations (learnings, benchmark)
- Patient Associations
 - Collaboration on optimal use
 - Data and knowledge-sharing (contingency, databases)
- Donor Associations
 - Awareness building
 - Donor-recruitment best practices
- Professional Societies
 - Optimal use

Policy options explored for the legal revision

Policy option 1:

Strengthened quality & safety requirements defined by blood and tissue establishments with strengthened national inspection, EU audits of national control systems (self-regulation)

Policy option 2:

EU-level safety and quality requirements defined by European Expert Bodies (ECDC, EDQM,...) and strengthened national inspection, EU audits of national control systems, and MS joint inspections (co-regulation)

Policy option 3:

EU-level safety and quality requirements laid down in the BTC legislation with improved national inspection systems, and MS joint inspections (horizontal regulation)



Measures common in all 3 options

All policy options:

- Safety and quality **PRINCIPLES** to be defined in EU legislation
- Rules to protect recipients, **DONORS** and **CHILDREN** born from donated gametes/embryos

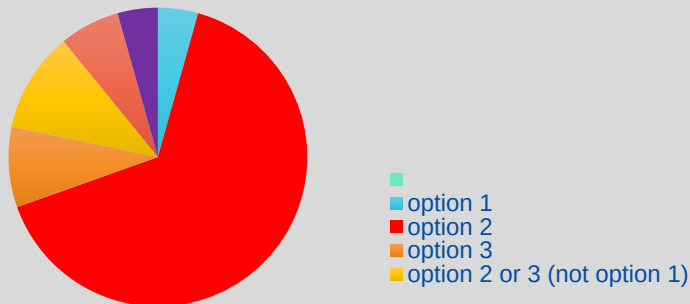
All policy options include clarification/extension of scope to include currently unregulated SoHO (FMT and HM)

- **Strengthen oversight** (gap 3) through:
 - stronger principles in EU legislation,
 - combined with mutual peer audits, training and guidance
- **Facilitate innovation** (gap 4) by:
 - clarifying the BTC scope and provide advice to Member States on scope
 - risk-based authorization of novel processes and use, with proportionate collection and assessment of outcome data
- **Manage supply issues** (gap 5) through:
 - strengthening supply monitoring
 - emergency supply measures

Policy Option 2 is preferred

- In IIA, ~half of the stakeholders who expressed a preference for a policy option, **option 2 is the preferred one**

Preferred policy option(s)



Key discussion points (workshops//OPC)

- Allow strong engagement professionals when drafting
- Member States want to keep a voice/say
- Concern fit to EDQM geography
- Transparent drafting/adoption mechanism EDQM
- Only for technical rules, not organisational (e.g., allocation, consent)
- Some MS have own/more stringent requirements (e.g., DE)

Online Public Consultation – Summary Report Published



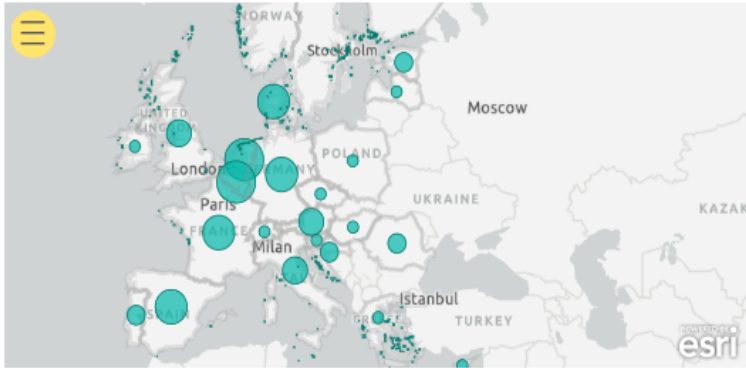
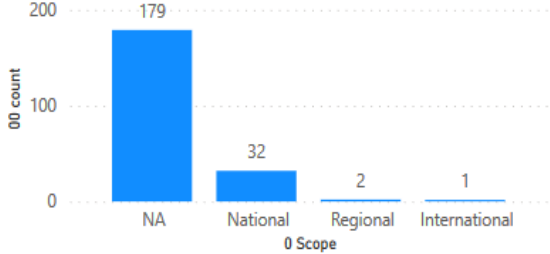
EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

 Ref. Ares(2021)5131819 - 16/08/2021

Health systems, medical products and innovation
Medical Products: quality, safety, innovation

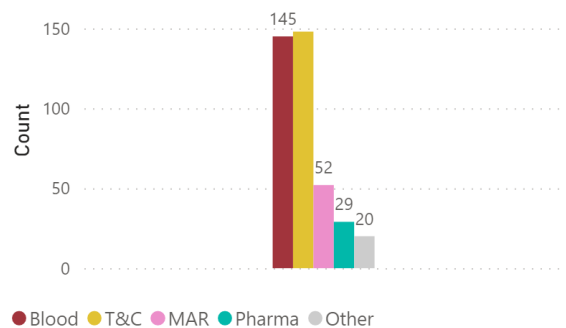
Disclaimer: "This document should be regarded solely as a summary of the contributions made by stakeholders to the Public Consultation for the Revision of the Union legislation on blood, tissues and cells (BTC). It cannot in any circumstances be regarded as the official position of the Commission or its services. Responses to the consultation activities cannot be considered as a representative sample of the views of the EU population."

Revision of the Union legislation on blood, tissues and cells
Public consultation factual summary report

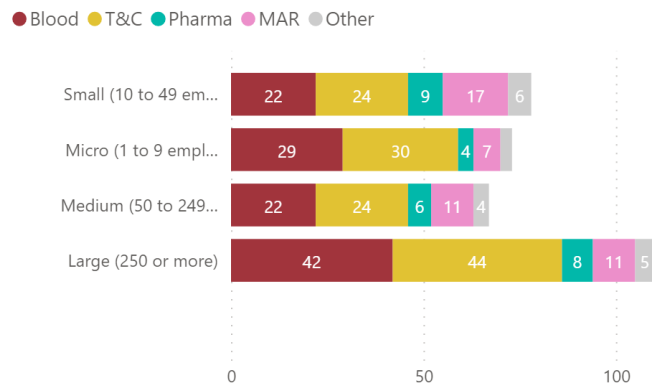
	PUBLIC CONSULTATION	TARGETED CONSULTATION
TOTAL NUMBER of RESPONSES	Responses for Open Public consultation 214	Responses for Targeted consultation 160
GEOGRAPHICAL coverage	Responses by Countries 	Responses by Countries 
SCOPE of organisation	Organisation by scope 	Organisation by scope 



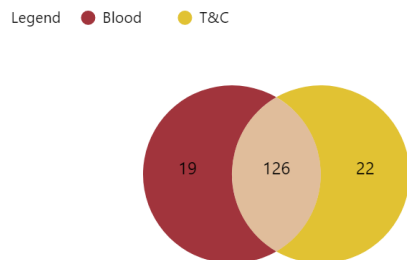
Sub-sector Responses



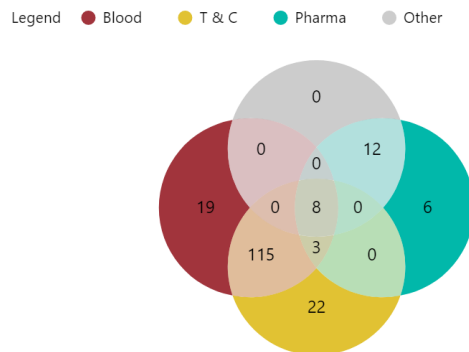
Size of organisations by field



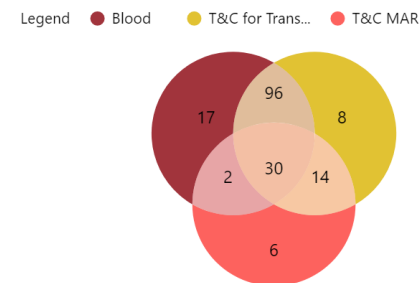
Overlap of blood and T&C sector



Overlap of all fields

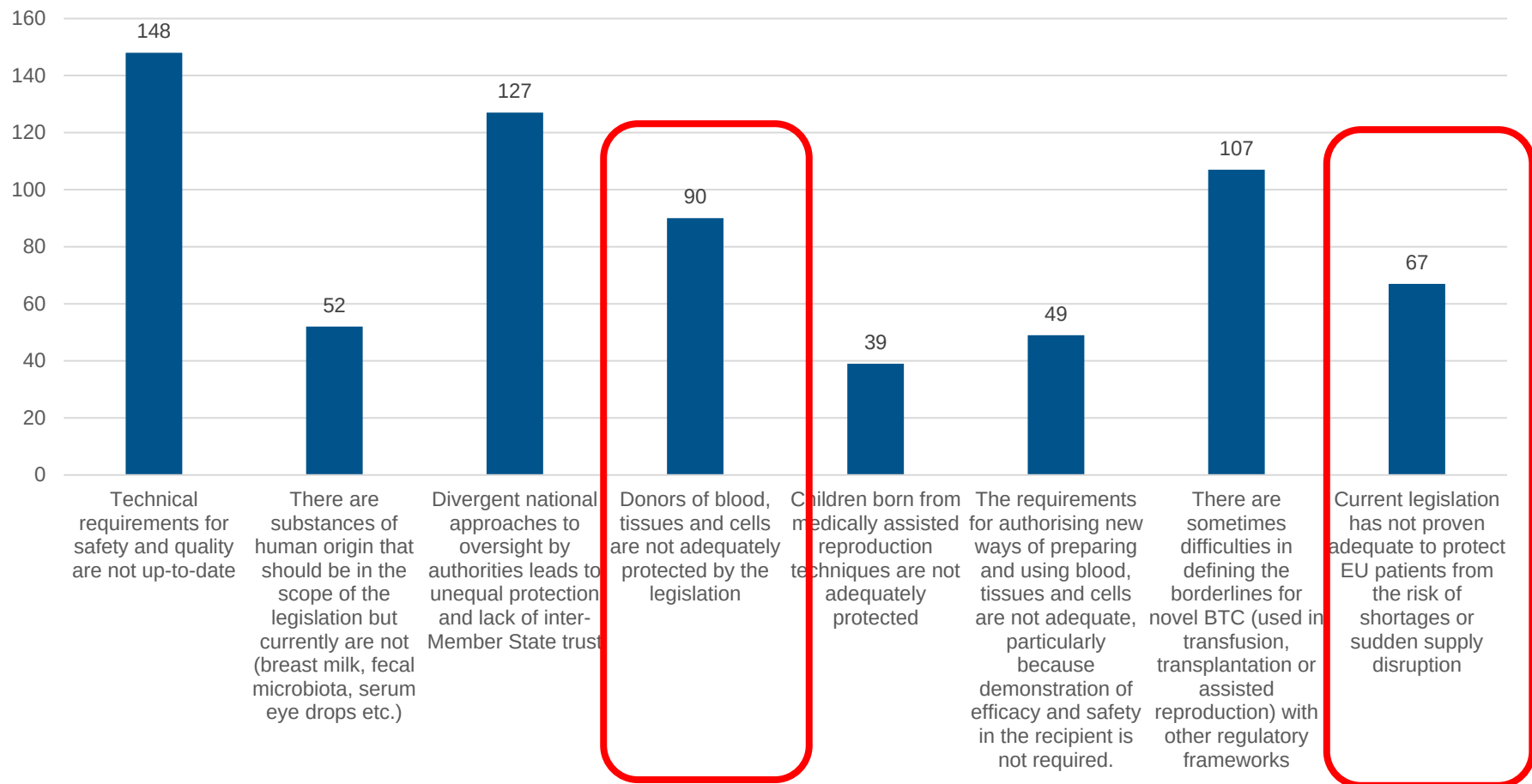


Organisations working in both blood and T&C sector



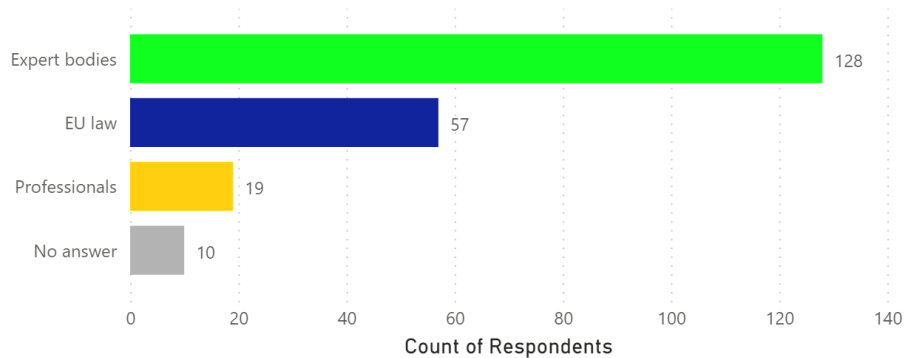
OPC2

Select up to 4 problems to which you would give highest priority:

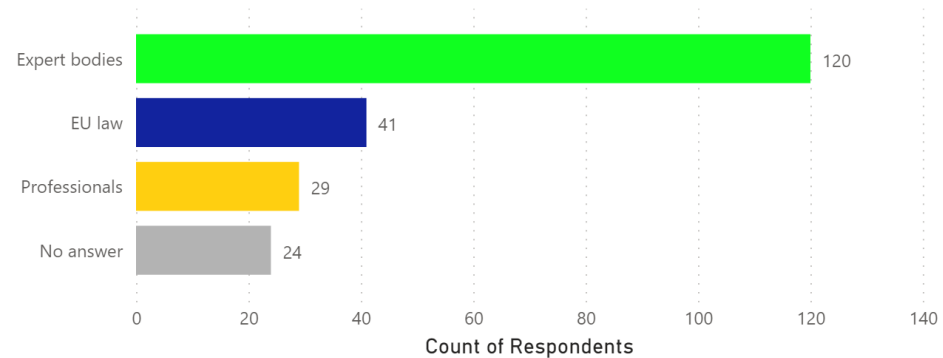


OPCS **Who should set out these technical rules to effectively achieve up-to-date safety and quality rules, based on good science?**

Rules on donor suitability and testing



Rules on donation frequency and donor monitoring.

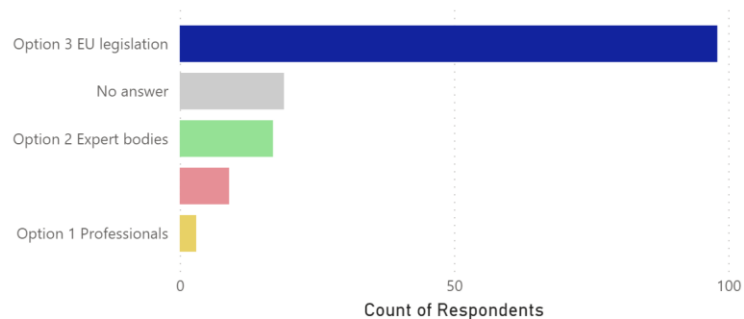


DAFT – detailed analysis not yet carried out

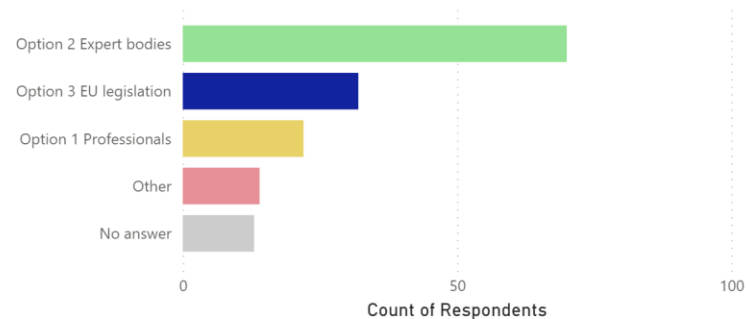
Which of the proposed policy options is most appropriate to define and update each of the following technical rules?

TPC15

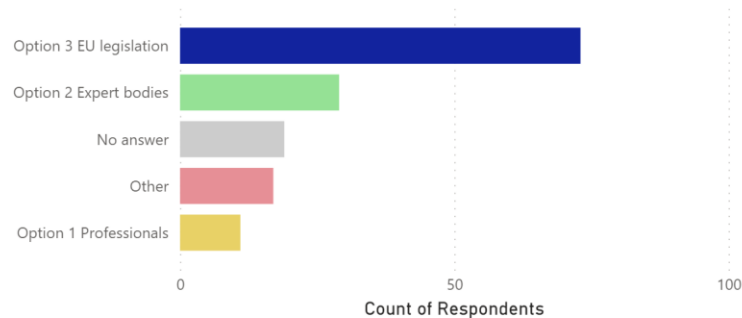
Donor reimbursement/compensation rules



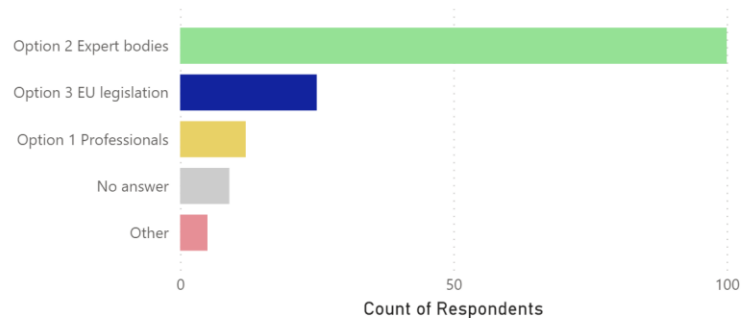
Donor age limit rules



Donor/donor family consent rules

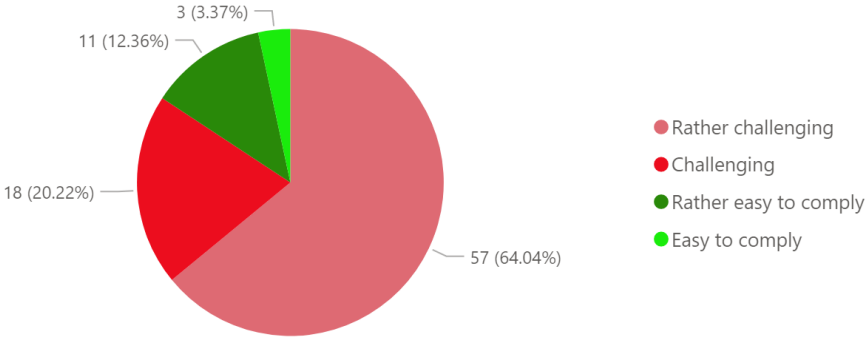


Rules regarding donor medical and behavioural history screening

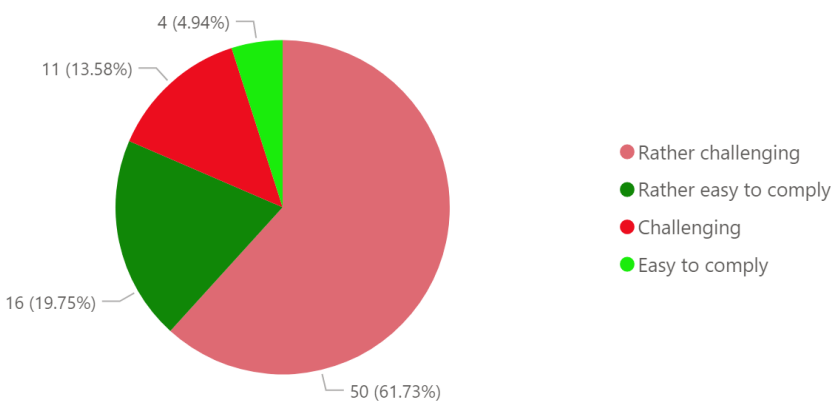


Given your experience, how easy do you consider it to comply with requirements across the frameworks?

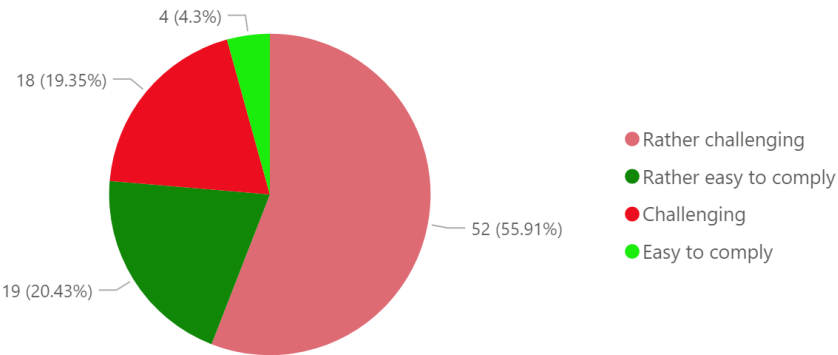
Inspection and authorisation procedures when more than one framework applies



Vigilance reporting when more than one framework applies

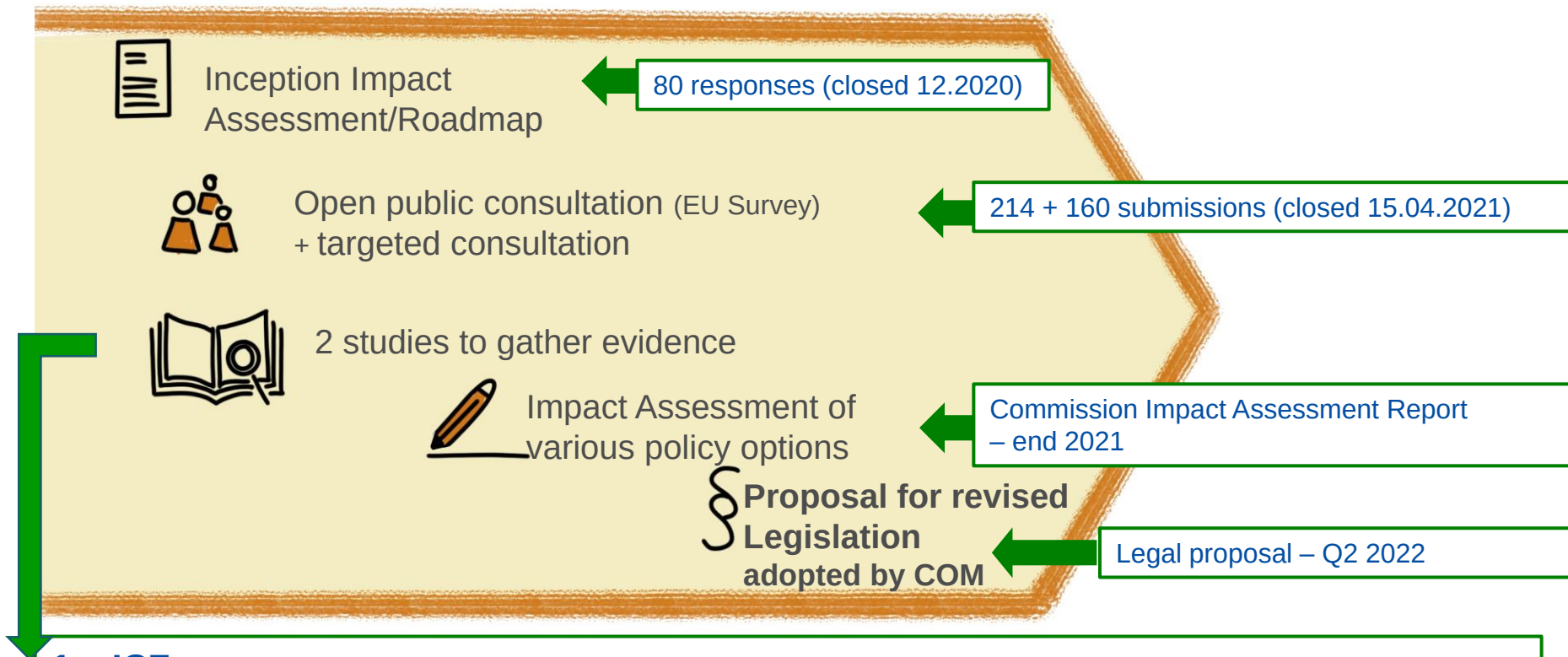


Meeting all technical provisions when more than one framework applies



BTC Revision – Impact Assessment and Legal Proposal

https://ec.europa.eu/health/blood_tissues_organ/policy/revision_en



1. ICF

Evidence gathering to support the Impact Assessment – Workshops, survey and expert interviews; borderline case studies, cost:benefit analysis

2. Deloitte

SoHO – X study - Exploring the options for the future digital system needs of the sector to support the implementation of the new legislation - Workshops in September – study continues into 2022

Revision of the EU legislation on blood, tissues and cells

In October 2020, the Commission adopted its [Work Programme for 2021](#). The [REFIT Annex](#) (#37 p.15)   to the Work Programme includes the revision of

- Directive 2002/98/EC on safety and quality of human blood and blood components, and
- Directive 2004/23/EC on safety and quality of human tissues and cells

and their implementing acts.

This revision comes after an [evaluation](#) of the legislation, published in October 2019, confirming that the legislation had improved safety and quality of blood, tissues and cells used for transfusion, transplantation or medically assisted reproduction. The evaluation also highlighted a number of gaps and short-comings which will be addressed to ensure the framework is up-to-date, fit for purpose and future-proof.

The initiative aims at

- updating the legislation in the direction of a more flexible alignment with scientific and technological developments
- tackling the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic
- focusing on the increasing commercialisation and globalisation of the sector
- removing from legislation many technical provisions, which will allow a faster update of standards
- possibly merging the basic acts into a single instrument.

The revision is planned to be adopted in the last quarter of 2021. The legal basis is provided by Article 168(4)(a) of the Treaty on the Functioning of the European Union.

In line with the Commission's [Better Regulation Guidelines](#), the legislative proposal will be preceded by an Impact Assessment, including the following steps:

Inception Impact Assessment

The Commission published a [roadmap](#) describing the scope of the initiative, defining the problems and outlining possible policy options to be considered in the Impact Assessment.

Stakeholders, authorities and citizens were invited to submit comment on the roadmap up to 14 December 2020. The feedback period is now closed and, at the same link, the 82 submissions received are published. The feedback received will be taken into account as the Impact Assessment proceeds.

Stakeholder Consultation

EUROPE'S BEATING CANCER PLAN
LET'S STRIVE FOR MORE

#EUCancerPlan

**CORONAVIRUS
COVID-19**

e-newsletter

Mon, 05/31/2021

a healthy body: promoting mental health 

Latest updates

Meeting minutes - Stakeholder Workshop with Blood Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718) - 4 May 2021  
Released 11 August 2021

Meeting minutes - Workshop with Stakeholders and Tissue and Cell Competent Authorities Substances of Human Origin Expert Group (CASoHO E01718) - 5 May 2021  
Released 11 August 2021



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