IVD-R

What is it?

Why does it matter to you?

What is it?

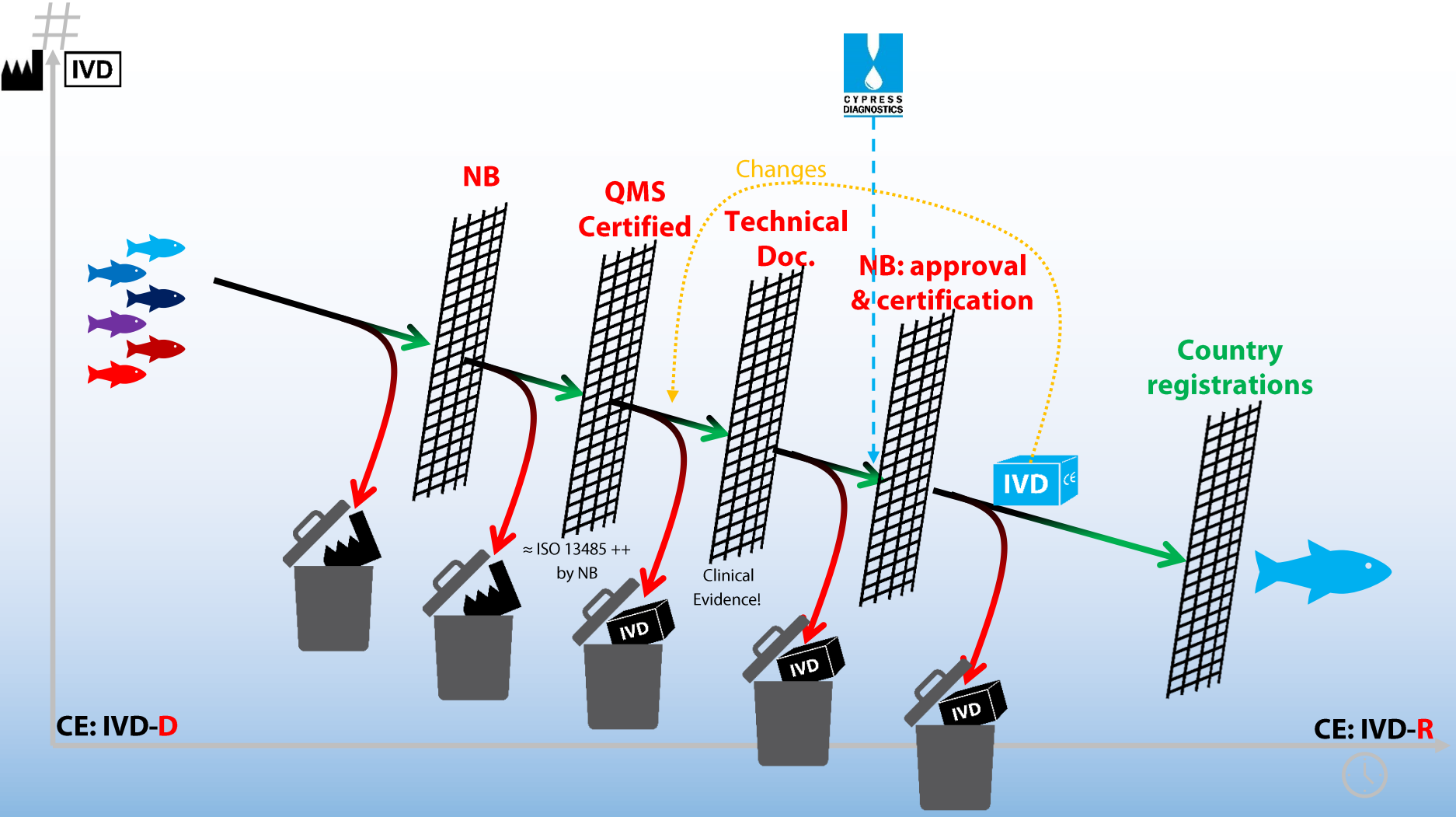
- Law
- Requirements for IVD's
- For obtaining CE marking
- For use in EU
- For EU manufacturers to obtain a Free Sales Certificate
- Replaces IVD-D

IVD-R

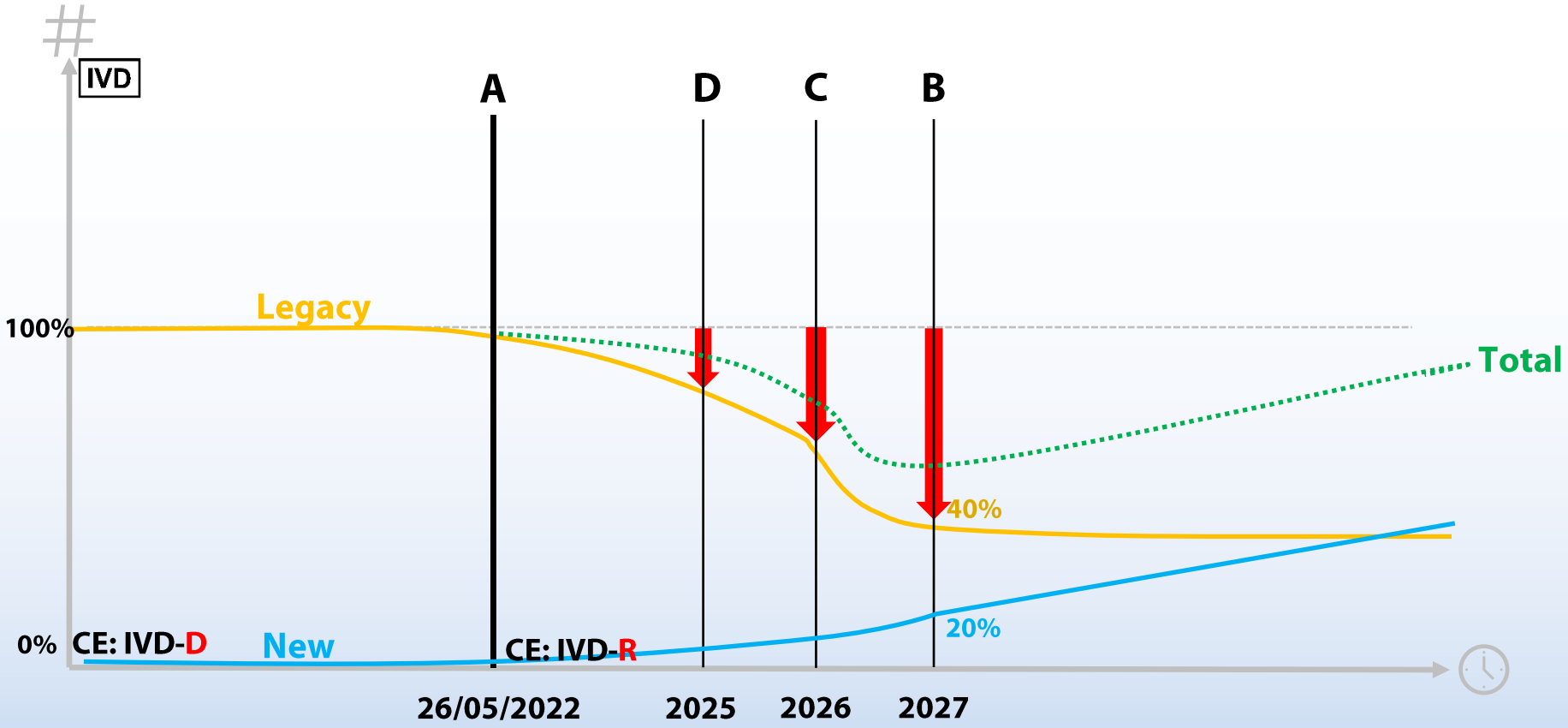
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- https://eur-lex.europa.eu/eli/reg/2017/746

What will happen?

For cat. B, C & D (85% of IVD's)



IVD-R: impact on IVD's



Less innovation
Less diversity
Less products

Are you safe?

Important questions

1. Notified Body?
2. Certified QMS?
3. Product selection made?
4. Technical Doc. Submission?
5. Product approval & certification?

Cypress Diagnostics

- ✓ Yes, Dekra
- ✓ Yes, certified and covering applicable IVD-R legislation
- ✓ Yes, process finished
- ✓ Yes, done in November 2022
- ✓ Glucose HBL04 expected by end 2022

What about your other partners?

IVD-R impact on distributors (IVDR, article 14)

Distributor responsibilities

- Safeguard of product integrity and storage
- Traceability
- Audit participation
- Legal after-sales service
- Reporting and NC's
- Execution of FSN
- Participation in PMS

Impact on distributors

- Cost increase
- Products & manufacturers discontinuation
- Slower innovation
- More paperwork
- Regulatory affairs department