



# NB Survey on certifications and applications for Directives and Regulations on medical devices and IVDs

DG SANTE

*27 May 2021*

# Medical devices notified bodies – replies received May\* 2021

- MDD/AIMDD: 48 replies received – out of 52 notified bodies designated under the MDD, 10 of which are also designated under the AIMDD (all notified bodies designated under the AIMDD replied)
- MDR: 20 replies received – out of 20 notified bodies designated under the MDR

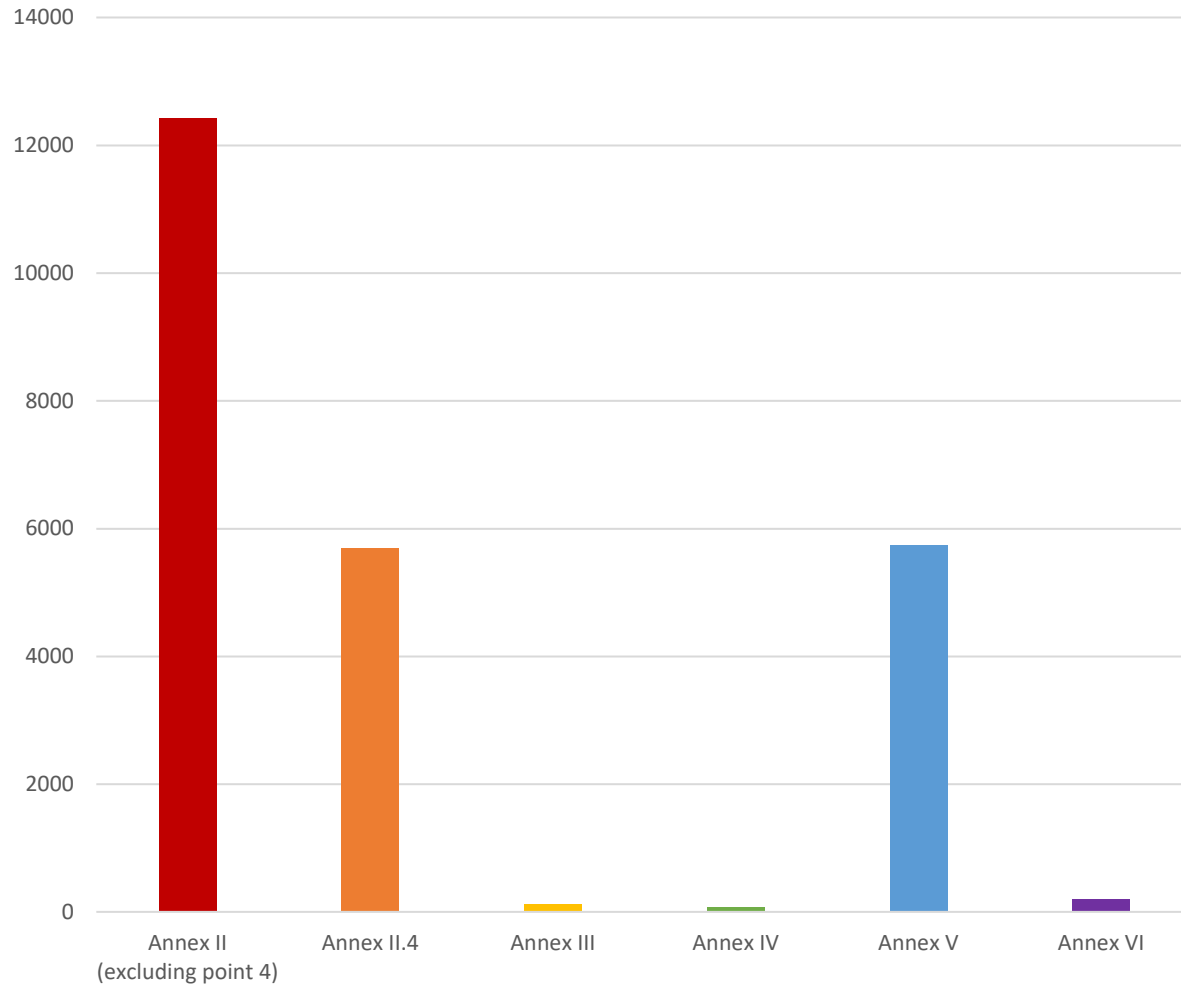
\*Actual replies received from 23/04 to 26/05

# AIMDD/MDD data request

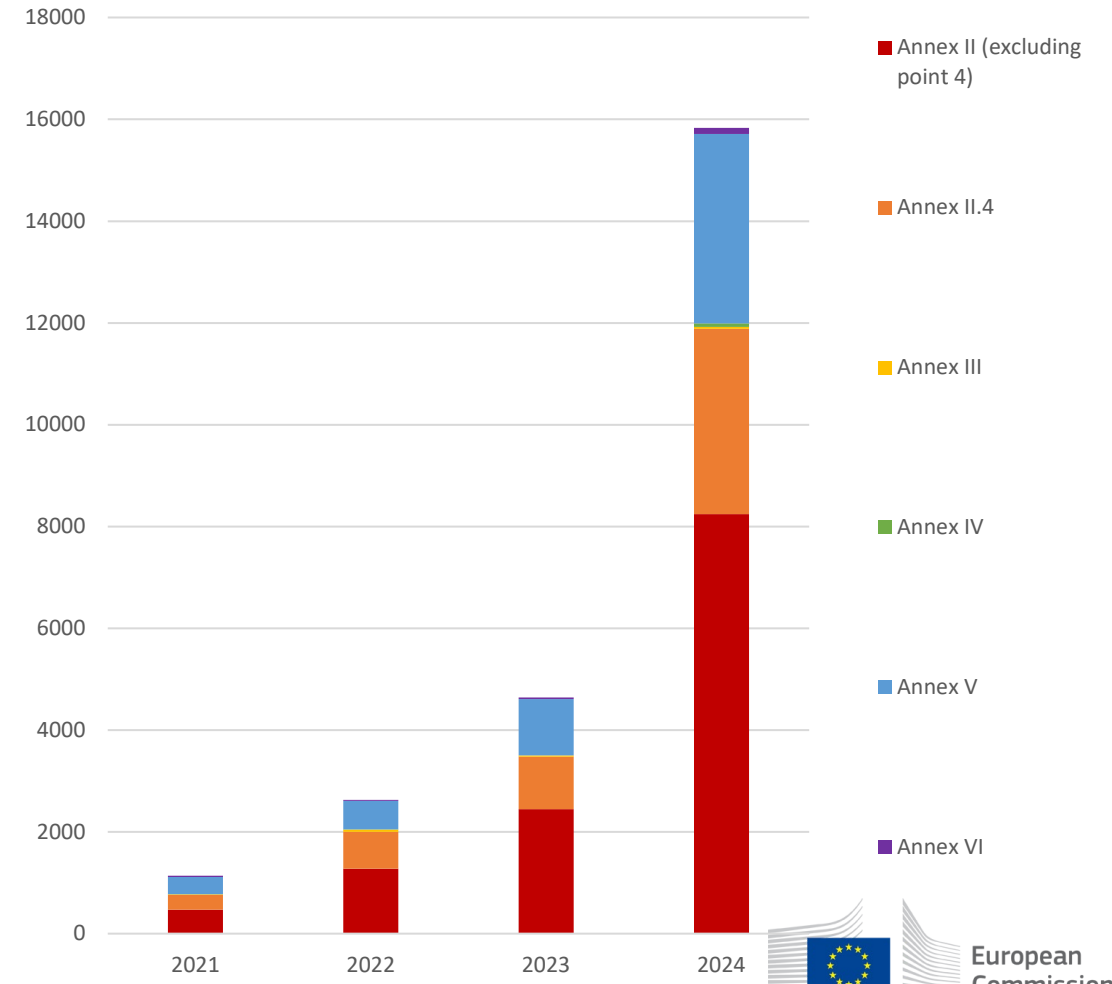
	CERTIFICATION UNDER AIMDD/MDD					
	Total Number of valid certificates under AIMDD/MDD by annex	Number of certificates, by year of expiry and by annex				
		2020	2021	2022	2023	2024
Annex 2/II (excluding point 4)						
Annex 2. 4/II.4						
Annex 3/III						
Annex 4/IV		N.A	N.A	N.A	N.A	N.A.
Annex 5/V						
Annex VI						

# AIMDD/MDD valid certificates (1/4)

Breakdown by Annex

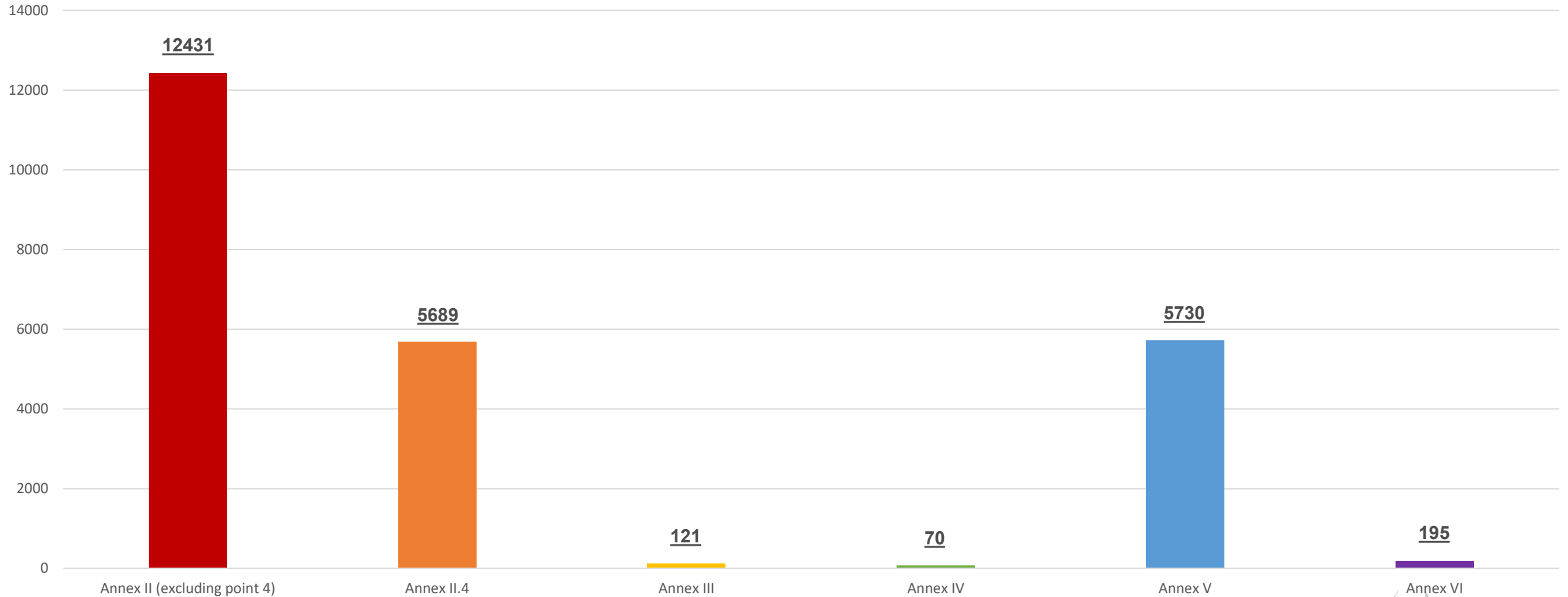


Breakdown by year of expiry



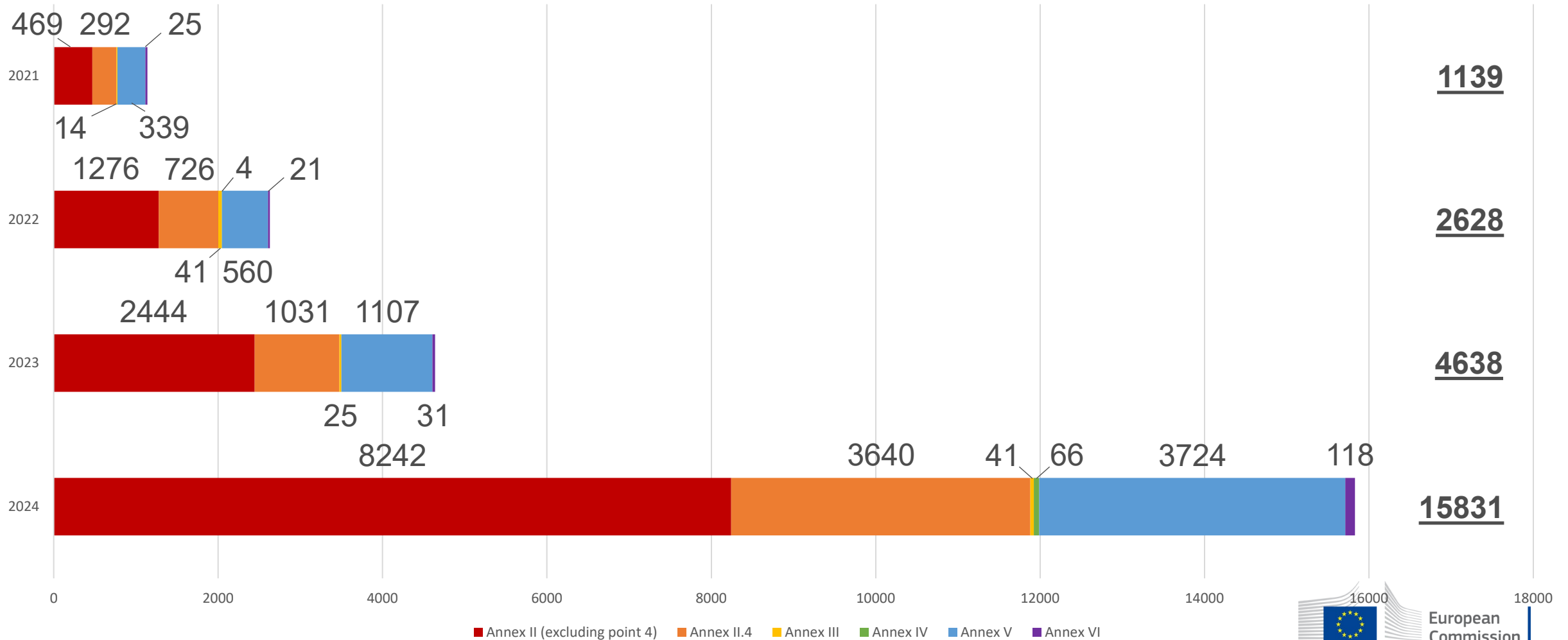
# AIMDD/MDD valid certificates (2/4)

Breakdown by Annex



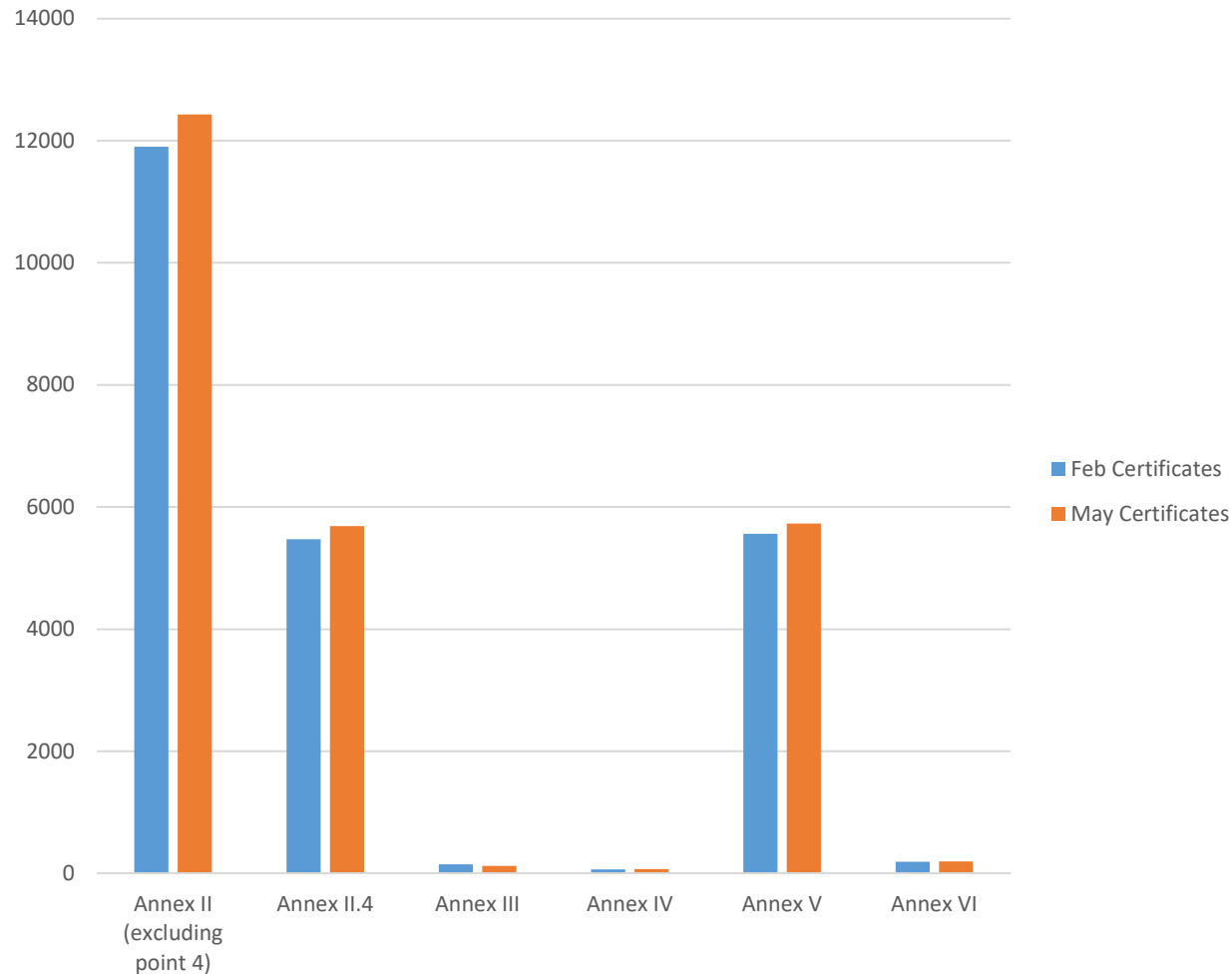
# AIMDD/MDD valid certificates (3/4)

Breakdown by year of expiry

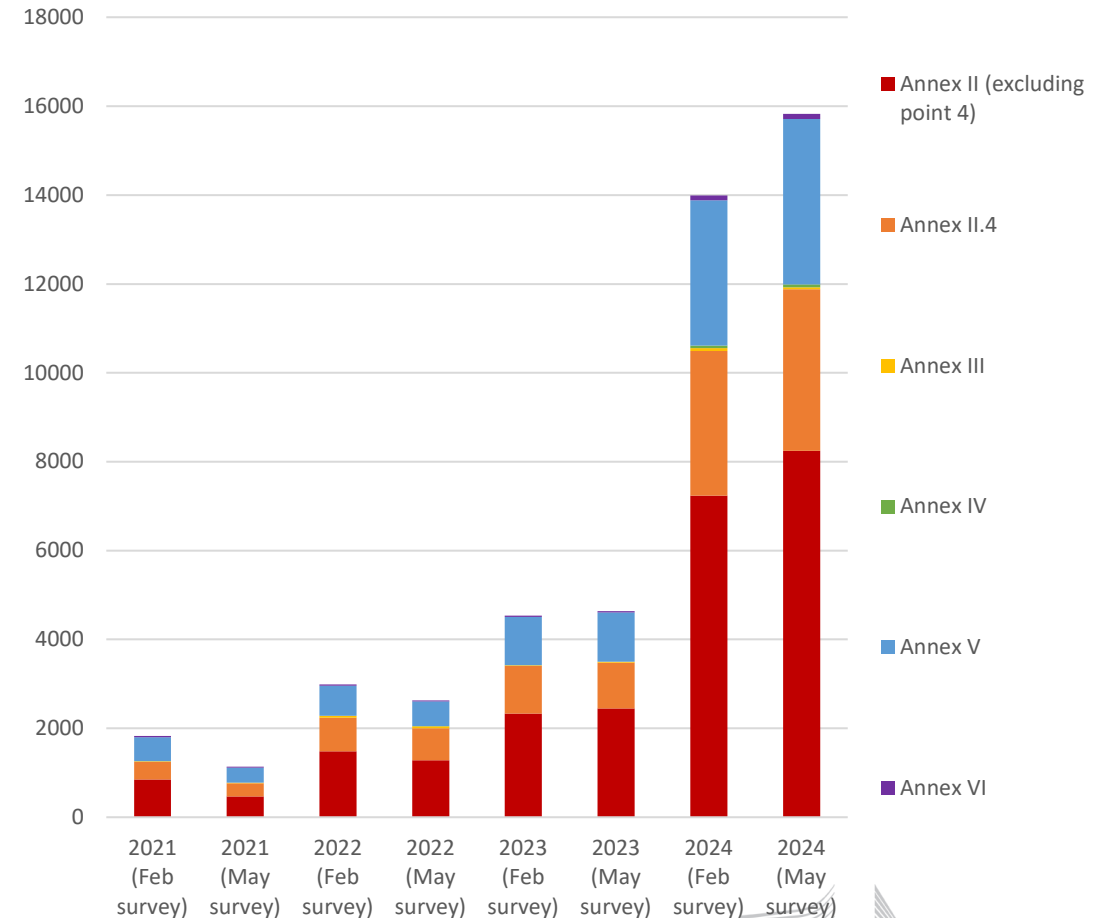


# AIMDD/MDD valid certificates – comparison Feb 21 and in May 21 (4/4)

Breakdown by Annex



Breakdown by year of expiry



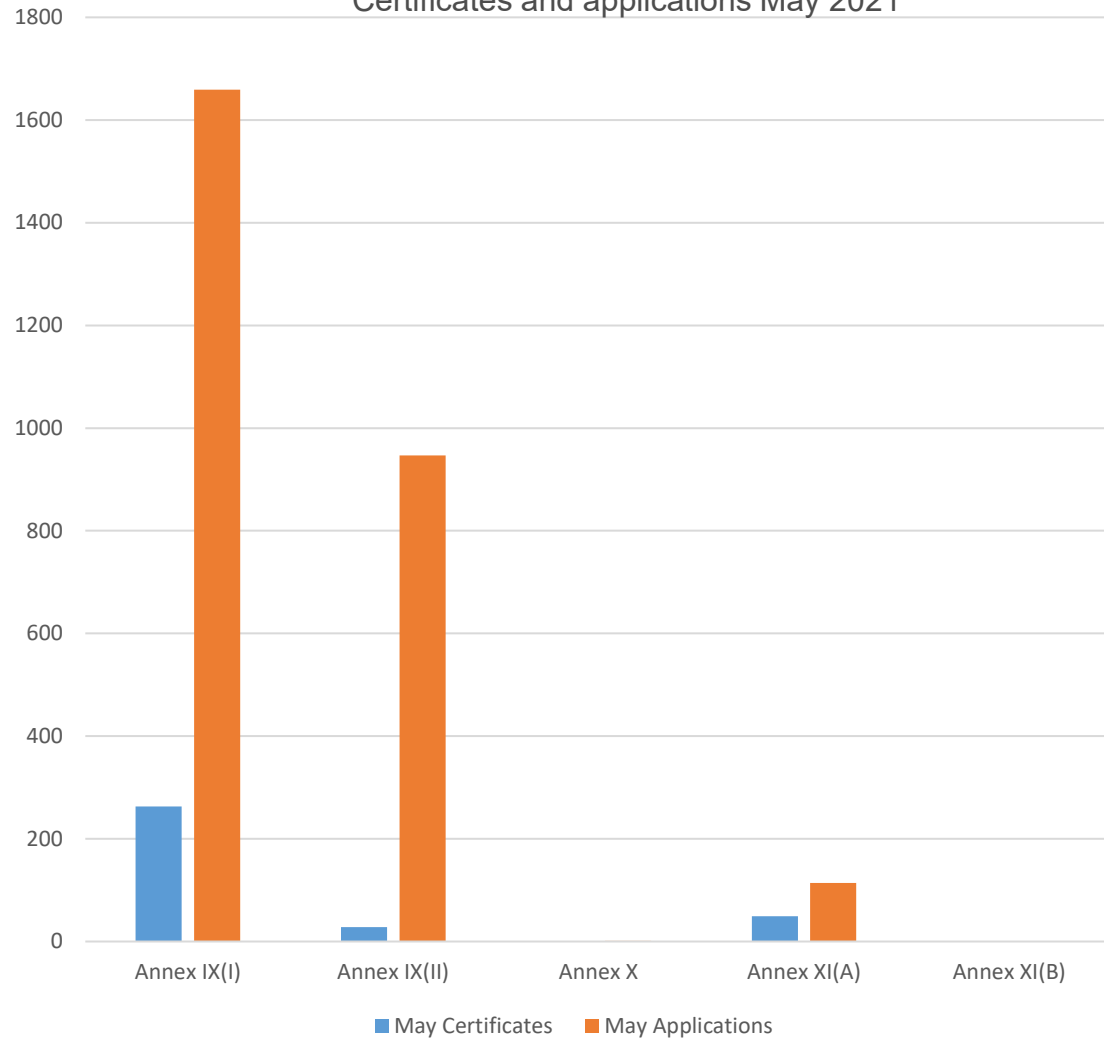
# MDR - data request

	<i>Number of certificates issued under the MDR</i>	<i>Number of application filed under the MDR</i>
<i>Annex IX(I)</i>		
<i>Annex IX(I)</i>		
<i>Annex X</i>		
<i>Annex XI(A)</i>		
<i>Annex XI(B)</i>		

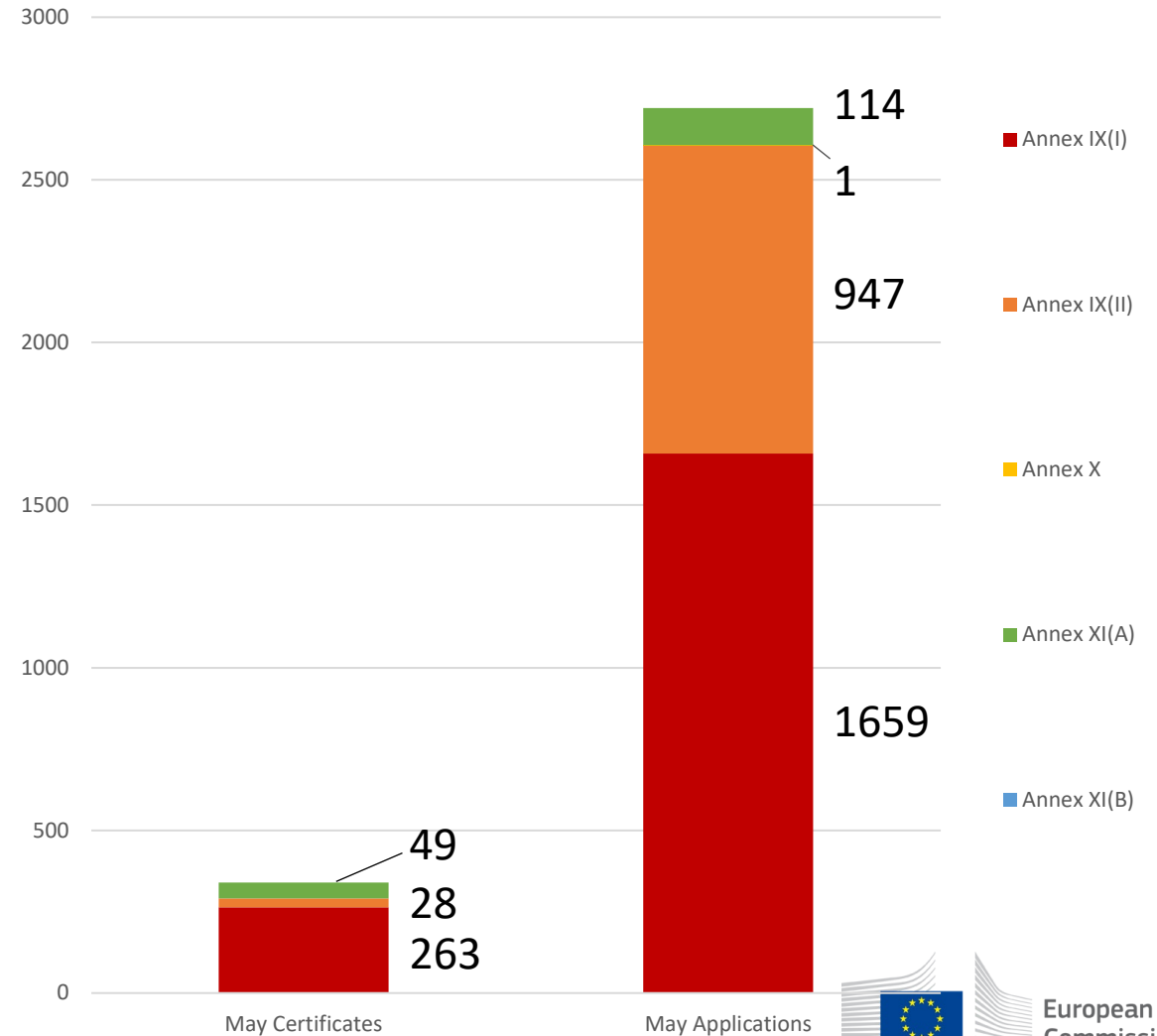


# MDR – certificates issued and applications filed (1/2)

Breakdown by Annex  
Certificates and applications May 2021

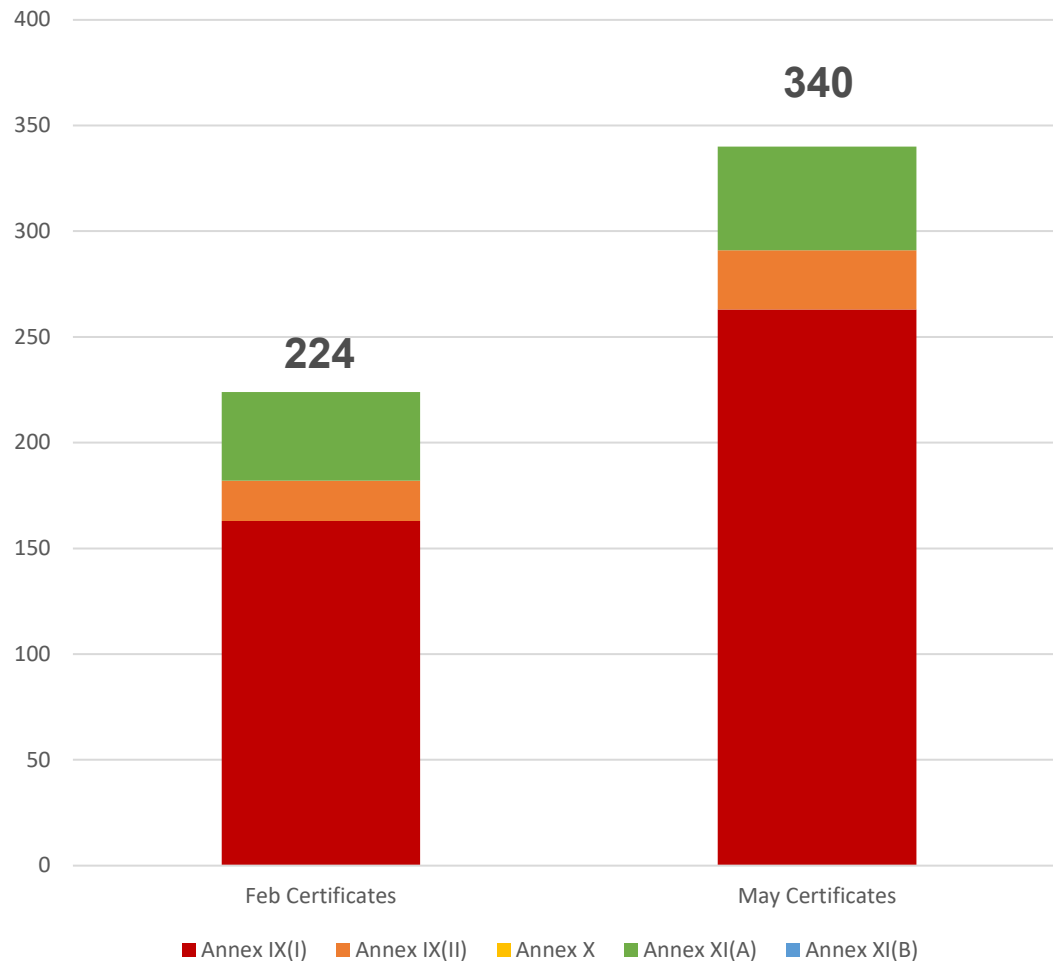


Total number of certificates and applications May 2021

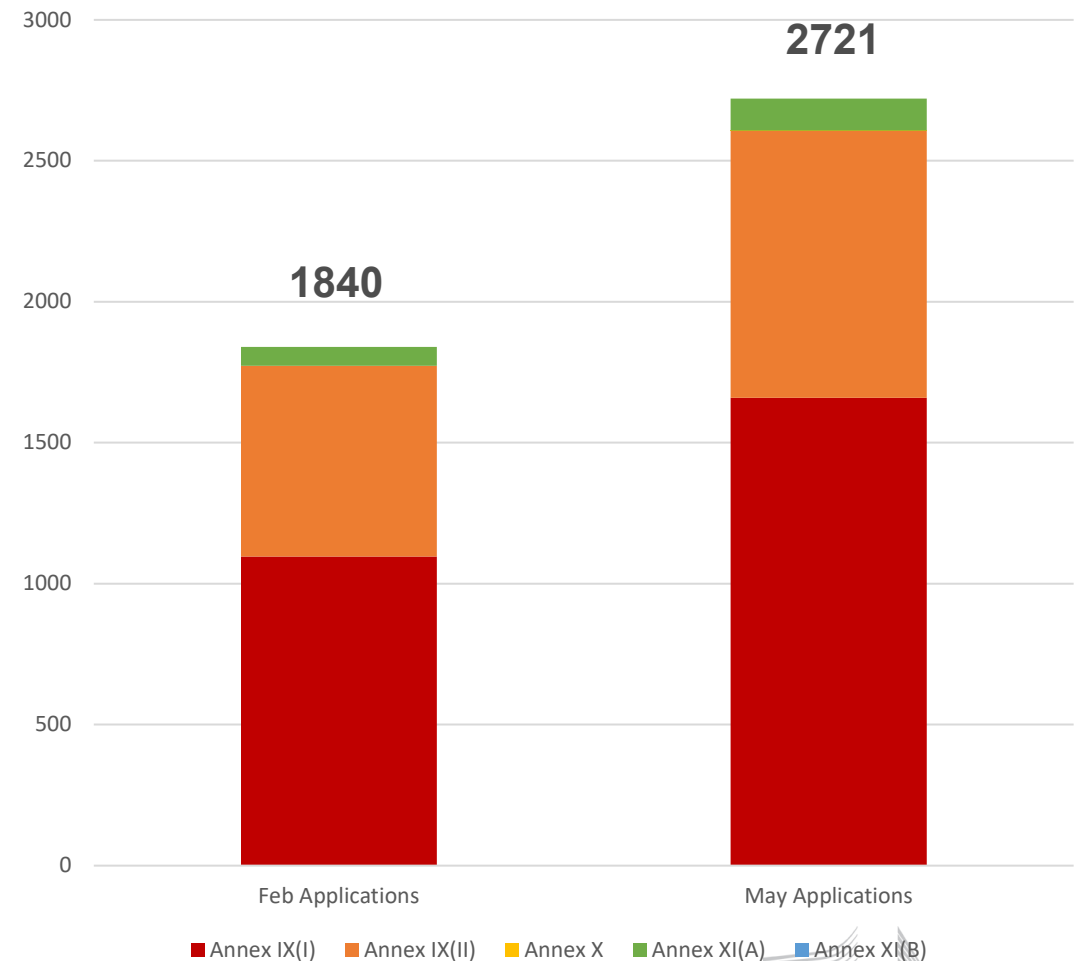


# MDR – certificates issued and applications filed (2/2)

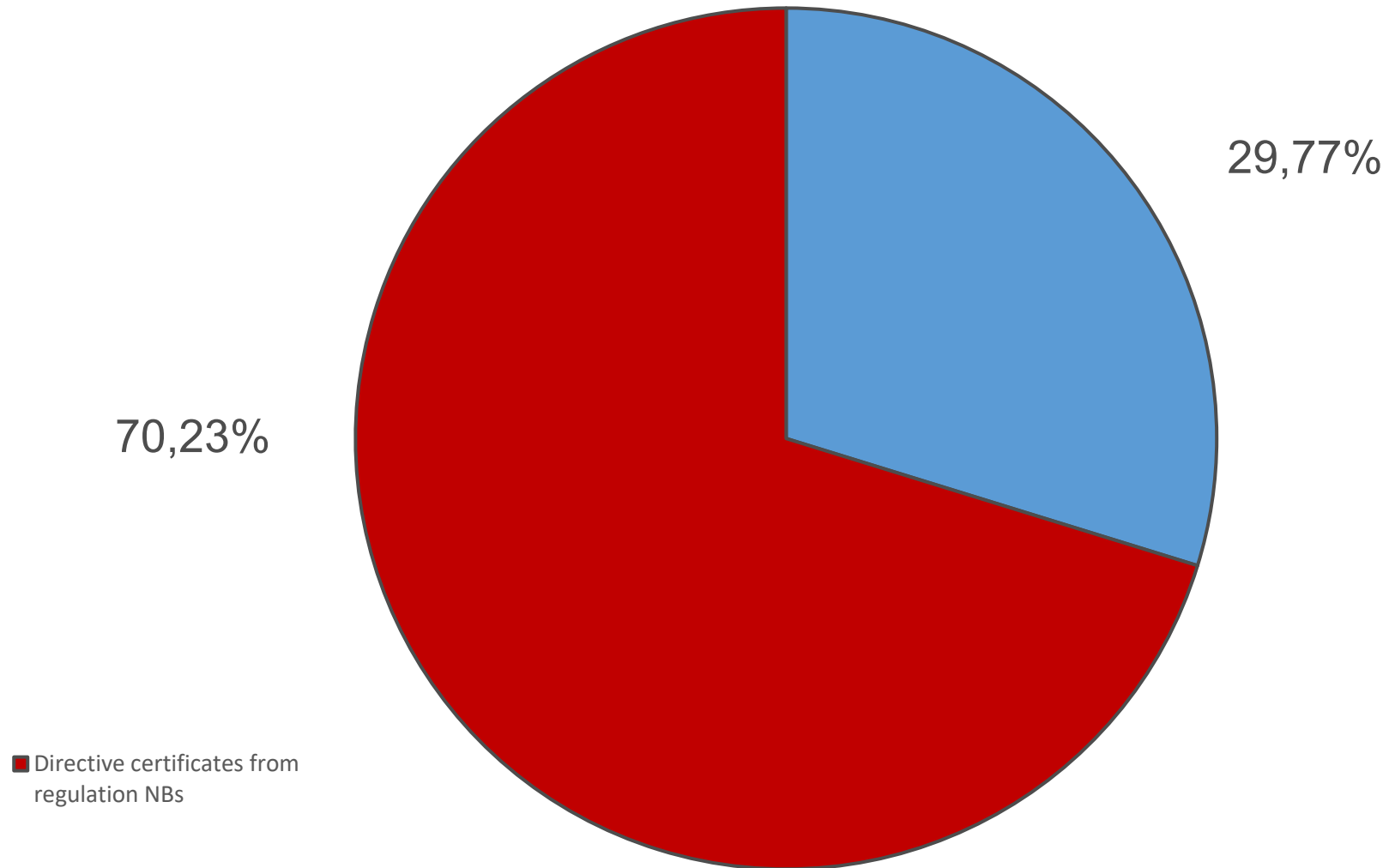
Certificates issued Feb 21 and May 21



Applications filed Feb 21 and May 21



# Directive certificates issues by NBs already designated under the MDR



■ Directive certificates from regulation NBs

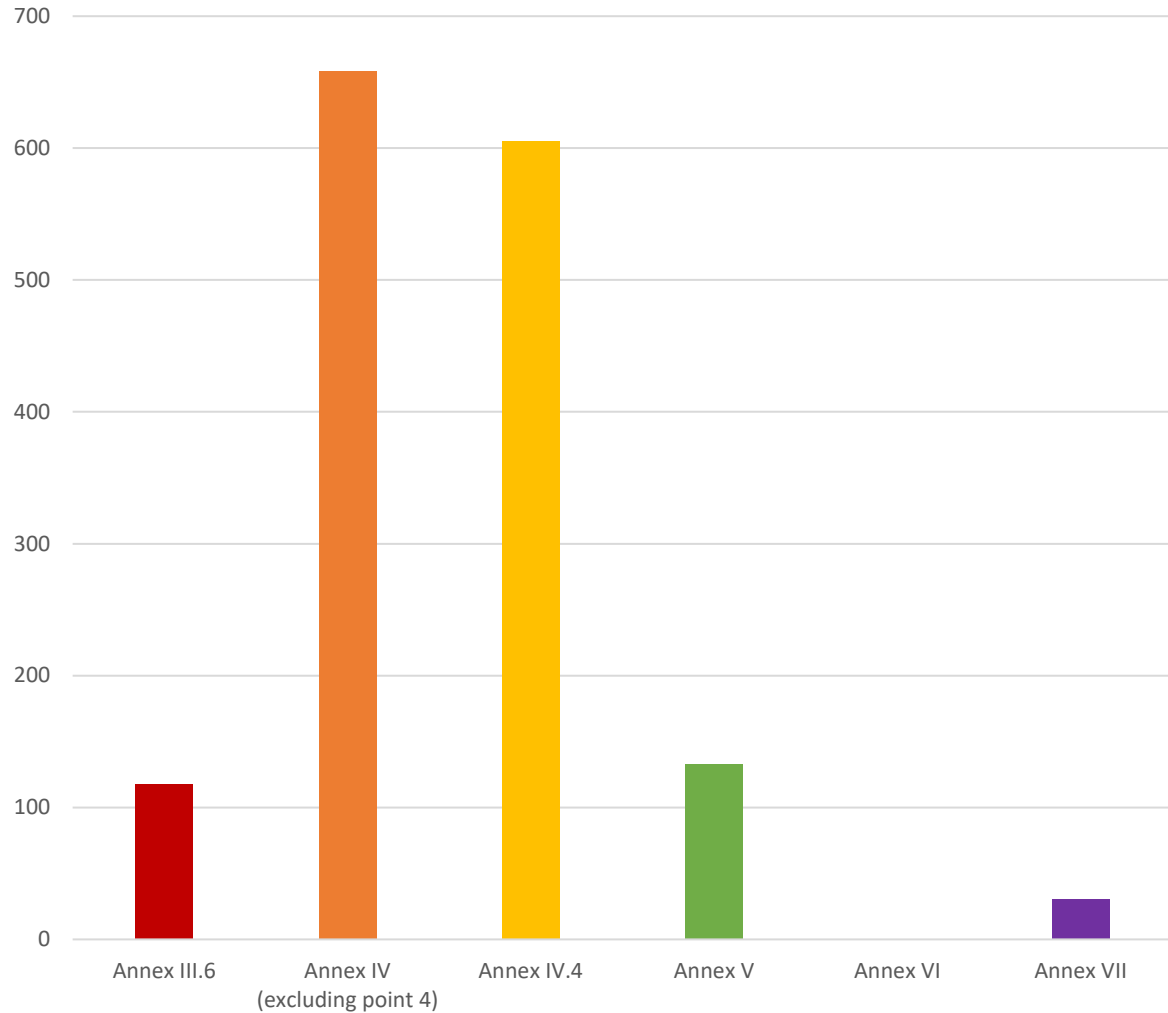
# IVD notified bodies – replies received May\* 2021

- IVDD: 18 replies received – out of 18 notified bodies designated under the IVDD
- IVDR: 4 replies received – out of 4 notified bodies designated under the IVDR

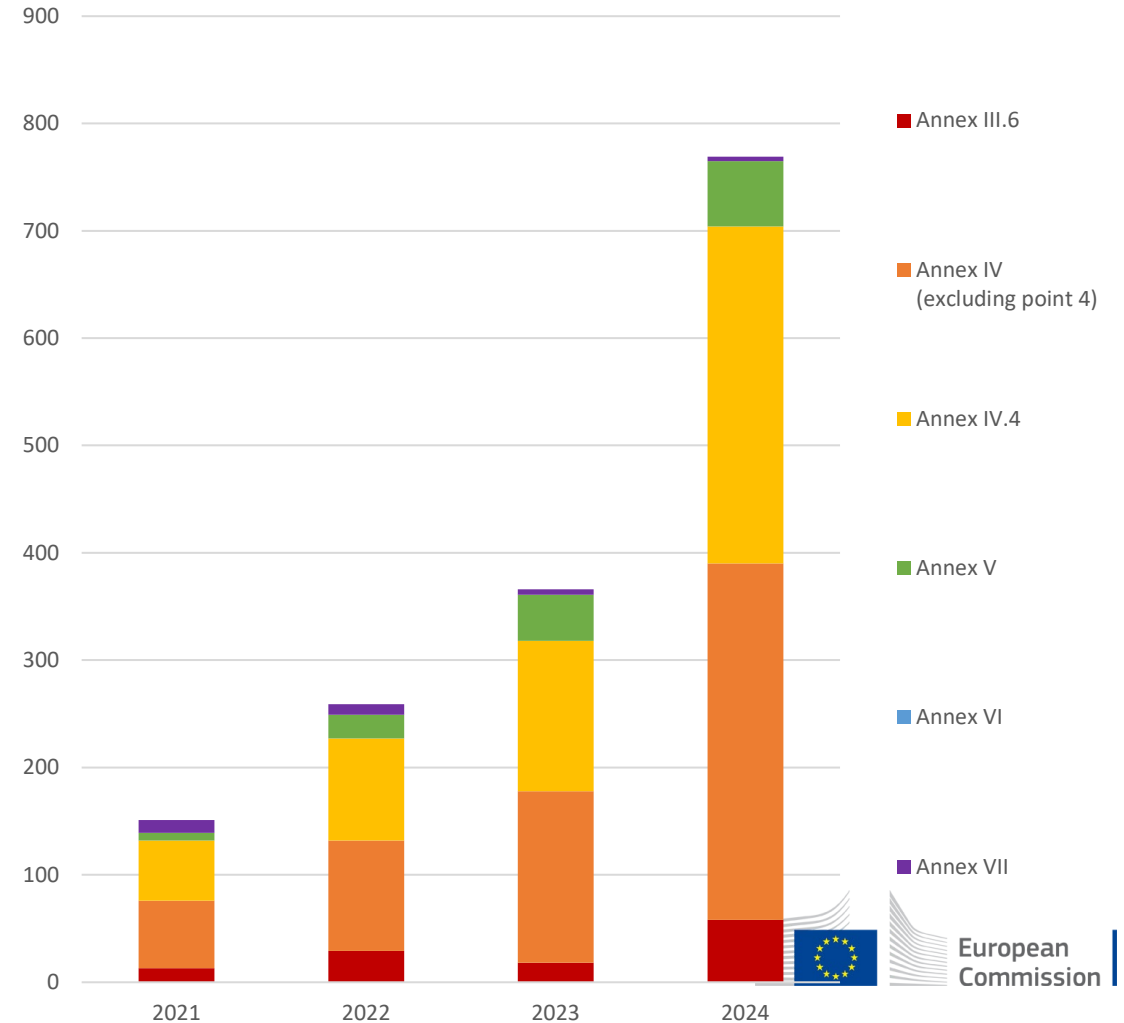
\*Actual replies received from 23/04 to 26/05

# IVDD – valid certificates (1/3)

Breakdown by Annex

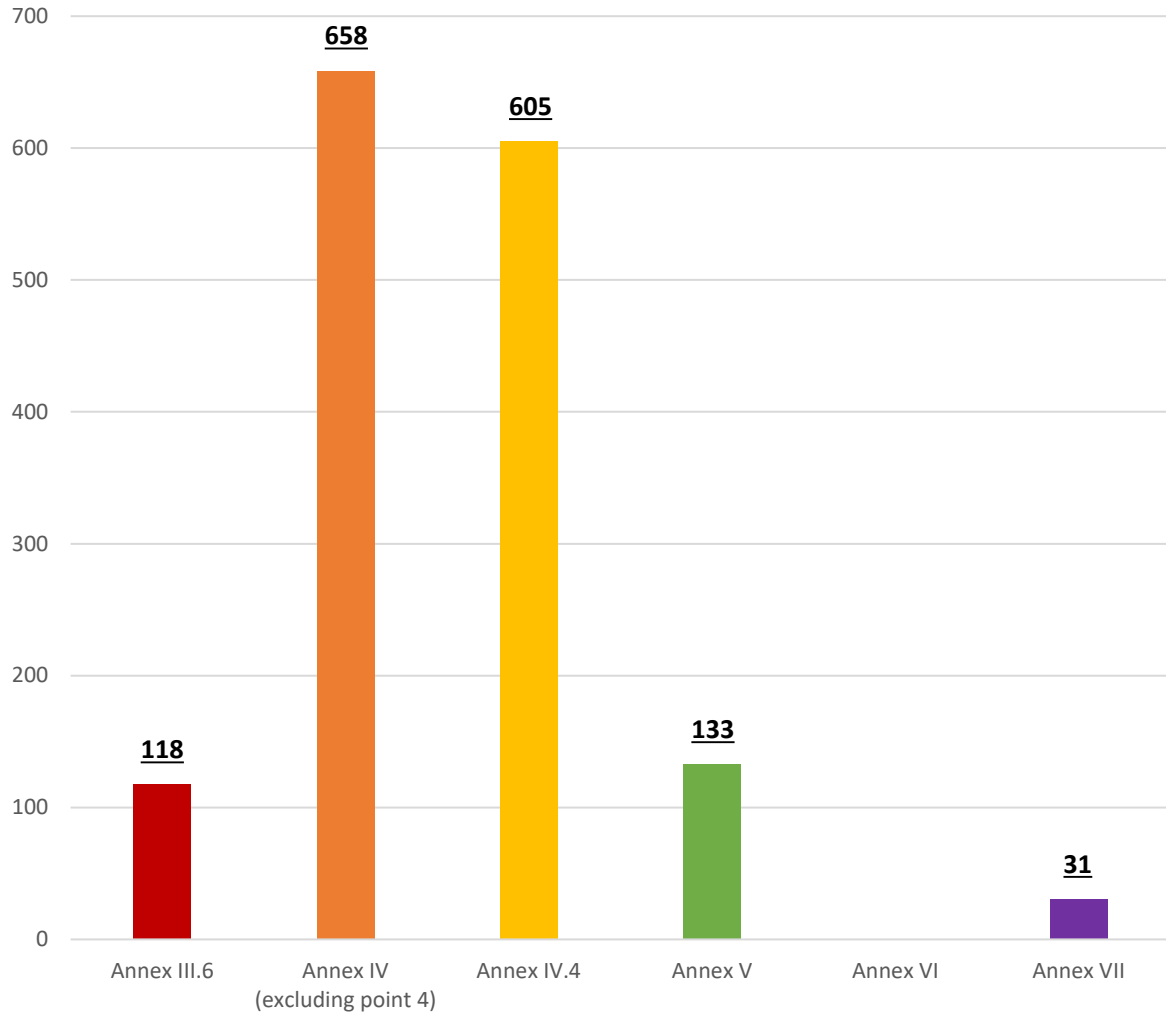


Breakdown by year of expiry

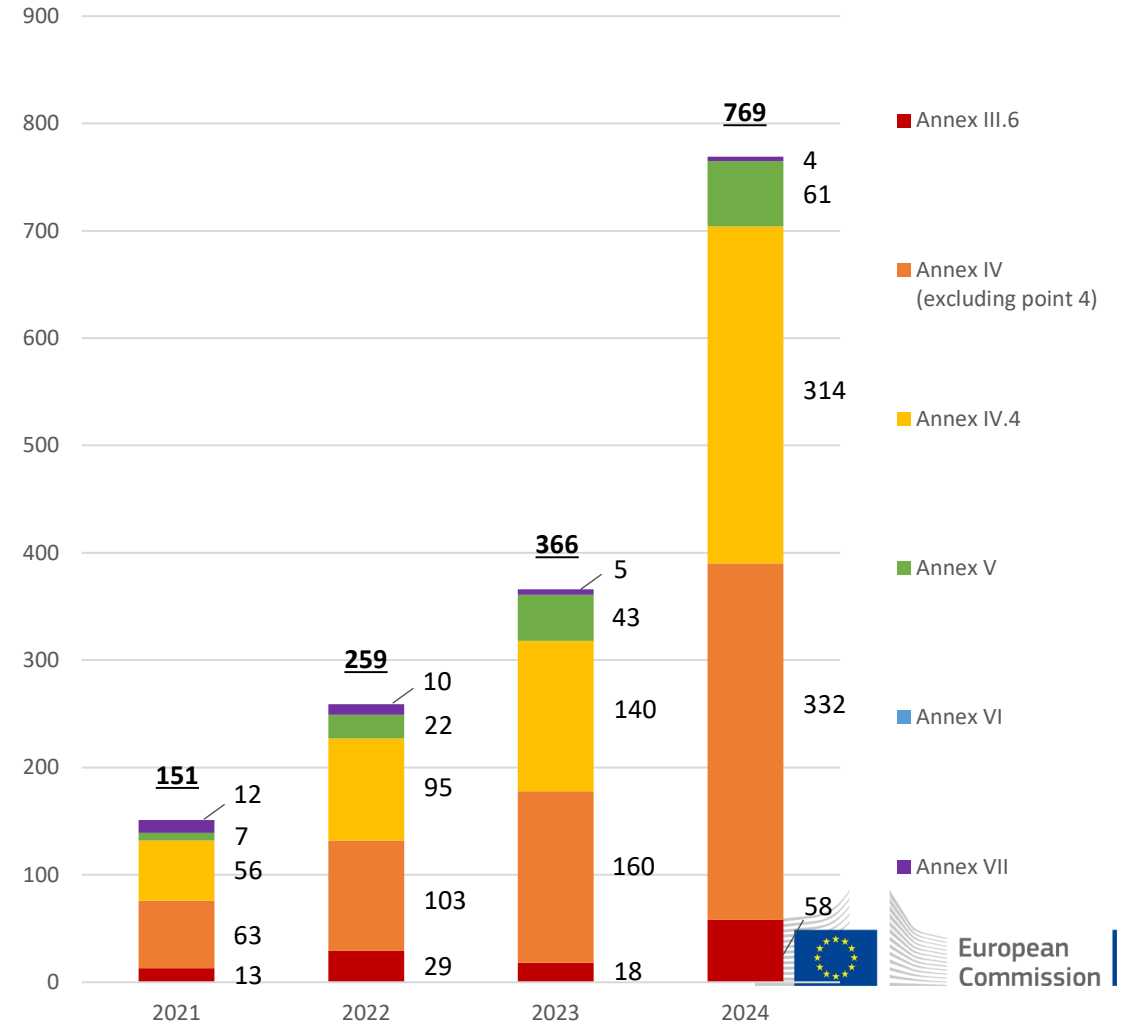


# IVDD – valid certificates (2/3)

Breakdown by Annex

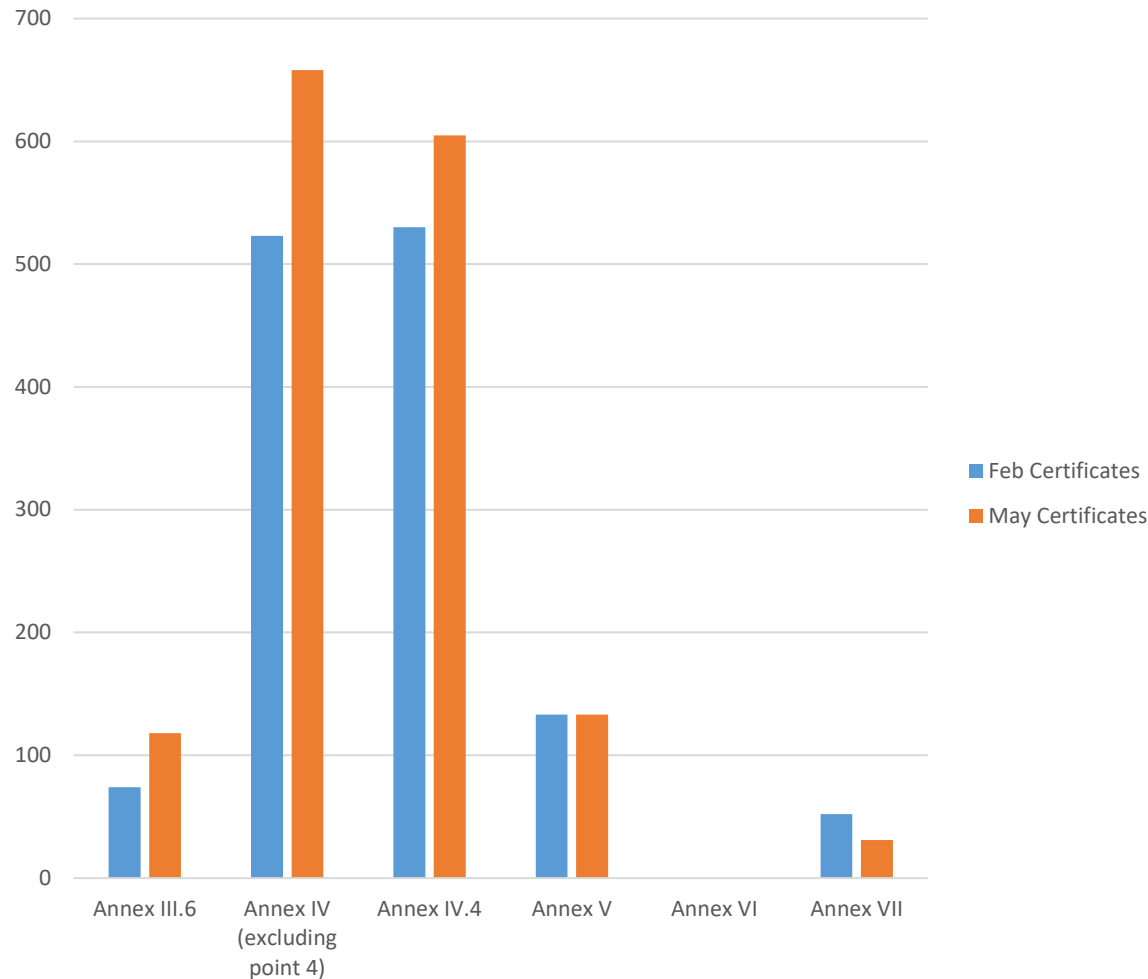


Breakdown by year of expiry

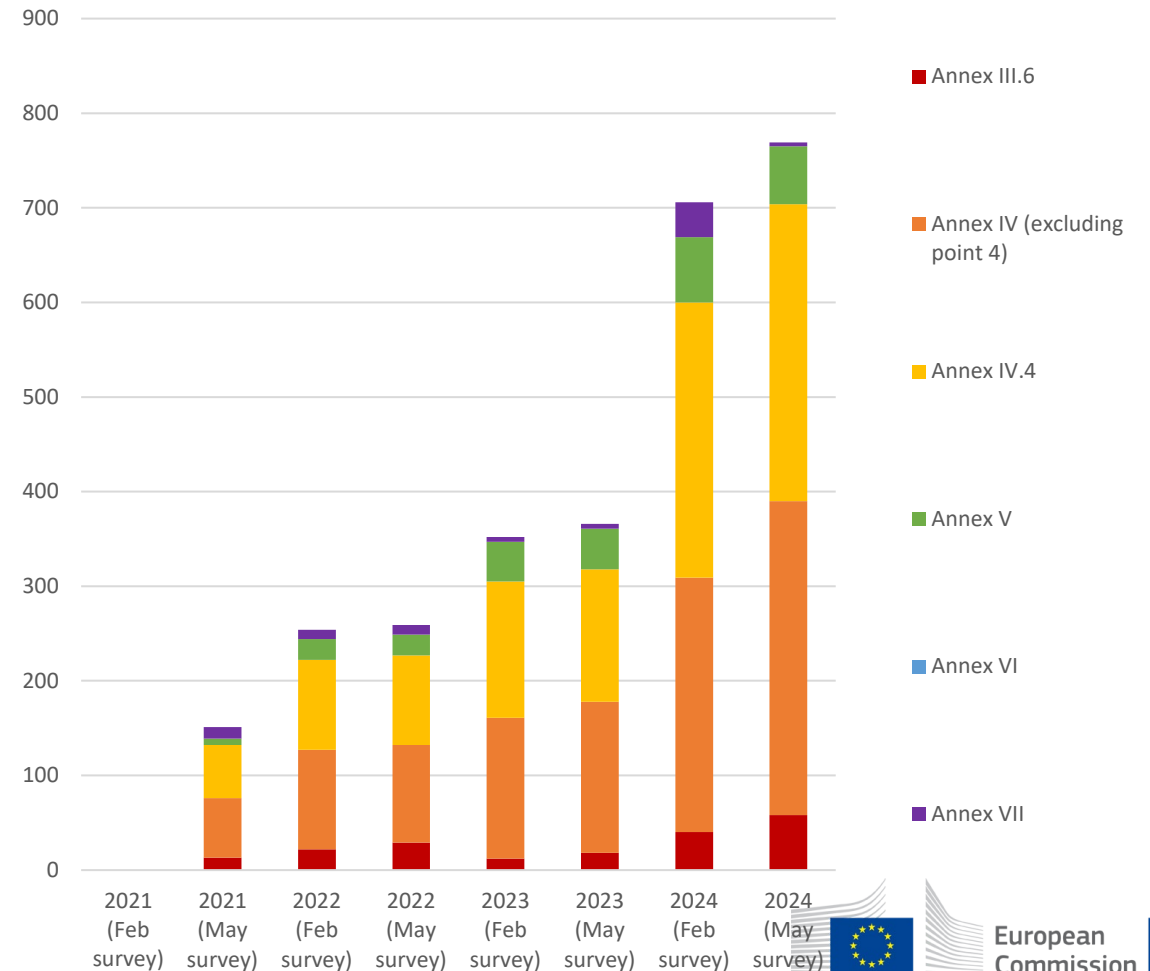


# IVDD – valid certificates – comparison Feb 21 and in May 21(3/3)

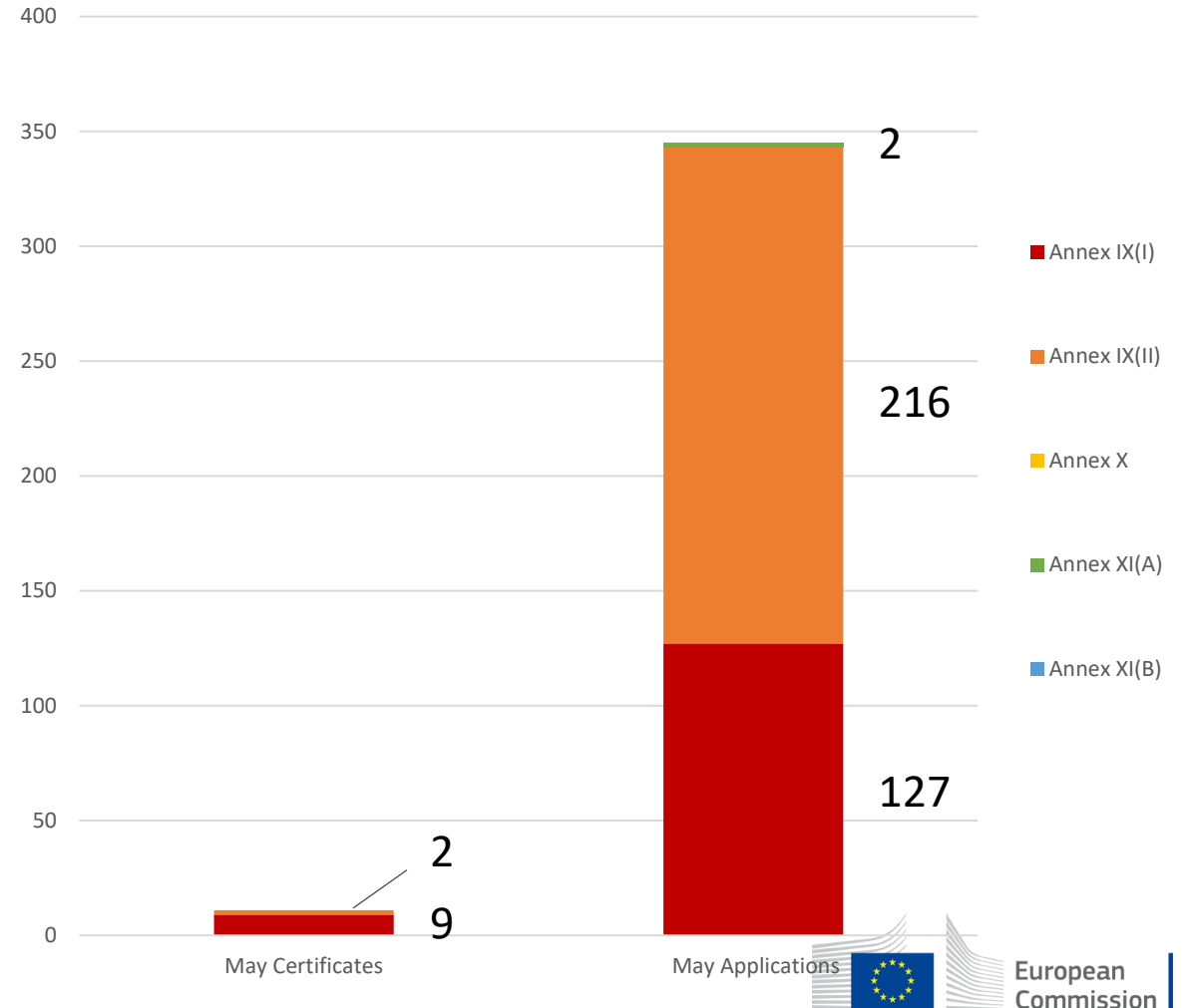
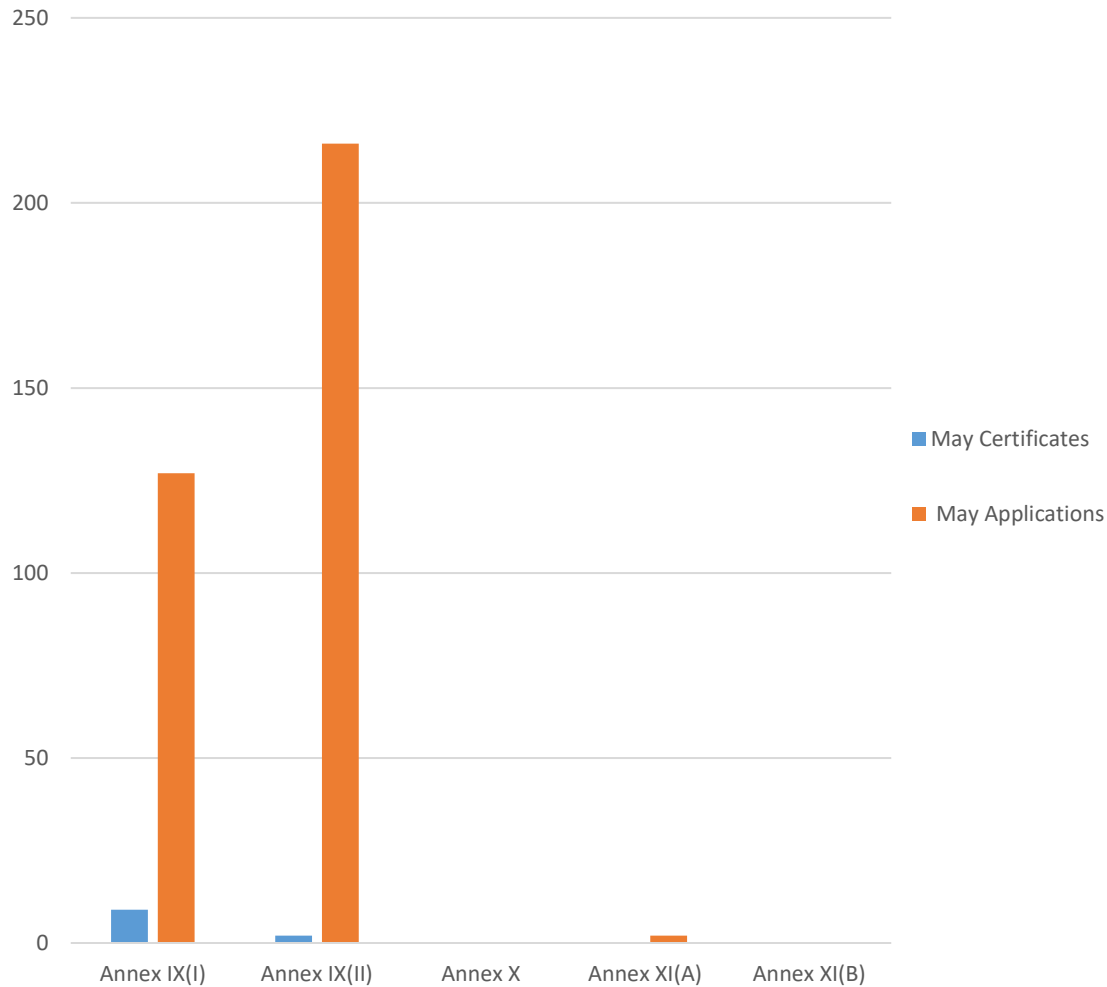
Breakdown by Annex



Breakdown by year of expiry

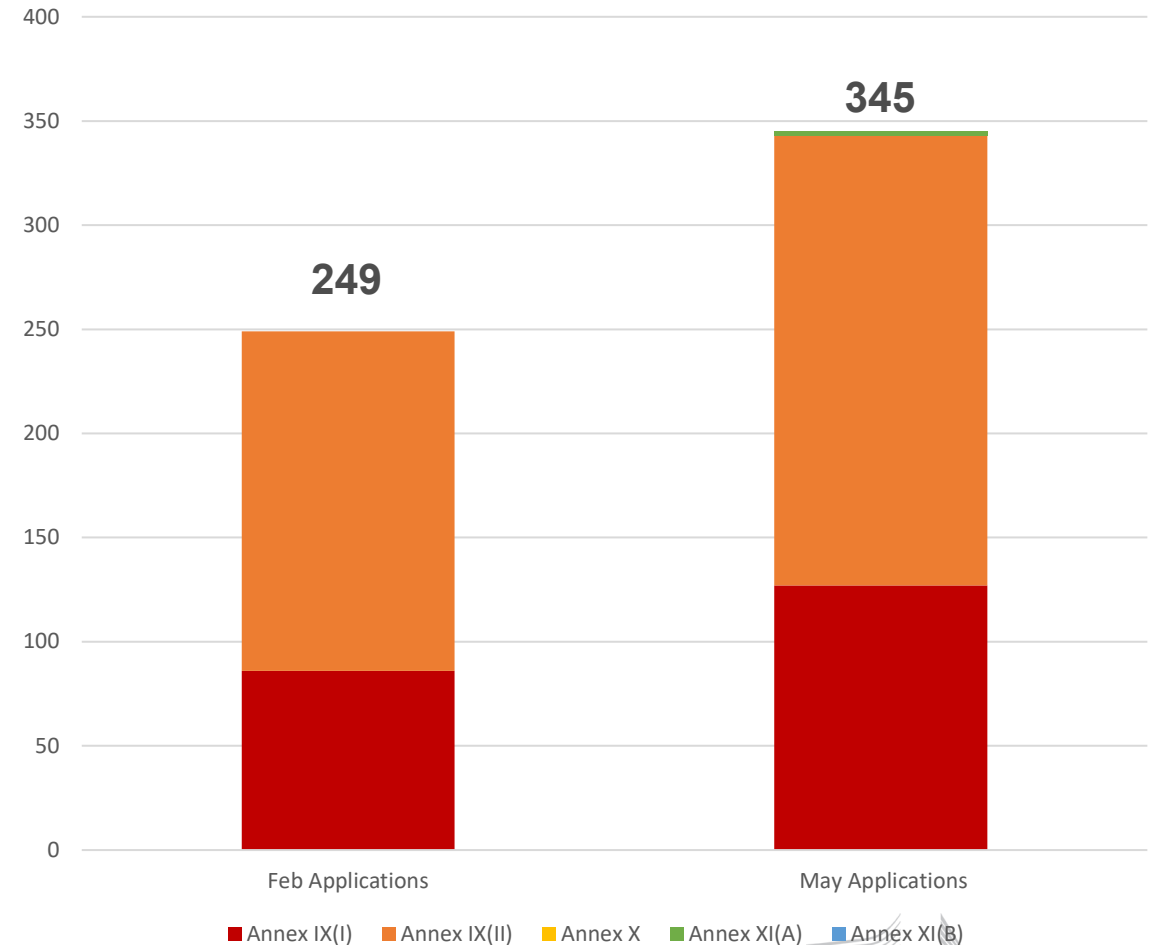
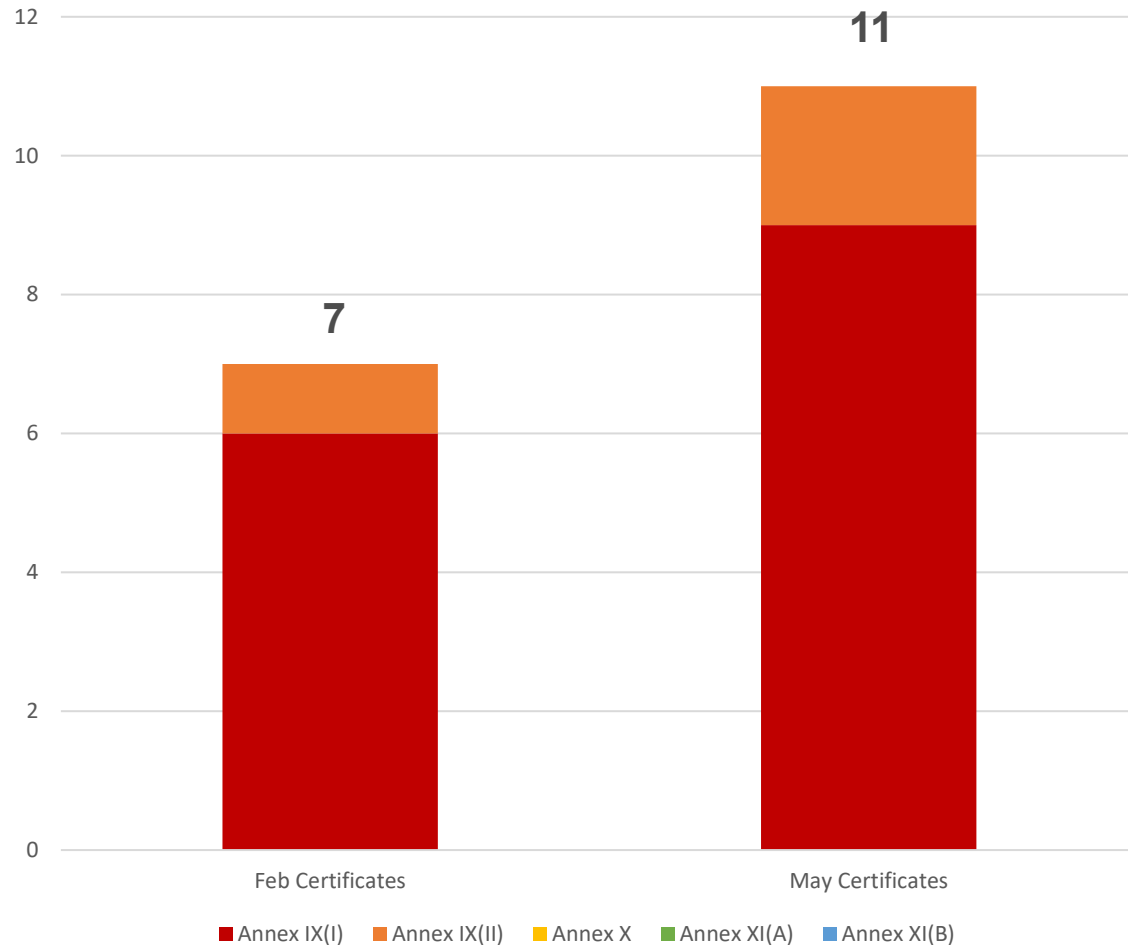


# IVDR – certificates issued and applications filed (1/2)

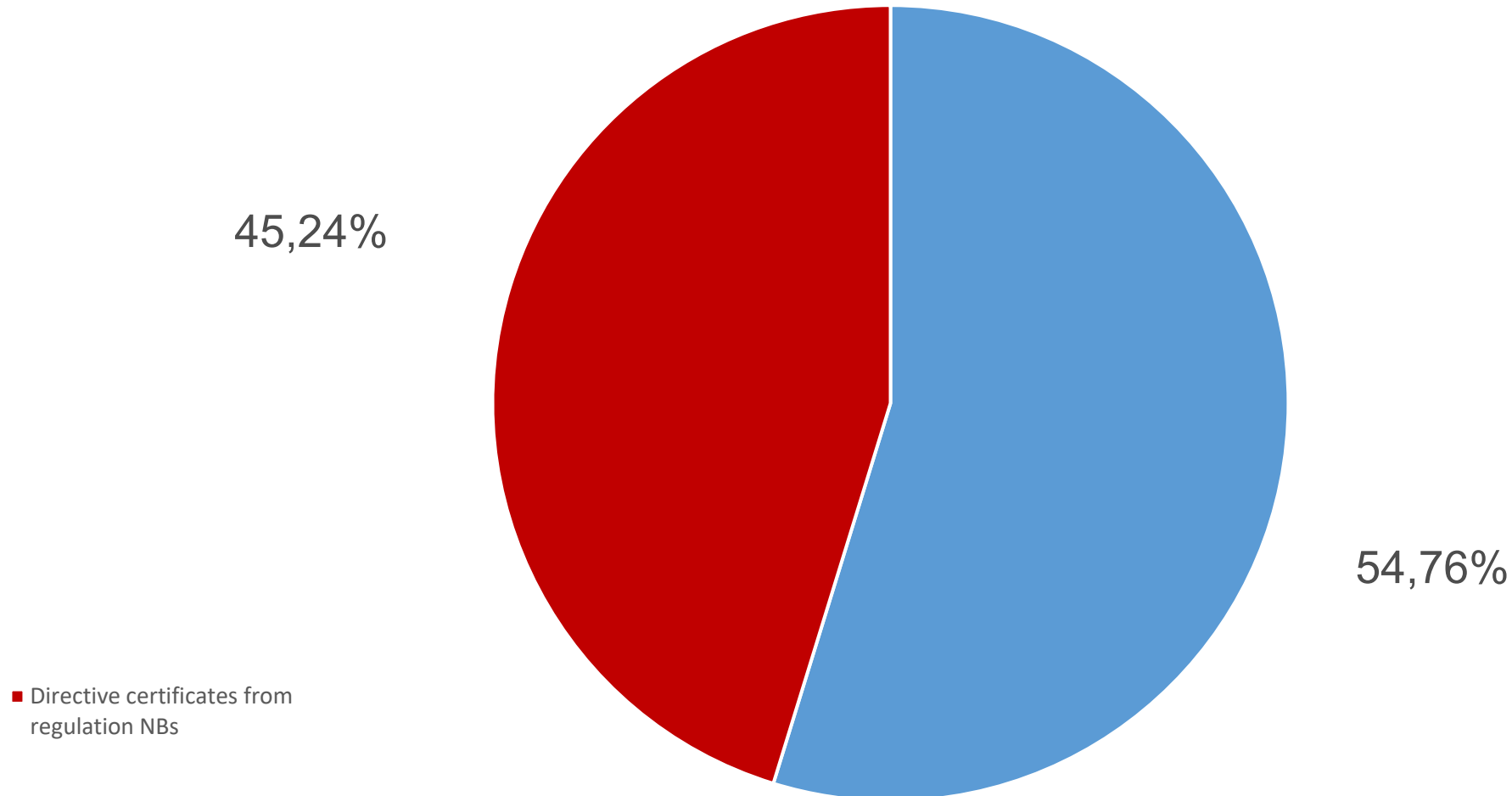




# IVDR – certificates issued and applications filed (2/2)



# IVDD certificates issues by NBs already designated under the IVDR



Thank you!