



Animals in science



AP 09 Rabbit Pyrogen Test

*NCP27
1-2 October 2024*

Introduction



- *Replacement a legal requirement*
- *Use of rabbit pyrogen test in the EU*
- *Efforts at EU level to accelerate replacement*

What changed in 2013



Photo by Vincent Pelletier - Pexels

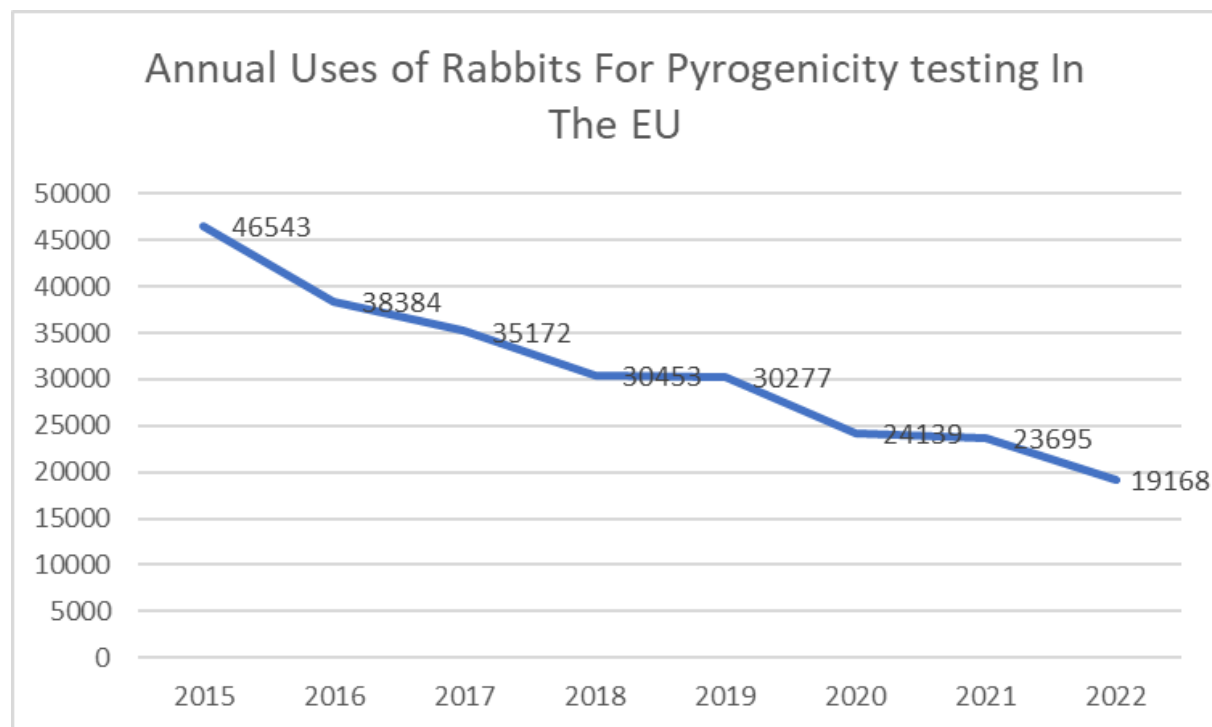


➤ *Article 13 of the Directive:*

Animal use **can no longer be authorised**^{*)} if another method, not entailing the use of animals, is recognized under the legislation of the Union.

^{*)} *unless product specific validation fails*

Total RPT use in the EU



- *MAT test adopted in the European Pharmacopeia in 2009*
 - *Directive 2010/63/EU took effect in 2013*
- *In 2022, almost 20K uses of rabbits in RPT persist*

RPT use in the EU by MS



4. PYROGENICITY

Year	BG	CZ	DE	IE	EL	ES	FR	IT	HU	PL	RO	SI	Total
2020	309	41	3223	943	0	7005	10325	2025	14	186	0	68	24139
2021	3100	0	1371	657	0	7055	9711	1531	0	177	25	68	23695
2022	1800	0	1078	966	12	6429	7145	1518	0	147	0	73	19168
2022 % of all EU uses	9%		6%	5%	< 1%	34%	37%	8%		1%		0%	

- 2015: 14 MS reported RPT
- 2022: down to 9 MS of which 70% uses by 2 MS

Current efforts at EU level



Photo by FeelLoona - Pixabay

- *Animal use for areas where alternatives exist highlighted regularly at NCP meetings*
- *Annual reporting changed to require explanation of justifications for animal use where alternatives are available (MS narratives from 2021 data onward)*
- *EPAA-EDQM project on RPT*

EPAA/EDQM Pyrogenicity event

February 2023



- *EPAA/EDQM co-hosted event on phasing-out RPT in Brussels, 14-16 February 2023, including a satellite training event on the MAT.*
 - Presentations under this [LINK](#).
 - The future of pyrogenicity testing: Phasing out the rabbit pyrogen test. A meeting report (<https://doi.org/10.1016/j.biologicals.2023.101702>)
 - Participation from all regions
- *Follow-up actions from pyrogenicity event*
 - Dedicated training on MAT superiority to EU and non-EU regulators
 - Promotion of inter-pharmacopoeias dialogue
 - White Paper to summarize limitations of RPT and superiority of MAT – guidance on decision making and validation.

Conclusions and next steps



*Between 2015 - 2020, RPT use decreased by 49%;
between 2018 - 2022 RPT use decreased by 36%*

Significant progress, but:

- *What issues slow down the transition to alternatives?*
- *What needs to happen to replace all RPT in EU?*
- *The role of competent authorities under the Directive*



Thank you for your attention!

More information at:

<https://ec.europa.eu/animals-in-science>

The views expressed in this presentation are solely those of the presenter and do not reflect the official view of the European Commission.

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