Ref. Ares(2024)7203397 - 10/10/2024

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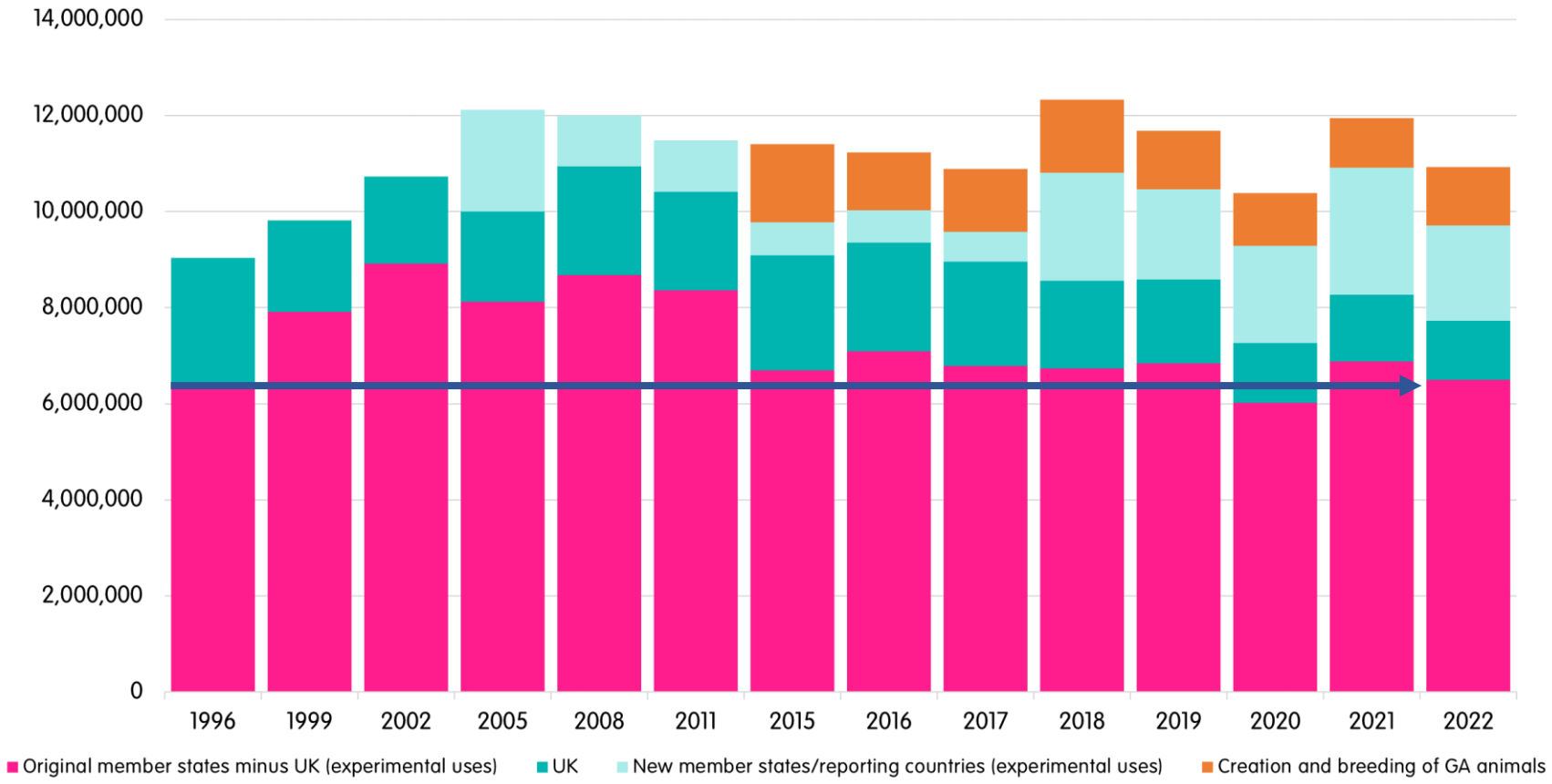
Directive 2010/63 - Implementation report, 2022

Senior Science Advisor, Cruelty Free Europe



EU figures over time

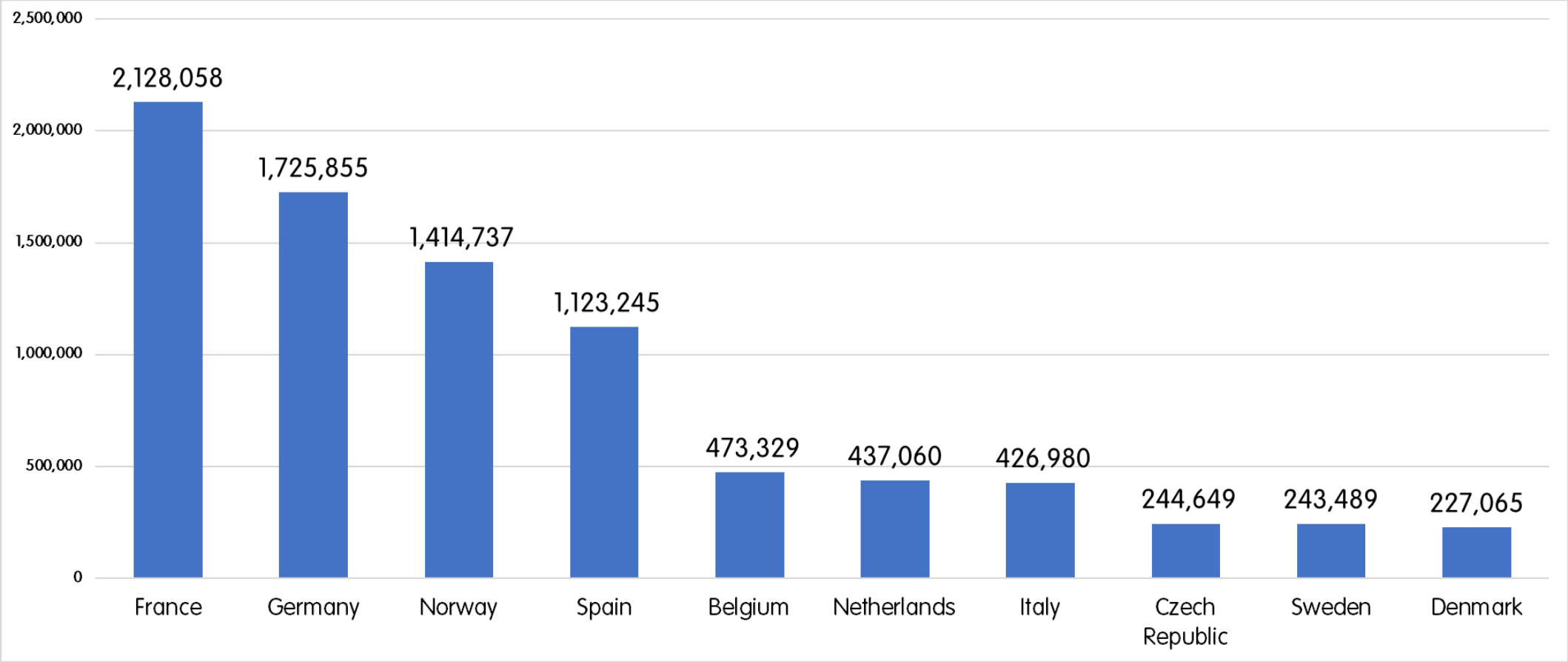
9.3 million experiments conducted by EU Member States and Norway in 2022



Note: these figures are only uses of animals in experiments - relevant to Directive 2010/63 (not detailed in the Implementation report)

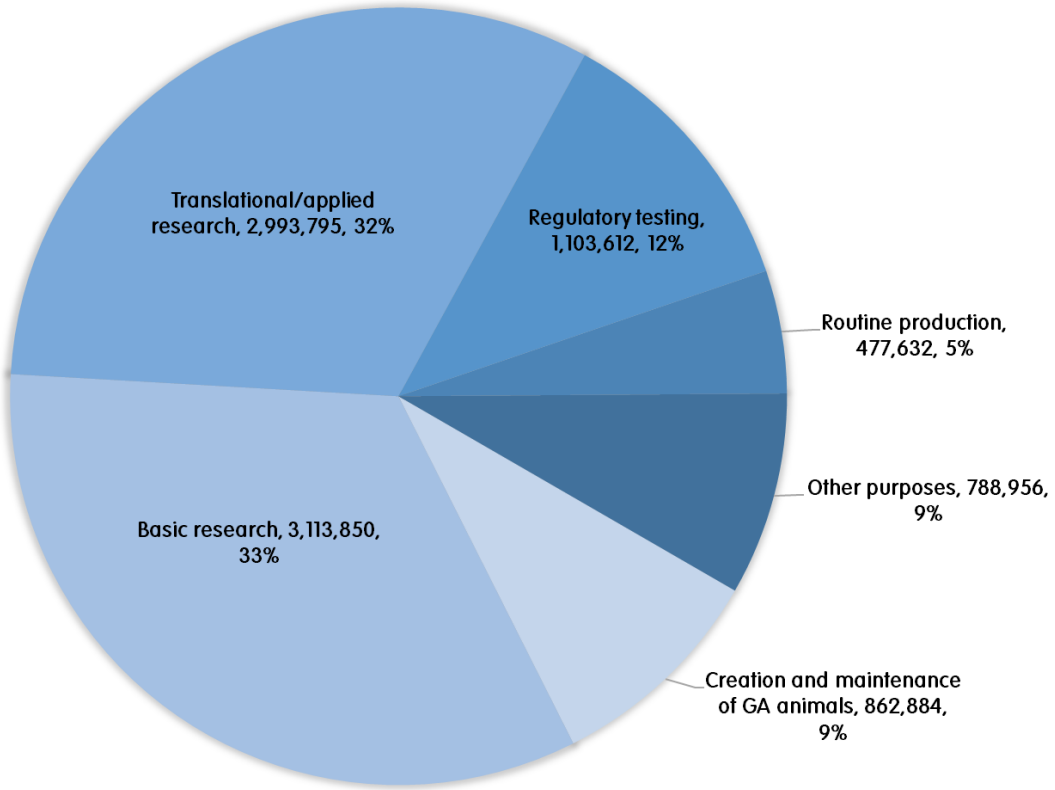
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2022 EU figures – top 10 users

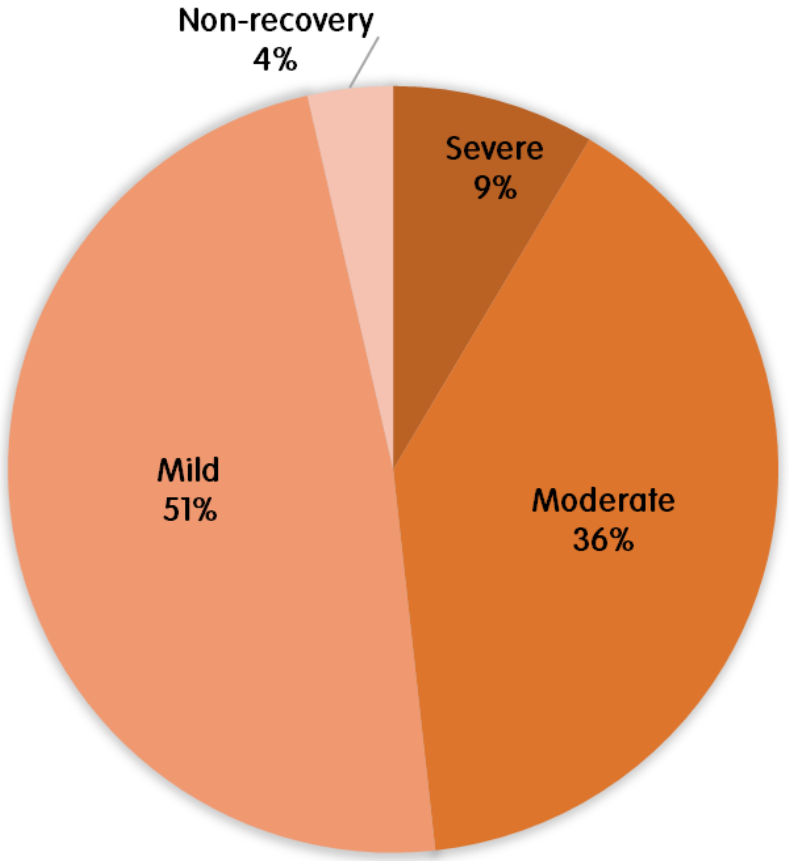


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Purpose of animal use across EU Member States and Norway in 2022



Severity of animal tests across EU Member States and Norway in 2022



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2022 Implementation Report

Top-line figures

- **9.6 million animals** were bred, killed and not used in 2022
- **No significant change**, compared to 2017
- Total uses of animals for scientific purposes: **18.9 million** for 2022
  (including those used directly in experiments)



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Animals not used in procedures

Animals bred, killed and not used in procedures in 2022 (*compared to 2017*):

- Conventional animals: **3.5 million** (*30% reduction*)
- Genetically normal but associated with genetically altered (GA) lines: **~0.2 million** (*60 % reduction*)
- Animals used to establish GA lines: **5.9 million** (*60 % increase*)

  Note: new guidance was developed "Framework for the Genetically Altered Animals" (published in 2022)

- 304 dogs and 207 monkeys were bred but not used

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3Rs considerations

Number of countries which:

- Reported re-use of an animal after a severe procedure: *zero*
- Have project applications reviewed by a non-animal methods specialist: 15
- Mandate advice from an animal welfare body: 13
- Use inspections to ensure 3Rs are addressed: *all*
- Have a written strategy to minimise surplus: 11

In 2022, 6 million animals had tissues sampled for genotyping:

- 1.3 million were subject to invasive methods of tissue sampling
- 4.7 million, either surplus tissue /non-invasive methods
- One country reported only using non-invasive methods



A European database of available non-animal methods – could be helpful

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Inspections

Inspection of 1/3 of users each year is a requirement under Directive 2010/63

Over 2018-2022:

- 18 countries did not meet the minimum inspection requirements across the whole 5-year period
- 3 countries failed to meet target in *any* one year

In 2022, 9 countries still did not meet the target

Note: inspections a key measure to help ensure that the 3Rs are being applied.

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Project authorisations

Between 2018 and 2022:

- 15,000 projects/year were authorised, on average. Only 4.5 % were rejected.
- 9 countries reported withdrawal of project authorisations (7 countries report animal welfare reasons)

In 2022:

- 3,222 projects authorised, 480 projects rejected
- 8 countries did not refuse any project applications
- A further 12 countries rejected fewer than 10 proposals
- Hungary (15.3%), Lithuania (24%) and Poland (13.2%) rejected the most projects, proportionally



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Managing surplus

12 countries produced more total surplus animal than they used (*note: breeders may supply to many countries)*

A number of initiatives have been introduced, including:

- optimisation of breeding strategies
- use of new technology to better inform breeding requirements
- purchasing only the required number of animals from breeders
- use of both sexes
- use of surplus in education and training
- collaboration within and between establishments to minimise duplication
- widening of rehoming policies



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Compliance & penalties

Between 2018 – 2022

71% of countries reported non-compliance, incl:

- poor record keeping
- inappropriate enclosures
- regular failure to complete health checks
- exceeding the permitted number of animals used in experiments
- failure to administer pain relief
- humane end-points reached and animal not killed
- inadequate treatment of sick/injured animals

Penalties

- 7 countries withdrew/suspended establishments' authorisation
- 19 countries – no withdrawn authorisations
- 6 countries - no penalty issued, no reported non-compliance (5 countries fell below the required number of inspections)
- 75% of countries took administrative action, including:
  - written orders of improvement or warnings
  - verbal orders of improvement
  - follow-up checks.
- 43% of countries took legal action (mostly fines)
- 4 countries took legal action leading to prosecution

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Improving protection

Steps to improve the protection and welfare of animals used in science:

- *All* project applications: reviewed by a non-animal methods specialist + input from animal welfare body
- Support use of non-animal approaches, e.g. for REACH testing, with an EU-database

  → decrease the number of animals used in experiments

- Support and enforce the meeting of national inspection targets
- Further roll-out of initiatives to manage/reduce surplus. Explore – could technological advances help?
- Ensure non-invasive tissue sampling wherever possible
- Encourage stronger penalties for non-compliance
- More frequent (interim) reports from all EU member states and Norway



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Thank you

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