

Annual statistical report for animals used in Ireland under scientific animal protection legislation - 2024

CONTENTS

1	INTRODUCTION	3
2	SUMMARY	5
3	DATA ON THE USES OF ANIMALS FOR RESEARCH AND TESTING PURPOSES	6
3.1	Species and numbers of uses of animals for research and testing purposes	6
3.2	Reuse of animals	7
3.3	Origin of animals at the first use	8
3.4	Project purposes	9
3.5	Use of animals to meet legislative requirements	13
3.6	Use by genetic status for research and testing purposes	13
3.7	Actual severity of uses of animals for research and testing purposes	14
4	DATA ON THE USES OF ANIMALS FOR THE CREATION AND MAINTENANCE	
	OF GENETICALLY ALTERED ANIMAL LINES	15
5	TRENDS	18
6	CONCLUSION	22
7	APPENDIX: DEFINITIONS	22

1 INTRODUCTION

The Health Products Regulatory Authority (HPRA) is the State agency with responsibility for the protection of animals used for scientific purposes, the regulation of human and veterinary clinical trials, and the regulation of human and veterinary medicines, medical devices and other health products, amongst other regulatory functions. The European legislation regulating the use of animals for scientific purposes is Directive 2010/63/EU (hereafter referred to as the Directive), and the HPRA is the competent authority responsible for the Directive's implementation in Ireland.

The Directive is among the world's most advanced pieces of animal welfare legislation. The restrictions and standards set by the Directive aim to enhance animal welfare and ensure that animals are used in studies only when necessary and following independent assessment. The Directive firmly anchors in EU Legislation the 3R principles, i.e. Replacement, Reduction, and Refinement:

- Replacement involves the acceleration of the development and use of models and tools, based on the latest science and technologies, to address important scientific questions without the use of animals. Examples of alternative methods would include in vitro tests such as the use of cell lines, organ-on-a-chip technologies, computer and mathematical simulation and modelling, video material, or the use of invertebrates such as fruit flies or worms.
- Reduction refers to methods that minimise the number of animals used per project or study consistent with the scientific aims. It is essential that studies using animals are appropriately designed and analysed to ensure robust and reproducible findings. Reduction also includes methods that allow the information gathered per animal in a study to be maximised in order to reduce the use of additional animals. Examples of this include the use of some imaging modalities which allow repeated measurements in the same animal to be taken over time (rather than, for example, imaging different animals at each time point) or microsampling of blood, where limiting the amount of blood taken each time to small volumes enables repeat sampling in the same animal.
- Refinement refers to methods that minimise the pain, suffering, distress or lasting harm that may be experienced by the animals, and which improve their welfare.
 Refinement means that animals are provided with the best possible care, and this applies to all aspects of animal use from the animals' housing and husbandry to the scientific procedures performed on them. Examples of refinement include ensuring that animals are provided with housing that allows the expression of species-specific behaviours, using appropriate anaesthesia and analgesia to minimise pain, and training animals to cooperate with procedures to minimise any stress.

Although complete replacement of animal studies is the ultimate goal of the Directive, for the moment, the use of live animals continues to be necessary in some circumstances, to protect

human and animal health and the environment. Where biological processes are not sufficiently understood or are very complex, non-animal research or test methods are often not available. After generating as much information as possible using non-animal alternatives, animal studies can sometimes be necessary to fill knowledge gaps. The Directive plays a vital role in protecting and improving the welfare of those animals that are required to be used for scientific purposes.

The HPRA regulates the sector by means of authorisation at three levels:

- (i) **Breeder/supplier/user establishments:** Breeders and suppliers of animals as well as establishments where procedures are performed must be authorised and are subject to HPRA inspections. During 2024, there were 40 inspections completed to monitor animal welfare standards and compliance with legislation, with 63% of these performed as unannounced inspections.
- (ii) **Projects:** Scientific procedures involving animals can only take place following a detailed submission of the planned study/studies and subsequent approval by the HPRA on the basis of a favourable harm/benefit analysis.
- (iii) **Individuals:** Any person wishing to carry out scientific procedures involving animals, as well as project managers and those conducting euthanasia in an authorised establishment, must hold a HPRA individual authorisation and be adequately trained to do so.

The HPRA aims to improve the welfare of animals used for scientific purposes and to promote the 3R principles. Every application received for a project involving animals is subject to a detailed evaluation process rooted in the 3R principles and requires robust scientific justification for the research techniques being applied. The HPRA considers whether alternative (non-animal) methods are available or appropriate, as alternatives to the use of live animals must be used where possible. Where non-animal methods to address the specific research or scientific question are not available/appropriate, the likely impact on the animals must be minimised in so far as possible by applying the principles of Reduction and Refinement, and any harms experienced by the animals must be outweighed by the expected benefits of the work.

In line with our mandate to promote the 3Rs, throughout 2024 the HPRA continued its efforts to raise awareness and encourage the adoption of non-animal methodologies to replace the use of animals. These efforts included close collaboration with the Irish National Committee for the Protection of Animals Used for Scientific Purposes to organise a training event focused on the topic of Replacement and alternatives to use of animals in research and testing. Furthermore, the HPRA continued to promote the 3Rs through its inspections and project evaluation processes, as well as via the regular dissemination of 3Rs updates to the regulated sector.

The objective of this report is to present statistical data on the number of uses of animals for scientific purposes in Ireland during 2024 in accordance with Article 54(2) of the Directive. This is the twelfth report to be prepared by the HPRA since it became the competent authority for the protection of animals used for scientific purposes.

As in previous years, the data provided are based on self-declarations by the establishments concerned. The data are presented in this report in accordance with Commission Implementing Decision 2020/569/EU, which sets out a common format for the submission of information to the European Commission. In line with the EU summary reports under Directive 2010/63/EU on the uses of animals for scientific purposes within the EU and Norway, data has been categorised in this report as follows:

- number of animals used in research, testing, routine production, and education and training purposes¹
- details of all uses (first and any subsequent reuse) of animals for research and testing
- numbers and uses of animals for the creation and maintenance of genetically altered animal lines

Please refer to the Appendix for definitions relating to some of the terminology used in this report.

2 SUMMARY

In 2024, there were a total of 113,759 uses of animals in procedures for research and testing purposes, with reuse representing 1% of this number (1,410 uses). Some 112,349 animals were reported as being used for the first time for research and testing purposes in 2024. Mice were the most commonly used species at 85% of total animal use. In addition, 920 mice and 1,108 zebrafish were reported as having been used to create and maintain colonies of genetically altered animals. These animals are not considered by the European Commission to have been directly used in research and testing.

Of the total number of uses of animals for research and testing purposes, 72% were used for regulatory purposes, which refers to legal requirements to test the safety, quality, and potency of medicines (e.g. biological medicines such as vaccines). 6,992 (6%) of the animals used for research and testing purposes in 2024 were reported as carrying a genetic alteration.

The most frequently reported actual severity experienced by animals during their uses in procedures for research and testing purposes was mild at 57%, followed by moderate at 25%. Of the animals reported as being used for the creation of new genetically altered lines, 56% were reported as having experienced an actual severity of moderate. Of the animals reported

¹ Hereafter referred to as 'research and testing'

as being used for the maintenance of genetically altered lines, 95% were reported as having experienced an actual severity of mild.

3 DATA ON THE USES OF ANIMALS FOR RESEARCH AND TESTING PURPOSES

3.1 Species and numbers of uses of animals for research and testing purposes

Table 1 shows the number of animals used (by species) for the first time in procedures performed for research and testing purposes. Each use of an animal extends from the time when the first intervention is applied to the animal until the completion of data collection under a project, or when the animal is removed from the project.

Mice (86% of total first uses of animals) were the most commonly used species, with rats (6% of total first uses) the second most commonly used species. The species reported as being used under the categories 'other birds' (0.1%) were bird species such as the Atlantic puffin, Black-legged kittiwake and Northern gannet, being studied as part of a conservation project aiming to protect their population numbers and habitats. The species reported under the category 'other fish' (0.1%) were wild fish such as bluefin tuna and ray being studied for conservation projects aimed at improving the survival of these species.

It should be noted that the following species have been excluded from this table as they were not reported as being used for the first time for research and testing purposes in 2024; Nonhuman primates, Mongolian gerbils, other rodents, cats, other carnivores, other mammals, turkeys, reptiles, *Rana*, other amphibians, sea bass, guppy, swordtail, molly, platy, and cephalopods.

Table 1: Numbers animals used for the first time by species

Animal species	Number of uses	Percentage
Mice	96,333	85.74%
Rats	6,221	5.54%
Guinea pigs	1,721	1.53%
Hamsters (Syrian)	36	0.03%
Hamsters (Chinese)	15	0.01%
Rabbits	964	0.86%
Dogs	56	0.05%
Ferrets	30	0.03%
Horses, donkeys and cross-breeds	100	0.09%
Pigs	2,233	1.99%
Goats	30	0.03%
Sheep	2,096	1.87%
Cattle	994	0.88%
Domestic fowl	51	0.05%
Other birds	115	0.10%
Xenopus	4	<0.01%
Zebrafish	115	0.10%
Salmon, trout, chars and graylings	1,125	1.00%
Other fish	110	0.10%
Total uses	112,349	100.00%

3.2 Reuse of animals

Table 2 shows the proportion of reuse (see Appendix for definition), which represents 1% of total animal use. Under the legislation, animals are only permitted to be reused on second or subsequent projects if the severity they have experienced to date is mild or moderate (see Appendix for definition of severity categories), and they have been assessed as having returned to full general health between studies.

It should be noted that the true number of animals that are reused cannot be deduced from these data as some animals may be reused more than once (i.e. the figure 1,410 represents the total reuses of animals, not actual numbers of animals reused). Dogs, pigs, sheep, cattle, horses, domestic fowl (chickens) and Xenopus were the species reused during 2024. Cattle are the species most commonly reused in Ireland. The reuse of cattle was in agricultural research studies investigating, for example, ways to protect the environment through the reduction of methane emissions. Sheep were reused in studies investigating strategies to reduce methane emissions and the environmental footprint of sheep production, as well as in projects to collect blood for use in the development of medical devices to treat patients with

cardiovascular diseases. Horses were reused for the purposes of training veterinary students, and the severity of the procedures did not exceed mild. In Ireland dogs are used exclusively for the development and testing of veterinary medicines to treat the canine pet population.

Table 2 shows the total numbers of all uses of animals (first time and reuse) in procedures performed for research and testing purposes, broken down by species.

Table 2: Numbers animals used (first time and reuse) by species

Animal species	First uses	Reuses	Percentage of reuses	Total uses (first use + reuse)
Mice	96,333	0	0.00%	96,333
Rats	6,221	0	0.00%	6,221
Guinea pigs	1,721	0	0.00%	1,721
Hamsters (Syrian)	36	0	0.00%	36
Hamsters (Chinese)	15	0	0.00%	15
Rabbits	964	0	0.00%	964
Dogs	56	49	3.48%	105
Ferrets	30	0	0.00%	30
Horses, donkeys and cross-breeds	100	9	0.64%	109
Pigs	2,233	60	4.26%	2,293
Goats	30	0	0.00%	30
Sheep	2,096	181	12.84%	2,277
Cattle	994	1,033	73.26%	2,027
Domestic fowl	51	40	2.83%	91
Other birds	115	0	0.00%	115
Xenopus	4	38	2.69%	42
Zebrafish	115	0	0.00%	115
Salmon, trout, chars and graylings	1,125	0	0.00%	1,125
Other fish	110	0	0.00%	110
Total uses	112,349	1,410	100.00%	113,759

3.3 Origin of animals at the first use

Table 3 shows the number of animals used according to their place of birth, but only includes animals used for the first time as the place of birth is not recorded for animals on their second (or subsequent) use(s). The majority (90%) of animals were born in the EU at a registered breeder, which means that they were born at breeding establishments authorised under the Directive. Animals born in the EU but not at a registered breeder (3%) includes wild animals and farm animals. Animals born in the rest of Europe (6%) represents rats and mice sourced from establishments authorised in the UK. Animals born in the rest of the world

(<1%) includes animals that have been obtained from breeding establishments outside of Europe (e.g. specific strains of mice not available in Europe) and wild fish species such as Basking sharks.

Table 3: Origin of animals at the first use

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	101,614	90.45%
Animals born in the EU not at a registered breeder	3,394	3.02%
Animals born in rest of Europe	6,835	6.08%
Animals born in rest of world	506	0.45%
Total uses	112,349	100.00%

3.4 Project purposes

Table 4 shows the primary purposes for which animals were used in research and testing. The most common primary purpose at 72% was 'Regulatory use and Routine production'. This is defined as the 'use of animals in procedures with a view to satisfying legal requirements for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed'.

The primary purposes are further sub-divided in **Tables 5-11**. It should be noted that the primary purposes 'Higher education' and 'Forensic enquiries' are excluded from this table as no uses were reported under these purposes for 2024.

Table 4: Primary purpose for which animals are used

Primary purpose	Number of uses	Percentage
Basic research	12,400	10.90%
Translational and applied research	15,903	13.98%
Regulatory use and routine production	82,155	72.22%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,565	1.38%
Preservation of the species	1,190	1.05%
Training for the acquisition, maintenance or improvement of vocational skills	546	0.48%
Total uses	113,759	100.00%

Table 5 shows the number of uses of animals in more specific categories of 'Basic research'. 'Basic research' refers to studies of a fundamental nature, which are designed to add knowledge about the structure, functioning, or behaviour of organisms. It should be noted that the sub-fields of 'musculoskeletal system', 'urogenital/reproductive system',

'developmental biology, and 'other basic research' were excluded from this table as no uses under these sub-fields were reported for 2024.

The most common sub-field of 'Basic research' at 38% was 'immune system', which relates to research investigating the functioning and activities of the immune system in health and disease. The next most common sub-field was 'ethology/animal behaviour/animal biology', representing 26% of all basic research performed. In Ireland, this is mainly accounted for by agricultural research into farm animal biology, for example research into genetic factors that impact methane production by sheep.

The third most common sub-field was 'nervous system', at 23%. Nervous system research involves studies investigating the physiology and functionality of the brain, spinal cord, and nerves (e.g. studies into behaviour and memory function). These types of studies most commonly use mice and rats.

Table 5: Uses of animals for basic research

Basic Research	Number of uses	Percentage
Oncology	75	0.60%
Cardiovascular, blood and lymphatic system	9	0.07%
Nervous system	2,855	23.02%
Respiratory system	41	0.33%
Gastrointestinal system including liver	109	0.88%
Immune system	4,764	38.42%
Sensory organs (skin, eyes and ears)	138	1.11%
Endocrine system/metabolism	248	2.02%
Multisystemic	990	7.98%
Ethology / animal behaviour /animal biology	3,171	25.57%
Total uses	12,400	100.00%

Table 6 shows the number of uses of animals in more specific categories of 'Translational and applied research', which refers to studies aimed at preventing, diagnosing, detecting or treating disease in animals or humans, as well as studies aimed at improving animal nutrition and welfare. It should be noted that the sub-fields of 'other human disorders', 'diagnosis of diseases', and 'plant diseases' were excluded from this table, as no uses under these sub-fields were reported for 2024.

The most common sub-field of 'Translational and applied research' at 36% of uses was research into 'human nervous and mental disorders'. This includes research into diagnostics and treatments for diseases such as epilepsy, autism and depression, using mice and rats. The next most common sub-field at 14% was 'human infectious disorders'. Studies conducted under this project purpose sub-field in 2024 included research into vaccines to prevent

serious infectious diseases in humans. The third most common sub-field at 8% was research into 'human cardiovascular disorders'. Studies performed under this sub-field included research into certain bleeding and clotting disorders.

Table 6: Uses of animals for translational and applied research

Translational and applied research	Number of uses	Percentage
Human cancer	1,296	8.15%
Human infectious disorders	2,173	13.66%
Human cardiovascular disorders	1,319	8.29%
Human nervous and mental disorders	5,666	35.63%
Human respiratory disorders	744	4.68%
Human gastrointestinal disorders including liver	451	2.83%
Human musculoskeletal disorders	185	1.16%
Human immune disorders	56	0.35%
Human urogenital/reproductive disorders	95	0.60%
Human sensory organ disorders (skin, eyes and ears)	580	3.65%
Human endocrine/metabolism disorders	610	3.84%
Animal diseases and disorders	1,122	7.06%
Animal nutrition	339	2.13%
Animal welfare	116	0.73%
Non-regulatory toxicology and ecotoxicology	1,151	7.24%
Total uses	15,903	100.00%

Table 7 shows the breakdown of animal uses for 'Routine production'. Routine production refers to the use of animals for the production of biological material, for example blood required in the development of diagnostic assays for the identification and treatment of diseases. The sub-fields 'monoclonal antibody by mouse ascites method only', 'monoclonal and polyclonal antibodies (excluding ascites method)', and 'other products' were excluded from this table as no uses under these sub-fields were reported in 2024.

Table 7: Uses of animals for routine production

Routine production uses	Number of uses	Percentage
Blood based products	25	100.00%
Total uses	25	100.00%

Table 8 shows the breakdown of animal uses for 'Regulatory testing'. The majority of reported uses (>99%) can be attributed to quality control testing. The animals used for 'toxicity and other safety testing' were pigs used to test the safety of a medical device. The

sub-field 'other efficacy and tolerance testing' was excluded from this table as no uses under this sub-field was reported in 2024.

Table 8: Uses of animals for regulatory testing

Regulatory use	Number of uses	Percentage
Quality control (including batch safety and potency	82,128	>99.99%
testing)		
Toxicity and other safety testing including pharmacology	2	<0.01%
Total uses	82,130	100.00%

Table 9 shows a further breakdown of animal use for 'quality control' tests. 'Quality control' refers to tests used to determine the purity, stability, efficacy, and potency parameters of a final medicinal product, in order to satisfy regulatory requirements for placement of the medicine on the market. The majority of quality control tests were for batch potency (93%), and of these tests, 94% were performed on mice. It should be noted that the sub-field of 'other quality controls' was excluded from this table as no uses under this sub-field were reported for 2024.

Batch potency testing is required for biological products, which are products made in a living system such as a microorganism, or plant or animal cells, as opposed to being manufactured through chemical synthesis. The nature of biological products is that they can be inherently variable, and so it is necessary to perform batch potency testing to ensure that each manufactured batch of product is of a consistent strength, and therefore both safe and effective for patients. It is also required as a safety/efficacy test for certain types of vaccine.

In relation to pyrogenicity testing (1%), non-animal alternatives have been developed to replace this type of testing for some medicines. However, for certain medicinal products where no validated non-animal alternative test had yet been accepted and approved by medicines regulators, the requirement remained to employ animal-based tests to test for pyrogenicity during 2024.

Table 9: Uses of animals for regulatory testing - quality control

Quality control	Number of uses	Percentage
Batch safety testing	4,615	5.62%
Pyrogenicity testing	957	1.17%
Batch potency testing	76,556	93.22%
Total uses	82,128	100.00%

Table 10 relates to the use of animals for regulatory testing under the sub-field 'toxicity and other safety testing including pharmacology'. Animals reported under this sub-field in 2024 were used to test the safety of medical devices. Since there were no animals reported under any other sub-fields of 'toxicity and other safety testing including pharmacology' in 2024, these have been excluded from this table.

Table 10: Uses of animals for regulatory testing - toxicity and other safety testing including pharmacology

Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Other toxicity/safety testing	2	100.00%
Total uses	2	100.00%

3.5 Use of animals to meet legislative requirements

Table 11 shows which type of legislation is being satisfied in the performance of the regulatory tests for which animals were used. Only categories of legislation under which animal use was reported are included in this table. The vast majority (>99%) were performed on medicinal products manufactured for use in humans. <0.01% of uses were to satisfy medical devices legislation.

Table 11: Regulatory testing by type of legislation

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	82,128	>99.99%
Medical devices legislation	2	<0.01%
Total uses	82,130	100.00%

Table 12 shows the geographical origin of the legal requirement. All tests were performed to satisfy EU legislative requirements.

Table 12: Origin of legislative requirement

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	82,130	100.00%
Legislation satisfying national requirements only [within EU]	0	0.00%
Legislation satisfying non-EU requirements only	0	0.00%
Total uses	82,130	100.00%

3.6 Use by genetic status for research and testing purposes

Table 13 shows the number of uses of animals for research and testing purposes that had a genetic alteration, broken down by whether the animal exhibited a harmful phenotype at the time of the study or not. The majority of animals (94%) were not genetically altered, with 2% of all uses involving animals with harmful phenotypes (see Appendix for definitions).

Table 13: Genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	106,767	93.85%
Genetically altered without a harmful phenotype	4,184	3.68%
Genetically altered with a harmful phenotype	2,808	2.47%
Total uses	113,759	100.00%

3.7 Actual severity of uses of animals for research and testing purposes

Table 14 shows the reported actual severity experienced by the animals during their uses for research and testing purposes. Overall, <2% of uses were classified as non-recovery, 57% were classified as mild, 25% were classified as moderate and 17% were classified as severe (see Appendix for definitions). Of the animals that were reported as experiencing severe severity in 2024, >99% were mice. It should be noted that there were no reports received of the severe classification being exceeded, nor did the HPRA grant any exemptions for the severe classification to be exceeded.

Table 14: Classification of actual severity

Severity	Number of uses	Percentage
Non-recovery	1,451	1.28%
Mild [up to and including]	64,854	57.01%
Moderate	28,400	24.97%
Severe	19,054	16.75%
Total uses	113,759	100.00%

4 DATA ON THE USES OF ANIMALS FOR THE CREATION AND MAINTENANCE OF GENETICALLY ALTERED ANIMAL LINES

Table 15 shows the number of animals (by species) used for the creation of new genetically altered animal lines for the first time. There was no reuse of animals reported for the creation of new genetically altered animal lines in 2024.

Table 15: Number of animals (by species) used for the creation of new genetically altered animal lines for the first time

Animal species	Number of uses	Percentage
Mice	728	42.40%
Zebrafish	989	57.60%
Total uses	1,717	100.00%

Table 16 shows the uses of animals for the creation of new genetically altered lines by severity.

Table 16: Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	0	0.00%
Mild [up to and including]	710	41.35%
Moderate	965	56.20%
Severe	42	2.45%
Total uses	1,717	100.00%

Table 17 shows the number of animals used for the creation of new genetically altered lines by genetic status of the animals. <1% of animals used in 2024 for the creation of a new genetically altered line were reported as not genetically altered. 13% were reported as genetically altered without a harmful phenotype, with 86% reported as genetically altered with a harmful phenotype.

Table 17: Uses of animals for the creation of new genetically altered animal lines by genetic status

Genetic status	Number of uses	Percentage
Not genetically altered	15	0.87%
Genetically altered without a harmful phenotype	223	12.99%
Genetically altered with a harmful phenotype	1,479	86.14%
Total uses	1,717	100.00%

Table 18 shows the uses of animals for the creation of new genetically altered lines by type of 'Basic research' purposes. 73% of animals used for the creation of a new genetically altered line for 'Basic research' were reported under the sub-field 'multisystemic', which relates to research looking at multiple organ systems, with the remaining uses reported under the sub-field of 'sensory organs (skin, eyes and ears). Since the remaining 'Basic research' sub-fields had no animals reported, they are excluded from this table.

Table 18: Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Sensory organs (skin, eyes and ears)	35	26.52%
Multisystemic	97	73.48%
Total uses	132	100.00%

Table 19 shows the uses of animals for the creation of new genetically altered lines by type of 'Translational and applied research' purposes. The majority of animals (98%) were reported as used under the 'Translational and applied research' sub-field 'human sensory organ disorders (skin, eyes and ears)', with small percentages of animals reported under the sub-fields 'human nervous and mental disorders' and 'human respiratory disorders'. Since the remaining 'Translational and applied research' sub-fields had no animals reported, they are excluded from this table.

Table 19: Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human nervous and mental disorders	42	2.65%
Human respiratory disorders	83	5.24%
Human sensory organ disorders (skin, eyes and ears)	1,460	92.11%
Total uses	1,585	100.00%

Table 20 shows the number of animals used (by species) for the maintenance of established genetically altered lines for the first time. Mice and zebrafish were the only species of animal reported as being used for the maintenance of established genetically altered lines during 2024. There was no reuse of animals reported for the maintenance of established genetically altered lines in 2024.

Table 20: Number of animals used for the maintenance of established genetically altered animal lines by species

Animal species	Number of uses	Percentage
Mice	192	61.74%
Zebrafish	119	38.26%
Total uses	311	100.00%

Table 21 shows the uses of animals for the maintenance of established genetically altered lines by severity. 95% of animals used for the maintenance of established genetically altered lines in 2024 were reported as having experienced mild severity.

Table 21: Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	0	0.00%
Mild [up to and including]	296	95.18%
Moderate	5	1.61%
Severe	10	3.22%
Total uses	311	100.00%

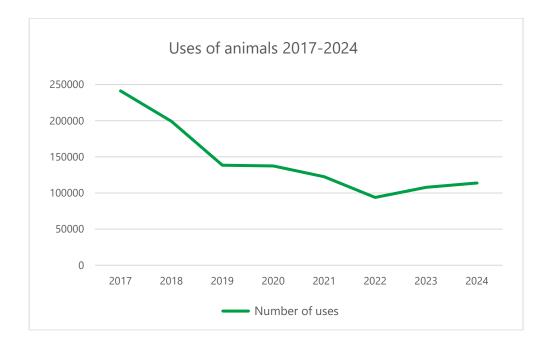
Table 22 shows the uses of animals for the maintenance of established genetically altered lines by genetic status of the animals. 60% of animals used for the maintenance of established genetically altered lines in 2024 were reported as genetically altered without a harmful phenotype, with 33% reported as genetically altered with a harmful phenotype.

Table 22: Uses of animals for the maintenance of established genetically altered animal lines by genetic status

Genetic status	Number of uses	Percentage
Not genetically altered	22	7.07%
Genetically altered without a harmful phenotype	187	60.13%
Genetically altered with a harmful phenotype	102	32.80%
Total uses	311	100.00%

5 TRENDS

a) In 2024, there were 113,759 uses of animals for research, testing, routine production, and education and training purposes. This represents a 5% increase from the number of uses reported for 2023 (107,873 uses in 2023). This increase was mirrored by a 5% increase in the numbers of animals used for first time in 2024 versus 2023 (112,349 in 2024 versus 106,639 animals in 2023). Overall, the total number of uses of animals in Ireland has decreased significantly since 2017, as illustrated by the graph below.



- b) There was a 12% decrease in the number of animals used for 'Basic research' in 2024 (12,400 animals) versus 2023 (14,105 animals). The reasons for this decrease are not known.
- c) There was a 9% increase in the number of animals used for the purpose 'Regulatory testing', driven by a 12% rise in the number of uses for the sub-field 'quality control (including batch safety and potency testing)', with 82,128 animals used for this secondary purpose in 2024 compared to 75,072 in 2023. This is primarily due to an increase in uses for batch potency testing of human medicines, such as botulinum toxin products and vaccines.
- d) There was a 141% increase in the number of animals used for the purpose 'Protection of the natural environment in the interests of the health or welfare of human beings or animals'. This increase was driven by several large-scale studies undertaken in

- ruminant species aimed at reducing environmental emissions of methane and nitrogen in Irish agriculture.
- e) There was a significant increase in the number of uses reported under the purpose 'Preservation of the species', rising from 195 in 2023 to 1,190 in 2024. This increase was driven by two large conservation projects undertaken during 2024 aimed at preserving native Irish freshwater species.
- f) There was a 90% increase in the number of uses of animals reported under the purpose 'Training for the acquisition, maintenance or improvement of vocational skills' rising from 287 in 2023 to 546 in 2024. This was largely due to an increased demand for qualified veterinarians to be trained in specific diagnostic testing skills essential for the control of various notifiable animal diseases.
- g) There was a 27% decrease in the number of animals reported as used for the creation and maintenance of genetically altered animals, thought to be attributable to year-to-year variation.
- h) Mice remain the most frequently used species, representing 86% of all uses of animals in 2024. The total number of mice used increased by 10%, rising from 86,871 uses in 2023 to 96,333 uses in 2024. This was mainly due to an increase in the number of mice used for the purpose 'Regulatory testing', e.g. for batch potency testing of human medicines, such as botulinum toxin products and human vaccines.
- i) The total number of rats used in 2024 decreased by 26% to 6,221, from 8,440 in 2023. This decline was primarily due to a 31% reduction in the use of rats for the purpose 'Regulatory testing' (specifically batch potency testing of human medicinal (biological) products), and a 19% reduction in the use of rats for the purposes of 'Translational and Applied research' and 'Basic research'.
- j) The number of guinea pigs used increased by 45%, from 1,188 in 2023 to 1,721 in 2024. This rise was due to an increase in the use of guinea pigs for the purpose 'Regulatory testing' (batch potency testing of human vaccines).
- k) The number of rabbits used decreased by 48%, from 1,852 in 2023 to 964 in 2024. This was largely due to a reduction in use for 'Regulatory testing' for detecting pyrogenic contaminants, reflecting sponsor companies' efforts to validate non-animal alternative methods for pyrogen testing, in preparation for the removal of the rabbit pyrogen test from the European Pharmacopoeia in 2025.
- There were no uses of cats reported for 2024 (down from 24 uses reported in 2023). The factors underlying this reduction are not fully understood, but it likely reflects a lower volume of research, development, and regulatory testing of feline veterinary medicinal products during 2024 compared to the previous year.

- m) The number of reported uses of dogs increased by 59%, from 66 uses in 2023 to 105 uses in 2024. The reasons for this increase are not fully understood, but it may be linked to a higher volume of research, development, and regulatory testing of canine veterinary medicinal products in 2024 compared to 2023.
- n) The number of ferrets used decreased by 83%, from 175 in 2023 to 30 in 2024. This significant decline was due to a reduction in the use of ferrets for the purpose of 'Regulatory testing' of influenza vaccines during 2024.
- o) There was a significant increase in the number of uses of horses reported, from 10 in 2023 to 109 in 2024. This rise was primarily driven by the enrolment of horses on several 'Translation and Applied' research projects undertaken by veterinary teams to investigate equine disease conditions and potential treatments.
- p) There was a significant increase in the number of uses of pigs, from 752 in 2023 to 2,293 in 2024. This increase was due to several large-scale agricultural projects focused on pig health, welfare and nutrition.
- q) The number of uses of sheep decreased significantly by 31%, from 3,280 in 2023 to 2,277 in 2024. This was largely due to the completion of a large-scale methane measurement project in 2023.
- r) The number of uses of cattle decreased by 29%, from 2,855 in 2023 to 2,027 in 2024. This was due to two large-scale agricultural research projects investigating strategies to improve the welfare of dairy cattle and to enhance genetic gain in the national dairy herd concluding in 2023.
- s) There was a significant increase of 146% in the number of uses of fowl reported, from 37 in 2023 to 91 in 2024. This was due to an increased demand for diagnostic testing for avian diseases during 2024.
- t) There was a significant increase in the number uses of 'other bird' species reported, from 6 in 2023 to 115 in 2024. This was due to the commencement of a large-scale conservation project aimed at preserving several seabird species during 2024.
- u) There was a significant increase in the number of uses of zebrafish for research and testing in 2024 when compared with 2023 (0 uses reported for 2023, 115 uses reported for 2024); these were fish enrolled in projects investigating human cancers.
- v) There was a 46% decrease in the number of uses of salmon, trout, chars and graylings reported for 2024 when compared to 2023 (1,125 uses in 2024 versus 2,068 uses in 2023). This was due to a large-scale research project investigating treatments for infectious diseases in salmon concluding in 2023.

w) The percentage distribution of uses across the four severity categories in 2024 remains broadly similar to that reported for 2023.

To Note: In addition to routine year-on-year variation in the number and nature of projects authorised, annual trend data can be impacted by a range of other factors which can lead to variation in the overall number of animals used. Decreases, for example, may arise as a result of the ongoing application of the 3Rs principles while certain extraneous developments may result in increases in the levels of animal use. Among the factors that should be considered when assessing annual trend data include:

- The relocation of existing regulatory testing either to or from Ireland.
- The regulatory requirement for the use of animal tests to determine the safety and effectiveness of new human medicines and vaccines developed in response to emerging and significant public health developments.
- The adoption, following regulatory approval, of alternative testing methods including in vitro tests.

6 CONCLUSION

In 2024 there were 113,759 reported uses of animals for research, testing, routine production, and education and training purposes in Ireland. Furthermore, 1,717 animals were reported as being used for the creation of new genetically altered animal lines, with 311 animals reported as being used for the maintenance of genetically altered animal lines.

The HPRA's focus will continue to be on promoting the replacement of animal tests using with suitable non-animal alternatives, ensuring that the principle of Reduction is applied appropriately when it is necessary to use animals, and refining the husbandry, care and use of animals in procedures. In addition, the HPRA will ensure that animals are used only when there is no equivalent alternative (non-animal) technique available, and the harm-benefit analysis of the proposed use is favourable.

7 APPENDIX: DEFINITIONS

Procedures

The Directive defines a procedure as: "any use of an animal for scientific or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice". This includes the creation and maintenance of any genetically altered animal lines that may result in pain or distress as per the above definition. Each procedure may consist of several stages or techniques for a single scientific purpose, which is then counted as *one* procedure and reported in the year it was completed.

Reuse

Reuse means that following a full recovery from a completed procedure and having been certified by a veterinarian as being returned to full health, that animal can then undergo a subsequent procedure.

Genetically altered animals

Genetically altered animals are those that have been genetically modified, for example, by the introduction (into an animal) of genetic material from another animal, or by 'knocking out' or disrupting an existing gene.

Actual severity

At the end of the use of an animal on a procedure, the impact of the procedure must be determined and reported as 'actual severity'. This means that the *highest severity* that an animal may have experienced throughout the course of their time on procedure (rather than the severity at the end or the average severity throughout) must be recorded. Therefore, it is based on the <u>real impact</u> of the procedure, rather than any predicted impact. The legislation defines four categories of actual severity, in order of least to most harmful, as: non-recovery, mild, moderate, and severe.

- Non-recovery: This means the entire procedure is carried out under general
 anaesthesia and, at the end, the animal is humanely euthanised rather than being
 allowed to wake up.
- Mild: Any pain or suffering experienced by the animal is only slight, minor, or temporary and so the animal recovers in a short period of time. This would include an injection, a short period of social isolation, or non-invasive imaging under sedation or anaesthesia (e.g. MRI scanning).
- Moderate: Any suffering experienced by the animal is short-term moderate pain, suffering, or distress; long-lasting mild pain, suffering, or distress; or involves a moderate impairment to their well-being. This would include surgery performed under general anaesthesia, repeated injections or blood tests, or the induction of tumours that cause moderate impairment to well-being.
- **Severe:** Severe procedures indicate a major departure from the animal's usual state of health or well-being, and cause long-lasting moderate pain, suffering or distress, or short-term severe pain. This might include toxicity testing under legislation where fatalities may occur, surgical procedures that cause severe post-operative pain, or the breeding of animals with serious genetic disorders.

It should be noted that procedures that involve severe pain, suffering, or distress that are *long-lasting* are prohibited under the legislation