

## Portugal

### Portugal: Narrative 2018

#### **1. General information on any changes in trends observed since the previous reporting period.**

In 2018 there was an increase in animal use compared to the previous year (2017). The total number of animals used in 2018 is 81107, which constitutes a 34,7% increase in animal use, compared to 2017 (total uses: 52983).

Mice continue to be the most used animal species (72,77%), followed by the entry Other fish (15,38%), Rats (6,62%) and Zebra fish (4,57%).

There is a significant increase in the use of Fish (19,95%) compared to 2017 (3,98%).

All animal species used in 2018 showed an increase compared to 2017, except Other rodents, Other mammals and Cephalopods that decreased. Domestic fowl was not used in 2018.

The use of Mammals dropped 14,90% but the the use of Fish increased 15,97% compared to the previous year.

There was a decrease on reuse (total reuses: 300) compared to the previous year (total reuses: 1509).

Compared to the previous year, there was an obvious increase in the use of animals in Basic research, Translational and applied research, Maintenance of colonies of established genetically altered animals, not used in other procedure and in the Protection of the natural environment in the interests of the health or welfare of human beings or animals.

Regulatory use and Routine production represents only 0,4% of all uses and animals used in Higher education or training for the acquisition, maintenance or improvement of vocational skills had a slight decrease compared to 2017, representing only 0,28% of all uses in 2018.

#### **2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

The increase in animal numbers in 2018 is mainly due to increased Basic research (64,73% of all use), Maintenance of colonies of established genetically altered animals, not used in other procedures (19,99% of all use), Translational and applied research (13,47% of all use) and Protection of the natural environment in the interests of the health or welfare of human beings or animals (1,13% of all use).

The increase in Basic reseach is related to the increase of studies in Oncology, Nervous System, Respiratory System, Sensory organs, Endocrine System/Metabolism, Multisystemic, Ethology/Animal behaviour/Animal Biology and Other Basic research (Animal nutrition, Nutrition, Infection, Embryonic development, for example).

The increase in Translational and applied research is related to the increase of studies in Human Infectious disorders, Human Cardiovascular Disorders, Human cancer, Human Gastrointestinal Disorders including Liver, Human Endocrine/metabolism Disorders and Other Human Disorders. Despite there was a very slight drop in the use of animals for studying Human Nervous and Mental Disorders, compared to the previous year, this is the second category of purposes for which more animals were used in Translational and applied research, representing 20,62% of all uses in this category.

The reason for an increase in uses reported in the category Maintenance of colonies of established genetically altered animals not used in other procedures, compared to the previous year, may be due to an increase in the existence of more genetically lines.

In fact, in the latest years, there has been an increase on the use of genetically altered animals (with or without a harmful phenotype) and, in 2018, the percentage of use of genetically altered animals is 49,71% of all uses.

The significant increase in the use of Other fish (15,38% of all uses) is mainly due to an increase in studies in the areas of Animal nutrition, digestibility and infectious diseases to support the field of Aquaculture and in studies of Basic research linked to the Immune system and Ethology, Animal behaviour and Animal biology.

### **3. Information on any changes in trends in actual severities and analysis of the reasons thereof.**

In 2018, the percentages reported for each of the categories of actual severities experienced by the animals were as follows:

- Non-recovery: 3,16%
- Mild: 67,96%
- Moderate: 18,98%
- Severe: 9,90%

Compared to the previous year, this represents an increase of 15,45% in Mild procedures (52,51% to 67,96%), a decrease of 0,65% in Non-recovery procedures (3,81% to 3,16%), a decrease of 5,05% in Moderate procedures (24,03% to 18,98%) and a decrease of 9,76% in Severe procedures (19,66% to 9,90%).

In general terms, We consider that this might probably due to a much wider and expressive application of human endpoints and to acquisition of knowledge and competence in monitoring the animals by the Animal Welfare Bodies.

Concerning the Non-recovery procedures, we have had an effort for clarifying the confusions that usually rise with the attribution of this category of severity.

### **4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

Despite not always being evident that the principle of replacement, reduction and refinement has an obvious impact and reflex on the statistics, somehow, we think it is the case.

The promotion and the implementation of the 3Rs is always present in all the authorisation processes and in the details that involve the use of animals for scientific purposes and is somehow applied by all the persons who in the course of the performance of their responsibilities are confronted with its application.

The competent authority has always contributed to the promotion of 3Rs, whether when carrying out inspections to establishments, when evaluating scientific projects submitted for subsequent authorization or in any opportunity it has to talk about the theme.

On the other hand, at the level of an establishment where animals are bred, used or from which are supplied for scientific purposes, the Animal Welfare Body has implicit functions for implementing measures to improve animal welfare and to promote 3Rs on a daily basis.

**5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

In 2018, the further breakdown on the use of "other" categories is as follows:

On Animal species:

"Other birds" include pigeons (*Columba livia*);

"Other fish" include:

Goby (*Pomatoschistus microps*)

Seabass (*Dicentrarchus labrax*)

Seabream (*Sparus aurata*)

*Argyrosomus argyrosomus regius*

*Atherina presbyter*

*Onchorrhynchus mykiss*

*Oreochromis mossambicus*

*Oreochromis niloticus*

*Scyliorhinus canicula*

On Purpose:

In Basic Research, “Other” include:

Nutrition

Animal nutrition/Digestibility

Obesity studies

Infectious disease / Infection

Malaria studies

Embrionic development

Intestinal microbiota composition

Genetic disorders

Bacterial metabolite profile *in vivo*

In Translational and applied research, “Other Human Disorders” include Aging.

**6. Details on cases where the 'severe' classification is exceeded, whether pre-authorized or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

These cases have not occurred.

## Portugal: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	41745	66.98%
Rats	5361	8.6%
Other rodents	37	0.06%
Rabbits	55	0.09%
Pigs	175	0.28%
Sheep	18	0.03%
Other mammals	2	0%
Zebra fish	2448	3.93%
Other fish	12474	20.02%
Cephalopods	8	0.01%
Total	62323	100.00%

#### Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	56569	90.77%
Animals born in the EU but not at a registered breeder	4829	7.75%
Animals born in rest of Europe	199	0.32%
Animals born in rest of world	726	1.16%
<b>Total</b>	<b>62323</b>	<b>100.00%</b>

#### Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
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No data reported

#### Generation of non-human primates

NHP Generation	Number of animals	Percentage
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No data reported

## Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

### First use versus reuses

Animal species	First uses	Reuses	Total
Mice	41745	60	41805
Rats	5361		5361
Other rodents	37		37
Rabbits	55		55
Cats		2	2
Dogs		18	18
Horses, donkeys and cross-breeds		9	9
Pigs	175		175
Goats		88	88
Sheep	18	22	40
Cattle		20	20
Other mammals	2		2
Other birds		66	66
Xenopus		15	15
Zebra fish	2448		2448
Other fish	12474		12474
Cephalopods	8		8
<b>Total</b>	<b>62323</b>	<b>300</b>	<b>62623</b>

### Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	50231	80.21%
Translational and applied research	10924	17.44%
Regulatory use and Routine production	322	0.51%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	918	1.47%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	228	0.36%
<b>Total</b>	<b>62623</b>	<b>100.00%</b>

### Basic research related uses

Basic research	Number of uses	Percentage
Oncology	5190	10.33%
Cardiovascular Blood and Lymphatic System	1045	2.08%
Nervous System	5773	11.49%
Respiratory System	517	1.03%
Gastrointestinal System including Liver	298	0.59%
Musculoskeletal System	104	0.21%
Immune System	16068	31.99%
Urogenital/Reproductive System	52	0.1%
Sensory Organs (skin, eyes and ears)	73	0.15%
Endocrine System/Metabolism	1908	3.8%
Multisystemic	430	0.86%
Ethology / Animal Behaviour /Animal Biology	4116	8.19%
Other basic research	14657	29.18%

<b>Total</b>	50231	100.00%
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#### Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	307	2.81%
Human Infectious Disorders	3785	34.65%
Human Cardiovascular Disorders	1901	17.4%
Human Nervous and Mental Disorders	2252	20.62%
Human Gastrointestinal Disorders including Liver	515	4.71%
Human Musculoskeletal Disorders	196	1.79%
Human Urogenital/Reproductive Disorders	35	0.32%
Human Sensory Organ Disorders (skin, eyes and ears)	256	2.34%
Human Endocrine/Metabolism Disorders	122	1.12%
Other Human Disorders	256	2.34%
Animal Diseases and Disorders	20	0.18%
Diagnosis of diseases	995	9.11%
Non-regulatory toxicology and ecotoxicology	284	2.6%
<b>Total</b>	10924	100.00%

#### Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	322	100%
<b>Total</b>	322	100.00%

#### Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
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No data reported

#### Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics	245	76.09%
Safety testing in food and feed area	77	23.91%
<b>Total</b>	322	100.00%

#### Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
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No data reported

#### Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
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No data reported

#### Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
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No data reported

#### Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	245	76.09%

<b>Food legislation including food contact material</b>	77	23.91%
<b>Total</b>	322	100.00%

#### Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
<b>Legislation satisfying EU requirements</b>	322	100%
<b>Total</b>	322	100.00%

#### Routine production uses by product type

Product type	Number of uses	Percentage
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No data reported

#### Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
<b>No</b>	62323	99.52%
<b>Yes</b>	300	0.48%
<b>Total</b>	62623	100.00%

#### Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
<b>Non-recovery</b>	2566	4.1%
<b>Mild [up to and including]</b>	37968	60.63%
<b>Moderate</b>	14158	22.61%
<b>Severe</b>	7931	12.66%
<b>Total</b>	62623	100.00%

#### Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
<b>Not genetically altered</b>	39563	63.18%
<b>Genetically altered without a harmful phenotype</b>	19209	30.67%
<b>Genetically altered with a harmful phenotype</b>	3851	6.15%
<b>Total</b>	62623	100.00%



### Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	1038		1038
Zebra fish	1230		1230
<b>Total</b>	2268		2268

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

Severity	Number of uses	Percentage
Mild [up to and including]	1127	49.69%
Moderate	1043	45.99%
Severe	98	4.32%
<b>Total</b>	2268	100.00%

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

Genetic status	Number of uses	Percentage
Not genetically altered	1221	53.84%
Genetically altered without a harmful phenotype	526	23.19%
Genetically altered with a harmful phenotype	521	22.97%
<b>Total</b>	2268	100.00%

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

Basic research	Number of uses	Percentage
Oncology	1488	65.61%
Cardiovascular Blood and Lymphatic System	145	6.39%
Nervous System	221	9.74%
Immune System	184	8.11%
Endocrine System/Metabolism	195	8.6%
Other basic research	35	1.54%
<b>Total</b>	2268	100.00%

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
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No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	16177		16177
Rats	9		9
Zebra fish	30		30
<b>Total</b>	16216		16216

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

Severity	Number of uses	Percentage
Mild [up to and including]	16026	98.83%
Moderate	190	1.17%
<b>Total</b>	16216	100.00%

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

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	15501	95.59%
Genetically altered with a harmful phenotype	715	4.41%
<b>Total</b>	<b>16216</b>	<b>100.00%</b>