

## Denmark

### Denmark: Narrative 2018

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

In 2018, the overall number of animals used for experimental procedures in Denmark was 249,747. The number is slightly higher than in 2017, where the total number of animals was 235,512 resulting in a 6 % increase. The increase can be explained by a rise in the use of mainly mice but also in mink and domestic fowl compared to 2017.

The majority of experimental procedures used mice (70 %), rats (15 %) and fish (6 %) and together these species were used in approx. 91 % of all experimental procedures in 2018. A high percentage of experimental procedures involving mice and rats are Oncology and Immune system (basic research purposes) and Human Endocrine / Metabolism Disorders and Human Nervous and Mental Disorders (translational and applied research purposes). Fish are mostly used for experimental procedures involving Ethology / Animal behavior / Animal biology (basic research purpose) and animal diseases and disorders (translational and applied research purpose).

The overall distribution in purposes of procedures for all animal species are 41 % Basic research, 46 % Translational and applied research and 10 % Regulatory testing for 2018.

The severity assessment for 2018 shows that 61 % of experimental procedures in animals were mild and 32 % were moderate. Only 1 % of the animals used for experimental procedures experienced severe suffering in 2018 and this confirms the trend from the previous years.

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

The number of mice and rats has remained stable for several years. In 2018 the number of mice is slightly higher (175.708 mice) compared to 2017 (163.281 mice) resulting in roughly 8 % increase, but there is no obvious reason. A rising use of GA animals could affect the number of mice, but the use of GA animals has not changed significantly from 2017 to 2018. The explanation could therefore be that in a small country like Denmark, a strengthened focus from a few research groups can have a large impact on the statistics.

The use of 3.077 mink in 2018 is remarkably high, as the number in 2017 was only 935 animals. This is due to two research groups, where one is new, both studying animal welfare and animal behavior in mink for farming. The research focus is especially on nutrition/metabolism and weaning of cups and the vast majority of these experiments are within mild severity.

Finally, there has been an increase in the use of domestic fowls from 402 animals in 2017 to 2.283 animals in 2018. A large public interest has caused an increased research effort on animal welfare for domestic fowls used in farming with special focus on combatting infectious diseases and pathology.

In recent years, Denmark is experiencing an increased public interest in animal welfare in farm animals. Therefore, the need for research within this area will probably continue the following years.

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

There has been an increase in the percentage of mild severity from 53 % in 2017 to 61 % in 2018 and a small drop in the percentage of moderate severity from 36 % in 2017 to 32 % in 2018. There is no apparent explanation for this change, but the Danish competent authority will follow the numbers closely in order to identify any lasting changes.

The number of animals experiencing severe severity has increased from 0.74 % in 2017 to 1.14 % in 2018. Compared to the number from 2016, which was 1.57%, the numbers are relatively stable and consistently low. As Denmark generally has few animals experiencing severe severity, a changed focus from just one or two research groups can affect the statistical outcome in one way or the other.

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

The Danish National Committee supports the animal welfare bodies by hosting a yearly meeting, providing platforms for charring best practice and dissemination of guidelines.

The National Committee has also initiated a survey to optimize the use of animals for the purpose of higher education and training in relation to the 3R's. In Denmark, 2 % of all animals used for scientific research purposes fall into this category.

The Danish 3R-center is still working hard to promote the 3R's and one way is by funding research. Another event is the 3R-centers annual symposium, which is open to all interested. In 2018, some of the key topics were improving reproducibility and translatability, animal free methods and unconscious bias in scientific research. Further information is available on [www.3rcenter.dk](http://www.3rcenter.dk).

The Danish Animal Experiments Inspectorate hosts three annual mini-seminars for both scientific staff and animal caretakers. The seminars are a good forum for discussing best practice and new models, as well as disseminating information on the legislation and correct statistical reporting.

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

On three cases the use of the category 'Other' is relatively high in Denmark – this concerns 'other carnivores', 'other fish' and 'other birds'.

Denmark has a large proportion of commercial aquaculture and fur production. Therefore, the distribution of carnivores and fish in the category 'other' is very high. The number of 'other fish' (82 %) is due to a large research focus on farming especially rainbow trout, seabass, cod and salmon. The number of 'other carnivores' (90 %) is due to a large research focus on improving animal welfare for farming mink.

Research involving “other birds” are primarily field studies on i.e. common eider, common redstart and willow warbler with focus on population research and spread of diseases studies.

**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.**

Denmark has no cases where the ‘severe’ classification was exceeded in 2018.

## Denmark: 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	172248	70.12%
Rats	36360	14.8%
Guinea-Pigs	2659	1.08%
Hamsters (Syrian)	292	0.12%
Other rodents	13	0.01%
Rabbits	3116	1.27%
Cats	3	0%
Dogs	357	0.15%
Other carnivores	3077	1.25%
Horses, donkeys and cross-breeds	178	0.07%
Pigs	6977	2.84%
Goats	13	0.01%
Sheep	75	0.03%
Cattle	1997	0.81%
Other mammals	28	0.01%
Domestic fowl	2283	0.93%
Other birds	559	0.23%
Reptiles	155	0.06%
Rana	809	0.33%
Xenopus	429	0.17%
Other amphibians	94	0.04%
Zebra fish	2028	0.83%
Other fish	11888	4.84%
<b>Total</b>	<b>245638</b>	<b>100.00%</b>

#### 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	212734	86.6%
Animals born in the EU but not at a registered breeder	23373	9.52%
Animals born in rest of Europe	2866	1.17%
Animals born in rest of world	6665	2.71%
<b>Total</b>	<b>245638</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

Speaking Of Research

## 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	172248	2263	174511
Rats	36360	920	37280
Guinea-Pigs	2659		2659
Hamsters (Syrian)	292		292
Other rodents	13		13
Rabbits	3116		3116
Cats	3		3
Dogs	357	13	370
Other carnivores	3077	270	3347
Horses, donkeys and cross-breeds	178	3	181
Pigs	6977	666	7643
Goats	13		13
Sheep	75	3	78
Cattle	1997	2	1999
Other mammals	28	1	29
Domestic fowl	2283		2283
Other birds	559		559
Reptiles	155		155
Rana	809		809
Xenopus	429	960	1389
Other amphibians	94		94
Zebra fish	2028		2028
Other fish	11888		11888
<b>Total</b>	<b>245638</b>	<b>5101</b>	<b>250739</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	101815	40.61%
Translational and applied research	117026	46.67%
Regulatory use and Routine production	24225	9.66%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1598	0.64%
Preservation of species	943	0.38%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5132	2.05%
<b>Total</b>	<b>250739</b>	<b>100.00%</b>

### Basic research related uses

Basic research	Number of uses	Percentage
Oncology	22009	21.62%
Cardiovascular Blood and Lymphatic System	5251	5.16%
Nervous System	15611	15.33%
Respiratory System	2608	2.56%
Gastrointestinal System including Liver	3676	3.61%
Musculoskeletal System	2935	2.88%

Immune System	25598	25.14%
Urogenital/Reproductive System	1119	1.1%
Sensory Organs (skin, eyes and ears)	401	0.39%
Endocrine System/Metabolism	11364	11.16%
Multisystemic	215	0.21%
Ethology / Animal Behaviour /Animal Biology	6370	6.26%
Other basic research	4658	4.57%
<b>Total</b>	<b>101815</b>	<b>100.00%</b>

#### Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	8285	7.08%
Human Infectious Disorders	7899	6.75%
Human Cardiovascular Disorders	4200	3.59%
Human Nervous and Mental Disorders	27344	23.37%
Human Respiratory Disorders	48	0.04%
Human Gastrointestinal Disorders including Liver	303	0.26%
Human Musculoskeletal Disorders	398	0.34%
Human Immune Disorders	2678	2.29%
Human Urogenital/Reproductive Disorders	904	0.77%
Human Sensory Organ Disorders (skin, eyes and ears)	126	0.11%
Human Endocrine/Metabolism Disorders	44717	38.21%
Other Human Disorders	6537	5.59%
Animal Diseases and Disorders	9314	7.96%
Animal Welfare	2516	2.15%
Diagnosis of diseases	1231	1.05%
Non-regulatory toxicology and ecotoxicology	526	0.45%
<b>Total</b>	<b>117026</b>	<b>100.00%</b>

#### Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	18545	76.55%
Other efficacy and tolerance testing	619	2.56%
Toxicity and other safety testing including pharmacology	4275	17.65%
Routine production	786	3.24%
<b>Total</b>	<b>24225</b>	<b>100.00%</b>

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3484	18.79%
Batch potency testing	15061	81.21%
<b>Total</b>	<b>18545</b>	<b>100.00%</b>

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

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	160	3.74%
Skin irritation/corrosion	16	0.37%
Skin sensitisation	118	2.76%
Repeated dose toxicity	2292	53.61%
Reproductive toxicity	480	11.23%
Kinetics	361	8.44%
Pharmaco-dynamics (incl safety pharmacology)	687	16.07%
Ecotoxicity	154	3.6%

<b>Other toxicity/safety testing</b>	7	0.16%
<b>Total</b>	4275	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
<b>Non lethal methods</b>	160	100%
<b>Total</b>	160	100.00%

#### 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
<b>up to 28 days</b>	1174	51.22%
<b>29 - 90 days</b>	895	39.05%
<b>&gt; 90 days</b>	223	9.73%
<b>Total</b>	2292	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
<b>Acute toxicity</b>	154	100%
<b>Total</b>	154	100.00%

#### Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
<b>Legislation on medicinal products for human use</b>	22525	96.1%
<b>Industrial chemicals legislation</b>	634	2.7%
<b>Other legislation</b>	280	1.19%
<b>Total</b>	23439	100.00%

#### Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
<b>Legislation satisfying EU requirements</b>	23439	100%
<b>Total</b>	23439	100.00%

#### Routine production uses by product type

Product type	Number of uses	Percentage
<b>Blood based products</b>	786	100%
<b>Total</b>	786	100.00%

#### 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>	245638	97.97%
<b>Yes</b>	5101	2.03%
<b>Total</b>	250739	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>	14016	5.59%
<b>Mild [up to and including]</b>	151794	60.54%
<b>Moderate</b>	82027	32.71%
<b>Severe</b>	2902	1.16%

<b>Total</b>	250739	100.00%
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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>	212489	84.75%
<b>Genetically altered without a harmful phenotype</b>	28009	11.17%
<b>Genetically altered with a harmful phenotype</b>	10241	4.08%
<b>Total</b>	250739	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	3281		3281
Zebra fish	649		649
<b>Total</b>	<b>3930</b>		<b>3930</b>

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

Severity	Number of uses	Percentage
Non-recovery	109	2.77%
Mild [up to and including]	3787	96.36%
Moderate	31	0.79%
Severe	3	0.08%
<b>Total</b>	<b>3930</b>	<b>100.00%</b>

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	1947	49.54%
Genetically altered without a harmful phenotype	1982	50.43%
Genetically altered with a harmful phenotype	1	0.03%
<b>Total</b>	<b>3930</b>	<b>100.00%</b>

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	1	0.03%
Nervous System	415	10.81%
Gastrointestinal System including Liver	6	0.16%
Urogenital/Reproductive System	119	3.1%
Endocrine System/Metabolism	150	3.91%
Multisystemic	358	9.32%
Other basic research	2791	72.68%
<b>Total</b>	<b>3840</b>	<b>100.00%</b>

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 Musculoskeletal Disorders	60	66.67%
Human Endocrine/Metabolism Disorders	30	33.33%
<b>Total</b>	<b>90</b>	<b>100.00%</b>

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

Animal species	First uses	Reuses	Total uses
Mice	179		179
<b>Total</b>	<b>179</b>		<b>179</b>

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

Severity	Number of uses	Percentage
Mild [up to and including]	2	1.12%
Moderate	173	96.65%
Severe	4	2.23%
<b>Total</b>	<b>179</b>	<b>100.00%</b>

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

Genetic status	Number of uses	Percentage
<b>Genetically altered with a harmful phenotype</b>	179	100%
<b>Total</b>	179	100.00%

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