

Bulgaria

Bulgaria: Narrative 2018

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

The total number of animals, used for 2018, compared to 2017 is reduced. The number of re-used animals is increased. The used animals are only animals born in the EU at register breeder. The number of used rodents is slightly increased, but the number of used rabbits and artiodactyla are reduced.

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

The number of used for 2018 animals, compared to 2017 is reduced. In some cases, depending on the project type, the Ethic Commission made recommendations for reduction of the used animals. The project authorization is not given of projects, who do not consider with the recommendation. It was asked, some of the tests to be filmed.

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

The procedures with non-recovery severity are increased. The number of procedures with moderate or severe severity are decreased. The reason for minimizing the procedures with severe severity in 2018 is:

- a lot of procedures for the purpose of training students were filmed;
- existing scientific publications in connection with experiments conducted for the same purpose.

The reason for increasing the procedures with non-recovery severity is the following: Often, in one authorization project are combined several diagnostic procedures, related to diagnostic purposes or testing new pharmaceutical products for which there is no literature available regarding the subsequent impact on treated animals.

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

The number of re-used animals is increased. Often, the Ethic Commission made recommendations for reduction of the used animals.

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

No.

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

No.

Bulgaria : 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	1176	16.78%
Rats	1861	26.55%
Guinea-Pigs	1800	25.68%
Rabbits	293	4.18%
Dogs	25	0.36%
Pigs	104	1.48%
Domestic fowl	60	0.86%
Rana	1420	20.26%
Other amphibians	270	3.85%
Total	7009	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	7009	100%
Total	7009	100.00%

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	1176		1176
Rats	1861	16	1877
Guinea-Pigs	1800	1	1801
Rabbits	293	132	425
Dogs	25		25
Pigs	104		104
Domestic fowl	60		60
Rana	1420		1420
Other amphibians	270		270
Total	7009	149	7158

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	2439	34.07%
Translational and applied research	97	1.36%
Regulatory use and Routine production	2955	41.28%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1667	23.29%
Total	7158	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	94	3.85%
Nervous System	1236	50.68%
Gastrointestinal System including Liver	9	0.37%
Musculoskeletal System	195	8%
Immune System	15	0.62%
Sensory Organs (skin, eyes and ears)	64	2.62%
Endocrine System/Metabolism	500	20.5%
Multisystemic	326	13.37%
Total	2439	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	30	30.93%
Human Respiratory Disorders	37	38.14%
Human Endocrine/Metabolism Disorders	30	30.93%
Total	97	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2782	94.15%
Toxicity and other safety testing including pharmacology	173	5.85%
Total	2955	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
Batch safety testing	2650	95.26%
Pyrogenicity testing	132	4.74%
Total	2782	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin irritation/corrosion	30	17.34%
Repeated dose toxicity	60	34.68%
Pharmaco-dynamics (incl safety pharmacology)	73	42.2%
Ecotoxicity	10	5.78%
Total	173	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
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
> 90 days	60	100%
Total	60	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
Acute toxicity	10	100%
Total	10	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2822	95.5%
Legislation on medicinal products for veterinary use and their residues	133	4.5%
Total	2955	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2955	100%
Total	2955	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
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
No	7009	97.92%
Yes	149	2.08%
Total	7158	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	2881	40.25%
Mild [up to and including]	3849	53.77%
Moderate	428	5.98%
Total	7158	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
Not genetically altered	7158	100%
Total	7158	100.00%