

# EU Statistical Data of all uses of animals

Member State: Belgium

Year: 2017

## All uses of animals by species

Animal Species	Number of uses	Percentage
Mice	334,054	61.51%
Rats	23,826	4.39%
Guinea-Pigs	15,541	2.86%
Hamsters (Syrian)	1,147	0.21%
Hamsters (Chinese)		
Mongolian gerbil	174	0.03%
Other Rodents	115	0.02%
Rabbits	57,888	10.66%
Cats	61	0.01%
Dogs	1,856	0.34%
Ferrets	26	0.00%
Other carnivores		
Horses, donkeys & cross-breeds	234	0.04%
Pigs	4,970	0.92%
Goats	78	0.01%
Sheep	666	0.12%
Cattle	1,558	0.29%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	44	0.01%
Vervets Chlorocebus spp.		
Baboons		
Squirrel monkey		
Other species of New World Monkeys (Ceboidea)		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of non-human primates		
Apes		
Other Mammals	140	0.03%
Domestic fowl	39,674	7.31%
Other birds	7,138	1.31%
Reptiles	181	0.03%
Rana		
Xenopus	918	0.17%
Other Amphibians	323	0.06%
Zebra fish	28,435	5.24%
Other Fish	24,027	4.42%
Cephalopods		
<b>Total uses</b>	<b>543,074</b>	<b>100.00%</b>

## Origin as registered at the first use

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	511,268	95.03%
Animals born in the EU but not at a registered breeder	22,269	4.14%
Animals born in rest of Europe	903	0.17%
Animals born in rest of world	3,594	0.67%
<b>Total uses</b>	<b>538,034</b>	<b>100.00%</b>

NHP Source (origin)	Number of uses	Percentage
Animals born at a registered breeder within EU	9	100.00%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
<b>Total uses</b>	<b>9</b>	<b>100.00%</b>

NHP Generation	Number of uses	Percentage
F0		
F1		
F2 or greater	9	100.00%
Self-sustaining colony		
<b>Total uses</b>	<b>9</b>	<b>100.00%</b>

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## Purpose for which animals are used

Purpose Category level 1	Number of uses	Percentage
Basic Research	272,795	50.23%
Translational and applied research	117,258	21.59%
Regulatory use and Routine production	141,853	26.12%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	706	0.13%
Preservation of species	151	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8,051	1.48%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2,260	0.42%
<b>Total uses</b>	<b>543,074</b>	<b>100.00%</b>

Basic Research	Number of uses	Percentage
Oncology	58,087	21.29%
Cardiovascular Blood and Lymphatic System	13,462	4.93%
Nervous System	42,974	15.75%
Respiratory System	3,583	1.31%
Gastrointestinal System including Liver	16,775	6.15%
Musculoskeletal System	4,967	1.82%
Immune System	70,105	25.70%
Urogenital/Reproductive System	5,852	2.15%
Sensory Organs (skin, eyes and ears)	4,785	1.75%
Endocrine System/Metabolism	14,861	5.45%
Multisystemic	5,600	2.05%
Ethology / Animal Behaviour /Animal Biology	14,701	5.39%
Other basic research	17,043	6.25%
<b>Total uses</b>	<b>272,795</b>	<b>100.00%</b>

Translational and applied research	Number of uses	Percentage
Human Cancer	12,720	10.85%
Human Infectious Disorders	15,691	13.38%
Human Cardiovascular Disorders	1,573	1.34%
Human Nervous and Mental Disorders	28,936	24.68%
Human Respiratory Disorders	5,945	5.07%
Human Gastrointestinal Disorders including Liver	977	0.83%
Human Musculoskeletal Disorders	783	0.67%
Human Immune Disorders	2,039	1.74%
Human Urogenital/Reproductive Disorders	503	0.43%
Human Sensory Organ Disorders (skin, eyes and ears)	5,441	4.64%
Human Endocrine/Metabolism Disorders	3,722	3.17%
Other Human Disorders	40	0.03%
Animal Diseases and Disorders	17,960	15.32%
Animal Welfare	3,525	3.01%
Diagnosis of diseases	4,292	3.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	13,111	11.18%
<b>Total uses</b>	<b>117,258</b>	<b>100.00%</b>

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Regulatory use and routine Production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68,615	48.37%
Other efficacy and tolerance testing	17,201	12.13%
Toxicity and other safety testing including pharmacology	4,133	2.91%
Routine production	51,904	36.59%
<b>Total uses</b>	<b>141,853</b>	<b>100.00%</b>

Regulatory use and routine production – Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	8,016	11.68%
Pyrogenicity testing		
Batch potency testing	57,716	84.12%
Other quality controls	2,883	4.20%
<b>Total uses</b>	<b>68,615</b>	<b>100.00%</b>

Regulatory use and routine production - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1,037	25.09%
Skin irritation/corrosion		
Skin sensitisation		
Eye irritation/corrosion		
Repeated dose toxicity	672	16.26%
Carcinogenicity		
Genotoxicity		
Reproductive toxicity	290	7.02%
Developmental toxicity	11	0.27%
Neurotoxicity	20	0.48%
Kinetics	399	9.65%
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Ecotoxicity	1,418	34.31%
Safety testing in food and feed area	150	3.63%
Target animal safety	136	3.29%
Other toxicity/safety testing		
<b>Total uses</b>	<b>4,133</b>	<b>100.00%</b>

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	4.82%
Other lethal methods		
Non lethal methods	987	95.18%
<b>Total uses</b>	<b>1,037</b>	<b>100.00%</b>

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Repeated dose toxicity	Number of uses	Percentage
up to 28 days	505	75.15%
29 - 90 days	42	6.25%
> 90 days	125	18.60%
<b>Total uses</b>	<b>672</b>	<b>100.00%</b>

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Ecotoxicity	Number of uses	Percentage
Acute toxicity	1,202	84.77%
Chronic toxicity	216	15.23%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
<b>Total uses</b>	<b>1,418</b>	<b>100.00%</b>

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Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products	51,804	99.81%
Monoclonal antibody by mouse ascites method		
Other product types	100	0.19%
<b>Total uses</b>	<b>51,904</b>	<b>100.00%</b>

## Use of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	113,897	80.29%
Legislation on medicinal products for veterinary use and their residues	25,559	18.02%
Medical devices legislation	779	0.55%
Industrial chemicals legislation	216	0.15%
Plant protection product legislation	52	0.04%
Biocides legislation		
Food legislation including food contact material	74	0.05%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1,276	0.90%
<b>Total uses</b>	<b>141,853</b>	<b>100.00%</b>

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	128,208	90.38%
Legislation satisfying national requirements only [within EU]	50	0.04%
Legislation satisfying Non-EU requirements only	13,595	9.58%
<b>Total uses</b>	<b>141,853</b>	<b>100.00%</b>

## First use and re-use

Re-Use	Number of uses	Percentage
No	538,043	99.07%
Yes	5,031	0.93%
<b>Total uses</b>	<b>543,074</b>	<b>100.00%</b>

## Use in creation of a new genetic line

Creation of New GL	Number of uses	Percentage
No	513,454	94.55%
Yes	29,620	5.45%
<b>Total uses</b>	<b>543,074</b>	<b>100.00%</b>

## Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	26,546	4.89%
Mild [up to and including]	297,189	54.72%
Moderate	134,577	24.78%
Severe	84,762	15.61%
<b>Total uses</b>	<b>543,074</b>	<b>100.00%</b>

## Use by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	402,289	74.08%
Genetically altered without a harmful phenotype	118,326	21.79%
Genetically altered with a harmful phenotype	22,459	4.14%
<b>Total uses</b>	<b>543,074</b>	<b>100.00%</b>

## MEMBER STATE NARRATIVE

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

Compared to 2016 (534.854 animals used), there is an increase of 1.54% in the number of animals used for scientific purposes in 2017 (543.074 animals used) but still a decrease of 3.29% compared to 2015 (561.551 animals used). The increase in 2017 is the result of an increased use of poultry merely in translational and applied research (animal diseases and disorders) and for forensic enquiries.

Number of use in 2017	Number of use in 2016	Number of use in 2015
543074	534854	561551

Since 2015 the numbers of re-used animals continues to decline: 3.74% of all uses in 2015, 1.52% in 2016 and 0.93% in 2017.

Re-Use	Number of use in 2017	Number of use in 2016	Number of use in 2015
No	538043	526723	540571
Yes	5031	8131	20980
<b>Total uses</b>	<b>543074</b>	<b>534854</b>	<b>561551</b>

There is a significant increase in the use of birds (108.94% compared with the use of birds in 2015). This is due to an increase in the area of Animal Diseases and Disorders and Regulatory use and Routine production (Legislation on medicinal products for veterinary use and their residues). The fish decreased with 48,73% compared to 2015. No apparent reason was noted.

Species	Number of use in 2017	Number of use in 2016	Number of use in 2015
Mammals	442378	440501	435333
Birds	46812	30734	22405
Fish	52462	62221	102330
Amphibians	1241	1226	1350
Reptiles	181	172	133
Cephalopods	0	0	0
<b>Total uses</b>	<b>543074</b>	<b>534854</b>	<b>561551</b>

In the mammals the use of rabbits and Artiodactyla increased. The use of rabbits has increased in the Legislation on medicinal products for human use area. This is reflected in an increase of 33.68% compared to 2015. The use of Artiodactyla augmented (61.53% more Artiodactyla used compared to 2015). This is due to an increase in Basic research (this was caused by zootechnics (selection)), Translational and applied research (Animal Diseases and Disorders) and Protection of the natural environment in the interests of the health or welfare of human beings or animals. The use of all other species remained unchanged.

Mammals	Number of use in 2017	Number of use in 2016	Number of use in 2015
Rodents	374857	384785	385298
Rabbits	57888	48036	43304
Carnivores	1943	1665	1937
Equidae	234	231	115
Artiodactyla	7272	5591	4502
Non-human primates	44	40	46
Other mammals	140	153	131
<b>Total uses</b>	<b>442378</b>	<b>440501</b>	<b>435333</b>

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

Between 2015 and 2017, basic research diminished with 11,79%. This was in particular due to decreases in the area of Musculoskeletal System, Urogenital/Reproductive System, Multisystemic research, Endocrine System/Metabolism and Respiratory System. However, the research in the domain of the Immune System and Oncology significantly increased between 2015 and 2017.

During the same time period Translational and applied research augmented with 23.77%. We noted a significant increase in Animal Welfare (3,525 animals in 2017 compared to 165 in 2015), Animal Diseases and Disorders, Human Endocrine/Metabolism Disorders, Human Sensory Organ Disorders (skin, eyes and ears), Human Nervous and Mental Disorders and Non-regulatory toxicology and ecotoxicology. A decrease was noted in Diagnosis of diseases and Human Infectious Disorders.

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

Within the actual severities classification we note that the category "severe" decreased from 18.10% in 2016 to 15.61% in 2017.

This is due to a diminution of quality control research (incl. batch safety and potency testing). This percentage is still higher than the European average of 10% but in Belgium a lot of basic research was done with in particular research in the field of Oncology, Immune system and Nervous system. Another important area in the research concerns Translational and applied research with again Human Nervous and Mental Disorders, Human Infectious Disorders and Human Cancer as the most important domains. Since, according to the legislation, tumours leading to metastases, tumours that lead to cachexia, invasive bone tumours, ulcerating tumours, loss of immunity, etc. (research that is often done in Belgium) should be classified as "severe", this can lead to an increase in this category.

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

- Funding of research projects for the development of alternative toxicity tests:
  - Thyroid hormone disruptors: There is a wide-variety of environmental contaminants that have the potential to cause thyroid hormone disruption<sup>1</sup>.

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<sup>1</sup> <http://www.oecd.org/chemicalsafety/oecd-encourages-development-of-non-animal-test-methods-for-detection-of-thyroid-disruptors.htm>

Exposure to specific environmental toxins, including polychlorinated biphenyls, dioxins, phthalates, polybrominated diphenyl ethers (PBDEs), and other halogenated compounds, has been shown to interfere with the production, transportation, and/or metabolism of thyroid hormones by a variety of mechanisms. Some chemicals, with structural similarity to thyroid hormones, have been shown to bind to thyroid receptors with both agonist and antagonist effects on thyroid hormone signalling. Thyroid hormone disruption can therefore cause severe adverse effects on *e.g.* brain development, growth and metabolism.

Validated and internationally recognised tests methods are essential in assessing the potential of chemicals to interact with the hormonal system and cause adverse effects. Non-animal test methods are needed for efficient testing and screening of substances. In 2014, OECD published a scoping document on *in vitro* and *ex vivo* assays for the identification of modulators of thyroid hormone signalling (OECD, 2014). Several key biological mechanisms of thyroid system disruption were reviewed and the corresponding methods evaluated for their state of readiness as candidates to enter the validation process. Relevant *in vitro* and *ex vivo* methods were identified and recommendations were given for their development/use. Eighteen methods were reported that cover the possible sites of action in the hypothalamic-pituitary-thyroid (HPT) axis. The research is carried out by EU-Netval facilities. By funding this research we enable our EU NETVAL facility to take part of this study.

- Differentiation of human skin-derived stem cells towards hepatic cells: new source for the "in vitro study" of liver toxicity of drugs. Liver toxicity is one of the most important research elements in drug development. In addition, liver toxicity is the main reason for withdrawing medicines from the market. Presently, pre-clinical drug safety tests are carried out by "in vivo studies", i.e. studies on laboratory animals. In addition to the ethical concerns and the high costs associated with these in vivo studies, it is important to note the relatively low correlation between the results of animals on humans (less than 60% of the results of tests on animals apply to humans). By funding the project, we contribute to research that will lead in the long term to the reduction of the number of laboratory animals that are used in the context of drug development.
- Collaboration with the university board to promote the development and promotion of alternative methods (for example, WALCOPA project in Wallonia).
- Collaboration between the different regions and other member states to promote the 3R principle.



- Establishment of RE-place: The RE-Place project will create a database that brings together all existing expertise on alternative methods for animal testing in the Flemish and Brussels regions. The RE-Place website will be expanded in a next phase into a platform where researchers can find more information about alternative methods for animal testing and share their research methodology with the rest of the research community. By charting and making known generally the available and developing alternative methods for animal testing, not only researchers but also the general public and the political world will be better informed about the expertise in their own region. In the long term, all collected information will be integrated at European level.

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

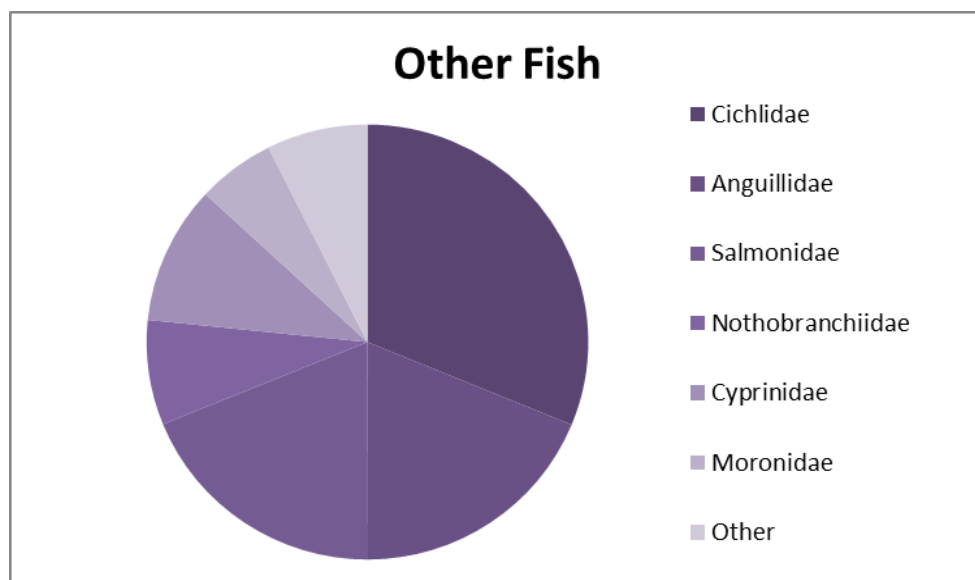
### 1. Other fish

45.80% of the fishes are reported under the “other” category.

They are mostly Cichlidae (*Oreochromis niloticus*) (31.21% of other fish), Salmonidae (*Salmo salar* and *Oncorhynchus mykiss*) (18.85% of other fish), Anguillidae (*Anguilla anguilla*) (18.75% of other fish), Cyprinidae (*Cyprinus carpio* and *Cyprinus carpio*) (10.27% of other fish), Nothobranchiidae (*Nothobranchius furzeri*) (7.79% of other fish) and Moronidae (*Dicentrarchus labrax*) (5.70% of other fish).

Other Fish	Number of uses
<i>Oreochromis niloticus</i>	7499
<i>Anguilla anguilla</i>	4506
<i>Salmo salar</i>	2012
<i>Oncorhynchus mykiss</i>	2522
<i>Nothobranchius furzeri</i>	1871
<i>Cyprinus carpio carpio</i>	1814
<i>Dicentrarchus labrax</i>	1370
<i>Cyprinus carpio</i>	654
<i>Scortum barcoo</i>	648
<i>Poecilia reticulata</i>	300
<i>Pleuronectes platessa</i>	229
<i>Lota lota</i>	144
<i>Gasterosteus aculeatus</i>	82
<i>Clarias gariepinus</i>	50
<i>Kryptolebias marmoratus</i>	50
<i>Limanda limanda</i>	48
<i>Gadus morhua</i>	47
<i>Pseudotropheus saulosi</i>	25
<i>Synodontis grandioops</i>	20

<i>Microsynodontis batesii</i>	12
<i>Myloplus schomburgkii</i>	8
<i>Catoprion mento</i>	7
<i>Metynnis hypsauchen</i>	7
<i>Pseudotropheus estherae</i>	7
<i>Pygopristis denticulata</i>	7
<i>Serrasalmus spilopleura</i>	7
<i>Ophthalmotilapia ventralis</i>	6
<i>Synodontis nigriventris</i>	6
<i>Maylandia zebra</i>	5
<i>Mochokiella paynei</i>	5
<i>Pygocentrus cariba</i>	5
<i>Pygocentrus nattereri</i>	5
<i>Pygocentrus piraya</i>	5
<i>Botia morleti</i>	3
<i>Myloplus rubripinnis</i>	3
<i>Pantodon buchholzi</i>	3
<i>Piaractus brachypomus</i>	3
<i>Synodontis acanthomias</i>	3
<i>Synodontis brichardi</i>	3
<i>Synodontis contractus</i>	3
<i>Synodontis elongatus</i>	3
<i>Synodontis flavitaeniatus</i>	3
<i>Synodontis lucipinnis</i>	3
<i>Synodontis notatus</i>	3
<i>Botia modesta</i>	2
<i>Serrasalmus manueli</i>	2
<i>Colossoma macropomum</i>	1
<i>Malapterurus electricus</i>	1
<i>Metynnis lippincottianus</i>	1
<i>Ophthalmotilapia nasuta</i>	1
<i>Platydoras hancockii</i>	1
<i>Synodontis eupterus</i>	1
<i>Synodontis schall</i>	1
<b>Total uses:</b>	<b>24027</b>

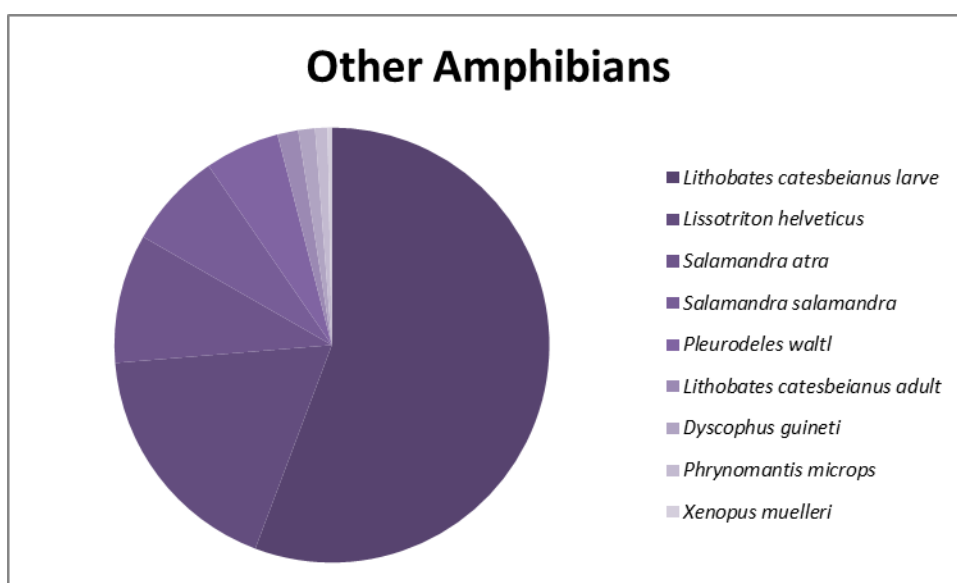


## 2. Other amphibians

26.03% of the amphibians are reported under the “other” category.

They are mostly Ranidae (*Lithobates catesbeianus larva + adult*) (57.27% of other amphibians) and Salamandridae (in order of importance: *Lissotriton helveticus*, *Salamandra atra*, *Salamandra salamandra*, *Pleurodeles waltl*) (40.24% of other amphibians).

Other Amphibians	Number of uses
<i>Lithobates catesbeianus larve</i>	180
<i>Lissotriton helveticus</i>	58
<i>Salamandra atra</i>	31
<i>Salamandra salamandra</i>	23
<i>Pleurodeles waltl</i>	18
<i>Lithobates catesbeianus adult</i>	5
<i>Dyscophus guineti</i>	4
<i>Phrynomantis microps</i>	3
<i>Xenopus muelleri</i>	1
<b>Total uses:</b>	<b>323</b>



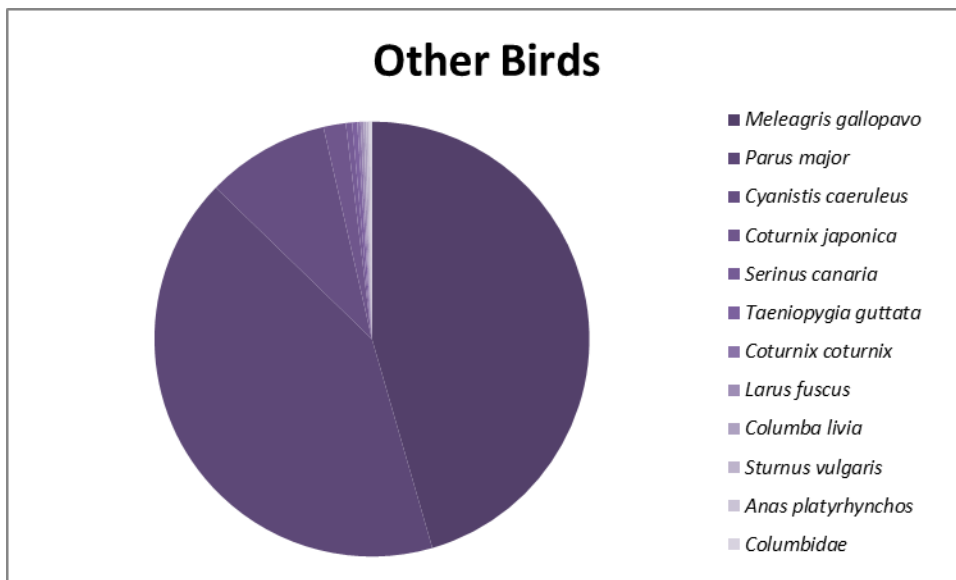
## 3. Other birds

15.25% of the birds are reported under the “other” category.

They are mostly Paridae (*Parus major and Cyanistis caeruleus*) (50.89% of other birds) and Phasianidae (*Meleagris gallopavo, Coturnix japonica, Coturnix coturnix*) (47.42% of other birds).

The other birds are members of Fringillidae (*Serinus canaria*), Estrildidae (*Taeniopygia guttata*), Laridae (*Larus fuscus*), Columbidae (*Columba livia*), Sturnidae (*Sturnus vulgaris*) and the Anatidae (*Anas platyrhynchos*).

Other Birds	Number of uses
<i>Meleagris gallopavo</i>	3249
<i>Parus major</i>	2979
<i>Cyanistis caeruleus</i>	654
<i>Coturnix japonica</i>	119
<i>Serinus canaria</i>	33
<i>Taeniopygia guttata</i>	27
<i>Coturnix coturnix</i>	17
<i>Larus fuscus</i>	17
<i>Columba livia</i>	14
<i>Sturnus vulgaris</i>	13
<i>Anas platyrhynchos</i>	8
Columbidae	8
<b>Total uses:</b>	<b>7138</b>



**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.**

As in previous years, there were no cases in which the 'severe' classification was exceeded.