<u>DP.1. Control tables</u>
Data inclusion criteria
Report year: 2019
EU Submission: ALL
Genetic status: ALL
Animal Species: ALL
Species grouping Level 1: ALL
Species grouping Level 2: ALL
Mammals: ALL
Non-human primates: ALL
Other Species: ALL
Creation of New GL: ALL
Purpose: ALL
Purpose Category level 1: ALL
Purpose Category level 2: ALL
Purpose Category level 3: ALL
Purpose Category level 4: ALL
Other Purpose: ALL
Re-use: ALL
Place of Birth: ALL
NHP Generation: ALL
NHP Source (origin): ALL
Legislative Requirement: ALL
Testing by Legislation: ALL
Other Legislation: ALL
Severity: ALL
Custom Severity: ALL
ld 1: ALL
ld 2: ALL
ld 3: ALL
EC ID: ALL

#### **Narrative**

Country: Slovenia

This report shows the total number of uses in all of the harmonised reported categories, including for non-EU submissions (unless specifically excluded). It provides at a glance information facilitating quality control of submitted data by highlighting e.g. especially high use of 'other' columns (in red font when above 10% and requiring further explanation in the Member State narrative), or any other unusual use patterns. The findings from this report provide a first line of alert for potential problems in data quality.

With the use of other Data Provider control reports, more detailed information can be elicited, narrowing down a potential problem to the level of National ID1/2/3s and EC (submission) ID (from DECLARE). With the help of Custom IDs and EC ID (submission) from DECLARE, the erroneous submission can quickly be identified and corrected. The report does not include free text fields.

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EU Submission	Number of uses	Percentage
Yes	5,317	100.00%
No		
Total uses	5,317	100.00%

Re-Use	Number of uses	Percentage
No	4,506	84.75%
Yes	811	15.25%
Total uses	5,317	100.00%

Creation of New GL	Number of uses	Percentage
No	5,311	99.89%
Yes	6	0.11%
Total uses	5,317	100.00%

Genetic Status	Number of uses	Percentage
Not genetically altered	4,953	93.15%
Genetically altered without a harmful phenotype	325	6.11%
Genetically altered with a harmful phenotype	39	0.73%
Total uses	5,317	100.00%

Severity	Number of uses	Percentage
Non-recovery	40	0.75%
Mild [up to and including]	4,723	88.83%
Moderate	497	9.35%
Severe	57	1.07%
Total uses	5,317	100.00%

Animal Species	Number of uses	Percentage
Mice	4,938	92.87%
Rats	94	1.77%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other rodents		
Rabbits	51	0.96%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.04%
Pigs	8	0.15%
Goats		
Sheep	42	0.79%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys		
(Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other mammals		
Domestic fowl	127	2.39%
Other birds		
Reptiles		
Rana		
Xenopus		
Other amphibians		
Zebra fish		
Other fish	55	1.03%
Cephalopods		
Total uses	5,317	100.00%

Rodents	Percentage
Mice	98.13%
Rats	1.87%
Guinea-Pigs	
Hamsters (Syrian)	
Hamsters (Chinese)	
Mongolian gerbil	

Carnivores	Percentage
Cats	
Dogs	
Ferrets	
Other carnivores	

New world monkeys	Percentage
Marmoset and tamarins	
Squirrel monkey	
Other species of New World Monkeys (Ceboidea)	

Old world monkeys	Percentage
Cynomolgus monkey	
Rhesus monkey	
Baboons	
Other species of Old World Monkeys (Cercopithecoidea)	

Birds	Percentage
Domestic fowl	100.00%
Other birds	

Fish		Percentage
Zebra	fish	

Amphibians	Percentage
Rana	
Xenopus	

Species grouping Level 1	Number of uses	Percentage
Warm-blooded vertebrates	5,262	98.97%
Cold-blooded vertebrates	55	1.03%
Invertebrates		
Total uses	5,317	100.00%

Species grouping Level 2	Number of uses	Percentage
Mammals	5,135	96.58%
Birds	127	2.39%
Fish	55	1.03%
Amphibians		
Reptiles		
Cephalopods		
Total uses	5,317	100.00%

Mammals	Number of uses	Percentage
Rodents	5,032	97.99%
Rabbits	51	0.99%
Carnivores		
Equidae	2	0.04%
Artiodactyla	50	0.97%
Non-human primates		
Other mammals		
Total uses	5,135	100.00%

Non-human primates	Number of uses	Percentage
Prosimians		
New World Monkeys		
Old World Monkeys		
Apes		
Total uses		

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	4,506	100.00%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total uses	4,506	100.00%

	Number of	
NHP Source (origin)	uses	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total uses		

	Number of	
NHP Generation	uses	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total uses		

Purpose Category level 1	Number of uses	Percentage
Basic Research	770	14.48
Translational and applied research	2,134	40.14
Regulatory use and Routine production	2,268	42.66
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	80	1.509
Higher education or training for the acquisition, maintenance or improvement of vocational skills	65	1.229
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Non-EU Purpose		
Total uses	5,317	100.00

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2,268	100.00%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total uses	2,268	100.00%

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2,268	100.00%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total uses	2,268	100.00%

Basic Research	Number of uses	Percentage
Oncology	261	33.90%
Cardiovascular Blood and Lymphatic System		
Nervous System	16	2.08%
Respiratory System		
Gastrointestinal System including Liver	227	29.48%
Musculoskeletal System	14	1.82%
Immune System	113	14.68%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	130	16.88%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research	9	1.17%
Total uses	770	100.00%

Translational and applied research	Number of uses	Percentage
Human Cancer	1,797	84.21%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	30	1.41%
Human Respiratory Disorders	46	2.16%
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	101	4.73%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare	40	1.87%
Diagnosis of diseases	120	5.62%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total uses	2,134	100.00%

Regulatory use and routine Production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2,268	100.00%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology		
Routine production		
Total uses	2,268	100.00%

Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total uses		

Regulatory use and routine production – Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	55	2.43%
Pyrogenicity testing	51	2.25%
Batch potency testing	2,162	95.33%
Other quality controls		
Total uses	2,268	100.00%

Regulatory use and routine production - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Skin irritation/corrosion		
Skin sensitisation		
Eye irritation/corrosion		
Repeated dose toxicity		
Carcinogenicity		
Genotoxicity		
Reproductive toxicity		
Developmental toxicity		
Neurotoxicity		
Kinetics		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Ecotoxicity		
Safety testing in food and feed area		
Target animal safety		
Other toxicity/safety testing		
Total uses		

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total uses		

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		
Other lethal methods		
Non lethal methods		
Total uses		

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total uses		