

## DP.1. Control tables

### Data inclusion criteria

Report year: 2016

Country: Croatia

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

Creation of New GL: ALL

Purpose Category level 1: ALL

Purpose Category level 2: ALL

Purpose Category level 3: ALL

Purpose Category level 4: ALL

Re-use: ALL

Place of Birth: ALL

NHP Generation: ALL

NHP Source (origin): ALL

Legislative Requirement: ALL

Testing by Legislation: ALL

Severity: ALL

EC ID: ALL

Id 1: ALL

Id 2: ALL

Id 3: ALL

### Narrative

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.

## DP.1. Control tables

EU Submission	Number of uses	Percentage
Yes	21,901	100.00%
No		
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Re-Use	Number of uses	Percentage
No	21,790	99.49%
Yes	111	0.51%
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Creation of New GL	Number of uses	Percentage
No	21,901	100.00%
Yes		
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Genetic Status	Number of uses	Percentage
Not genetically altered	19,493	89.01%
Genetically altered without a harmful phenotype	2,279	10.41%
Genetically altered with a harmful phenotype	129	0.59%
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Severity	Number of uses	Percentage
Non-recovery	3,220	14.70%
Mild [up to and including]	6,857	31.31%
Moderate	11,394	52.03%
Severe	430	1.96%
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Animal Species	Number of uses	Percentage
Mice	14,976	68.38%
Rats	5,762	26.31%
Guinea-Pigs	71	0.32%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	704	3.21%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys & cross-breeds	27	0.12%
Pigs	2	0.01%
Goats		
Sheep	49	0.22%
Cattle	50	0.23%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
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		
Domestic fowl	260	1.19%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Rodents	Percentage
Mice	71.97%
Rats	27.69%
Guinea-Pigs	0.34%
Hamsters (Syrian)	
Hamsters (Chinese)	
Mongolian gerbil	
Other Rodents	

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	
Vervets Chlorocebus spp.	
Baboons	
Other species of Old World Monkeys (Cercopithecoidea)	

Birds	Percentage
Domestic fowl	100.00%
Other birds	

Fish	Percentage
Zebra fish	
Other Fish	

Amphibians	Percentage
Rana	
Xenopus	
Other Amphibians	

## DP.1. Control tables

Species grouping Level 1	Number of uses	Percentage
Warm-blooded vertebrates	21,901	100.00%
Cold-blooded vertebrates		
Invertebrates		
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Species grouping Level 2	Number of uses	Percentage
Mammals	21,641	98.81%
Birds	260	1.19%
Fish		
Amphibians		
Reptiles		
Cephalopods		
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Mammals	Number of uses	Percentage
Rodents	20,809	96.16%
Rabbits	704	3.25%
Carnivores		
Equidae	27	0.12%
Artiodactyla	101	0.47%
Non-human primates		
Other mammals		
<b>Total uses</b>	<b>21,641</b>	<b>100.00%</b>

Non-human primates	Number of uses	Percentage
Prosimians		
New World Monkeys		
Old World Monkeys		
Apes		
<b>Total uses</b>		

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	21,701	99.59%
Animals born in the EU but not at a registered breeder	89	0.41%
Animals born in rest of Europe		
Animals born in rest of world		
<b>Total uses</b>	<b>21,790</b>	<b>100.00%</b>

NHP Source (origin)	Number of 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		
<b>Total uses</b>		

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

## DP.1. Control tables

Purpose Category level 1	Number of uses	Percentage
Basic Research	19,183	87.59%
Translational and applied research	456	2.08%
Regulatory use and Routine production	988	4.51%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,203	5.49%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	71	0.32%
Non-EU Purpose		
<b>Total uses</b>	<b>21,901</b>	<b>100.00%</b>

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	618	62.55%
Legislation on medicinal products for veterinary use and their residues	364	36.84%
Medical devices legislation	6	0.61%
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		
<b>Total uses</b>	<b>988</b>	<b>100.00%</b>

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	988	100.00%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
<b>Total uses</b>	<b>988</b>	<b>100.00%</b>

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Basic Research	Number of uses	Percentage
Oncology	708	3.69%
Cardiovascular Blood and Lymphatic System	510	2.66%
Nervous System	1,613	8.41%
Respiratory System	4,564	23.79%
Gastrointestinal System including Liver	663	3.46%
Musculoskeletal System	122	0.64%
Immune System	3,861	20.13%
Urogenital/Reproductive System	146	0.76%
Sensory Organs (skin, eyes and ears)	1,652	8.61%
Endocrine System/Metabolism	397	2.07%
Multisystemic	2,673	13.93%
Ethology / Animal Behaviour /Animal Biology	88	0.46%
Other basic research	2,186	11.40%
<b>Total uses</b>	<b>19,183</b>	<b>100.00%</b>

Translational and applied research	Number of uses	Percentage
Human Cancer	70	15.35%
Human Infectious Disorders		
Human Cardiovascular Disorders	119	26.10%
Human Nervous and Mental Disorders	60	13.16%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	37	8.11%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	120	26.32%
Other Human Disorders		
Animal Diseases and Disorders	50	10.96%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
<b>Total uses</b>	<b>456</b>	<b>100.00%</b>

## DP.1. Control tables

Regulatory use and routine Production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	831	84.11%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	98	9.92%
Routine production	59	5.97%
<b>Total uses</b>	<b>988</b>	<b>100.00%</b>

Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products	59	100.00%
Monoclonal antibodies		
Other product types		
<b>Total uses</b>	<b>59</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	210	25.27%
Pyrogenicity testing	67	8.06%
Batch potency testing	194	23.35%
Other quality controls	360	43.32%
<b>Total uses</b>	<b>831</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	88	89.80%
Skin irritation/corrosion		
Skin sensitisation		
Eye irritation/corrosion		
Repeated dose toxicity	4	4.08%
Carcinogenicity		
Genotoxicity		
Reproductive toxicity		
Developmental toxicity		
Neurotoxicity		
Kinetics	6	6.12%
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Ecotoxicity		
Safety testing in food and feed area		
Target animal safety		
Other toxicity/safety testing		
<b>Total uses</b>	<b>98</b>	<b>100.00%</b>

## DP.1. Control tables

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4	100.00%
29 - 90 days		
> 90 days		
<b>Total uses</b>	<b>4</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		
Other lethal methods		
Non lethal methods	88	100.00%
<b>Total uses</b>	<b>88</b>	<b>100.00%</b>

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		
<b>Total uses</b>		