

DP.1. Control tables

Data inclusion criteria

Report year: 2015

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	23,032	100.00%
No		
Total uses	23,032	100.00%

Re-Use	Number of uses	Percentage
No	22,885	99.36%
Yes	147	0.64%
Total uses	23,032	100.00%

Creation of New GL	Number of uses	Percentage
No	23,032	100.00%
Yes		
Total uses	23,032	100.00%

Genetic Status	Number of uses	Percentage
Not genetically altered	21,756	94.46%
Genetically altered without a harmful phenotype	1,143	4.96%
Genetically altered with a harmful phenotype	133	0.58%
Total uses	23,032	100.00%

Severity	Number of uses	Percentage
Non-recovery	3,714	16.13%
Mild [up to and including]	9,273	40.26%
Moderate	7,994	34.71%
Severe	2,051	8.91%
Total uses	23,032	100.00%

Animal Species	Number of uses	Percentage
Mice	16,197	70.32%
Rats	5,374	23.33%
Guinea-Pigs	264	1.15%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	472	2.05%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys & cross-breeds	26	0.11%
Pigs	1	0.00%
Goats		
Sheep	44	0.19%
Cattle	28	0.12%
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	626	2.72%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total uses	23,032	100.00%

Rodents	Percentage
Mice	74.18%
Rats	24.61%
Guinea-Pigs	1.21%
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	23,032	100.00%
Cold-blooded vertebrates		
Invertebrates		
Total uses	23,032	100.00%

Species grouping Level 2	Number of uses	Percentage
Mammals	22,406	97.28%
Birds	626	2.72%
Fish		
Amphibians		
Reptiles		
Cephalopods		
Total uses	23,032	100.00%

Mammals	Number of uses	Percentage
Rodents	21,835	97.45%
Rabbits	472	2.11%
Carnivores		
Equidae	26	0.12%
Artiodactyla	73	0.33%
Non-human primates		
Other mammals		
Total uses	22,406	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	22,347	97.65%
Animals born in the EU but not at a registered breeder	538	2.35%
Animals born in rest of Europe		
Animals born in rest of world		
Total uses	22,885	100.00%

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		
Total uses		

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

DP.1. Control tables

Purpose Category level 1	Number of uses	Percentage
Basic Research	18,073	78.47%
Translational and applied research	421	1.83%
Regulatory use and Routine production	3,321	14.42%
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	1,217	5.28%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Non-EU Purpose		
Total uses	23,032	100.00%

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1,964	59.14%
Legislation on medicinal products for veterinary use and their residues	1,078	32.46%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	279	8.40%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total uses	3,321	100.00%

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	3,321	100.00%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total uses	3,321	100.00%

DP.1. Control tables

Basic Research	Number of uses	Percentage
Oncology	447	2.47%
Cardiovascular Blood and Lymphatic System	412	2.28%
Nervous System	1,619	8.96%
Respiratory System	4,426	24.49%
Gastrointestinal System including Liver	565	3.13%
Musculoskeletal System	217	1.20%
Immune System	4,177	23.11%
Urogenital/Reproductive System	424	2.35%
Sensory Organs (skin, eyes and ears)	431	2.38%
Endocrine System/Metabolism	873	4.83%
Multisystemic	2,223	12.30%
Ethology / Animal Behaviour /Animal Biology	28	0.15%
Other basic research	2,231	12.34%
Total uses	18,073	100.00%

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	92	21.85%
Human Nervous and Mental Disorders	108	25.65%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	185	43.94%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1	0.24%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	35	8.31%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total uses	421	100.00%

DP.1. Control tables

Regulatory use and routine Production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2,894	87.14%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	359	10.81%
Routine production	68	2.05%
Total uses	3,321	100.00%

Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products	68	100.00%
Monoclonal antibodies		
Other product types		
Total uses	68	100.00%

Regulatory use and routine production – Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	569	19.66%
Pyrogenicity testing	63	2.18%
Batch potency testing	1,236	42.71%
Other quality controls	1,026	35.45%
Total uses	2,894	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	80	22.28%
Carcinogenicity		
Genotoxicity		
Reproductive toxicity		
Developmental toxicity		
Neurotoxicity		
Kinetics		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Ecotoxicity		
Safety testing in food and feed area	279	77.72%
Target animal safety		
Other toxicity/safety testing		
Total uses	359	100.00%

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	80	100.00%
29 - 90 days		
> 90 days		
Total uses	80	100.00%

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		