

DP.1. Control tables

Data inclusion criteria

Report year: 2014

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	25,978	99.92%
No	20	0.08%
Total uses	25,998	100.00%

Re-Use	Number of uses	Percentage
No	25,515	98.14%
Yes	483	1.86%
Total uses	25,998	100.00%

Creation of New GL	Number of uses	Percentage
No	25,998	100.00%
Yes		
Total uses	25,998	100.00%

Genetic Status	Number of uses	Percentage
Not genetically altered	18,525	71.26%
Genetically altered without a harmful phenotype	3,543	13.63%
Genetically altered with a harmful phenotype	3,930	15.12%
Total uses	25,998	100.00%

Severity	Number of uses	Percentage
Non-recovery	6,543	25.17%
Mild [up to and including]	13,915	53.52%
Moderate	4,551	17.51%
Severe	989	3.80%
Total uses	25,998	100.00%

Animal Species	Number of uses	Percentage
Mice	19,427	74.72%
Rats	4,962	19.09%
Guinea-Pigs	488	1.88%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	331	1.27%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys & cross-breeds		
Pigs		
Goats		
Sheep	18	0.07%
Cattle		
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	772	2.97%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total uses	25,998	100.00%

Rodents	Percentage
Mice	78.09%
Rats	19.95%
Guinea-Pigs	1.96%
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	

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Species grouping Level 1	Number of uses	Percentage
Warm-blooded vertebrates	25,998	100.00%
Cold-blooded vertebrates		
Invertebrates		
Total uses	25,998	100.00%

Species grouping Level 2	Number of uses	Percentage
Mammals	25,226	97.03%
Birds	772	2.97%
Fish		
Amphibians		
Reptiles		
Cephalopods		
Total uses	25,998	100.00%

Mammals	Number of uses	Percentage
Rodents	24,877	98.62%
Rabbits	331	1.31%
Carnivores		
Equidae		
Artiodactyla	18	0.07%
Non-human primates		
Other mammals		
Total uses	25,226	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	25,497	99.93%
Animals born in the EU but not at a registered breeder	18	0.07%
Animals born in rest of Europe		
Animals born in rest of world		
Total uses	25,515	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		

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Purpose Category level 1	Number of uses	Percentage
Basic Research	15,024	57.79%
Translational and applied research	671	2.58%
Regulatory use and Routine production	7,220	27.77%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,875	7.21%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,188	4.57%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Non-EU Purpose	20	0.08%
Total uses	25,998	100.00%

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3,724	51.58%
Legislation on medicinal products for veterinary use and their residues	1,123	15.55%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	2,373	32.87%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total uses	7,220	100.00%

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7,180	99.45%
Legislation satisfying national requirements only [within EU]	40	0.55%
Legislation satisfying Non-EU requirements only		
Total uses	7,220	100.00%

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Basic Research	Number of uses	Percentage
Oncology	444	2.96%
Cardiovascular Blood and Lymphatic System	759	5.05%
Nervous System	803	5.34%
Respiratory System	36	0.24%
Gastrointestinal System including Liver	392	2.61%
Musculoskeletal System	479	3.19%
Immune System	7,951	52.92%
Urogenital/Reproductive System	602	4.01%
Sensory Organs (skin, eyes and ears)	222	1.48%
Endocrine System/Metabolism		
Multisystemic	2,170	14.44%
Ethology / Animal Behaviour /Animal Biology	80	0.53%
Other basic research	1,086	7.23%
Total uses	15,024	100.00%

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	70	10.43%
Human Nervous and Mental Disorders	259	38.60%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	28	4.17%
Human Immune Disorders	21	3.13%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	293	43.67%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total uses	671	100.00%

DP.1. Control tables

Regulatory use and routine Production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4,770	66.07%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	2,450	33.93%
Routine production		
Total uses	7,220	100.00%

Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibodies		
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	840	17.61%
Pyrogenicity testing	75	1.57%
Batch potency testing	836	17.53%
Other quality controls	3,019	63.29%
Total uses	4,770	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	3	0.12%
Eye irritation/corrosion		
Repeated dose toxicity		
Carcinogenicity		
Genotoxicity		
Reproductive toxicity		
Developmental toxicity	10	0.41%
Neurotoxicity		
Kinetics	24	0.98%
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Ecotoxicity	40	1.63%
Safety testing in food and feed area	2,373	96.86%
Target animal safety		
Other toxicity/safety testing		
Total uses	2,450	100.00%

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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	40	100.00%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total uses	40	100.00%