

DP.F.2. Purposes and origin of legislative requirement

Data inclusion criteria

Report year: 2020
EU Submission: ALL
Animal Species: ALL
Species grouping Level 1: ALL
Species grouping Level 2: ALL
Mammals: ALL
Non-human primates: ALL
Genetic status: ALL
Re-use: ALL
Legislative Requirement: ALL
Severity: ALL
Submission Id: ALL
Id 1: ALL
Id 2: ALL
Id 3: ALL
Country: Denmark

Narrative

This report shows the number of uses of animals for the purposes of complying with legislation relating to the production, safety testing or marketing authorisation of products or substances such as medicines and chemicals. The report compares the type of testing with the geographical origin of the legal requirement i.e. national, EU or non-EU requirement. It shows both the first and all the subsequent uses of the animals completed in the reporting period (unless either option is specifically excluded in the data filtering criteria when selecting the report).

The Data Provider reports allow the creation of standard (public) reports

- before the reports are available for the general public (i.e. non-published data), and
- including information on non-EU submissions (as a default) i.e. Member State specific national data e.g. on animals killed for tissue/organs – unless specifically excluded in the data filtering criteria when selecting the report.

Data filtering criteria has been complemented with an option to filter data into the report also at the level of species groupings.

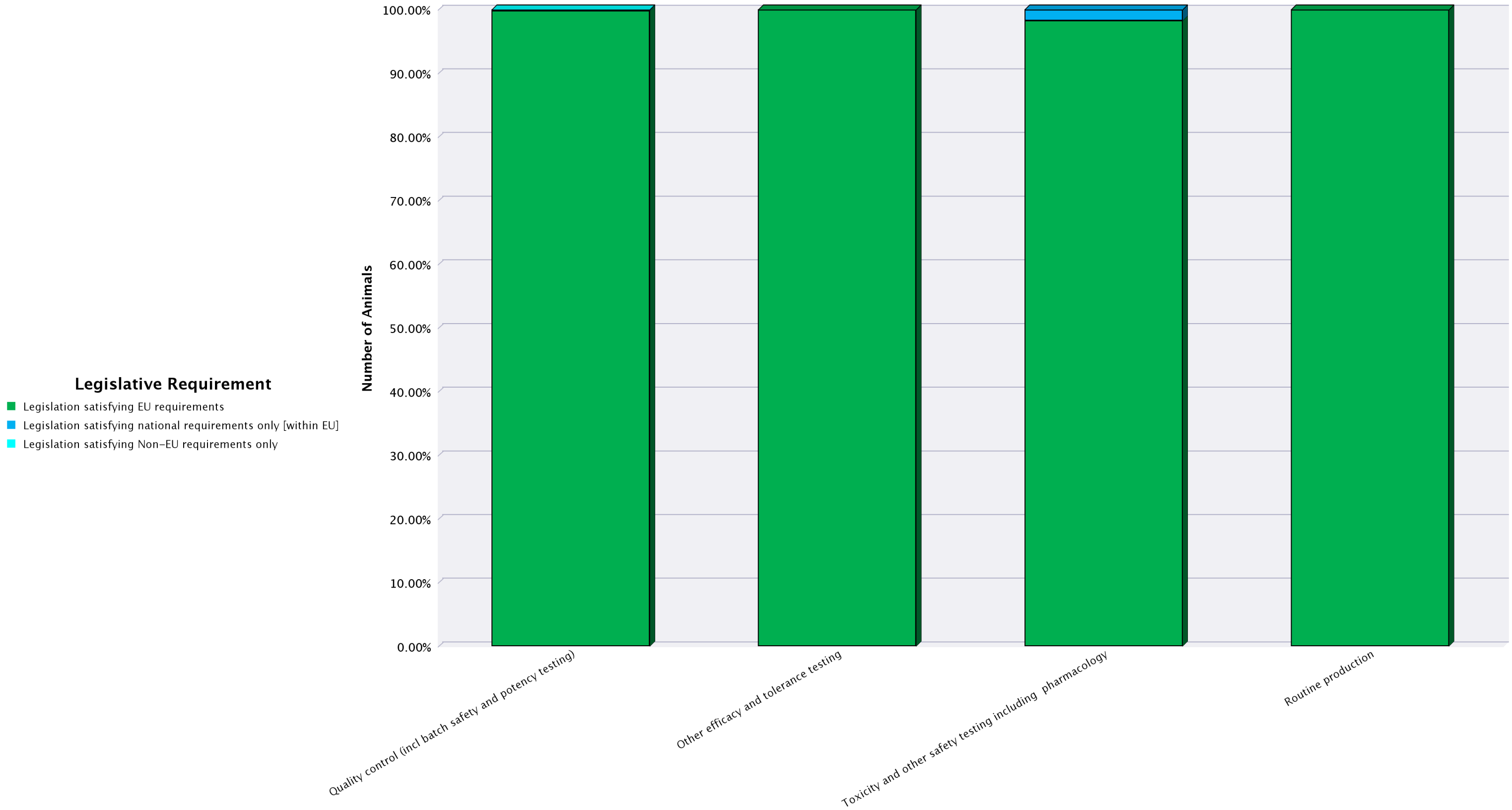
It should be remembered that by including one data filtering criterion, all others from that selection type are by default excluded. For example: if selecting "mouse" as the animal species, the data on the report will only show the results containing mice. However, if at the same time an incompatible selection is made e.g. selecting species grouping level 2 "birds" (excluding all other groups of species covering also "mammals" (including "mouse")), no data is shown in the report, as the two selections are incompatible.

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Regulatory use and routine production purposes

	Quality control (incl batch safety and potency testing)	Other efficacy and tolerance testing	Toxicity and other safety testing including pharmacology	Routine production	Total
Legislation satisfying EU requirements	15,510	1,091	2,685	1,058	20,344
Legislation satisfying national requirements only [within EU]			48		48
Legislation satisfying Non-EU requirements only	34				34
Total	15,544	1,091	2,733	1,058	20,426



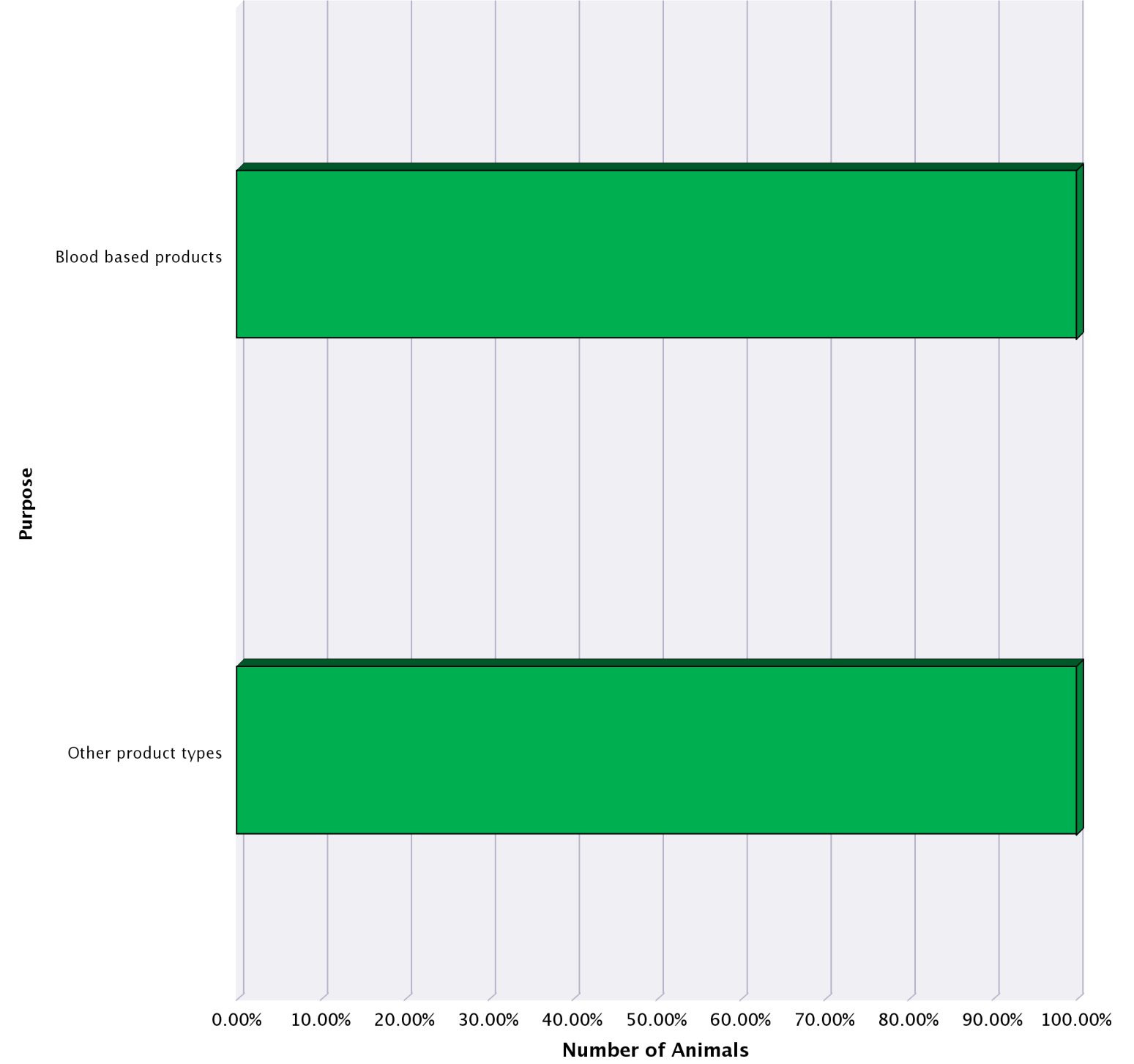
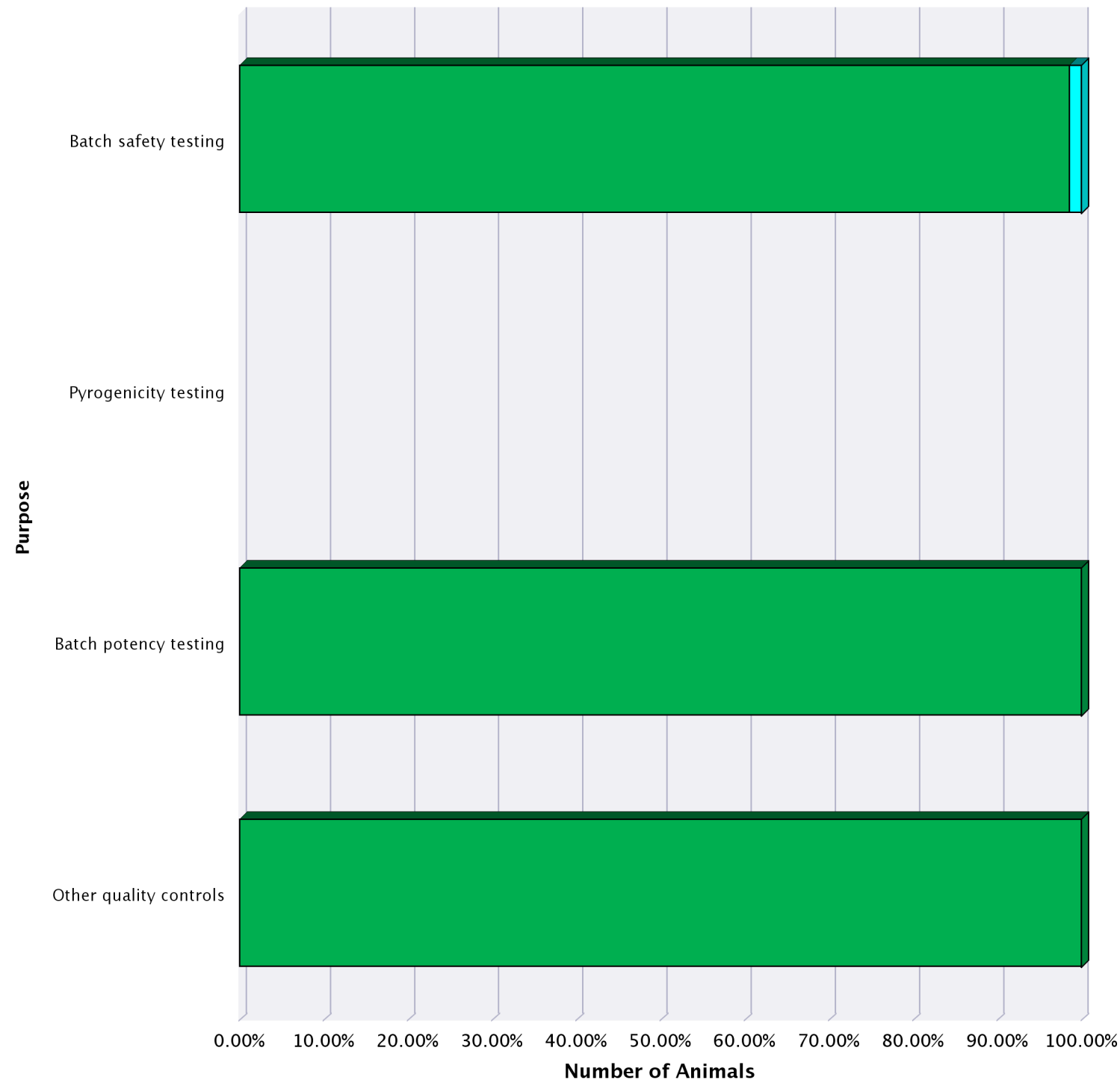
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Quality control purposes

	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Legislation satisfying EU requirements	2,332		13,137	41	15,510
Legislation satisfying national requirements only [within EU]					
Legislation satisfying Non-EU requirements only	34				34
Total	2,366		13,137	41	15,544

Routine production purposes

	Blood based products	Other product types	Total
Legislation satisfying EU requirements	996	62	1,058
Legislation satisfying national requirements only [within EU]			
Legislation satisfying Non-EU requirements only			
Total	996	62	1,058



Legislative Requirement

- Legislation satisfying EU requirements
- Legislation satisfying national requirements only [within EU]

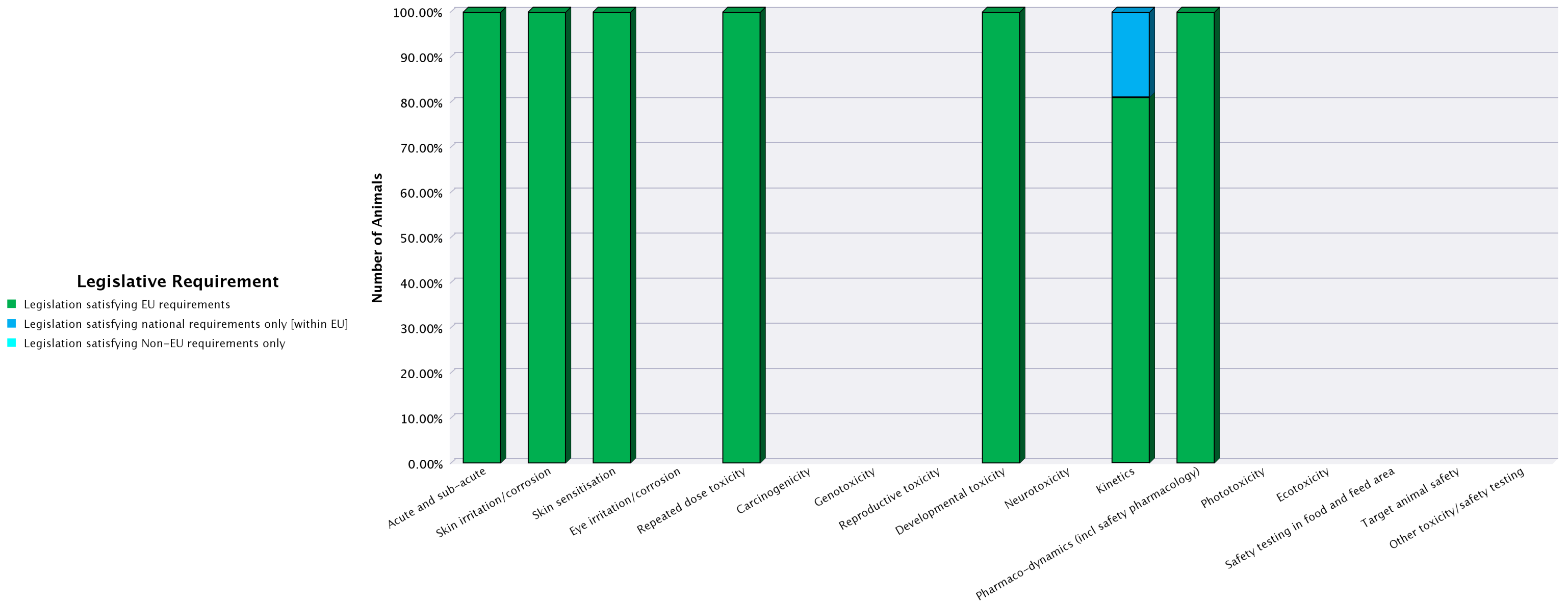
Legislative Requirement

- Legislation satisfying EU requirements
- Legislation satisfying national requirements only [within EU]

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Toxicity and other safety testing by test type purposes

	Legislation satisfying EU requirements	Legislation satisfying national requirements only [within EU]	Legislation satisfying Non-EU requirements only	Total
Acute and sub-acute	26			26
Skin irritation/corrosion	3			3
Skin sensitisation	32			32
Eye irritation/corrosion				
Repeated dose toxicity	1,662			1,662
Carcinogenicity				
Genotoxicity				
Reproductive toxicity				
Developmental toxicity	6			6
Neurotoxicity				
Kinetics	205	48		253
Pharmaco-dynamics (incl safety pharmacology)	751			751
Phototoxicity				
Ecotoxicity				
Safety testing in food and feed area				
Target animal safety				
Other toxicity/safety testing				
Total	2,685	48		2,733



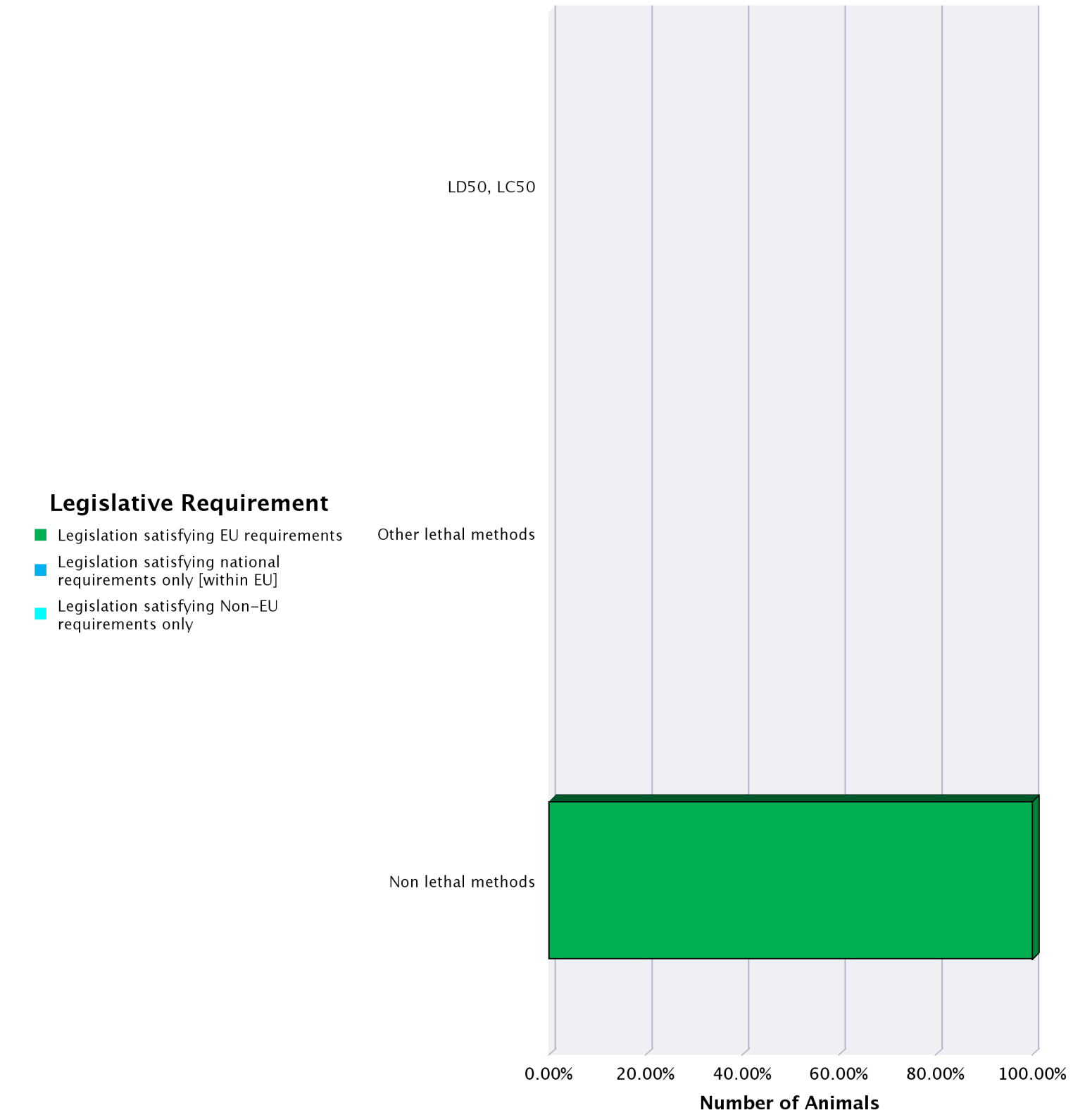
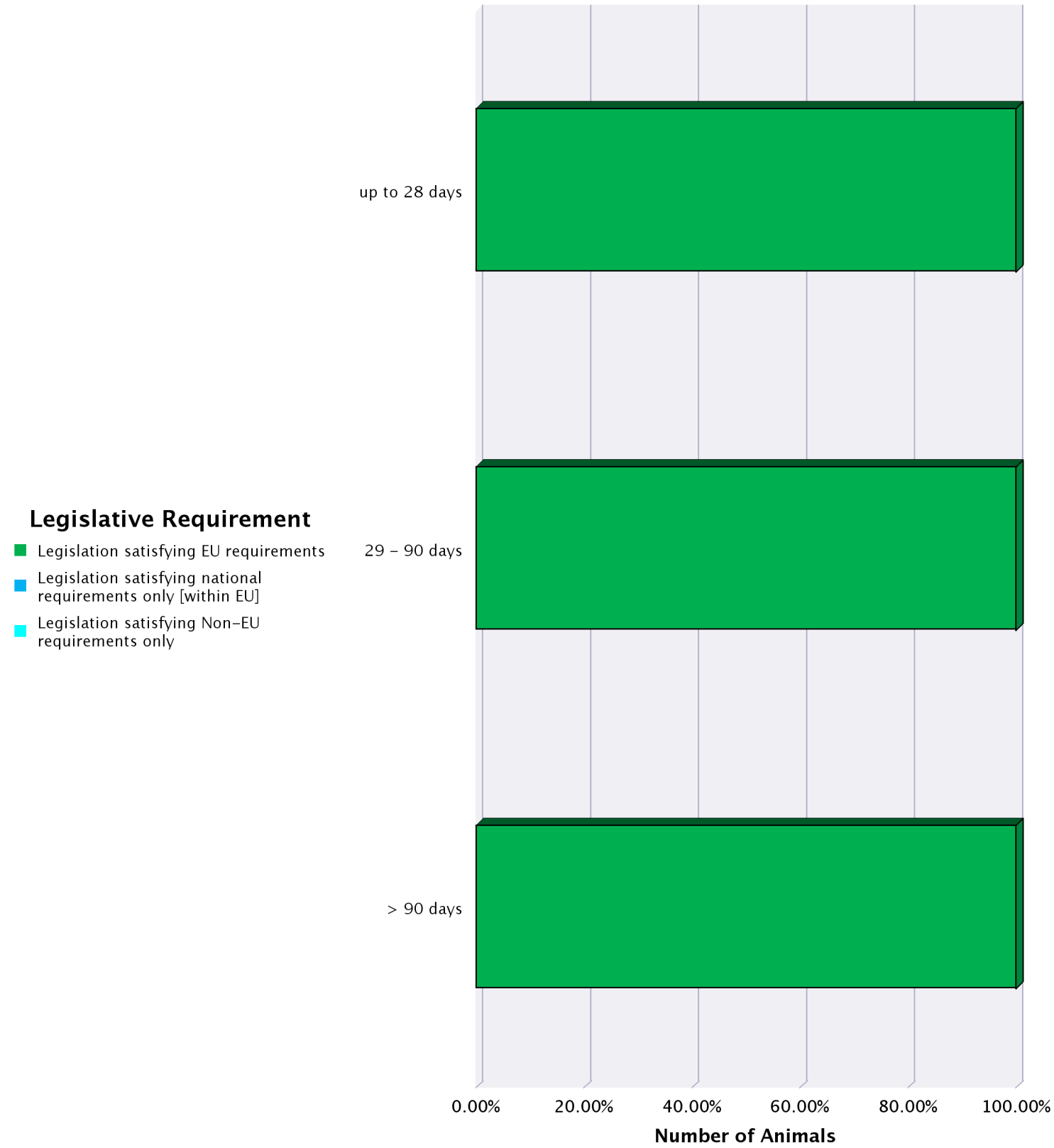
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Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	866	502	294	1,662
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	866	502	294	1,662

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements			26	26
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total			26	26



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Ecotoxicity purposes

	Acute toxicity	Chronic toxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Total
Legislation satisfying EU requirements						
Legislation satisfying national requirements only [within EU]						
Legislation satisfying Non-EU requirements only						
Total						

