

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

Data inclusion criteria

Report year: 2015

Country: Denmark

EU Submission: ALL

Re-use: ALL

Genetic status: ALL

Animal Species: ALL

Species grouping Level 1: ALL

Species grouping Level 2: ALL

Mammals: ALL

Non-human primates: ALL

Legislative Requirement: ALL

Severity: ALL

Submission Id: ALL

Id 1: ALL

Id 2: ALL

Id 3: ALL

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.

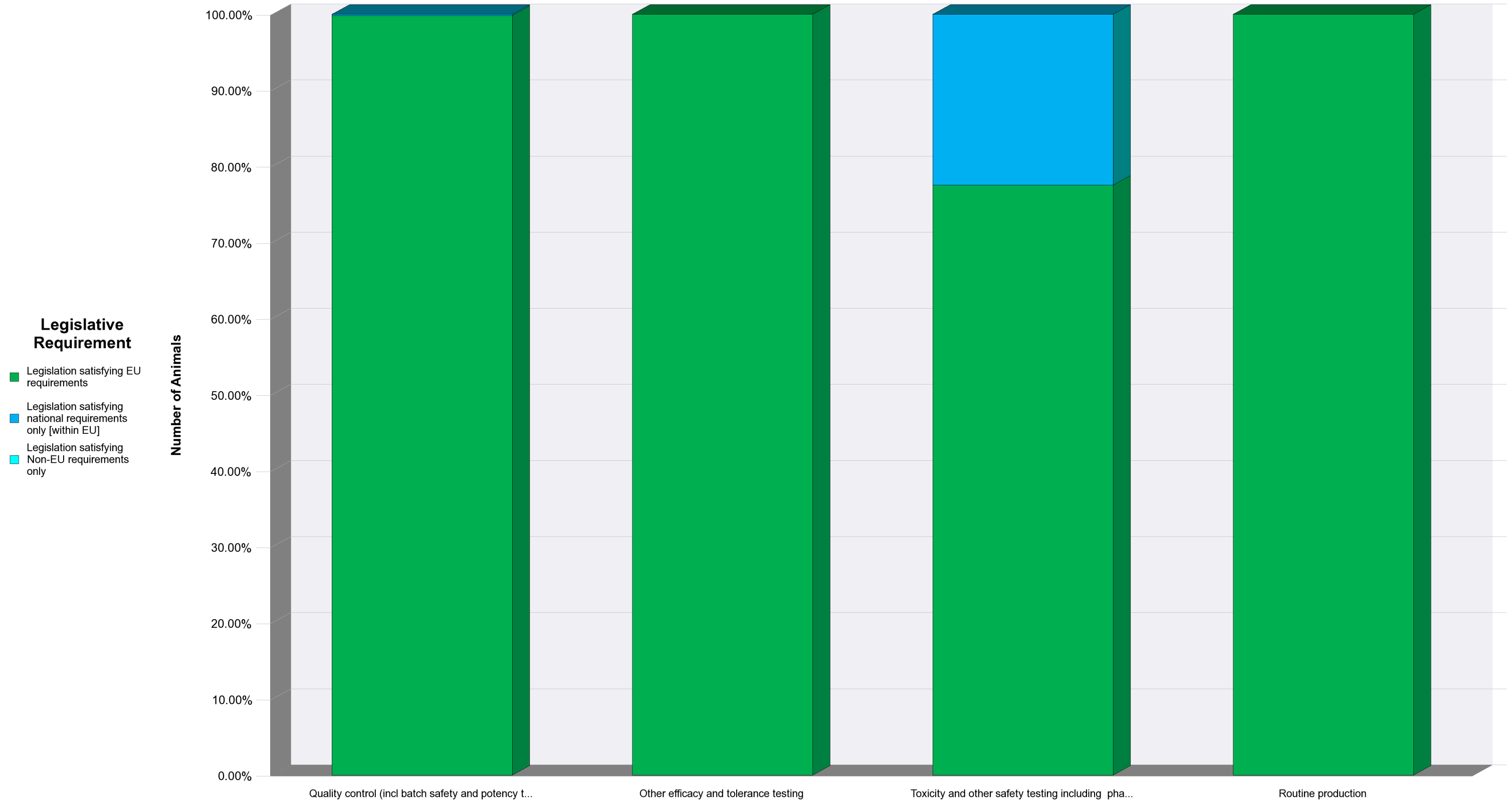
Data filtering criteria has been complemented with an option to filter data into the report also at the level of species groupings.

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	14,797	95	6,221	21	21,134
Legislation satisfying national requirements only [within EU]	22		1,800		1,822
Legislation satisfying Non-EU requirements only					
Total	14,819	95	8,021	21	22,956



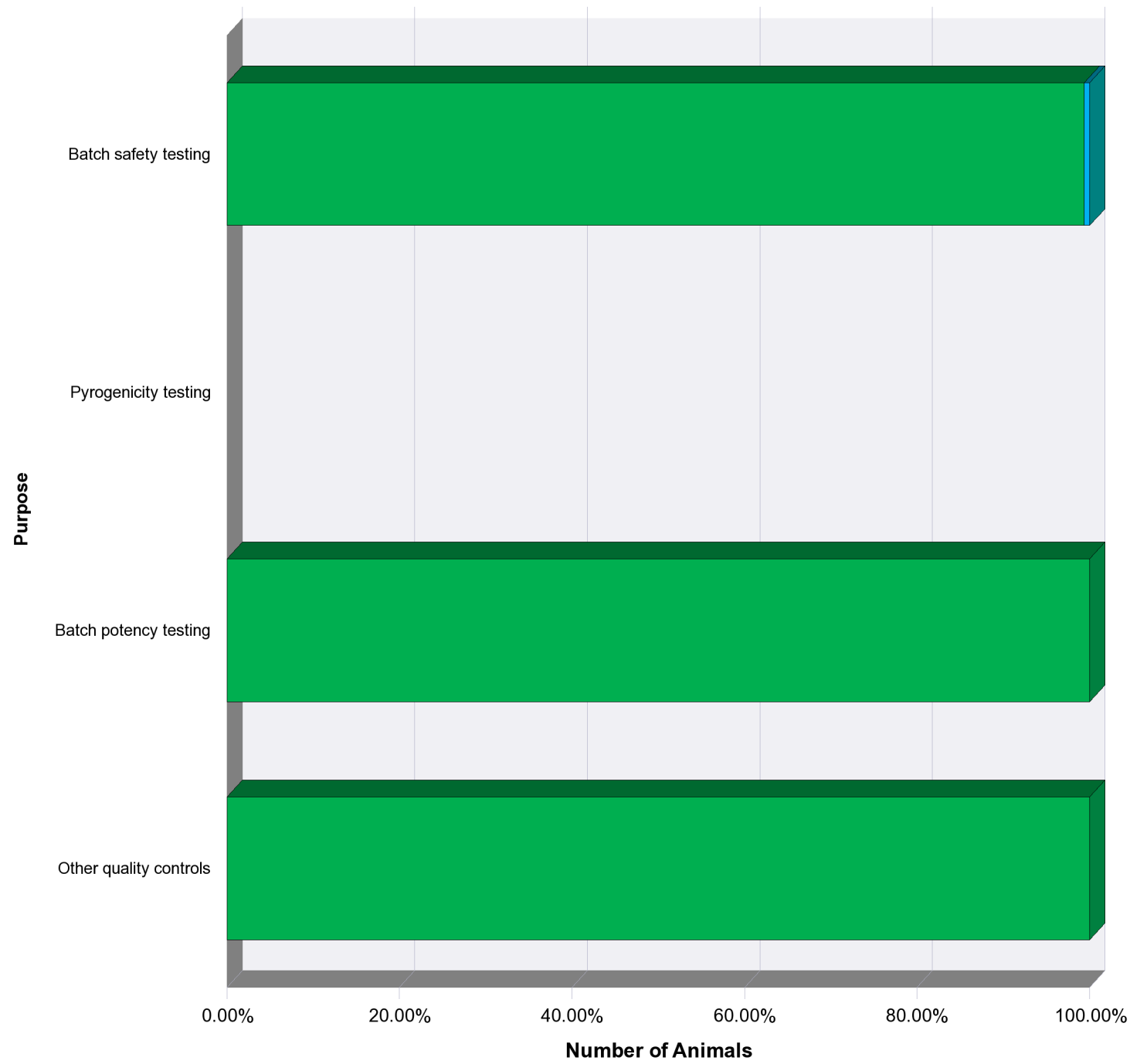
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Quality control purposes

	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Legislation satisfying EU requirements	3,665		11,105	27	14,797
Legislation satisfying national requirements only [within EU]	22				22
Legislation satisfying Non-EU requirements only					
Total	3,687		11,105	27	14,819

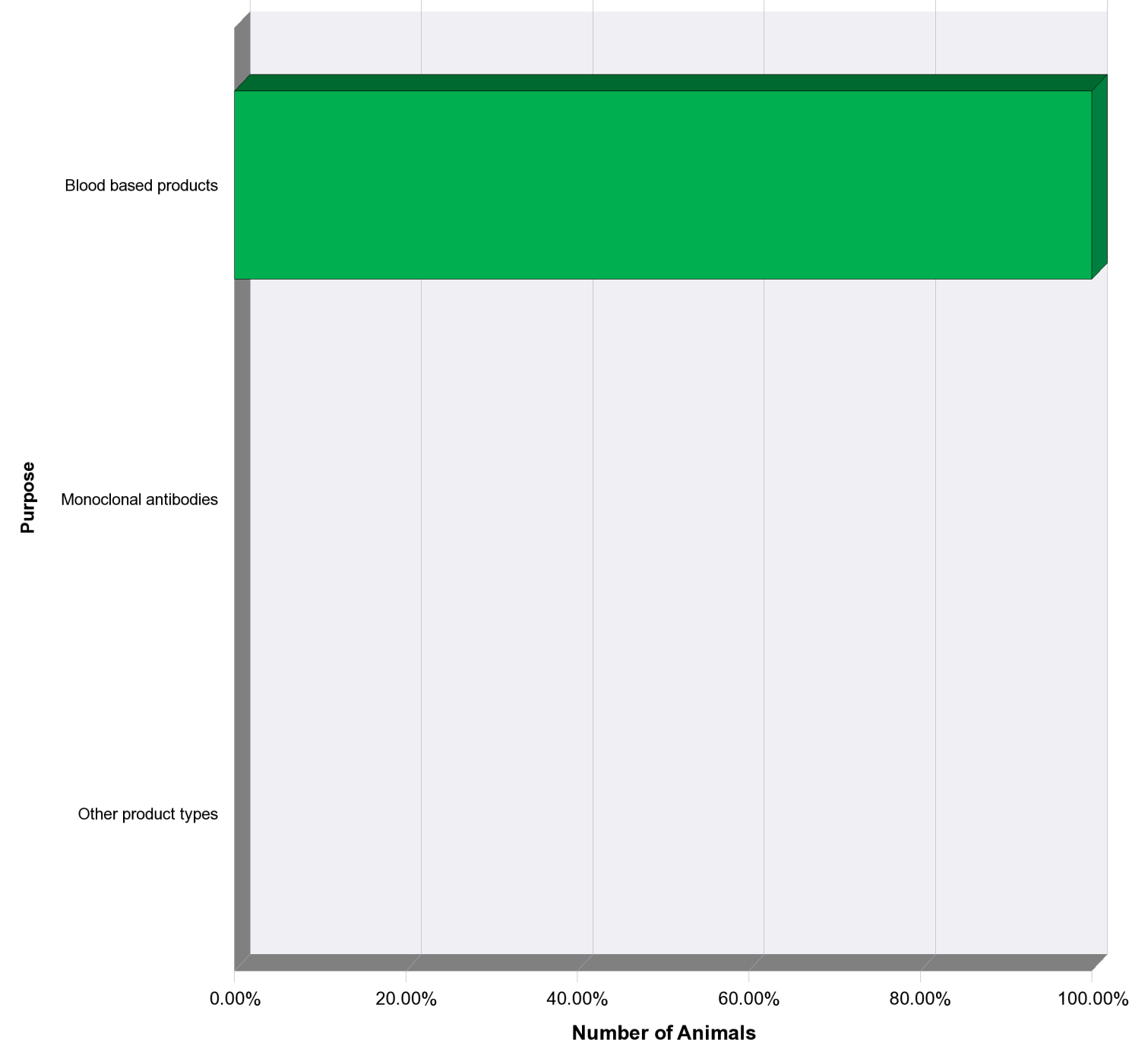
Routine production purposes

	Blood based products	Monoclonal antibodies	Other product types	Total
Legislation satisfying EU requirements	21			21
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	21			21



Legislative Requirement

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



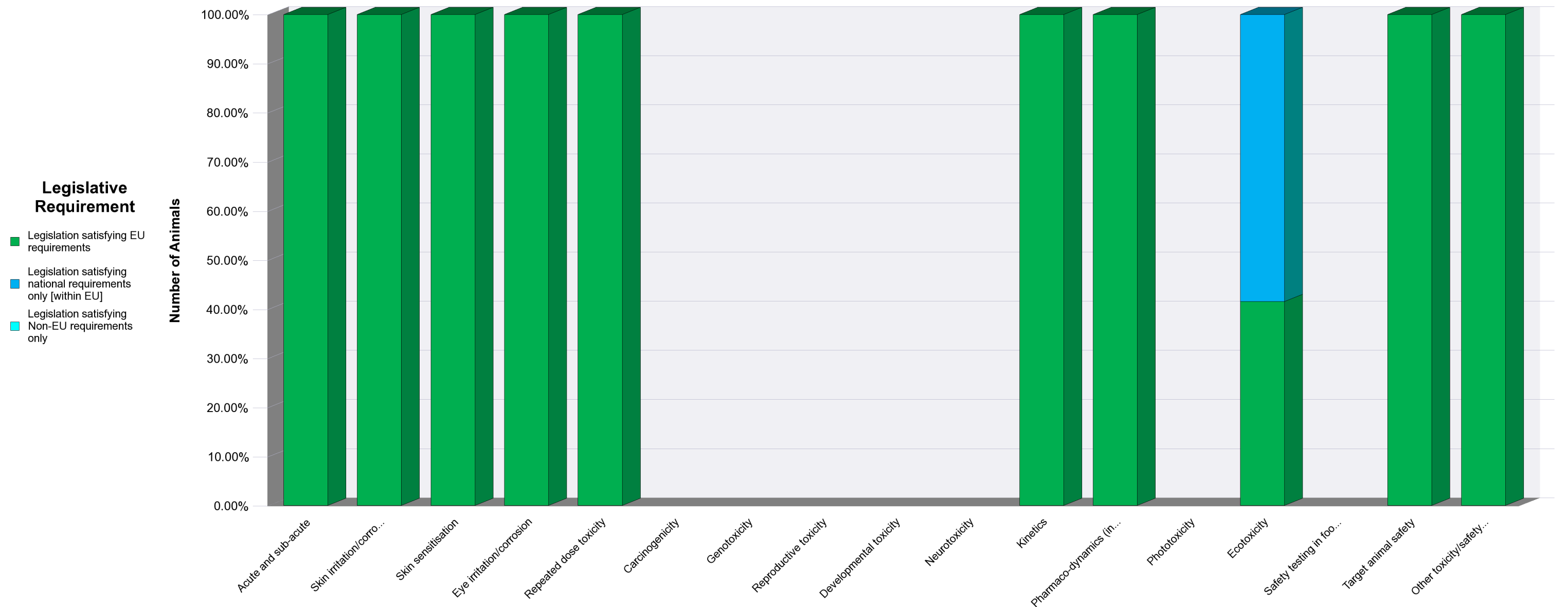
Legislative Requirement

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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	786			786
Skin irritation/corrosion	12			12
Skin sensitisation	138			138
Eye irritation/corrosion	6			6
Repeated dose toxicity	1,755			1,755
Carcinogenicity				
Genotoxicity				
Reproductive toxicity				
Developmental toxicity				
Neurotoxicity				
Kinetics	2,095			2,095
Pharmaco-dynamics (incl safety pharmacology)	9			9
Phototoxicity				
Ecotoxicity	1,280		1,800	3,080
Safety testing in food and feed area				
Target animal safety	120			120
Other toxicity/safety testing	20			20
Total	6,221		1,800	8,021



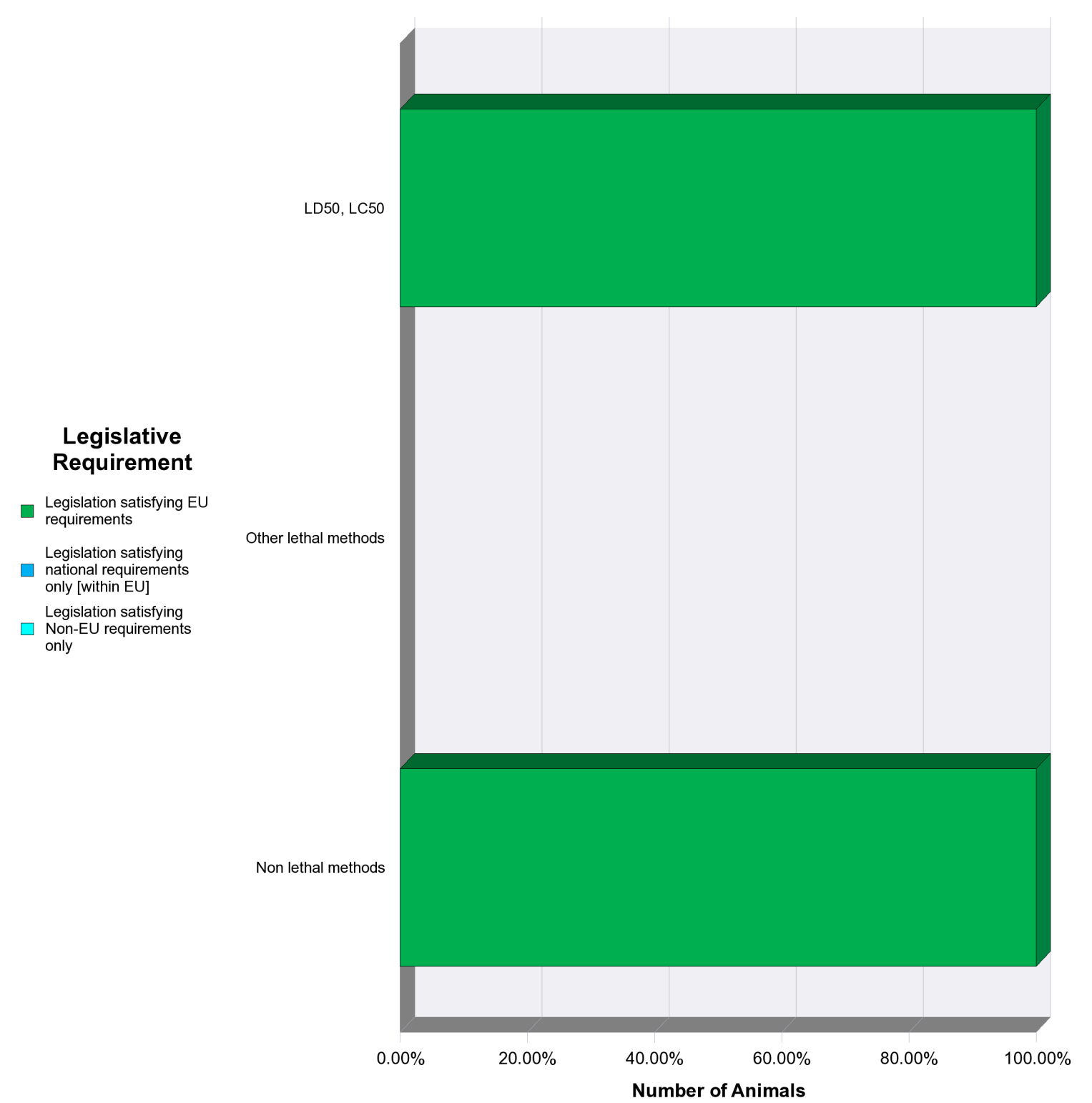
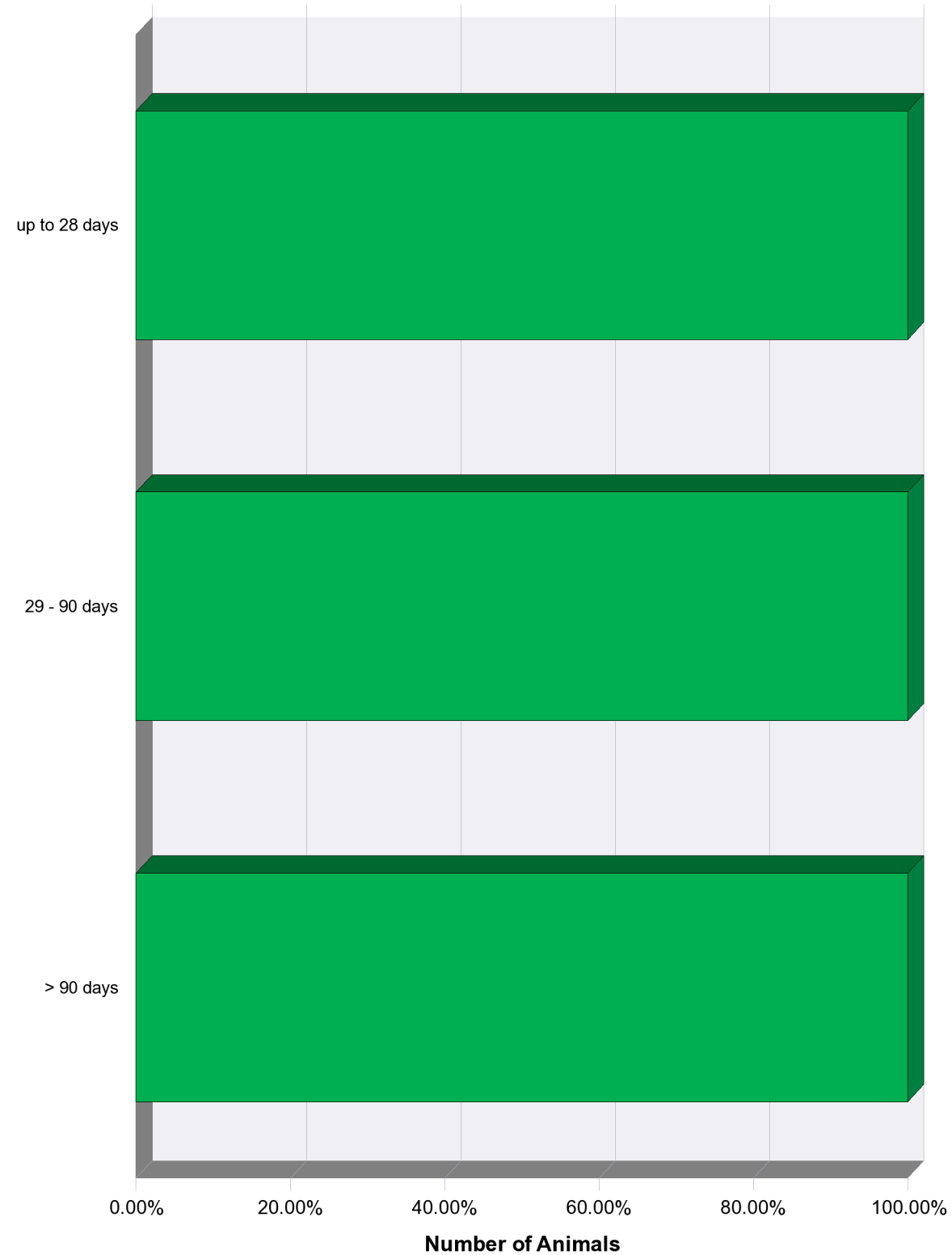
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Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	1,136	488	131	1,755
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	1,136	488	131	1,755

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements	80		706	786
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	80		706	786



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Ecotoxicity purposes

	Acute toxicity	Chronic toxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Total
Legislation satisfying EU requirements		1,280				1,280
Legislation satisfying national requirements only [within EU]		1,800				1,800
Legislation satisfying Non-EU requirements only						
Total		3,080				3,080

