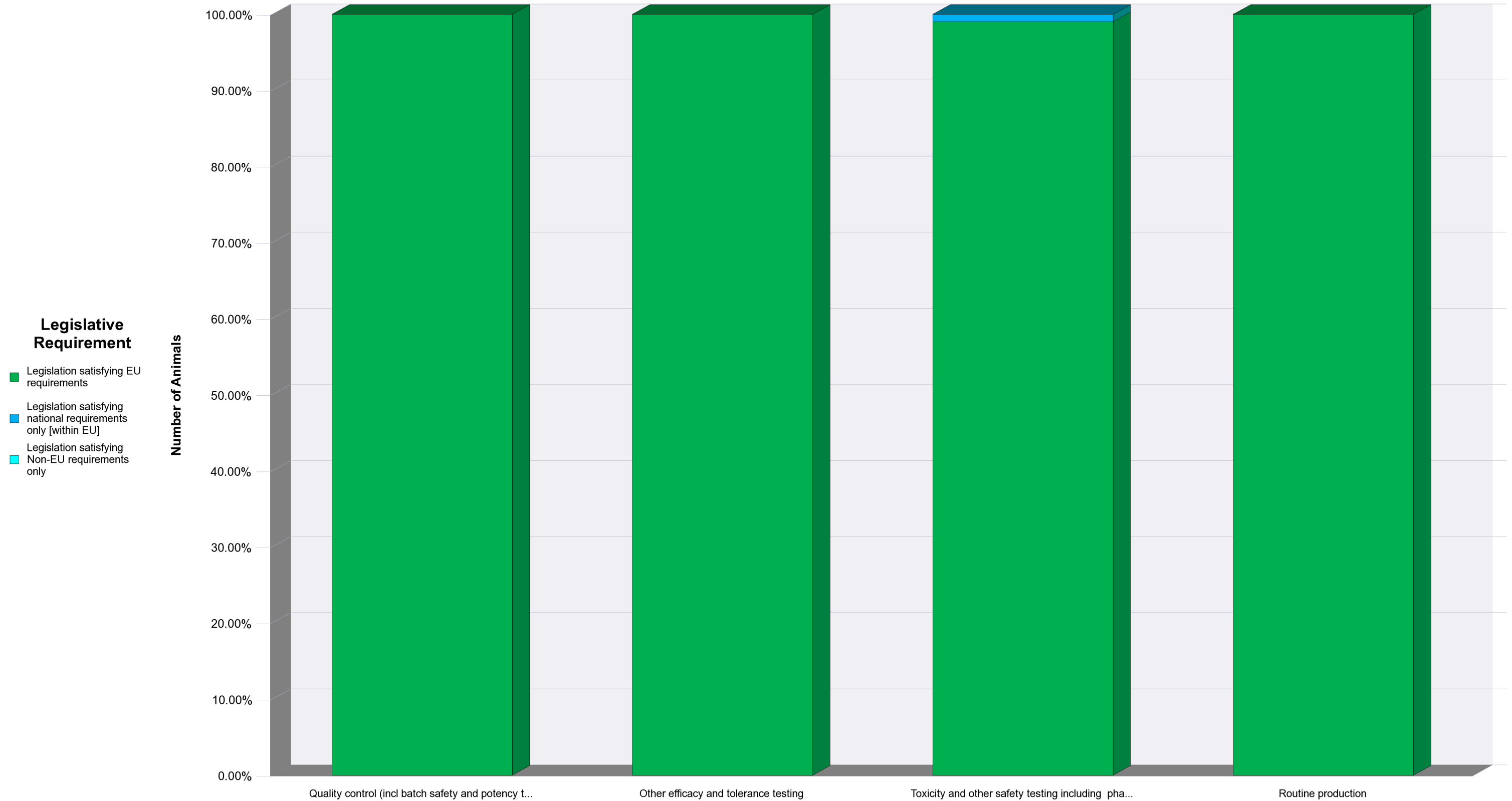


DP.F.2. Purposes and origin of legislative requirement

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	8,139	725	10,208	744	19,816
Legislation satisfying national requirements only [within EU]			100		100
Legislation satisfying Non-EU requirements only					
Total	8,139	725	10,308	744	19,916



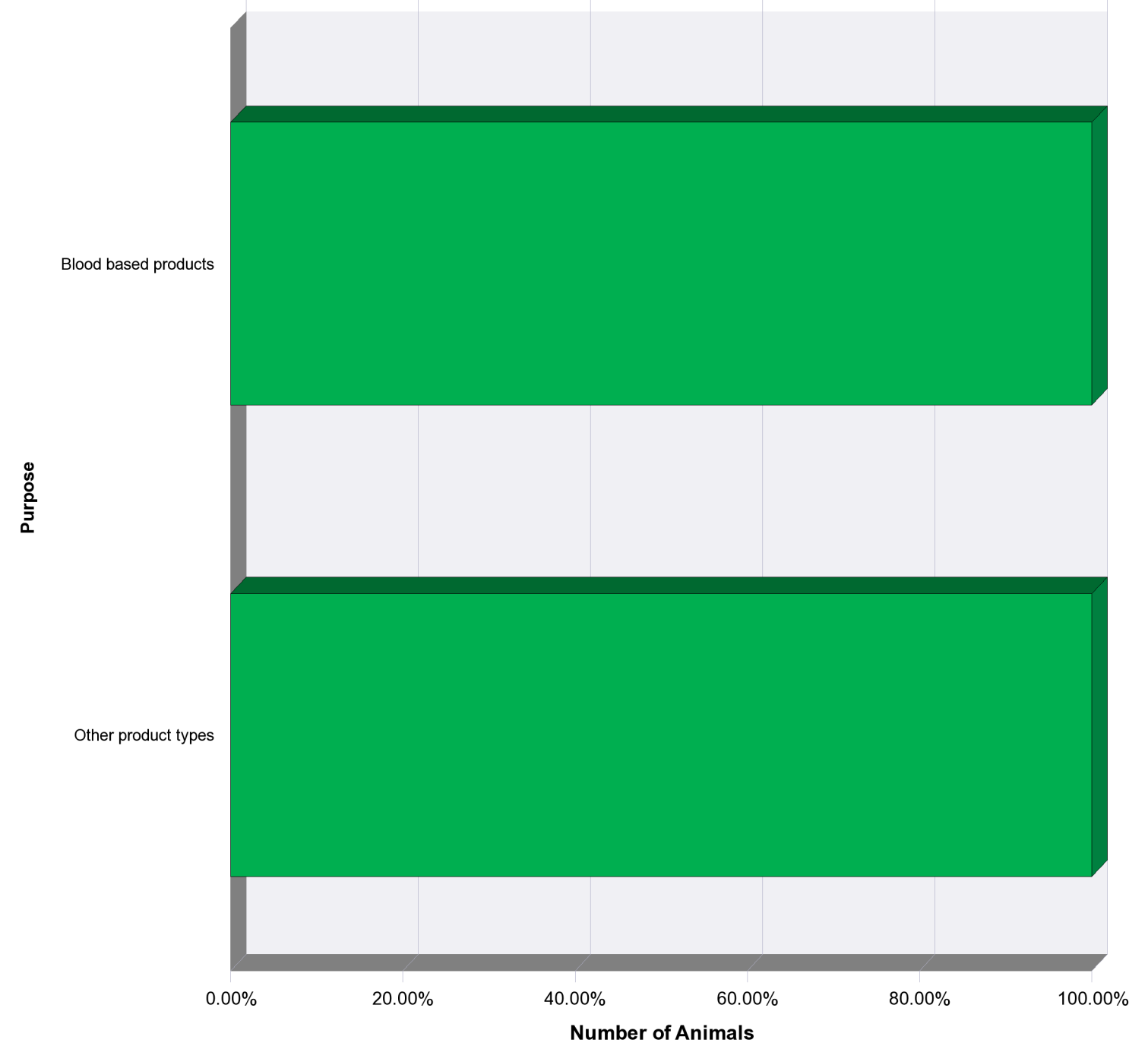
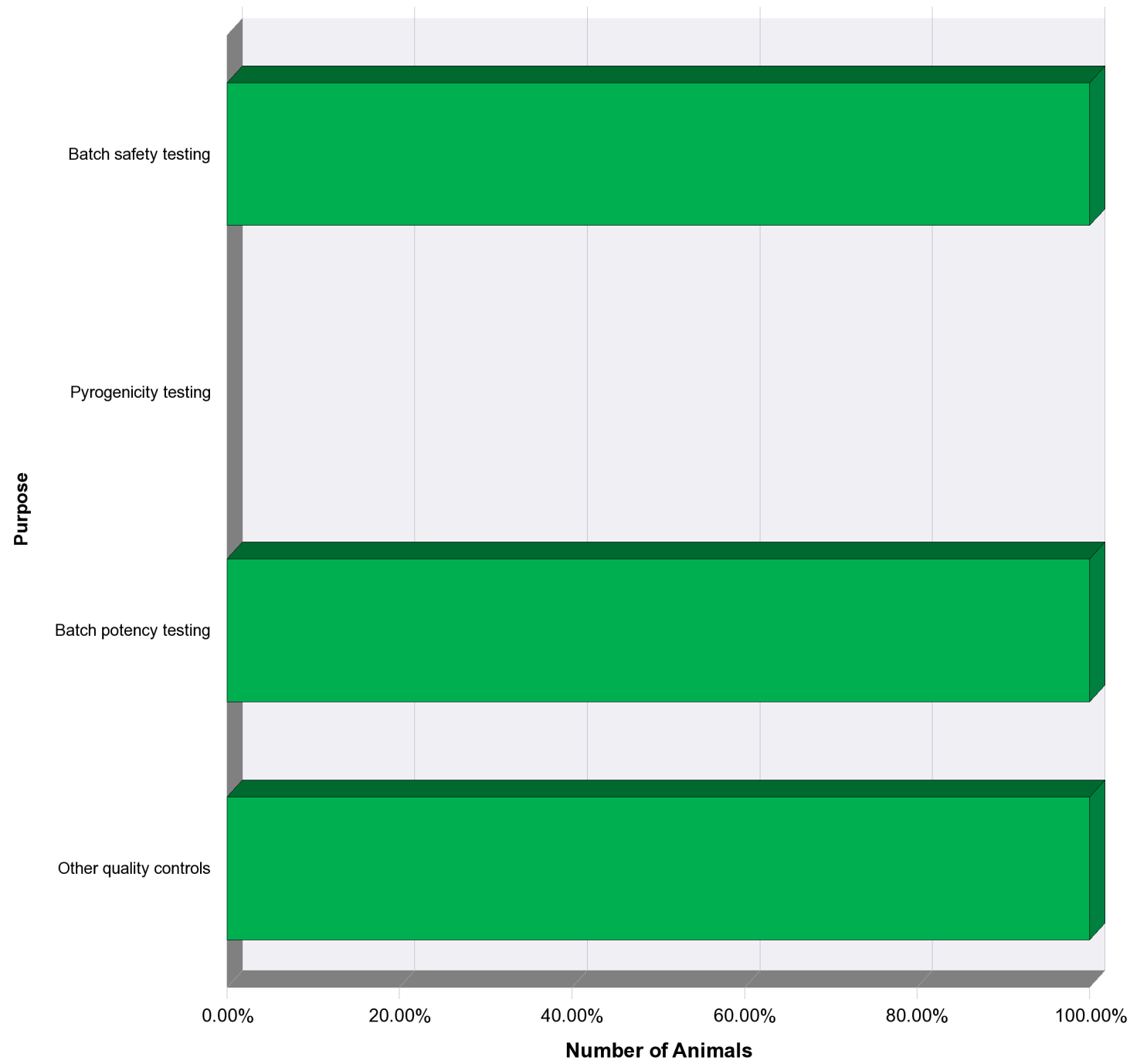
DP.F.2. Purposes and origin of legislative requirement

Quality control purposes

	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Legislation satisfying EU requirements	2,504		5,601	34	8,139
Legislation satisfying national requirements only [within EU]					
Legislation satisfying Non-EU requirements only					
Total	2,504		5,601	34	8,139

Routine production purposes

	Blood based products	Other product types	Total
Legislation satisfying EU requirements	18	456	474
Legislation satisfying national requirements only [within EU]			
Legislation satisfying Non-EU requirements only			
Total	18	456	474



Legislative Requirement

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

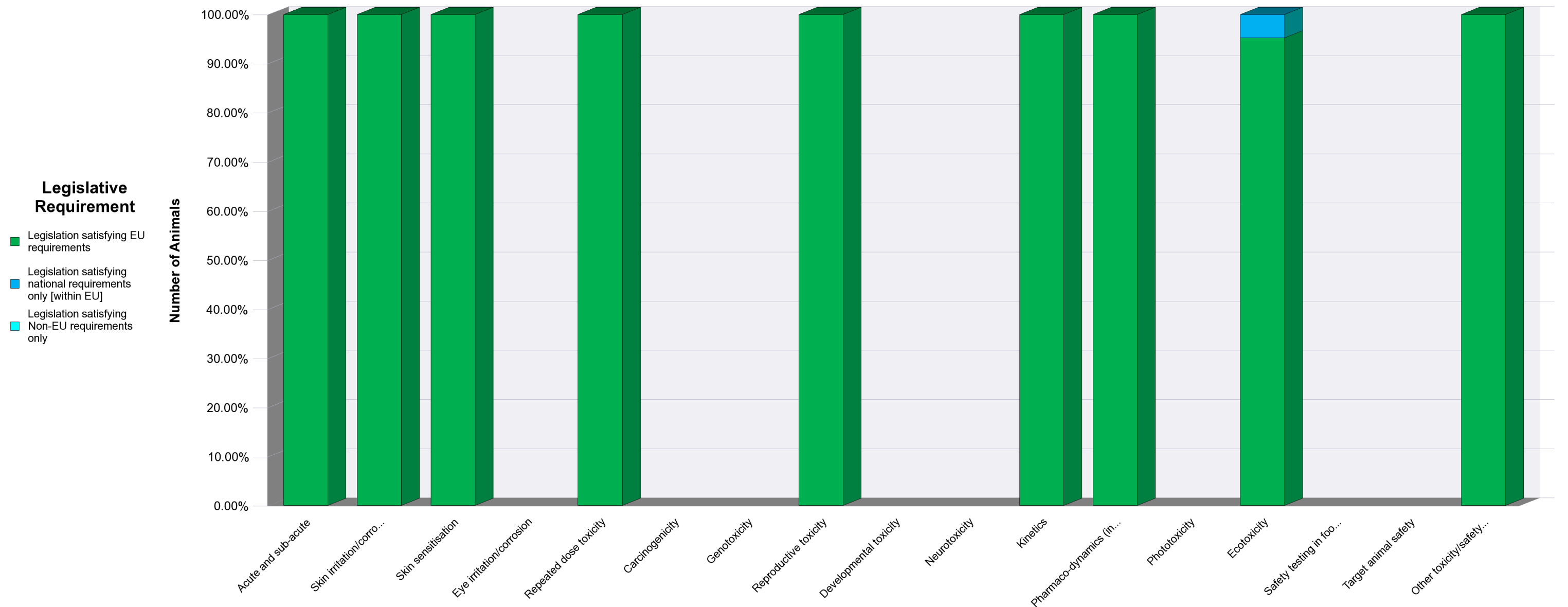
Legislative Requirement

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

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

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	3,968			3,968
Skin irritation/corrosion	28			28
Skin sensitisation	177			177
Eye irritation/corrosion				
Repeated dose toxicity	2,205			2,205
Carcinogenicity				
Genotoxicity				
Reproductive toxicity	935			935
Developmental toxicity				
Neurotoxicity				
Kinetics	818			818
Pharmaco-dynamics (incl safety pharmacology)	26			26
Phototoxicity				
Ecotoxicity	2,000		100	2,100
Safety testing in food and feed area				
Target animal safety				
Other toxicity/safety testing	51			51
Total	10,208		100	10,308



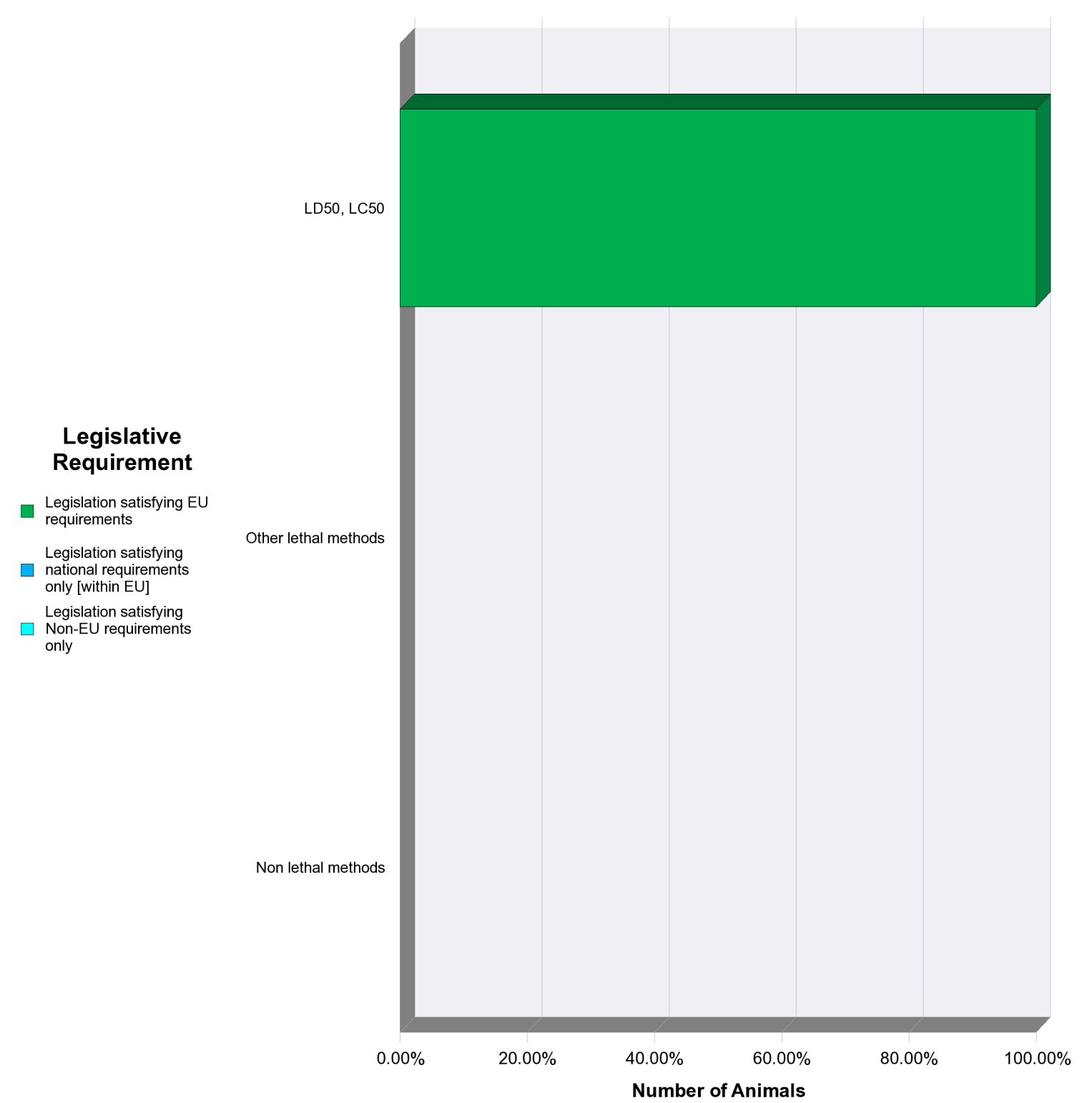
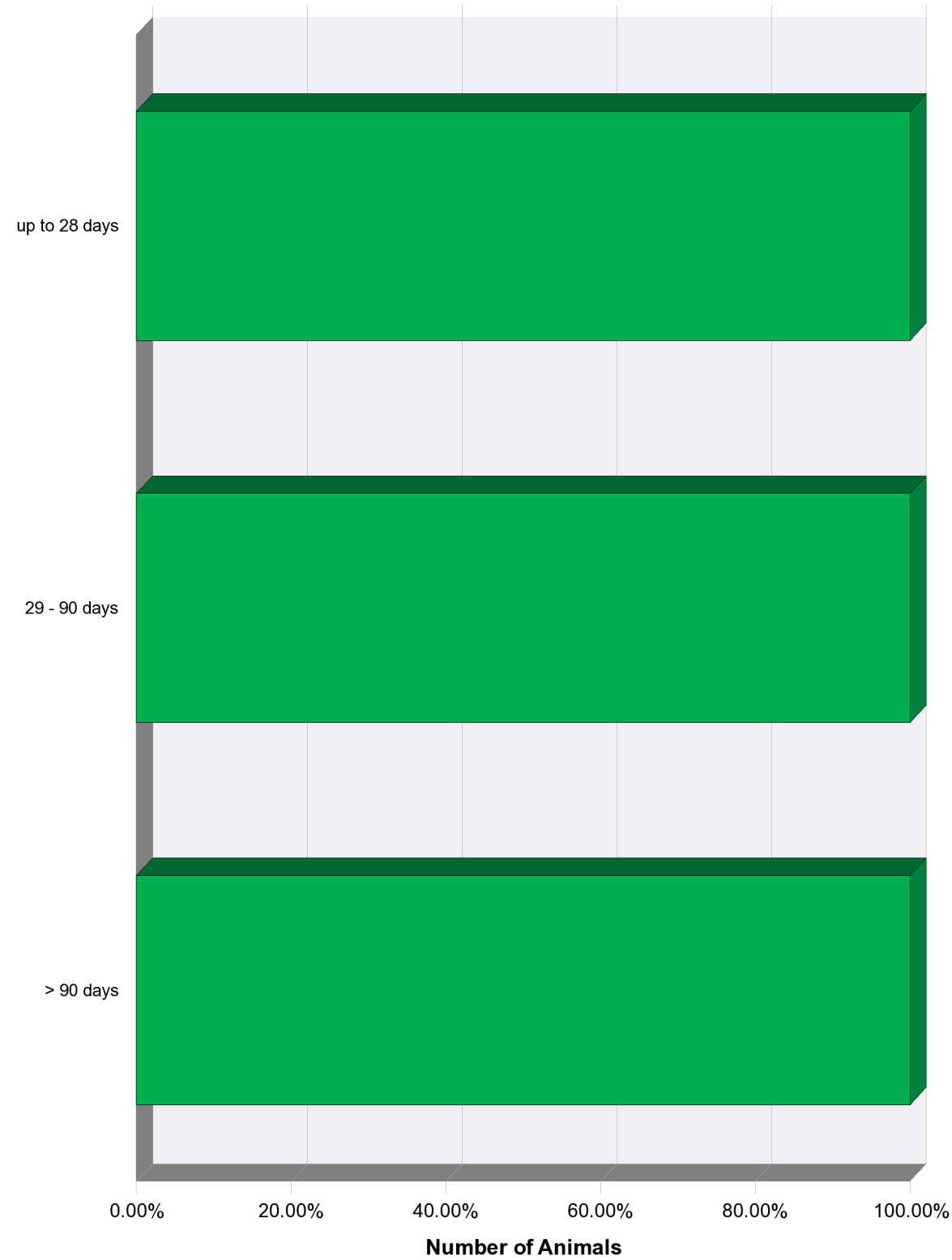
DP.F.2. Purposes and origin of legislative requirement

Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	1,382	586	237	2,205
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	1,382	586	237	2,205

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements	3,968			3,968
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	3,968			3,968



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

Ecotoxicity purposes

	Acute toxicity	Chronic toxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Total
Legislation satisfying EU requirements	120	1,800			80	2,000
Legislation satisfying national requirements only [within EU]					100	100
Legislation satisfying Non-EU requirements only						
Total	120	1,800			180	2,100

