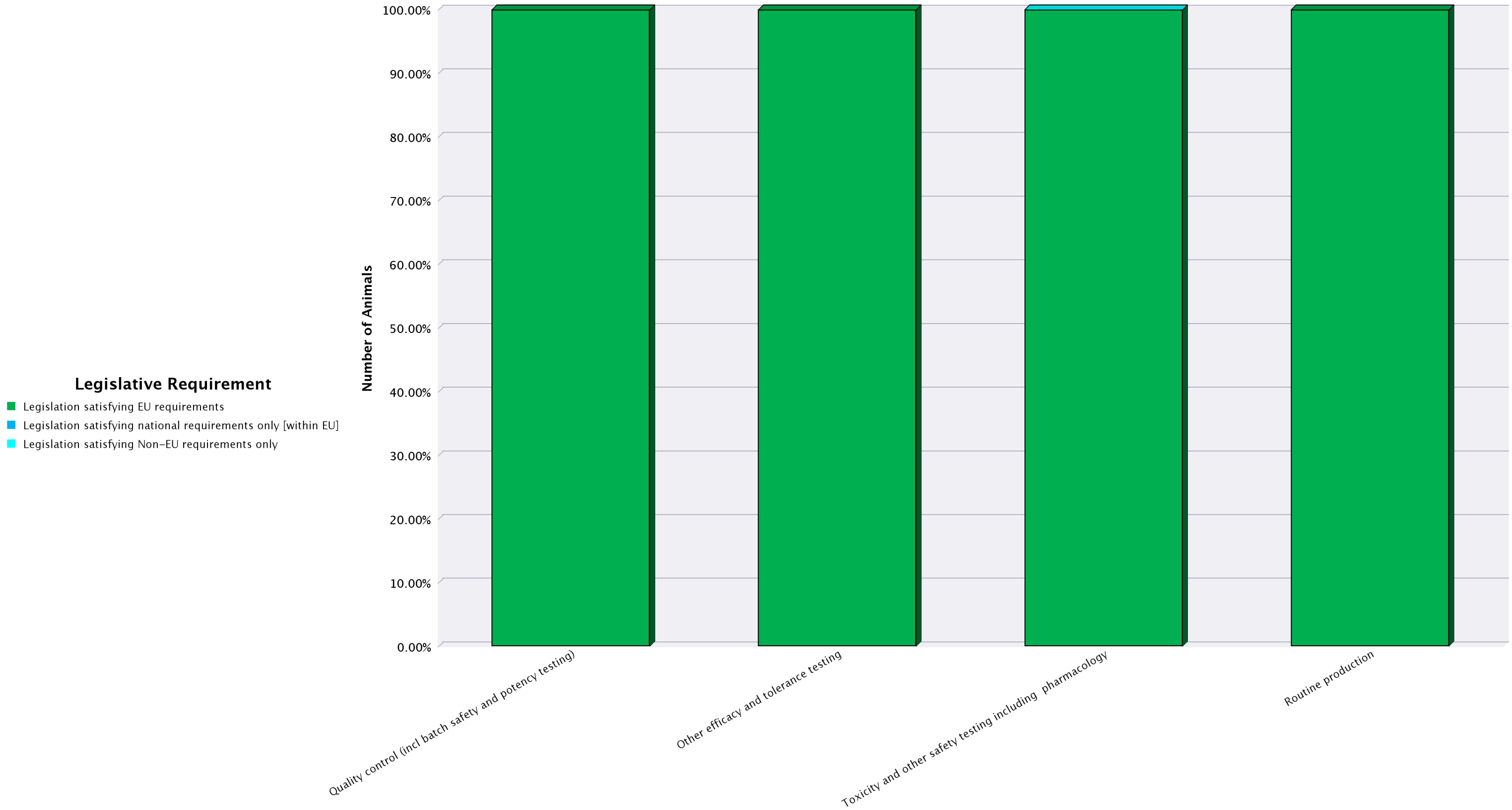


DP.F.2. Purposes and origin of legislative requirement

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	13,681	1,375	5,060	721	20,837
Legislation satisfying national requirements only [within EU]					
Legislation satisfying Non-EU requirements only			4		4
Total	13,681	1,375	5,064	721	20,841



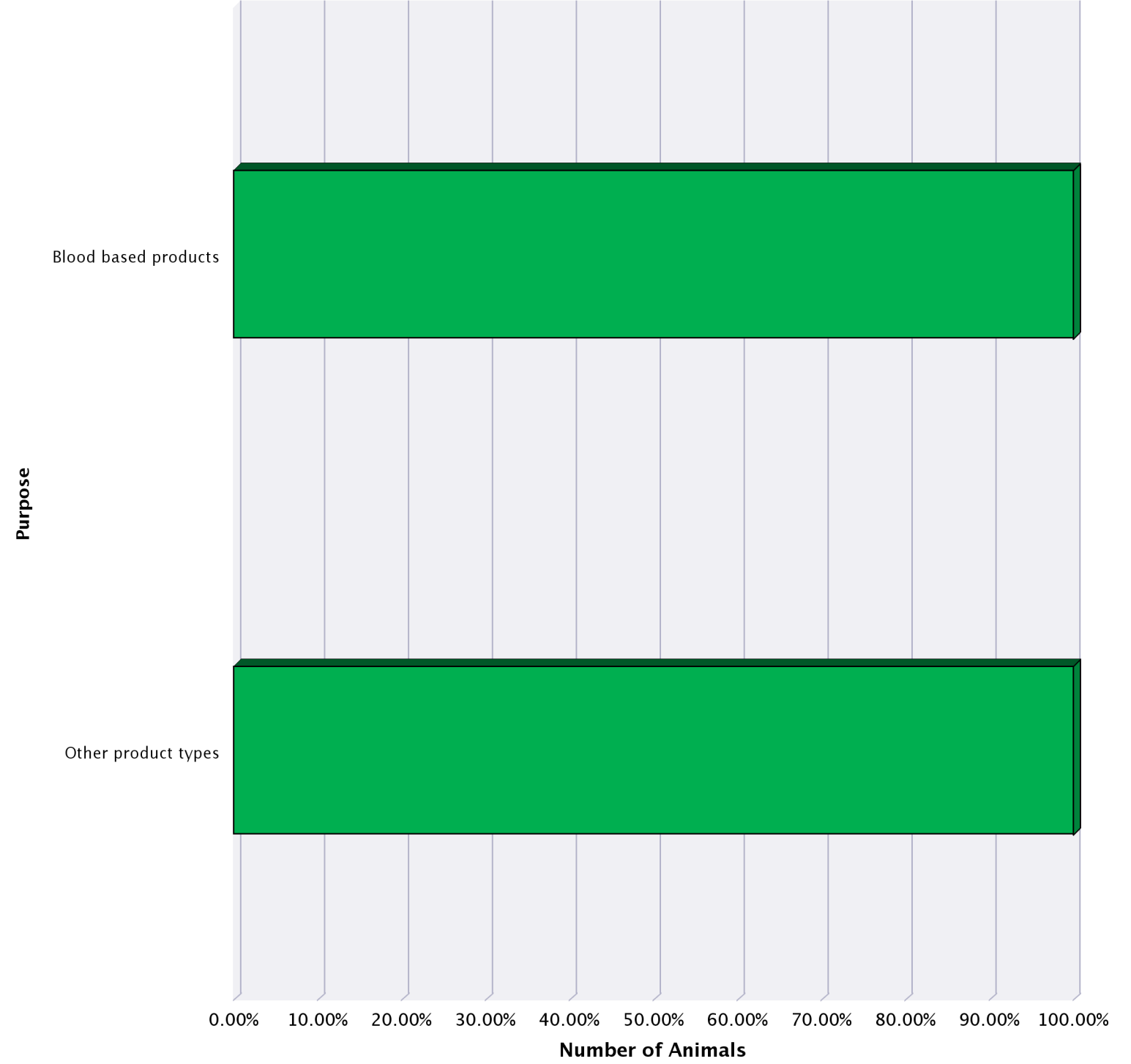
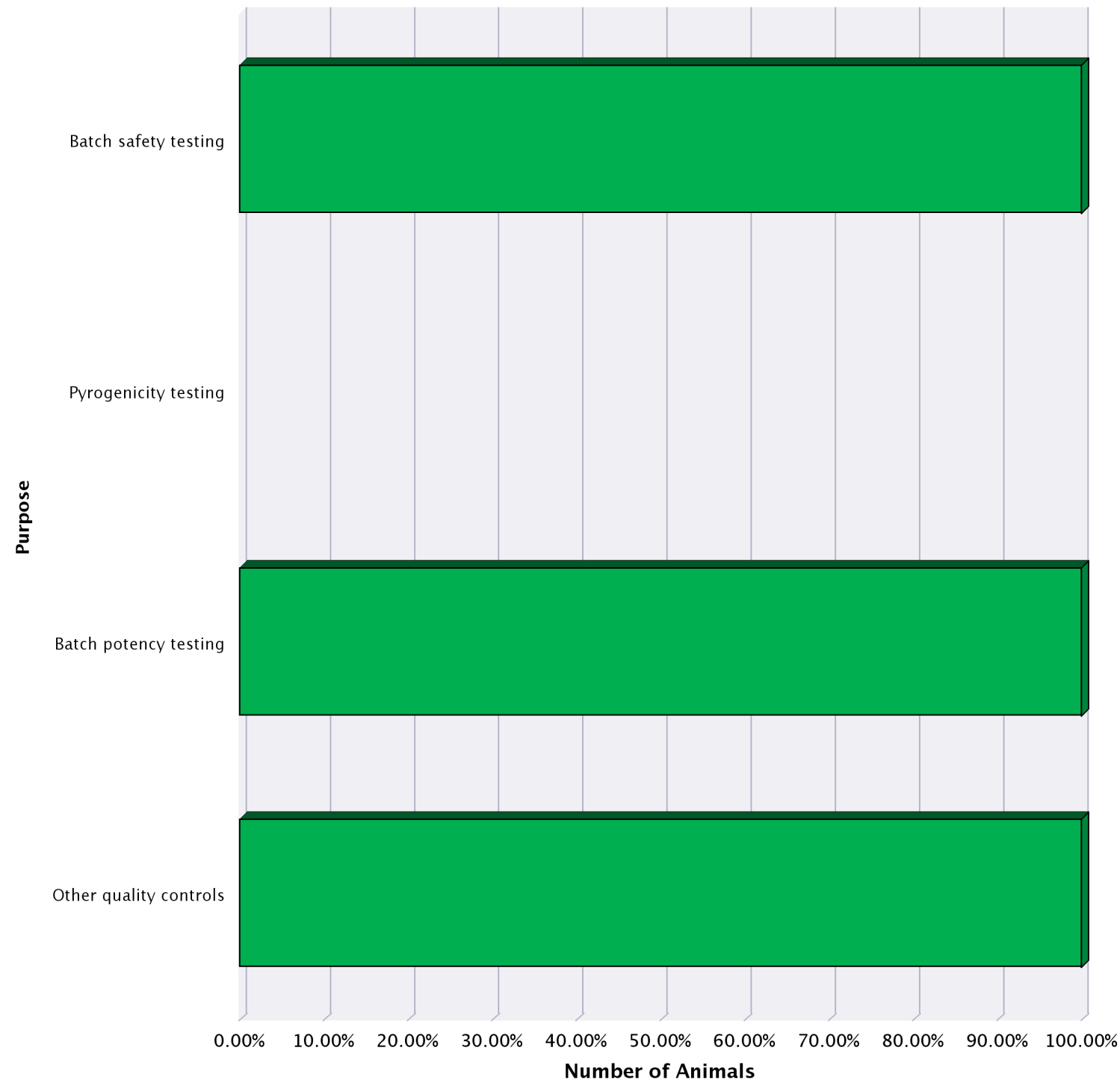
DP.F.2. Purposes and origin of legislative requirement

Quality control purposes

	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Legislation satisfying EU requirements	2,470		10,272	939	13,681
Legislation satisfying national requirements only [within EU]					
Legislation satisfying Non-EU requirements only					
Total	2,470		10,272	939	13,681

Routine production purposes

	Blood based products	Other product types	Total
Legislation satisfying EU requirements	687	34	721
Legislation satisfying national requirements only [within EU]			
Legislation satisfying Non-EU requirements only			
Total	687	34	721



Legislative Requirement

■ Legislation satisfying EU requirements ■ Legislation satisfying national requirements only [within EU] ...

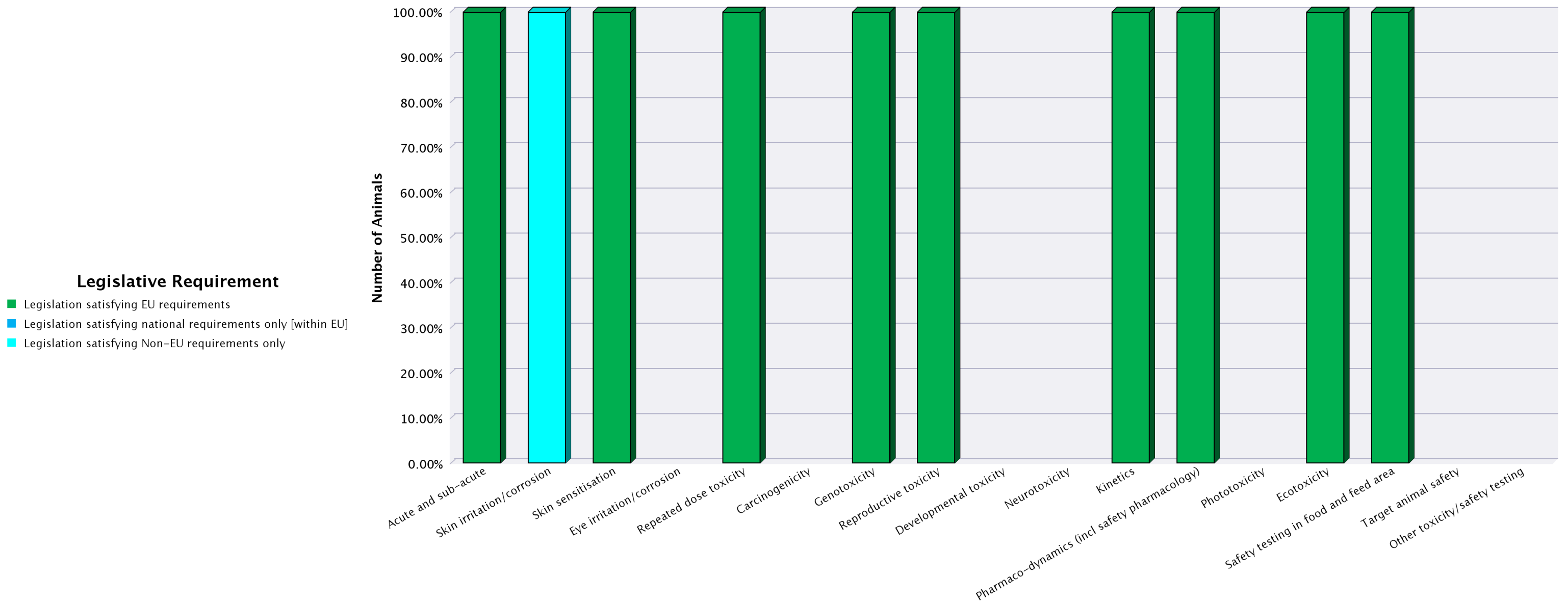
Legislative Requirement

■ Legislation satisfying EU requirements ■ Legislation satisfying national requirements only [within EU] ...

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	120			120
Skin irritation/corrosion			4	4
Skin sensitisation	74			74
Eye irritation/corrosion				
Repeated dose toxicity	1,612			1,612
Carcinogenicity				
Genotoxicity	22			22
Reproductive toxicity	35			35
Developmental toxicity				
Neurotoxicity				
Kinetics	510			510
Pharmaco-dynamics (incl safety pharmacology)	1,386			1,386
Phototoxicity				
Ecotoxicity	1,292			1,292
Safety testing in food and feed area	9			9
Target animal safety				
Other toxicity/safety testing				
Total	5,060		4	5,064



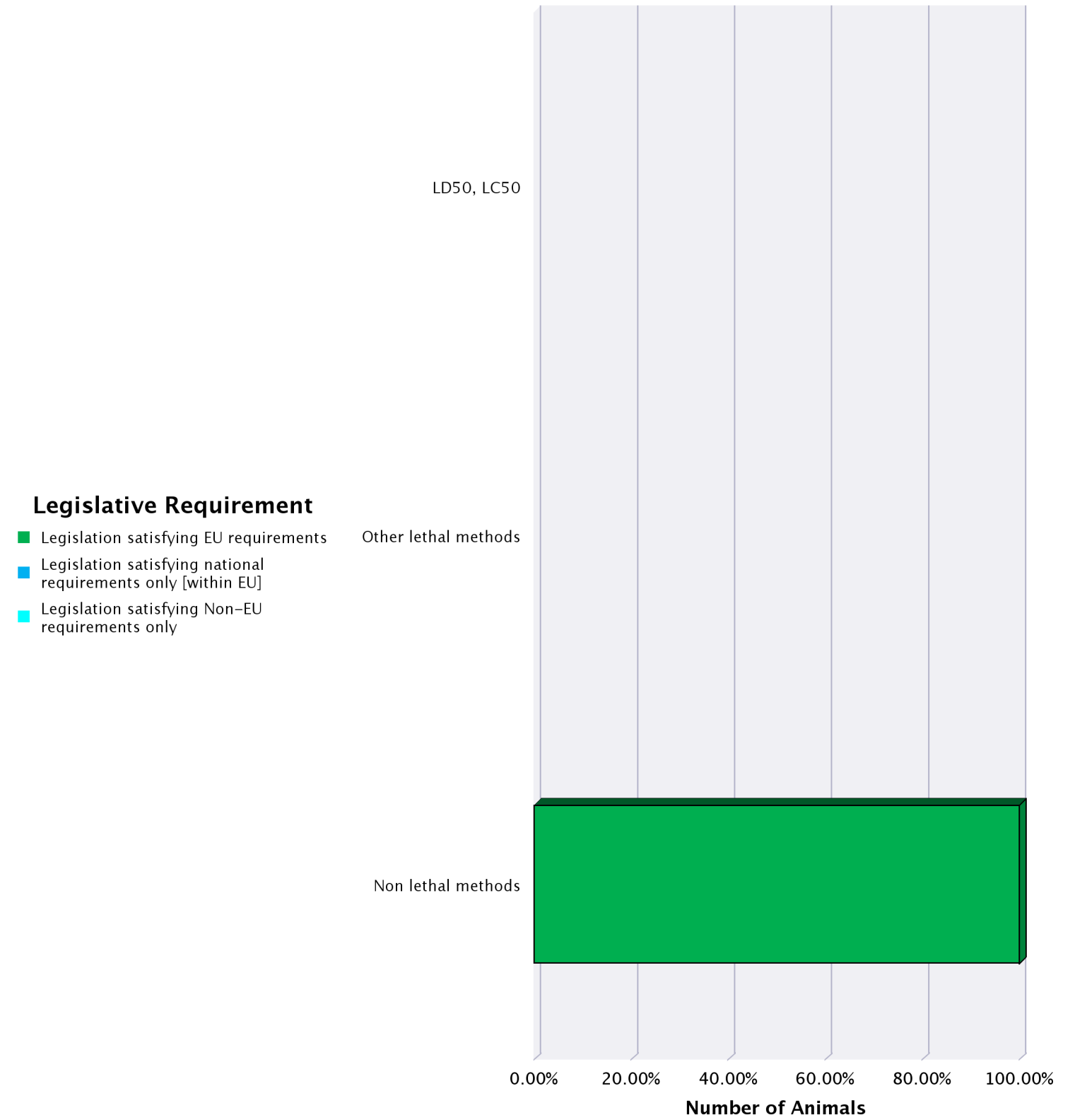
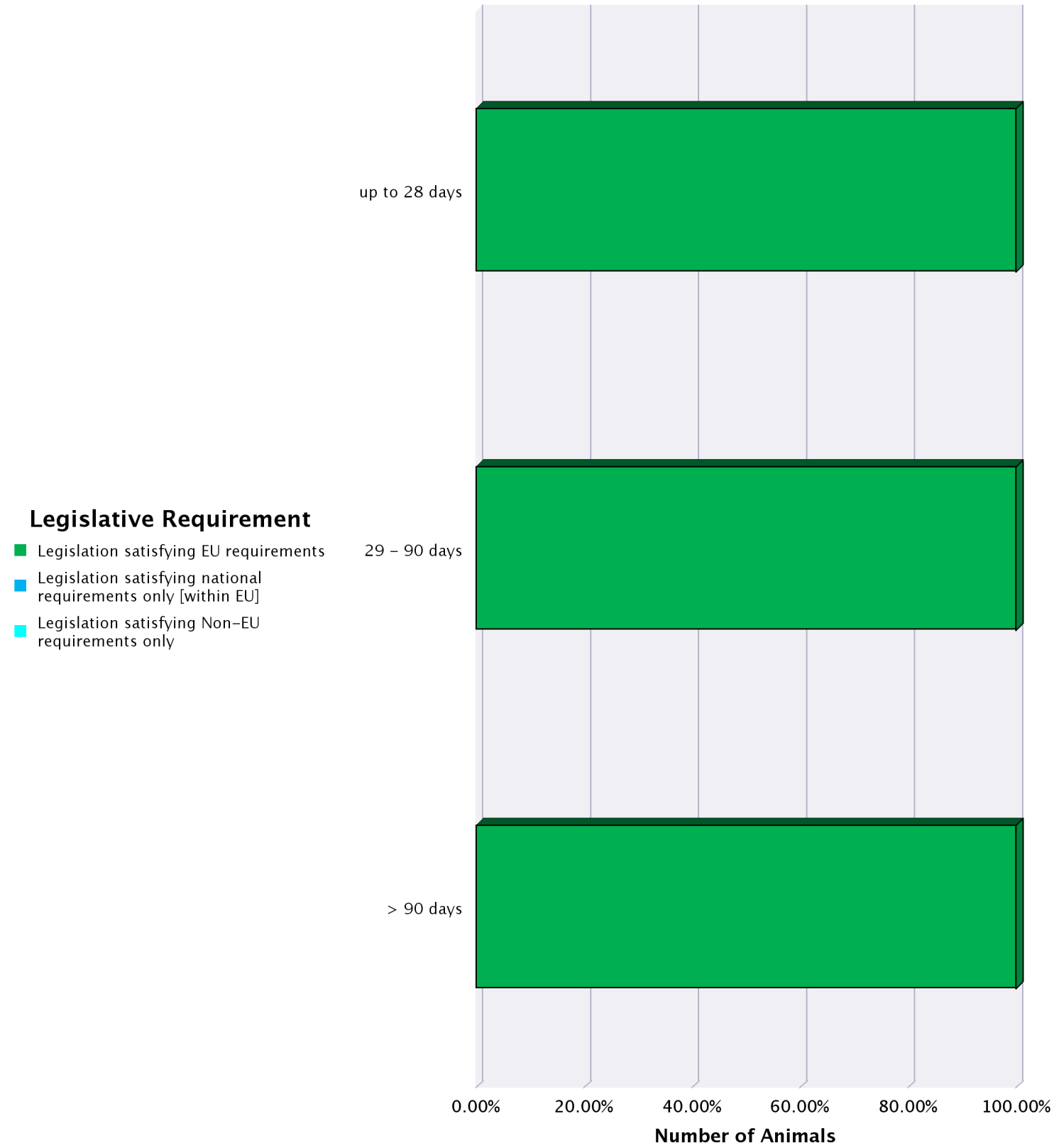
DP.F.2. Purposes and origin of legislative requirement

Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	657	651	304	1,612
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	657	651	304	1,612

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements			120	120
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total			120	120



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	182	1,110				1,292
Legislation satisfying national requirements only [within EU]						
Legislation satisfying Non-EU requirements only						
Total	182	1,110				1,292

