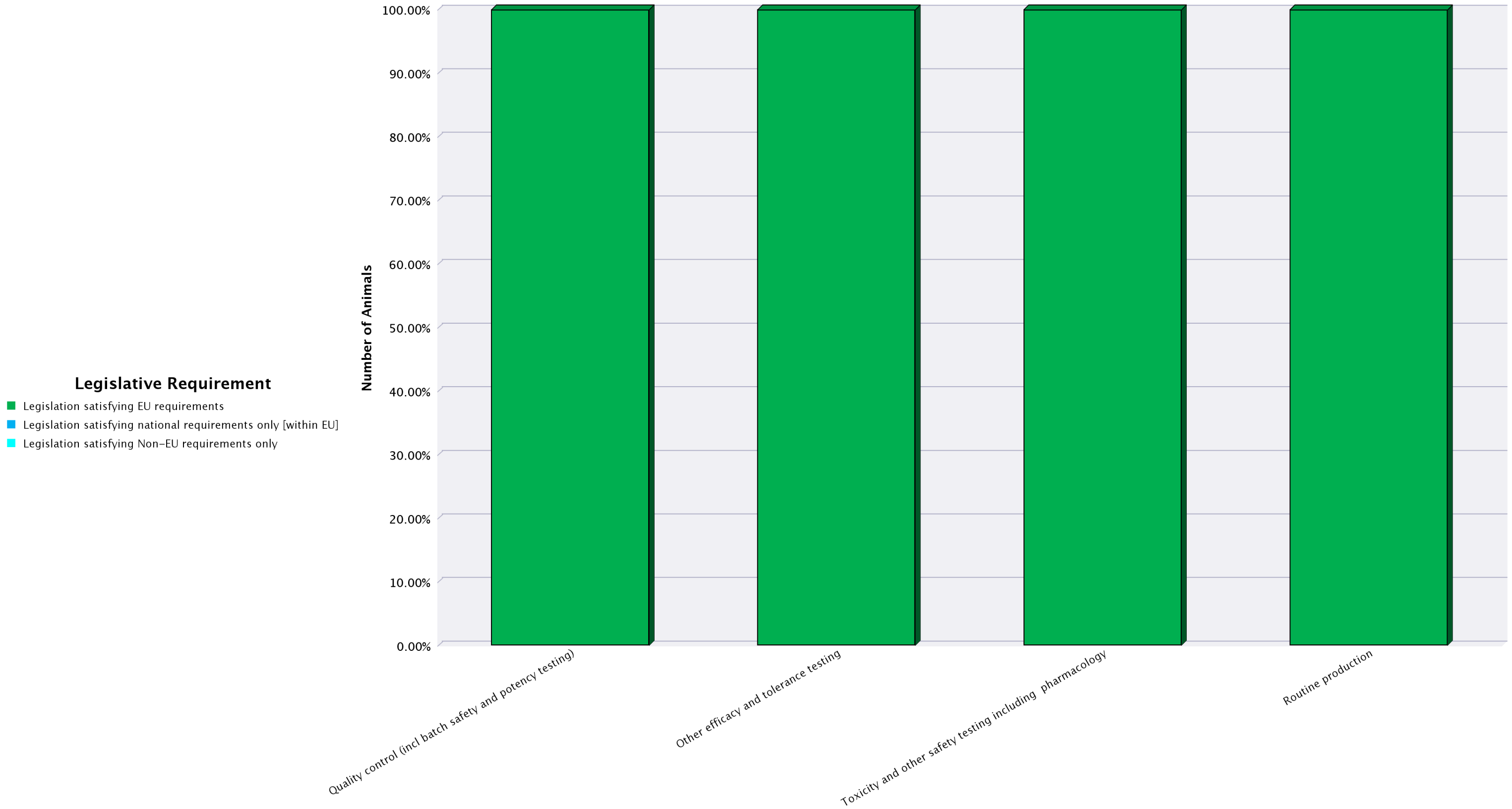


DP.F.2. Purposes and origin of legislative requirement

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	18,545	619	4,275	786	24,225
Legislation satisfying national requirements only [within EU]					
Legislation satisfying Non-EU requirements only					
Total	18,545	619	4,275	786	24,225



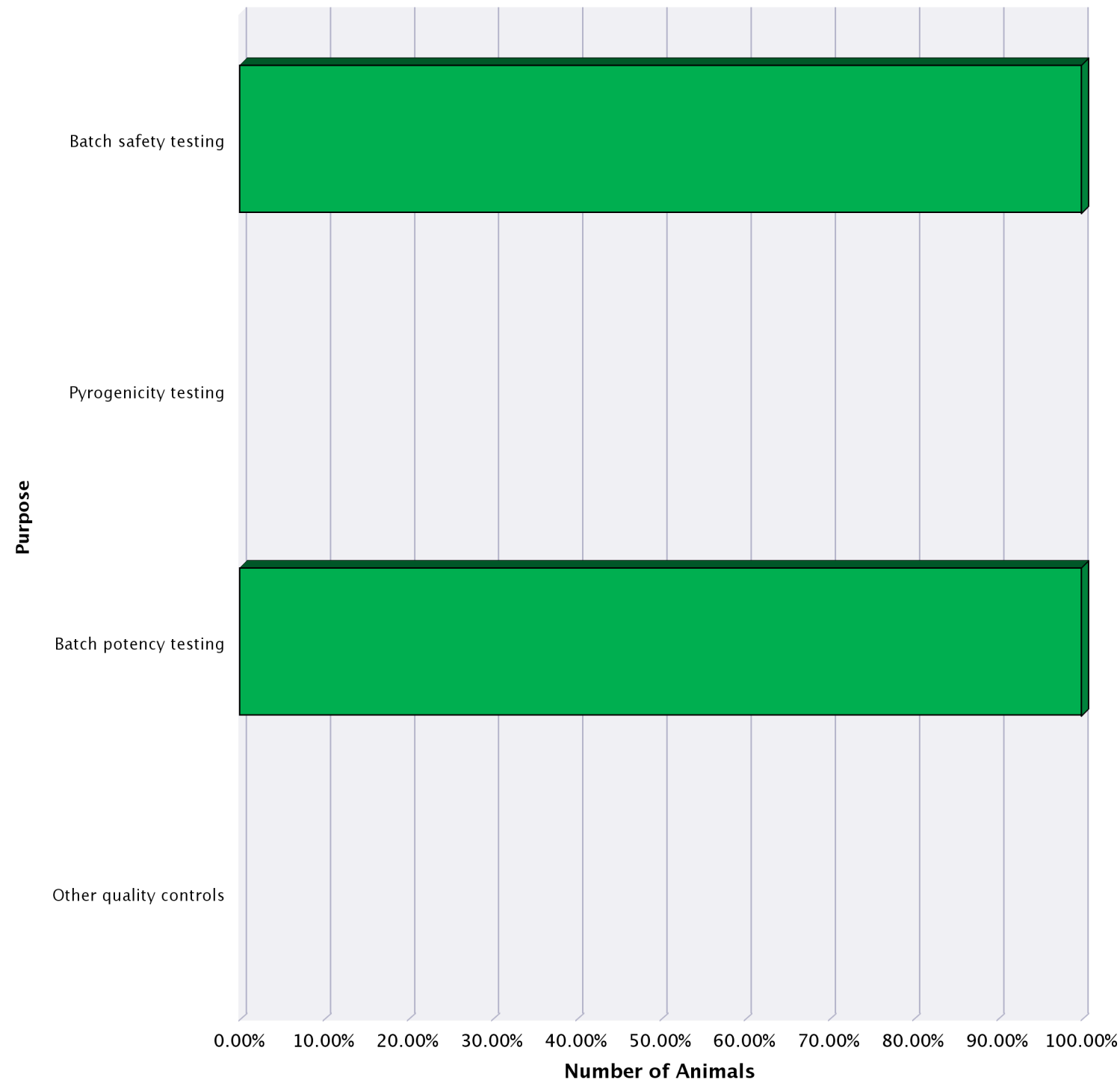
DP.F.2. Purposes and origin of legislative requirement

Quality control purposes

	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Legislation satisfying EU requirements	3,484		15,061		18,545
Legislation satisfying national requirements only [within EU]					
Legislation satisfying Non-EU requirements only					
Total	3,484		15,061		18,545

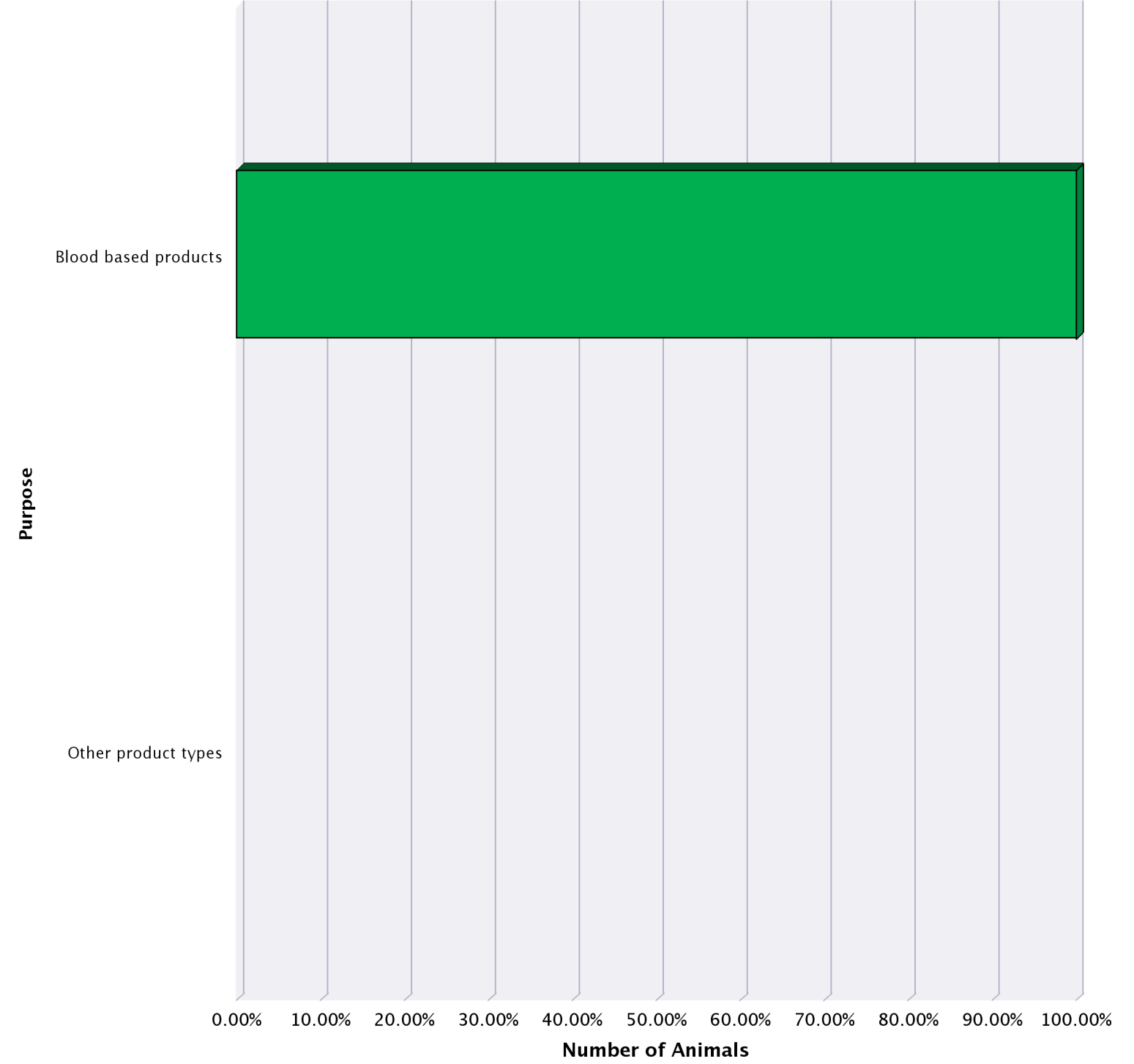
Routine production purposes

	Blood based products	Other product types	Total
Legislation satisfying EU requirements	786		786
Legislation satisfying national requirements only [within EU]			
Legislation satisfying Non-EU requirements only			
Total	786		786



Legislative Requirement

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



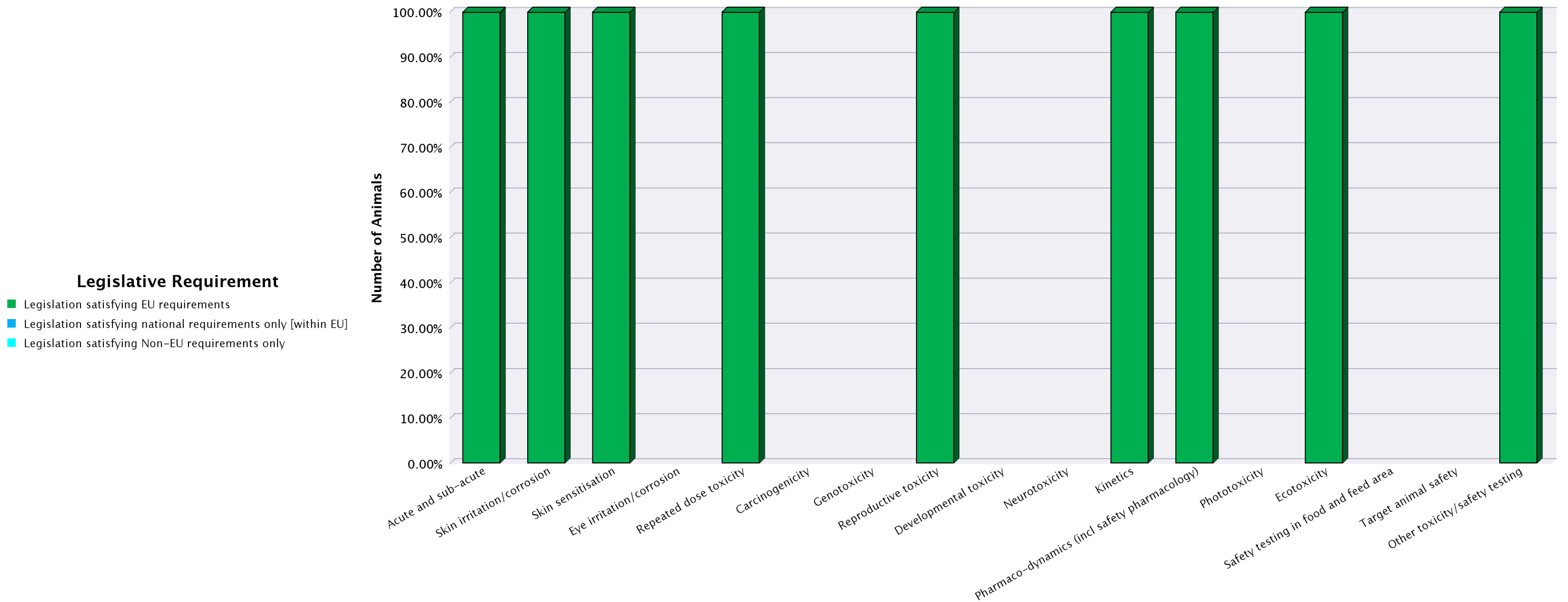
Legislative Requirement

■ 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	160			160
Skin irritation/corrosion	16			16
Skin sensitisation	118			118
Eye irritation/corrosion				
Repeated dose toxicity	2,292			2,292
Carcinogenicity				
Genotoxicity				
Reproductive toxicity	480			480
Developmental toxicity				
Neurotoxicity				
Kinetics	361			361
Pharmaco-dynamics (incl safety pharmacology)	687			687
Phototoxicity				
Ecotoxicity	154			154
Safety testing in food and feed area				
Target animal safety				
Other toxicity/safety testing	7			7
Total	4,275			4,275



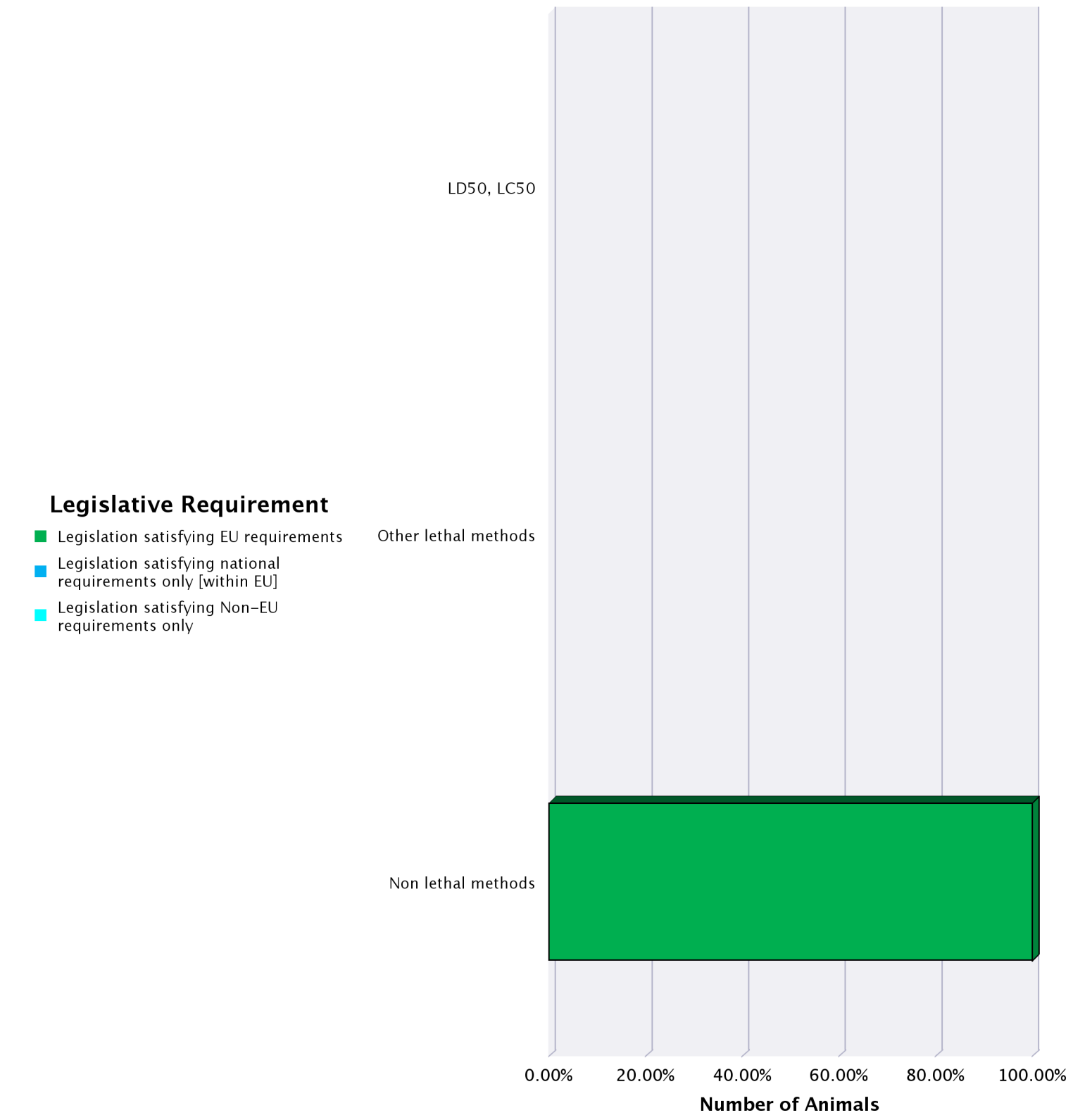
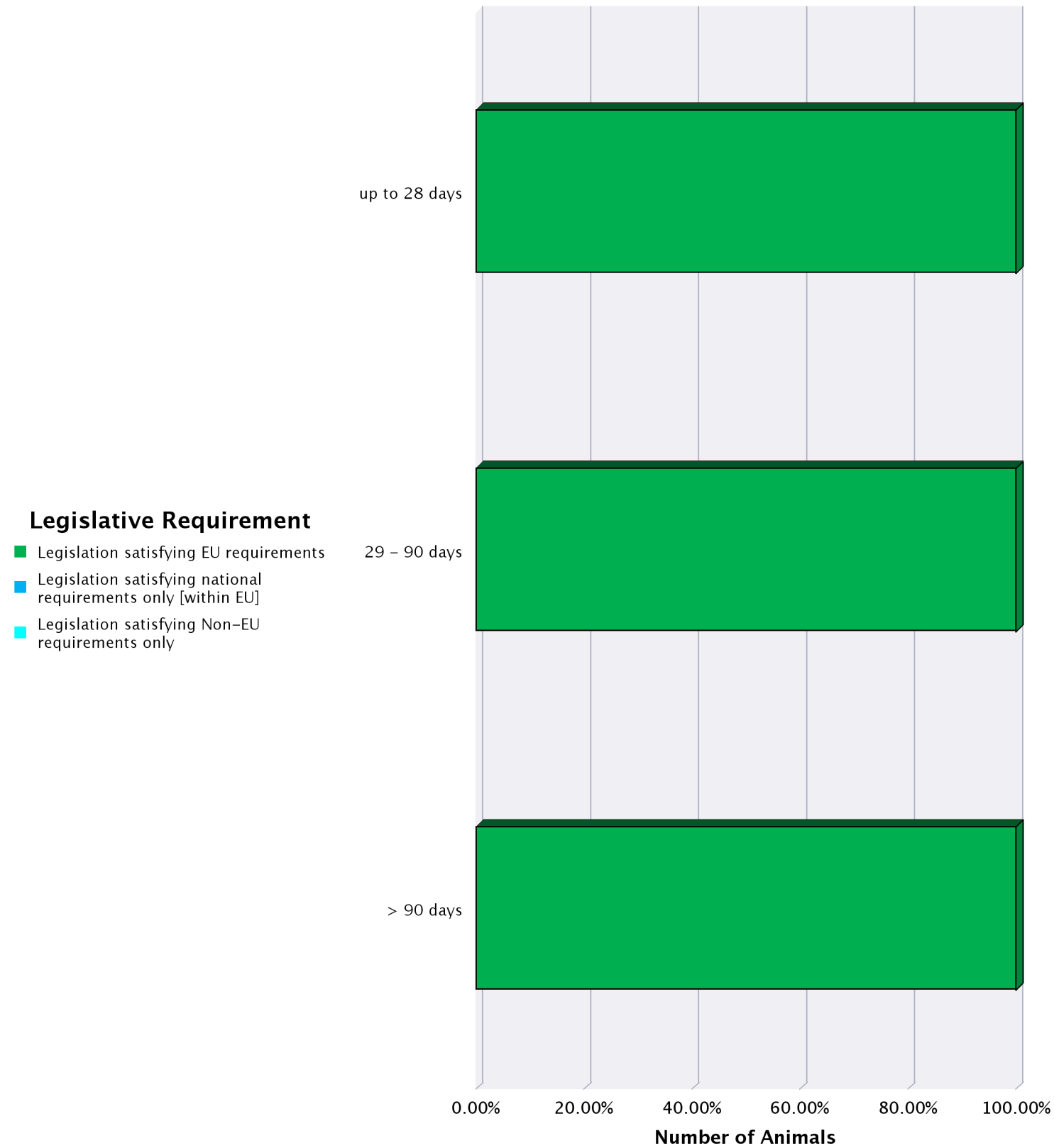
DP.F.2. Purposes and origin of legislative requirement

Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	1,174	895	223	2,292
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	1,174	895	223	2,292

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements			160	160
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total			160	160



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	154					154
Legislation satisfying national requirements only [within EU]						
Legislation satisfying Non-EU requirements only						
Total	154					154

