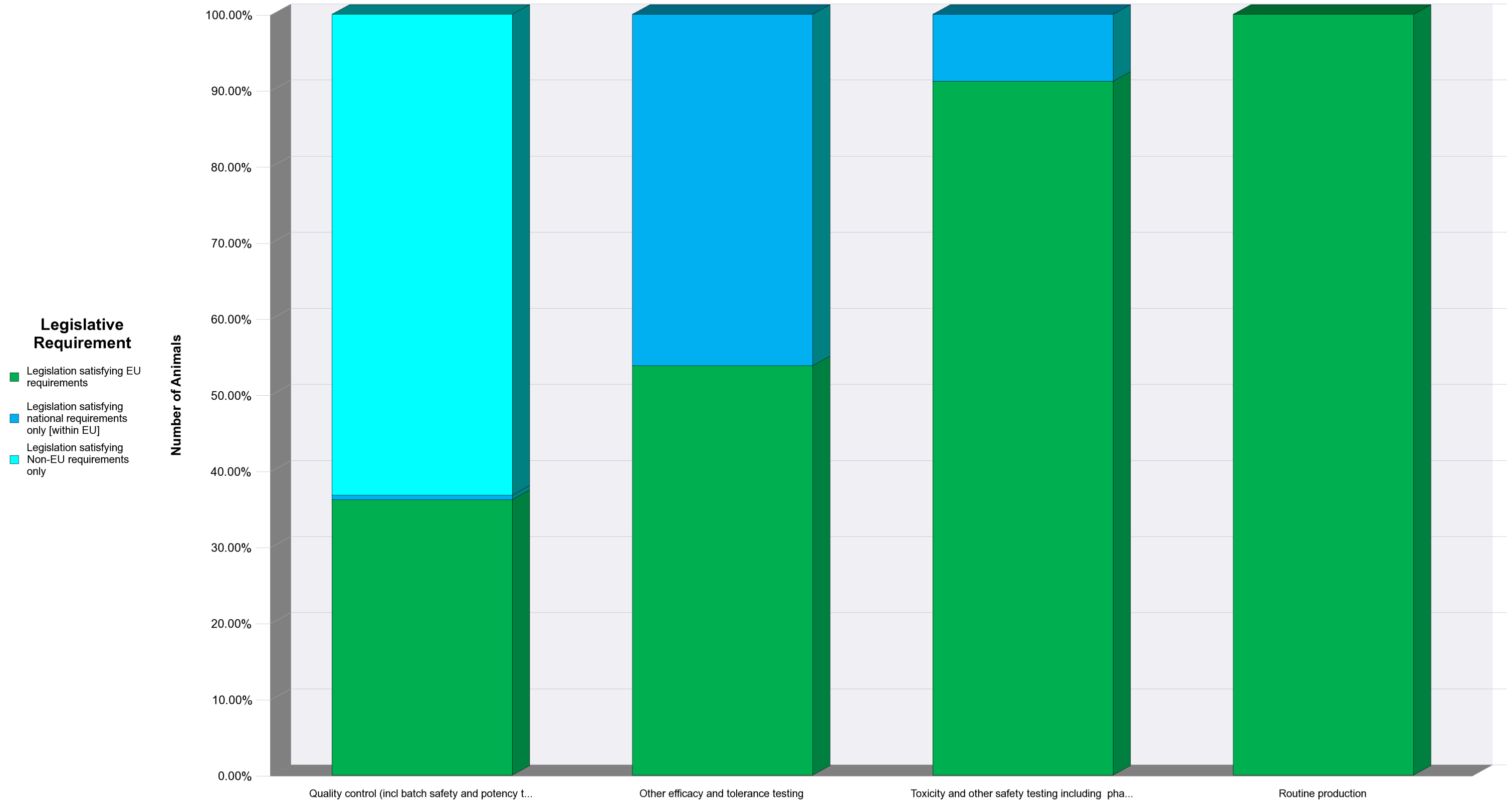


DP.F.2. Purposes and origin of legislative requirement

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	1,660	49	4,056	20	5,785
Legislation satisfying national requirements only [within EU]	27	42	390		459
Legislation satisfying Non-EU requirements only	2,897				2,897
Total	4,584	91	4,446	20	9,141



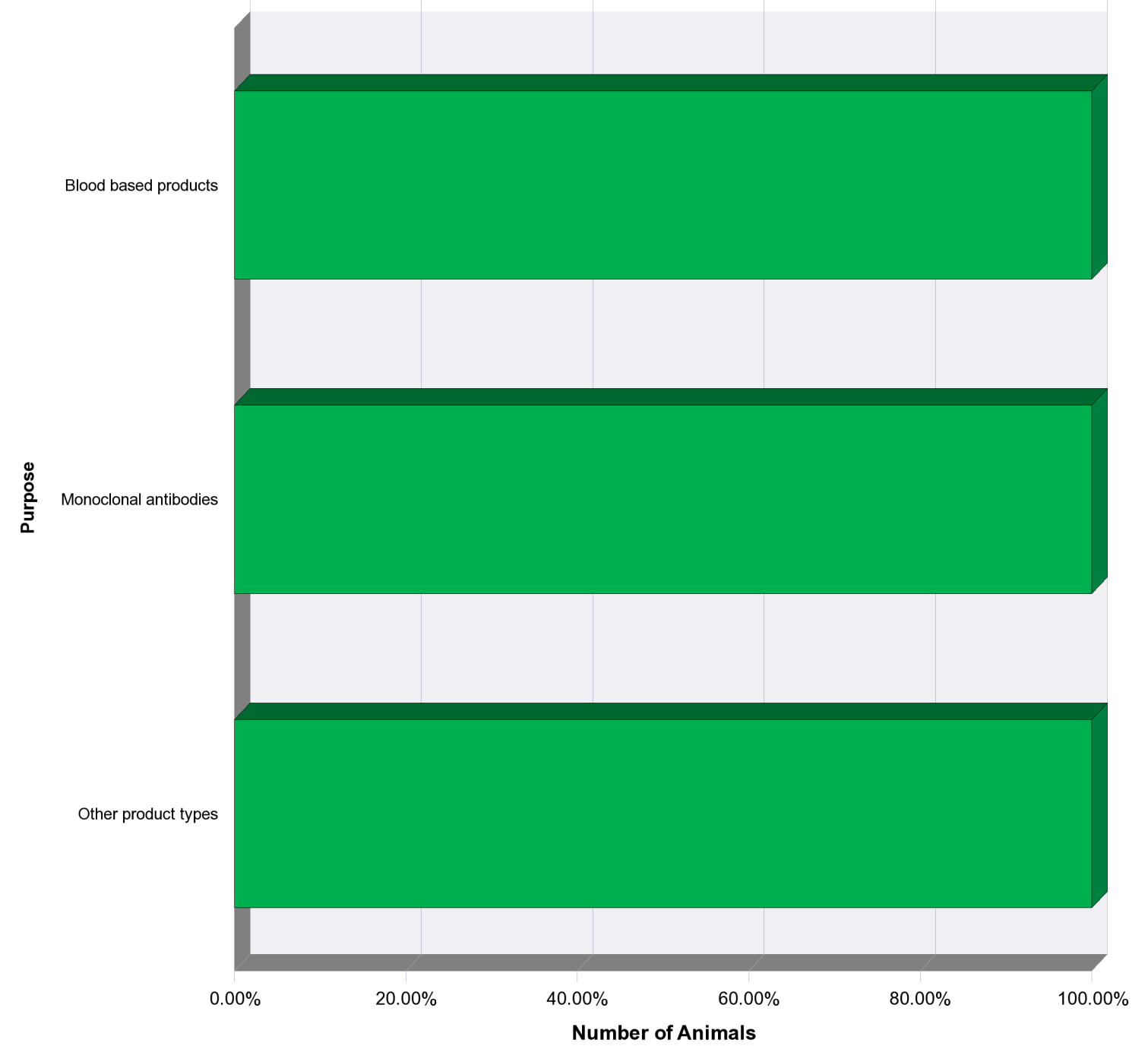
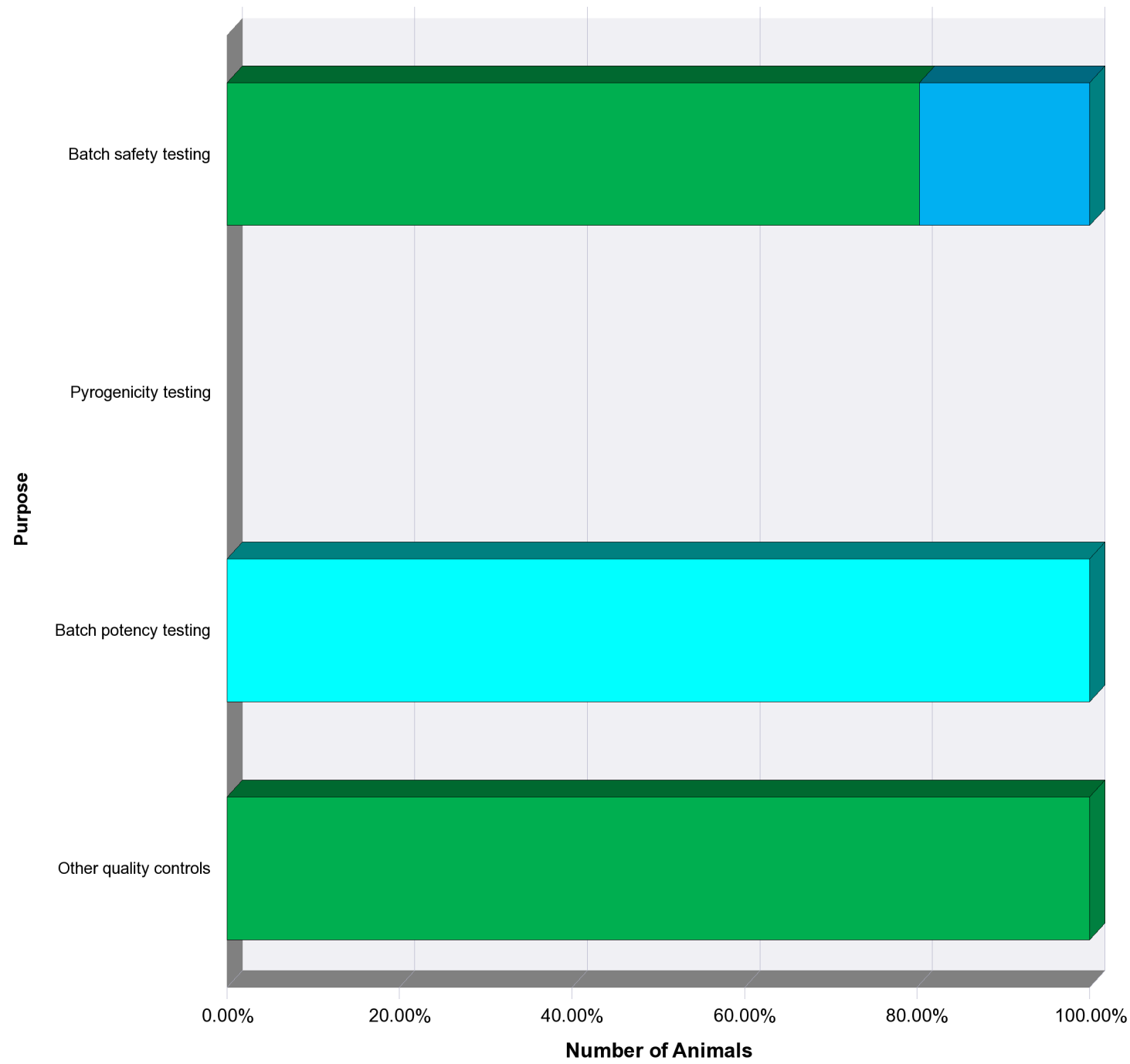
DP.F.2. Purposes and origin of legislative requirement

Quality control purposes

	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Legislation satisfying EU requirements	110			1,550	1,660
Legislation satisfying national requirements only [within EU]	27				27
Legislation satisfying Non-EU requirements only			2,897		2,897
Total	137		2,897	1,550	4,584

Routine production purposes

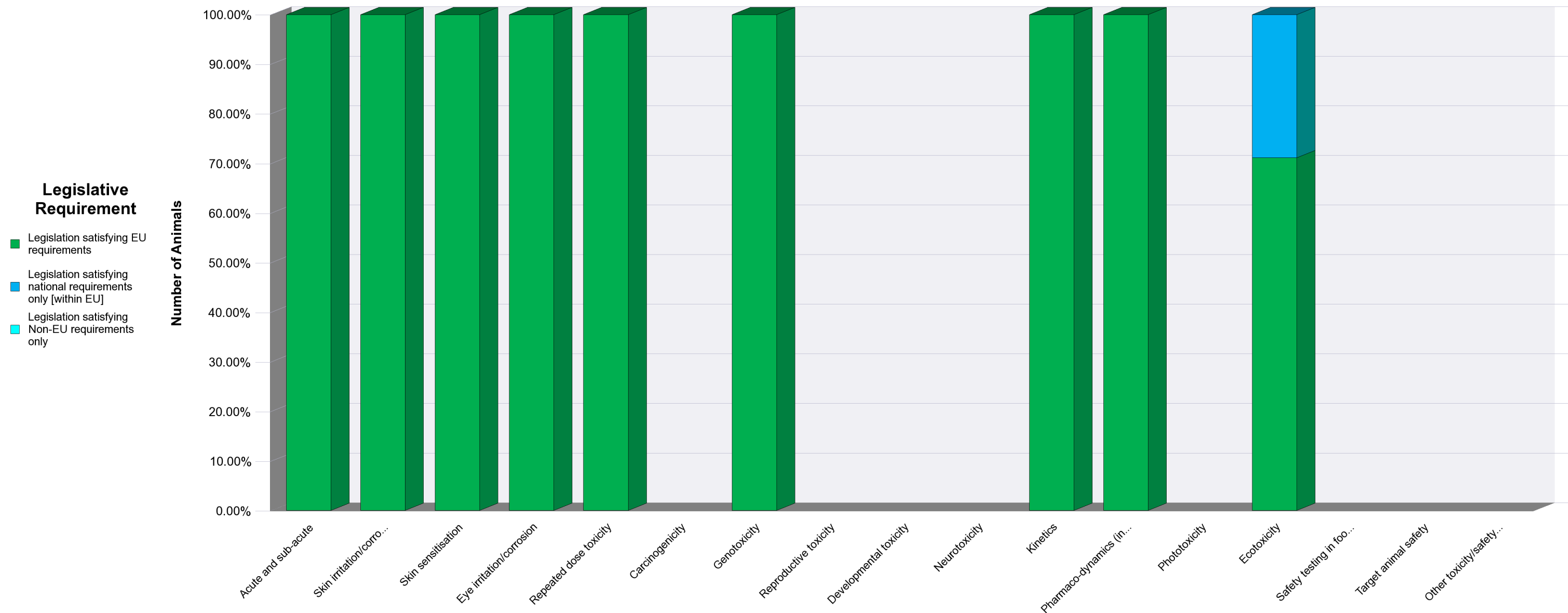
	Blood based products	Monoclonal antibodies	Other product types	Total
Legislation satisfying EU requirements	3	14	3	20
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	3	14	3	20



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	939			939
Skin irritation/corrosion	24			24
Skin sensitisation	192			192
Eye irritation/corrosion	3			3
Repeated dose toxicity	1,505			1,505
Carcinogenicity				
Genotoxicity	48			48
Reproductive toxicity				
Developmental toxicity				
Neurotoxicity				
Kinetics	337			337
Pharmaco-dynamics (incl safety pharmacology)	48			48
Phototoxicity				
Ecotoxicity	960		390	1,350
Safety testing in food and feed area				
Target animal safety				
Other toxicity/safety testing				
Total	4,056		390	4,446



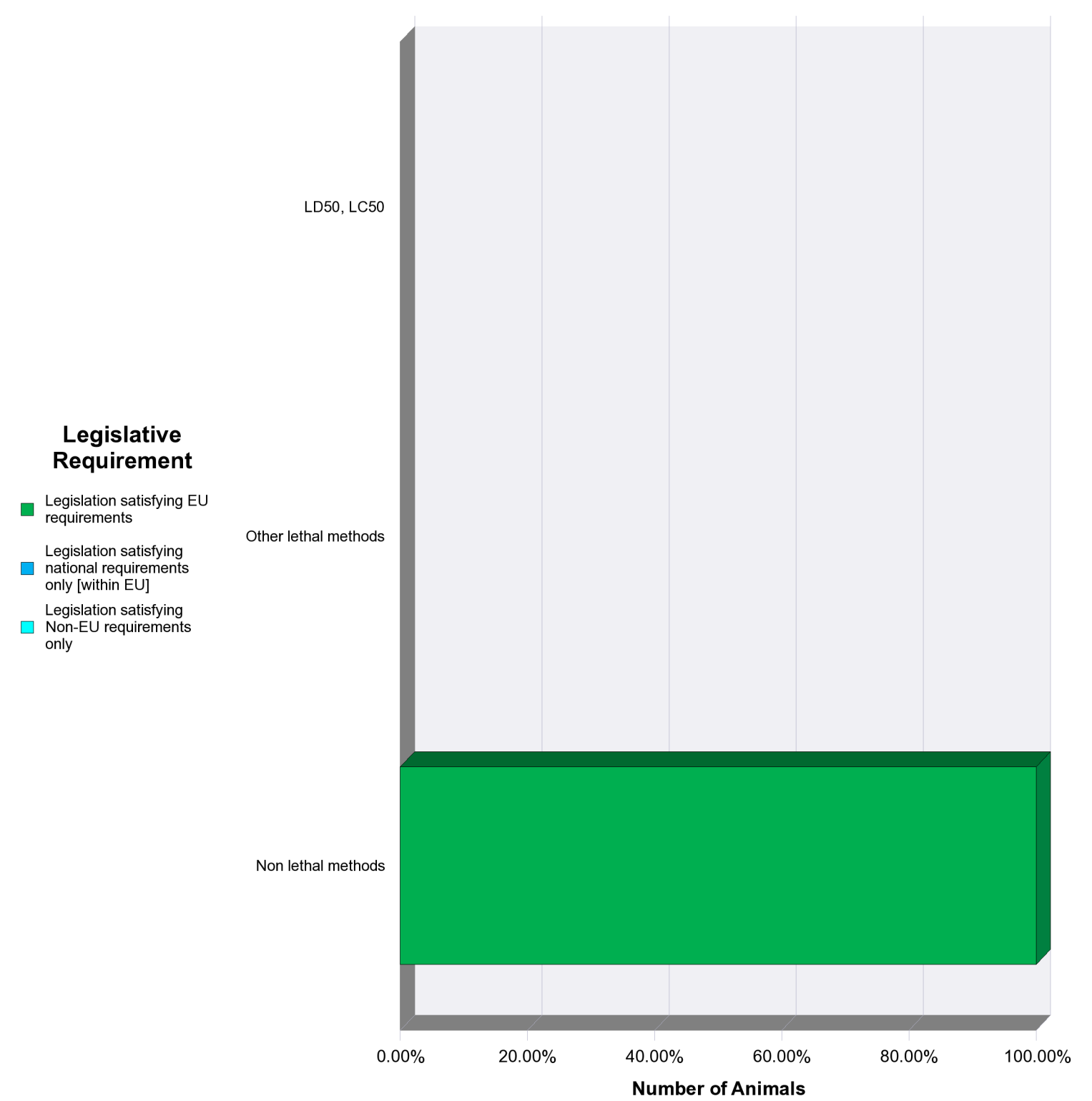
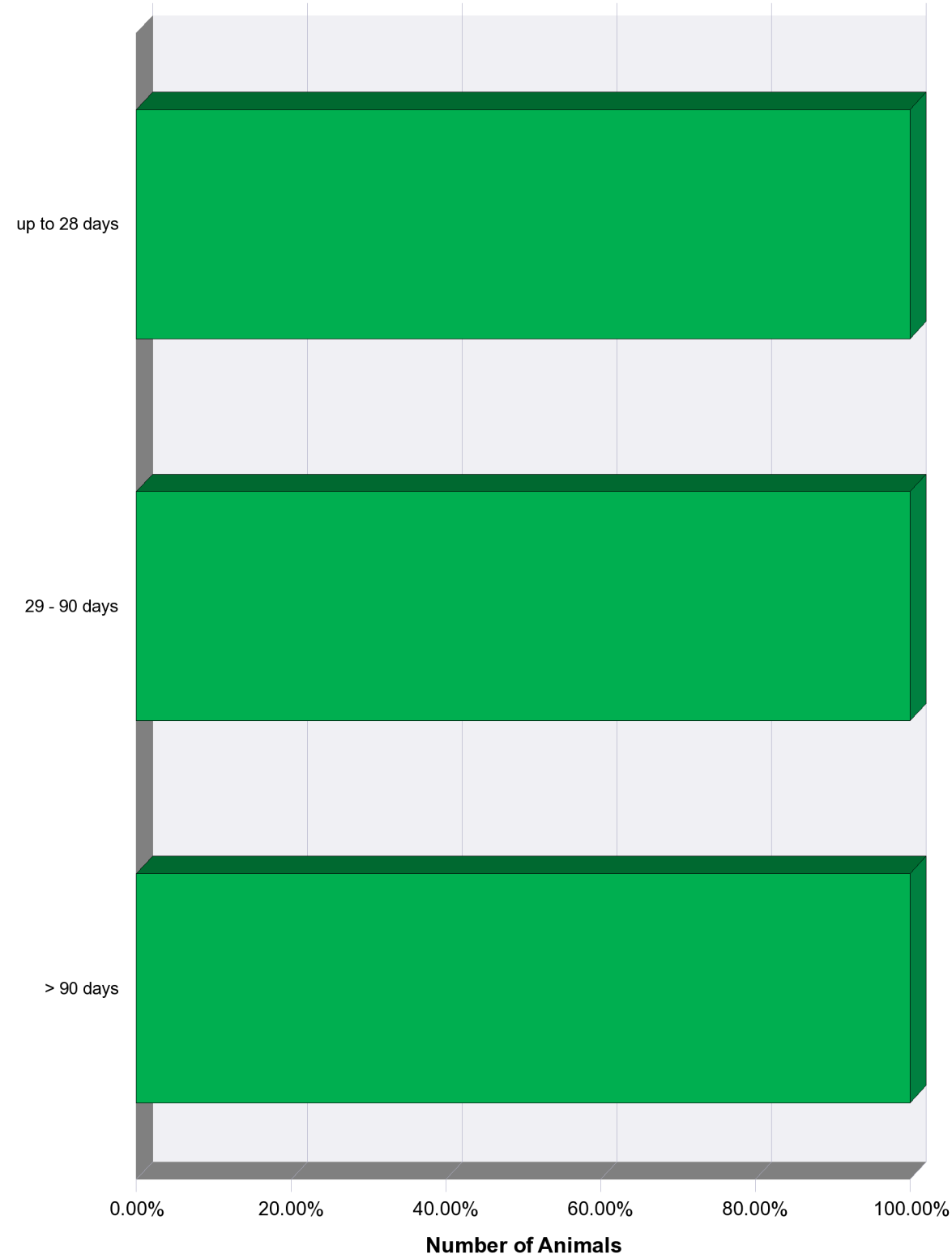
DP.F.2. Purposes and origin of legislative requirement

Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	885	362	258	1,505
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total	885	362	258	1,505

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements			939	939
Legislation satisfying national requirements only [within EU]				
Legislation satisfying Non-EU requirements only				
Total			939	939



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		960				960
Legislation satisfying national requirements only [within EU]		390				390
Legislation satisfying Non-EU requirements only						
Total		1,350				1,350

