

DP.F.1. Purposes and testing by type of legislation

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 type of legislation (product area).

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).

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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 of uses:	%
Legislation on medicinal products for human use	14,794	95	4,741		19,630	85.51%
Legislation on medicinal products for veterinary use and their residues	22		120		142	0.62%
Medical devices legislation	3			21	24	0.10%
Industrial chemicals legislation			1,360		1,360	5.92%
Plant protection product legislation						
Biocides legislation						
Food legislation including food contact material						
Feed legislation including legislation for the safety of target animals, workers and environment						
Cosmetics legislation						
Other legislation			1,800		1,800	7.84%
Total of uses:	14,819	95	8,021	21	22,956	

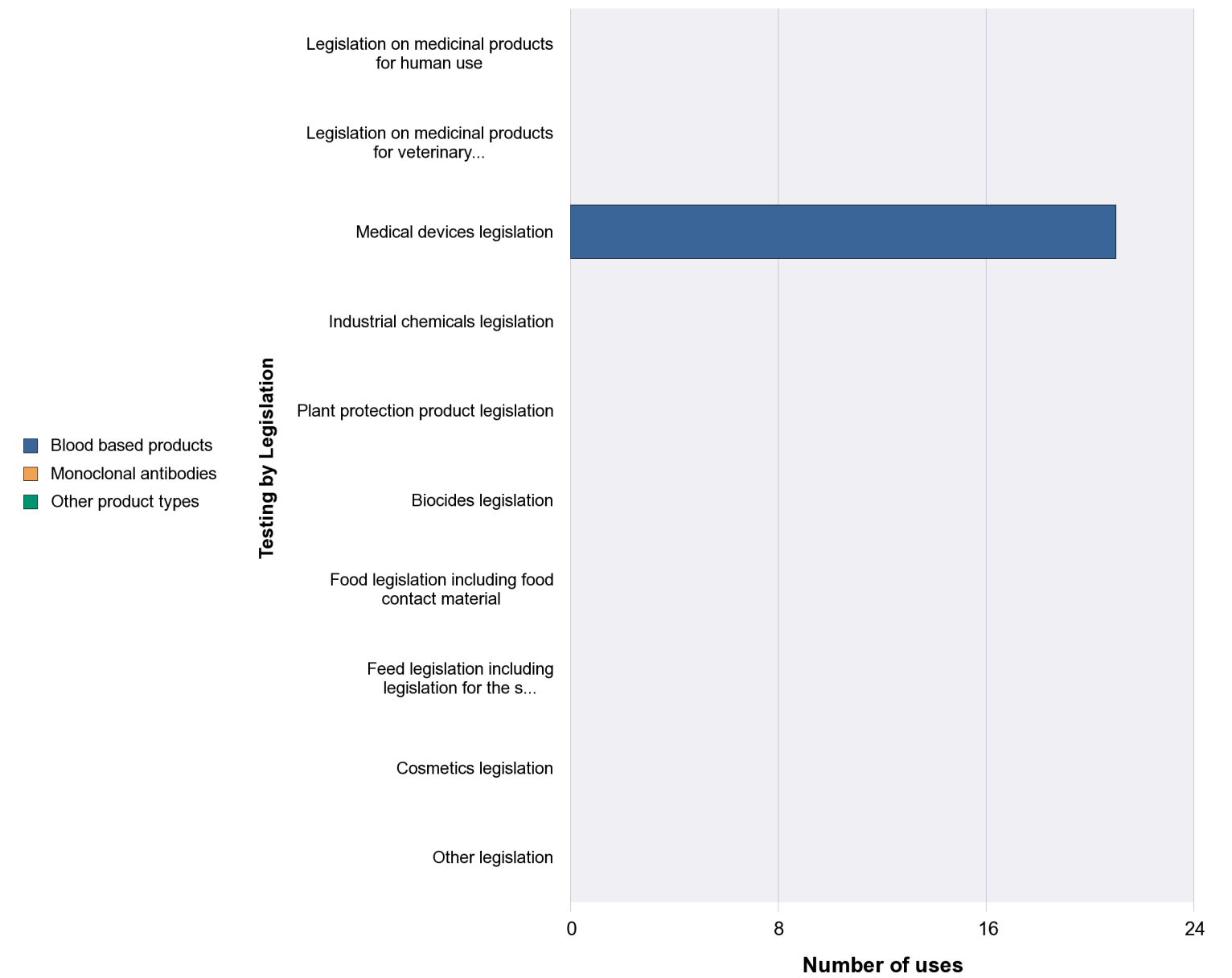
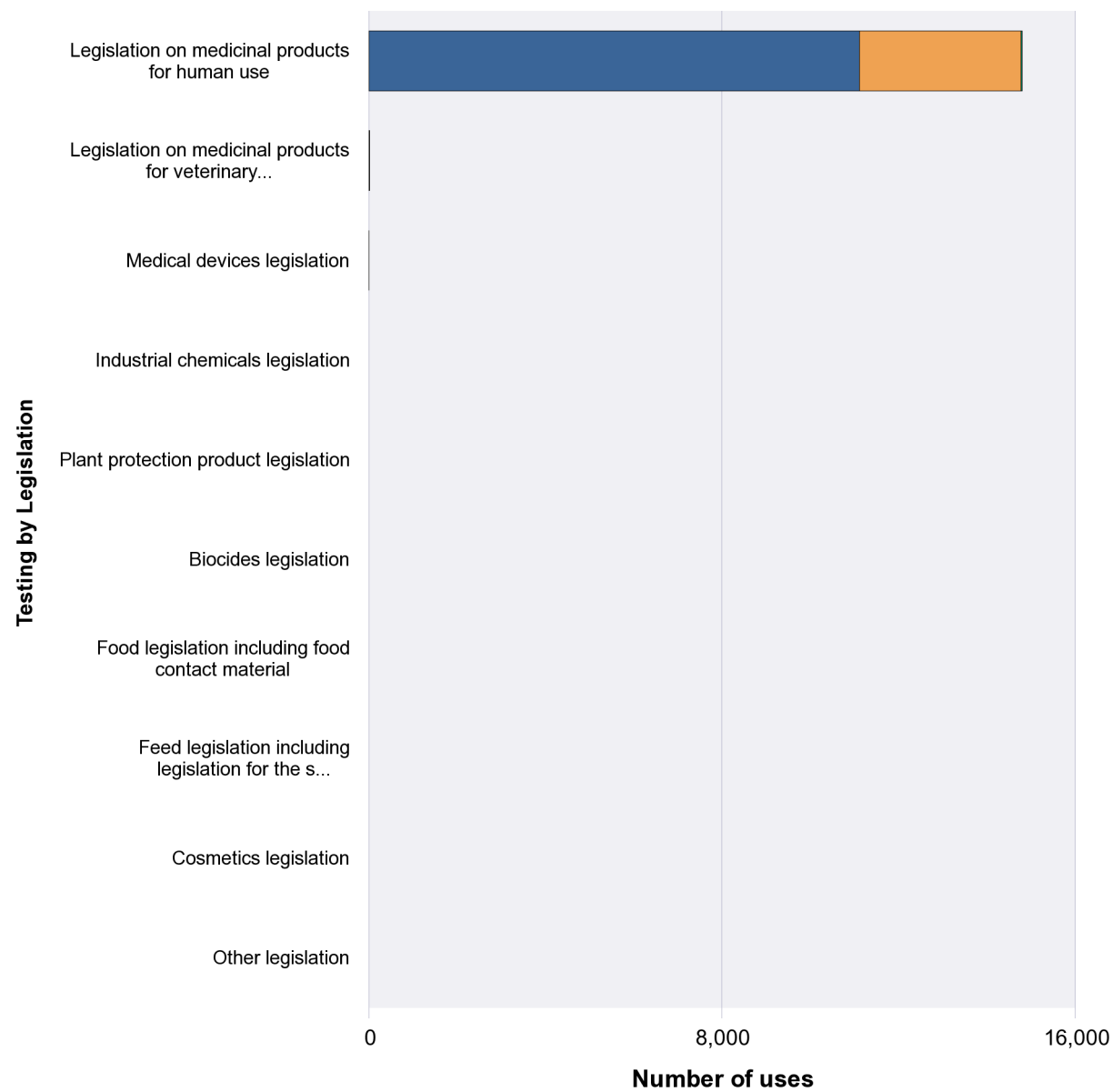
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Quality control purposes

	Batch potency testing	Batch safety testing	Other quality controls	Pyrogenicity testing	Total of uses:
Legislation on medicinal products for human use	11,105	3,665	24		14,794
Legislation on medicinal products for veterinary use and their residues		22			22
Medical devices legislation			3		3
Industrial chemicals legislation					
Plant protection product legislation					
Biocides legislation					
Food legislation including food contact material					
Feed legislation including legislation for the safety of target animals, workers and environment					
Cosmetics legislation					
Other legislation					
Total of uses:	11,105	3,687	27		14,819

Routine production purposes

	Blood based products	Monoclonal antibodies	Other product types	Total of uses:
Legislation on medicinal products for human use				
Legislation on medicinal products for veterinary use and their residues				
Medical devices legislation	21			21
Industrial chemicals legislation				
Plant protection product legislation				
Biocides legislation				
Food legislation including food contact material				
Feed legislation including legislation for the safety of target animals, workers and environment				
Cosmetics legislation				
Other legislation				
Total of uses:	21			21

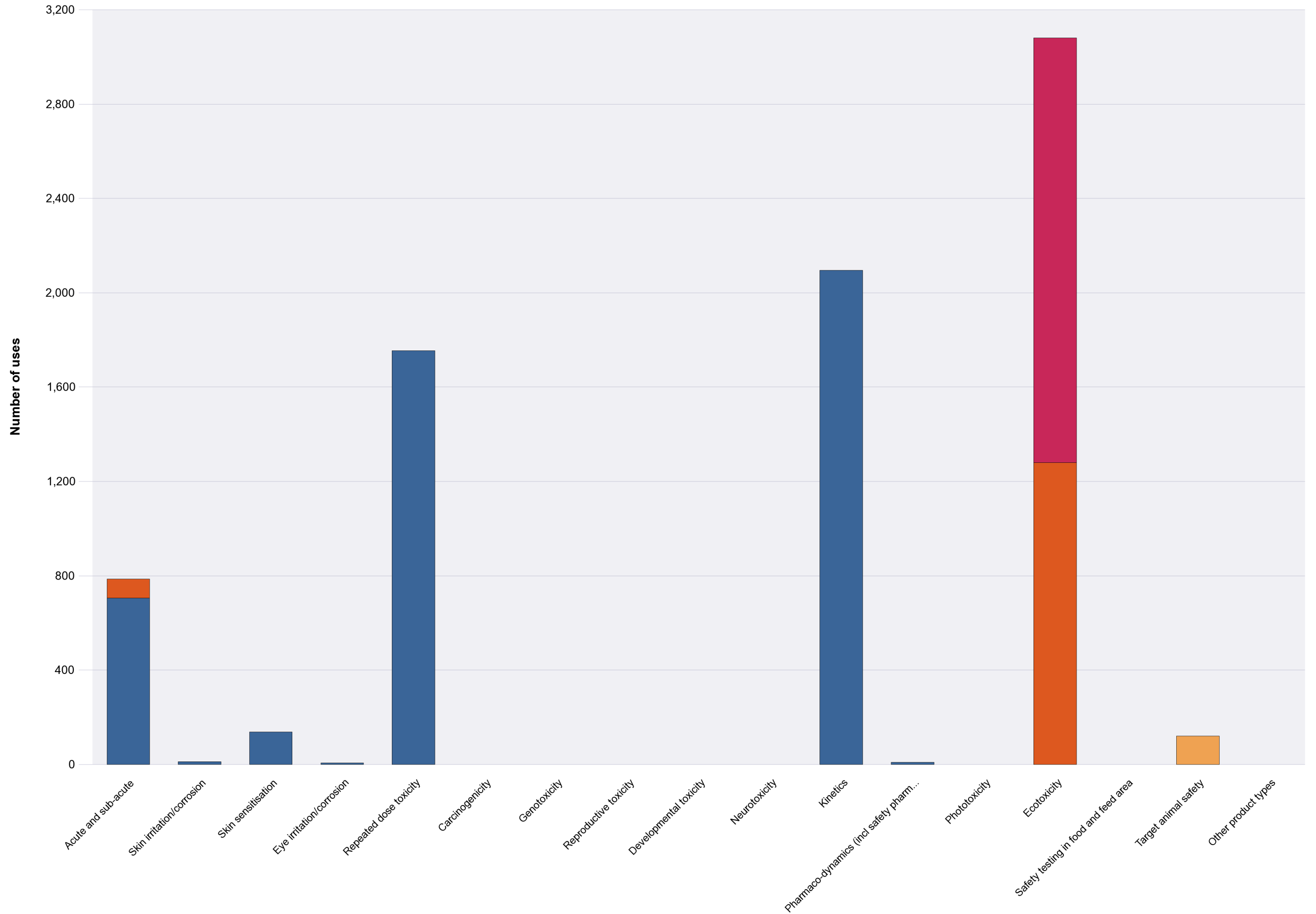


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Toxicity and other safety testing by test type purposes

	Legislation on medicinal products for human use	Legislation on medicinal products for veterinary use and their residues	Medical devices legislation	Industrial chemicals legislation	Plant protection product legislation	Biocides legislation	Food legislation including food contact material	Feed legislation including legislation for the safety of target animals, workers and environment	Cosmetics legislation	Other legislation	Total of uses:
Acute and sub-acute	706			80							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
Pharmacodynamics (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 of uses:	4,741	120		1,360						1,800	8,021

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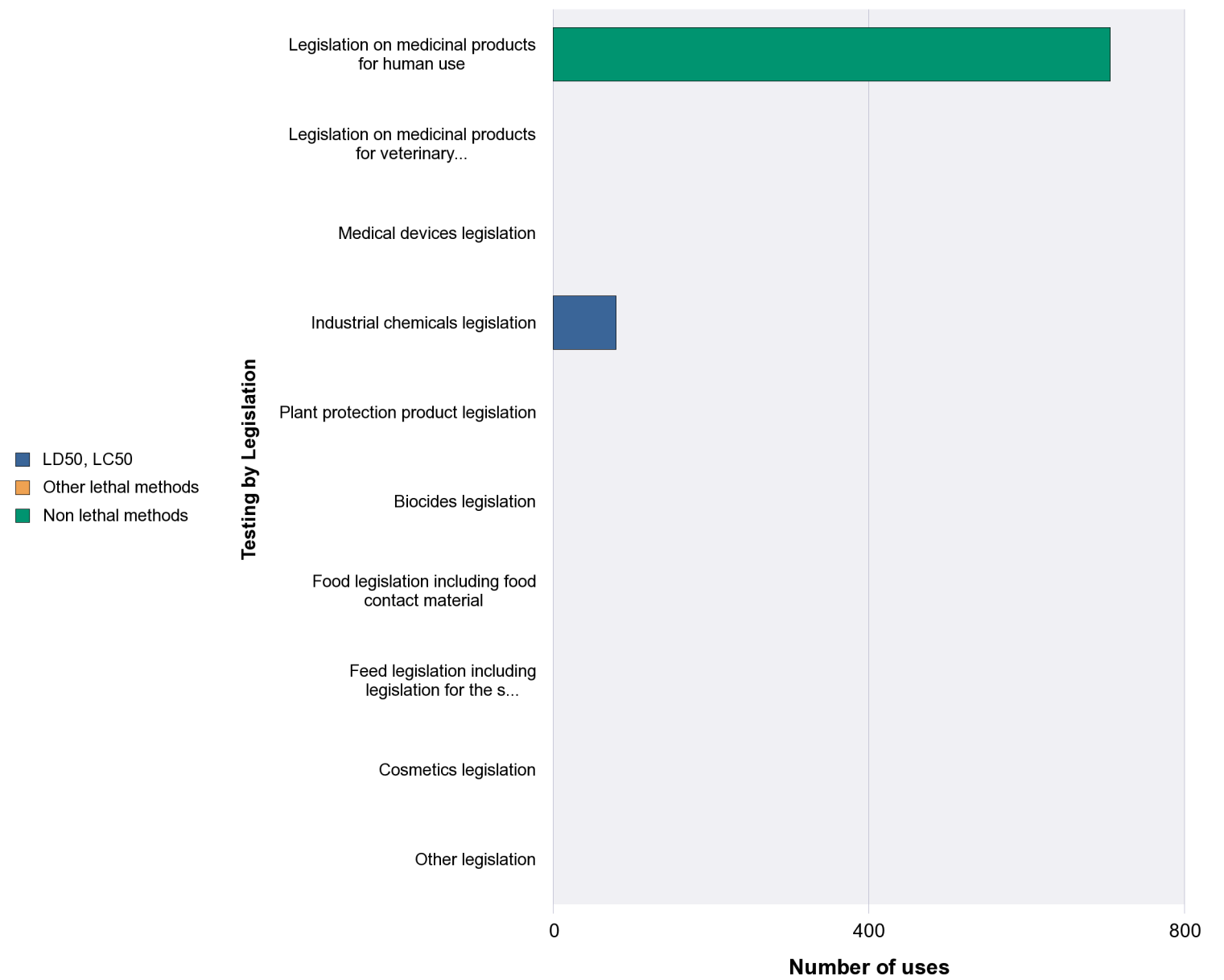
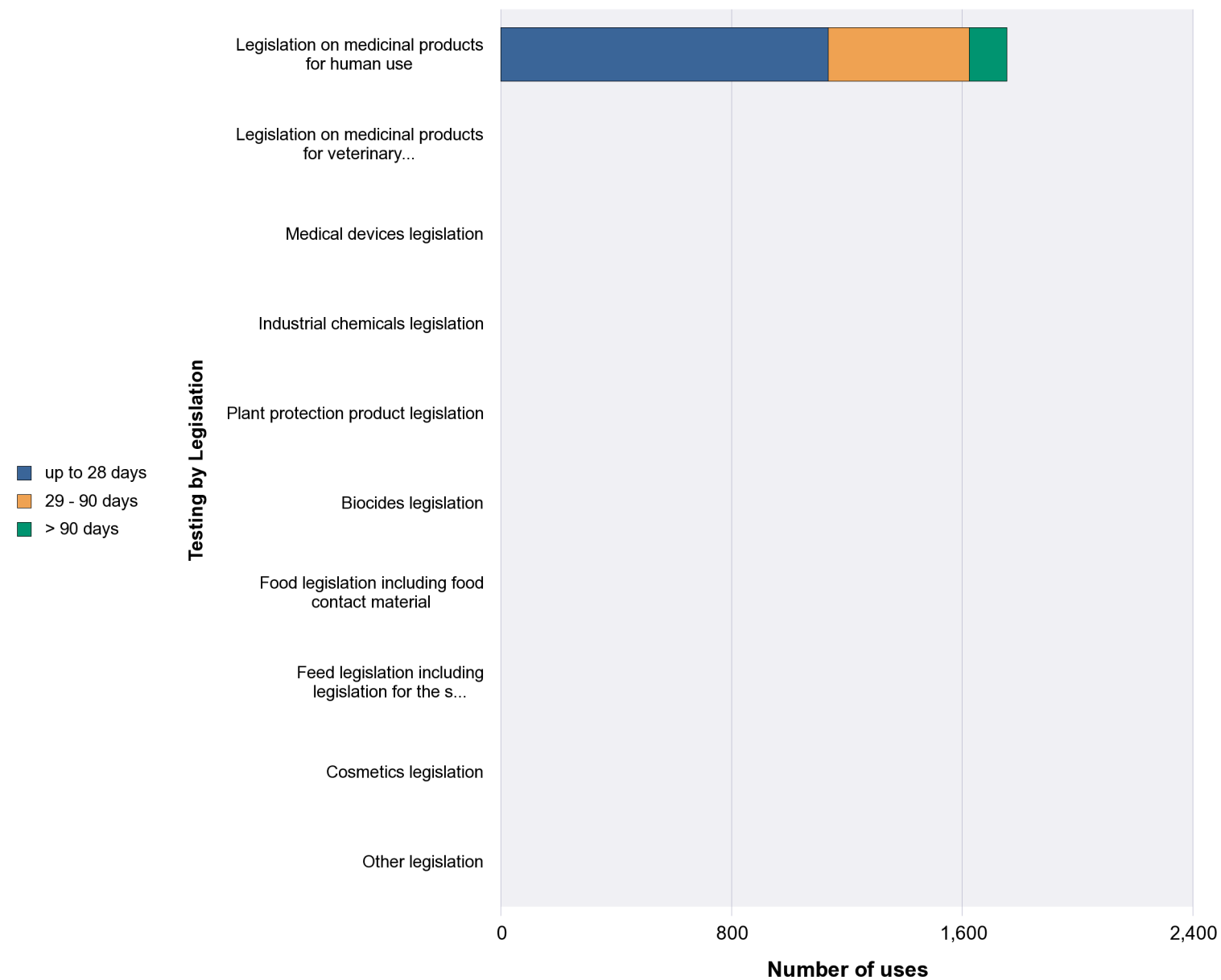
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Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total of uses:
Legislation on medicinal products for human use	1,136	488	131	1,755
Legislation on medicinal products for veterinary use and their residues				
Medical devices legislation				
Industrial chemicals legislation				
Plant protection product legislation				
Biocides legislation				
Food legislation including food contact material				
Feed legislation including legislation for the safety of target animals, workers and environment				
Cosmetics legislation				
Other legislation				
Total of uses:	1,136	488	131	1,755

Acute and sub-acute toxicity testing methods

	LD50, LC50	Other lethal methods	Non lethal methods	Total of uses:
Legislation on medicinal products for human use			706	706
Legislation on medicinal products for veterinary use and their residues				
Medical devices legislation				
Industrial chemicals legislation	80			80
Plant protection product legislation				
Biocides legislation				
Food legislation including food contact material				
Feed legislation including legislation for the safety of target animals, workers and environment				
Cosmetics legislation				
Other legislation				
Total of uses:	80		706	786



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Ecotoxicity purposes

	Acute toxicity	Chronic toxicity	Reproductive ecotoxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Total of uses:
Legislation on medicinal products for human use							
Legislation on medicinal products for veterinary use and their residues							
Medical devices legislation							
Industrial chemicals legislation		1,280					1,280
Plant protection product legislation							
Biocides legislation							
Food legislation including food contact material							
Feed legislation including legislation for the safety of target animals, workers and environment							
Cosmetics legislation							
Other legislation		1,800					1,800
Total of uses:		3,080					3,080

