

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

### Data inclusion criteria

Report year: 2016

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	8,829	113	8,058		17,000	78.95%
Legislation on medicinal products for veterinary use and their residues	4				4	0.02%
Medical devices legislation						
Industrial chemicals legislation			2,458		2,458	11.42%
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			2,070		2,070	9.61%
<b>Total of uses:</b>	<b>8,833</b>	<b>113</b>	<b>12,586</b>		<b>21,532</b>	

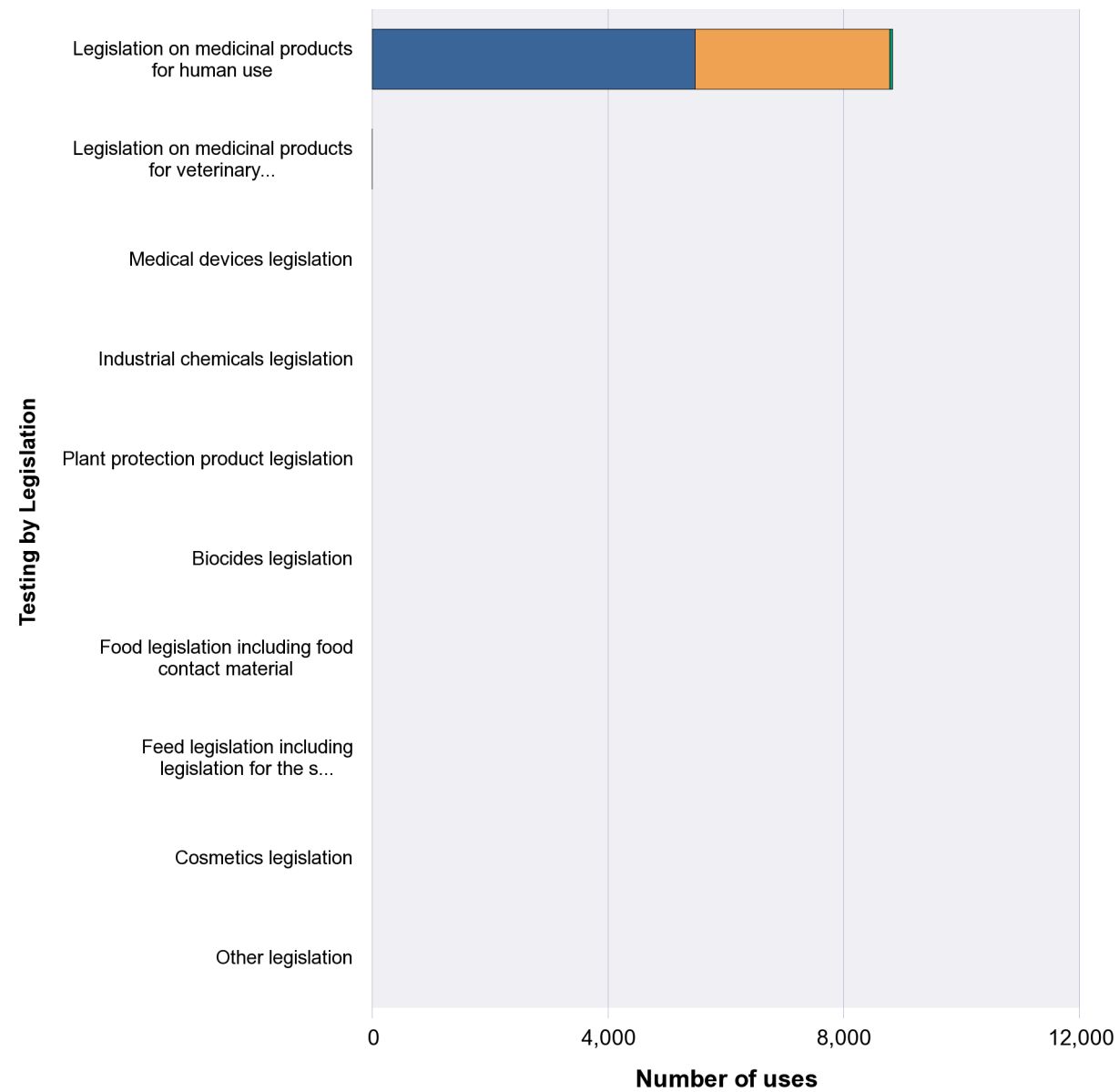
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### Quality control purposes

	Batch potency testing	Batch safety testing	Other quality controls	Pyrogenicity testing	Total of uses:
Legislation on medicinal products for human use	5,486	3,291	52		8,829
Legislation on medicinal products for veterinary use and their residues		4			4
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					
<b>Total of uses:</b>	<b>5,486</b>	<b>3,295</b>	<b>52</b>		<b>8,833</b>

### 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				
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				
<b>Total of uses:</b>				

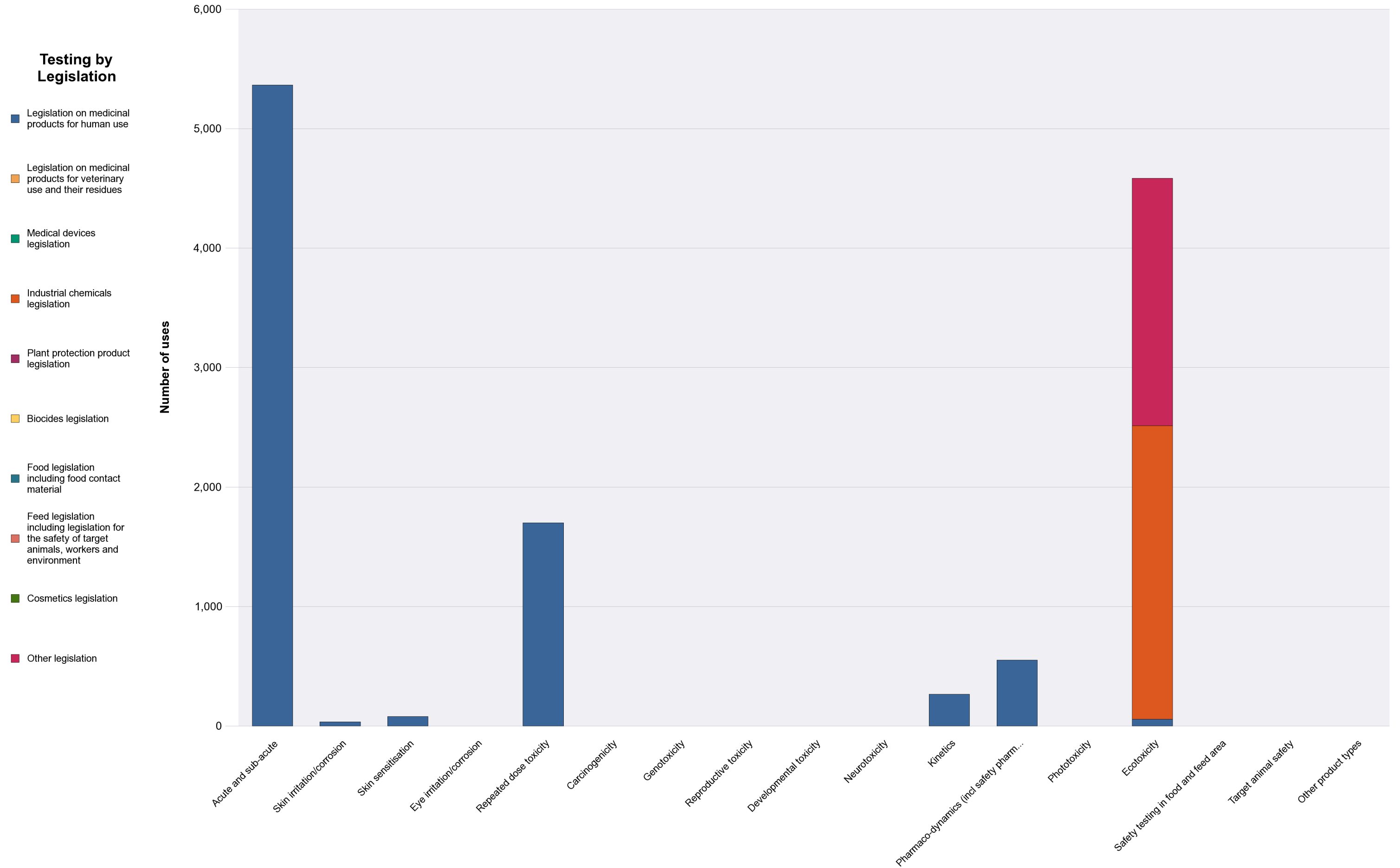


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### Toxicity and other safety testing by test type purposes

	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	5,366										5,366
Skin irritation/corrosion	35										35
Skin sensitisation	80										80
Eye irritation/corrosion											
Repeated dose toxicity	1,701										1,701
Carcinogenicity											
Genotoxicity											
Reproductive toxicity											
Developmental toxicity											
Neurotoxicity											
Kinetics	267										267
Pharmacodynamics (incl safety pharmacology)	552										552
Phototoxicity											
Ecotoxicity	57			2,458						2,070	4,585
Safety testing in food and feed area											
Target animal safety											
Other toxicity/safety testing											
<b>Total of uses:</b>	<b>8,058</b>			<b>2,458</b>						<b>2,070</b>	<b>12,586</b>

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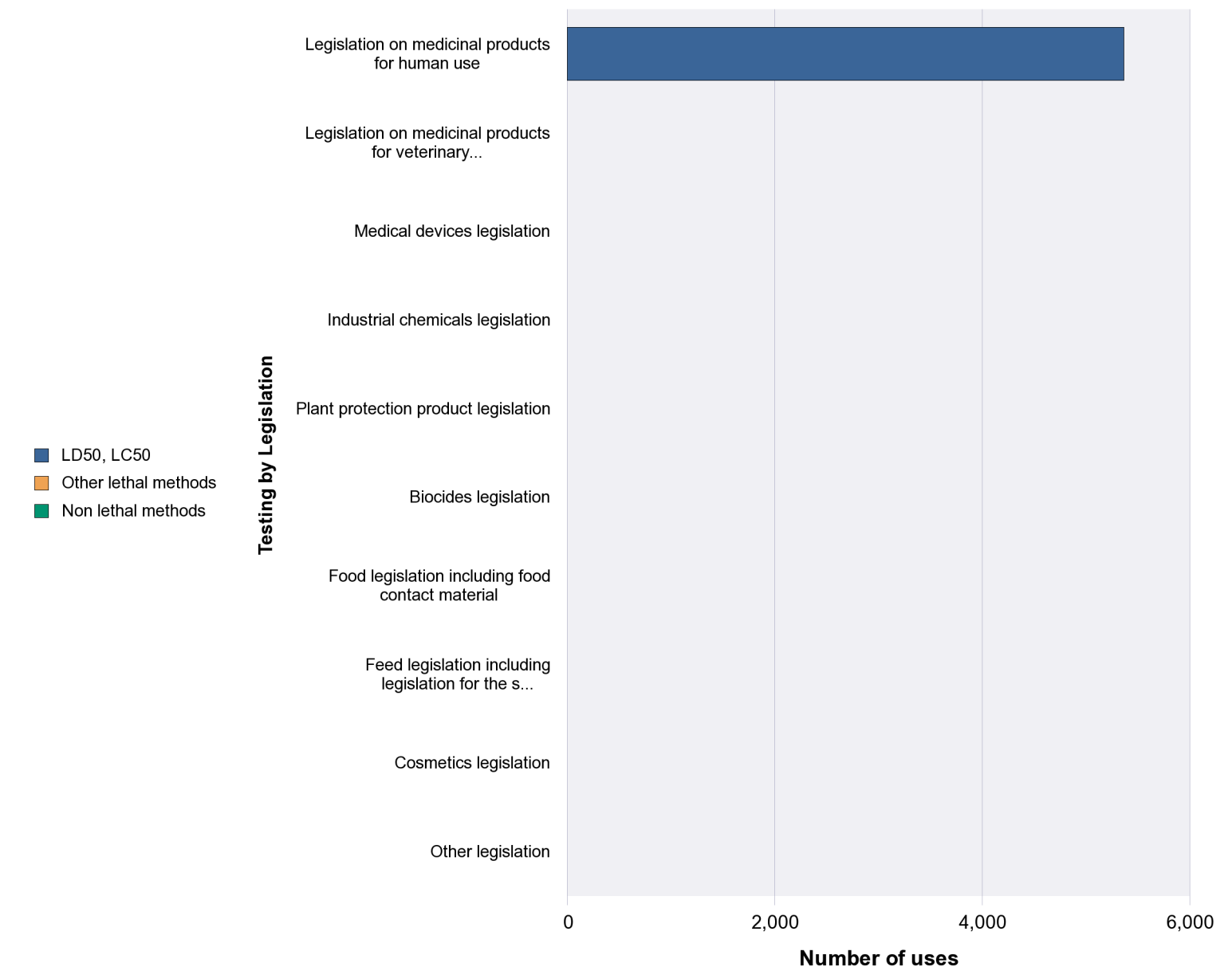
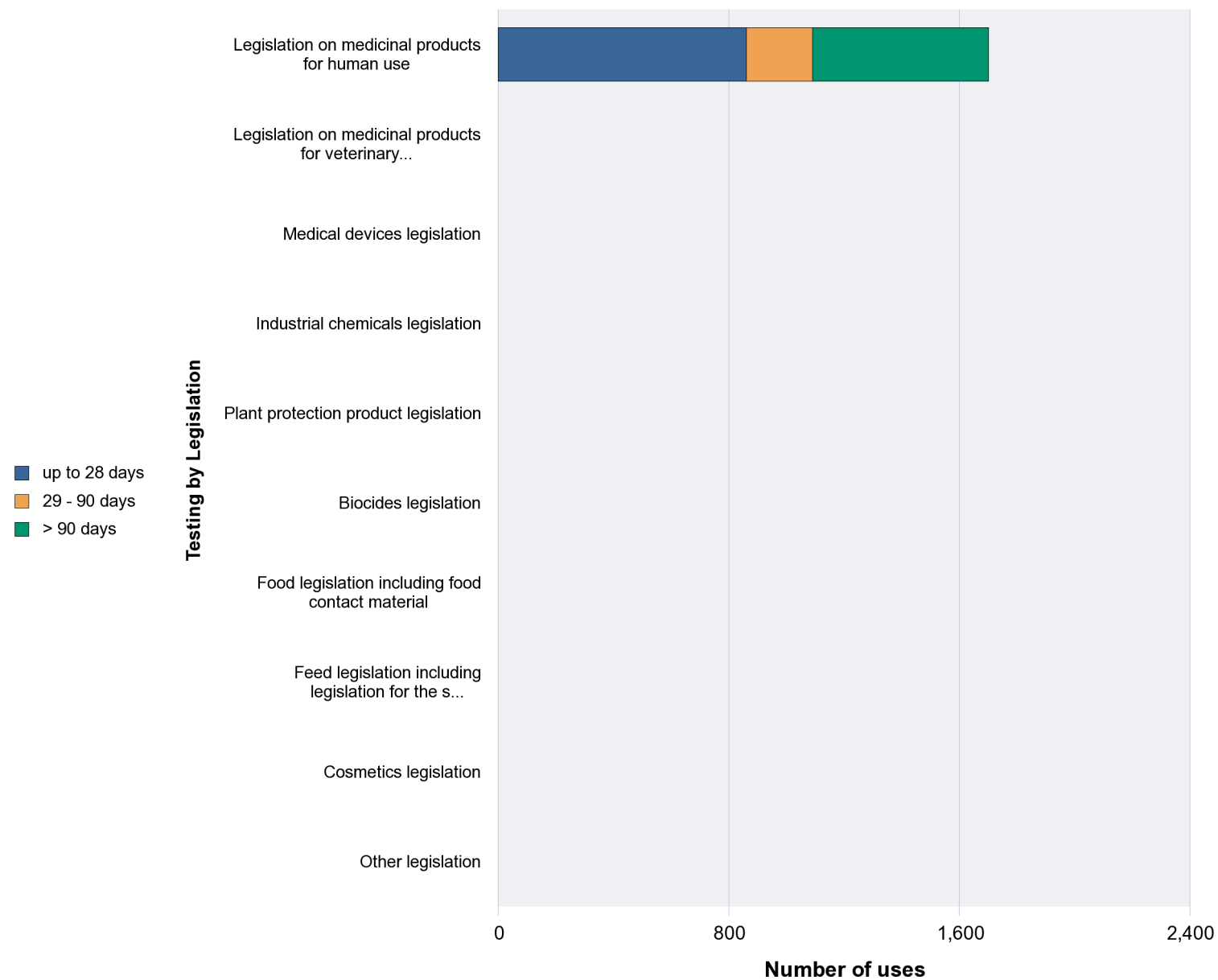
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## Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total of uses:
Legislation on medicinal products for human use	862	229	610	1,701
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				
<b>Total of uses:</b>	<b>862</b>	<b>229</b>	<b>610</b>	<b>1,701</b>

## 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	5,366			5,366
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				
<b>Total of uses:</b>	<b>5,366</b>			<b>5,366</b>



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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	57						57
Legislation on medicinal products for veterinary use and their residues							
Medical devices legislation							
Industrial chemicals legislation		960		1,440	58		2,458
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		2,070					2,070
<b>Total of uses:</b>	<b>57</b>	<b>3,030</b>		<b>1,440</b>	<b>58</b>		<b>4,585</b>

