

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

Data inclusion criteria

Report year: 2020

Country: Denmark

EU Submission: ALL

Animal Species: ALL

Species grouping Level 1: ALL

Species grouping Level 2: ALL

Mammals: ALL

Non-human primates: ALL

Genetic status: ALL

Legislative Requirement: ALL

Re-use: ALL

Severity: 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	15,544	1,091	2,679	398	19,712	96.50%
Legislation on medicinal products for veterinary use and their residues						
Medical devices legislation			6	660	666	3.26%
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			48		48	0.23%
Total of uses:	15,544	1,091	2,733	1,058	20,426	

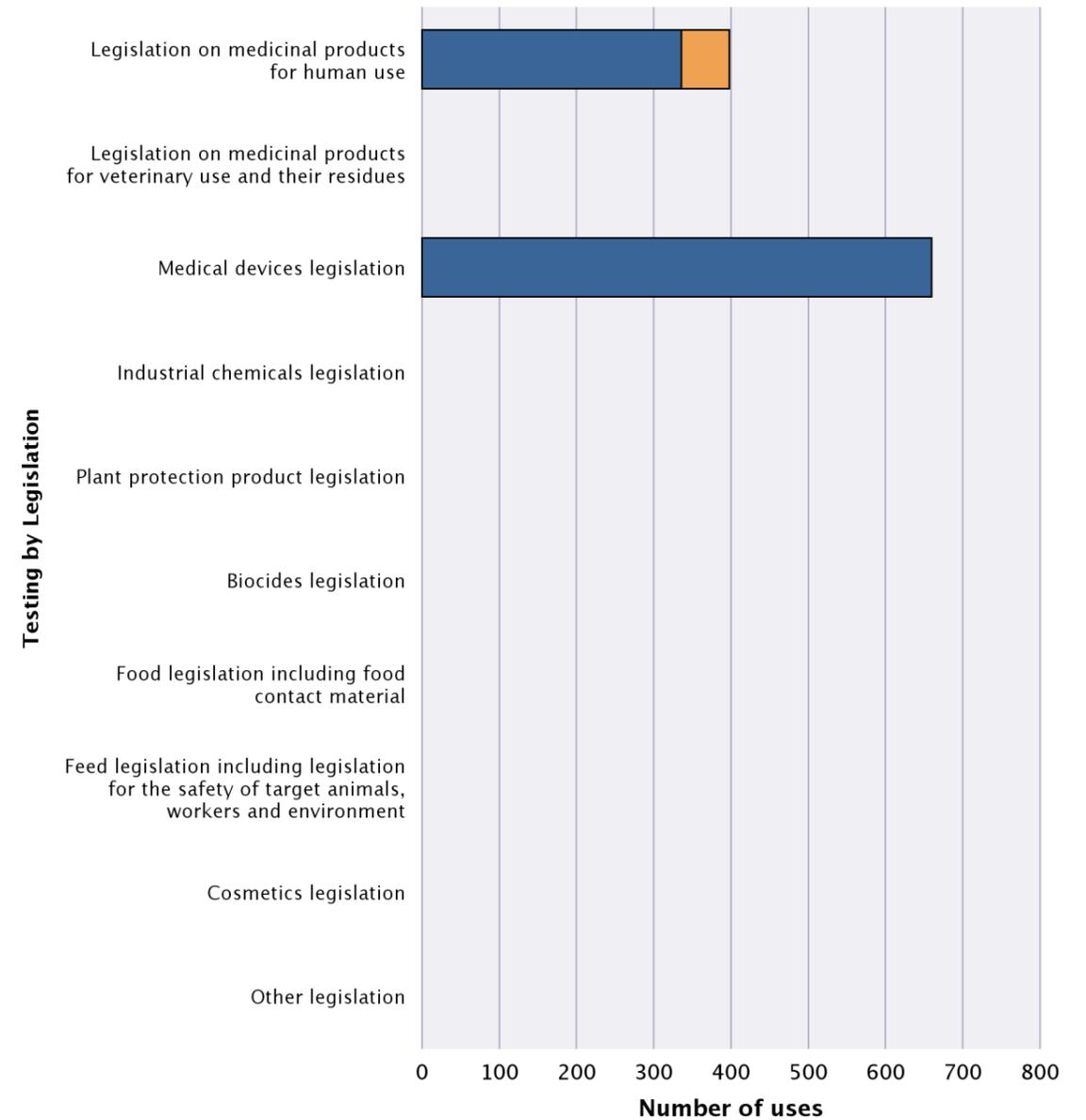
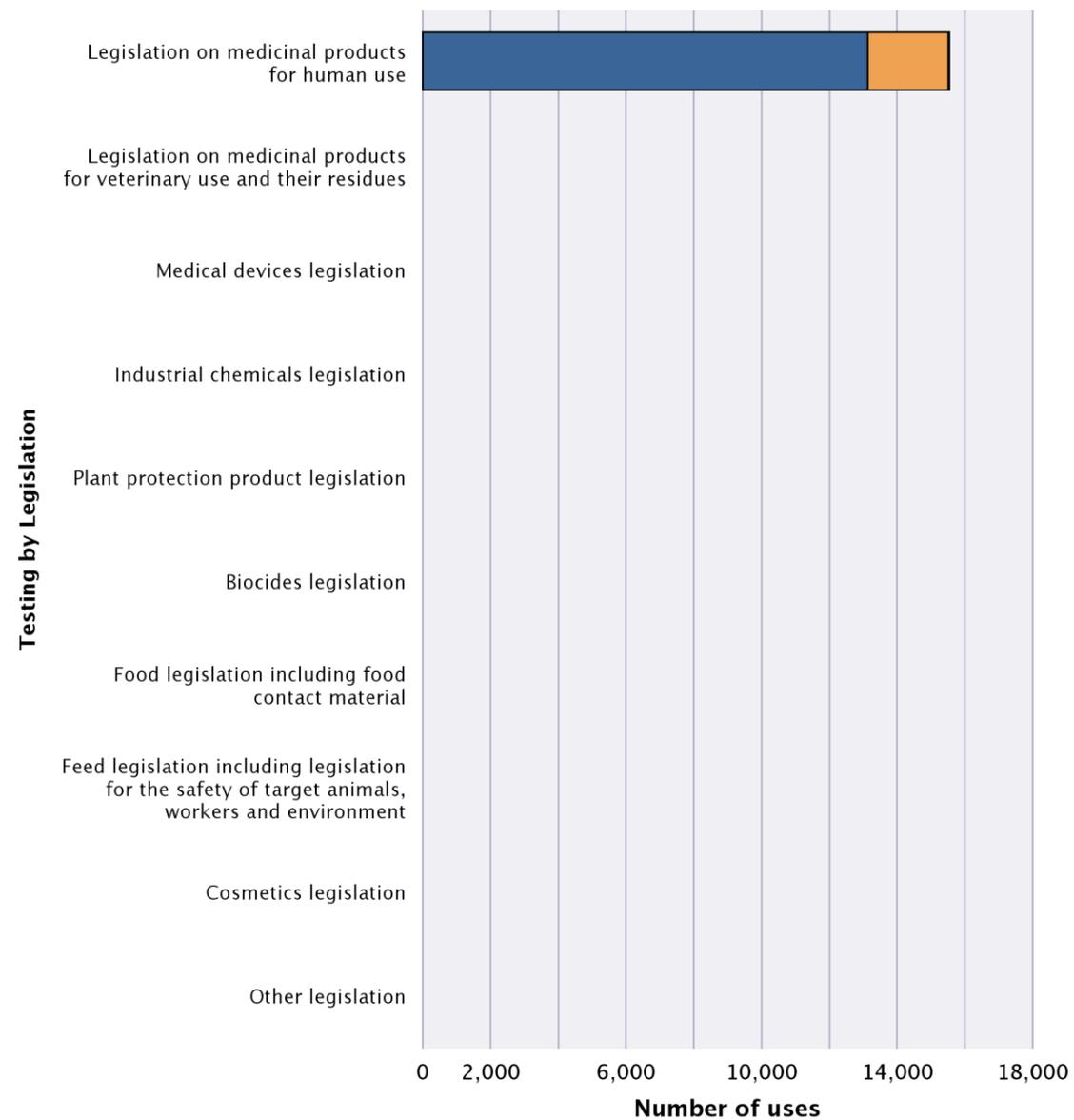
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Quality control purposes

	Batch potency testing	Batch safety testing	Other quality controls	Pyrogenicity testing	Total of uses:
Legislation on medicinal products for human use	13,137	2,366	41		15,544
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:	13,137	2,366	41		15,544

Routine production purposes

	Blood based products	Other product types	Total of uses:
Legislation on medicinal products for human use	336	62	398
Legislation on medicinal products for veterinary use and their residues			
Medical devices legislation	660		660
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:	996	62	1,058



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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	26										26
Skin irritation/corrosion	3										3
Skin sensitisation	32										32
Eye irritation/corrosion											
Repeated dose toxicity	1,662										1,662
Carcinogenicity											
Genotoxicity											
Reproductive toxicity											
Developmental toxicity	6										6
Neurotoxicity											
Kinetics	199		6							48	253
Pharmacodynamics (incl safety pharmacology)	751										751
Phototoxicity											
Ecotoxicity											
Safety testing in food and feed area											
Target animal safety											
Other toxicity/safety testing											
Total of uses:	2,679		6							48	2,733

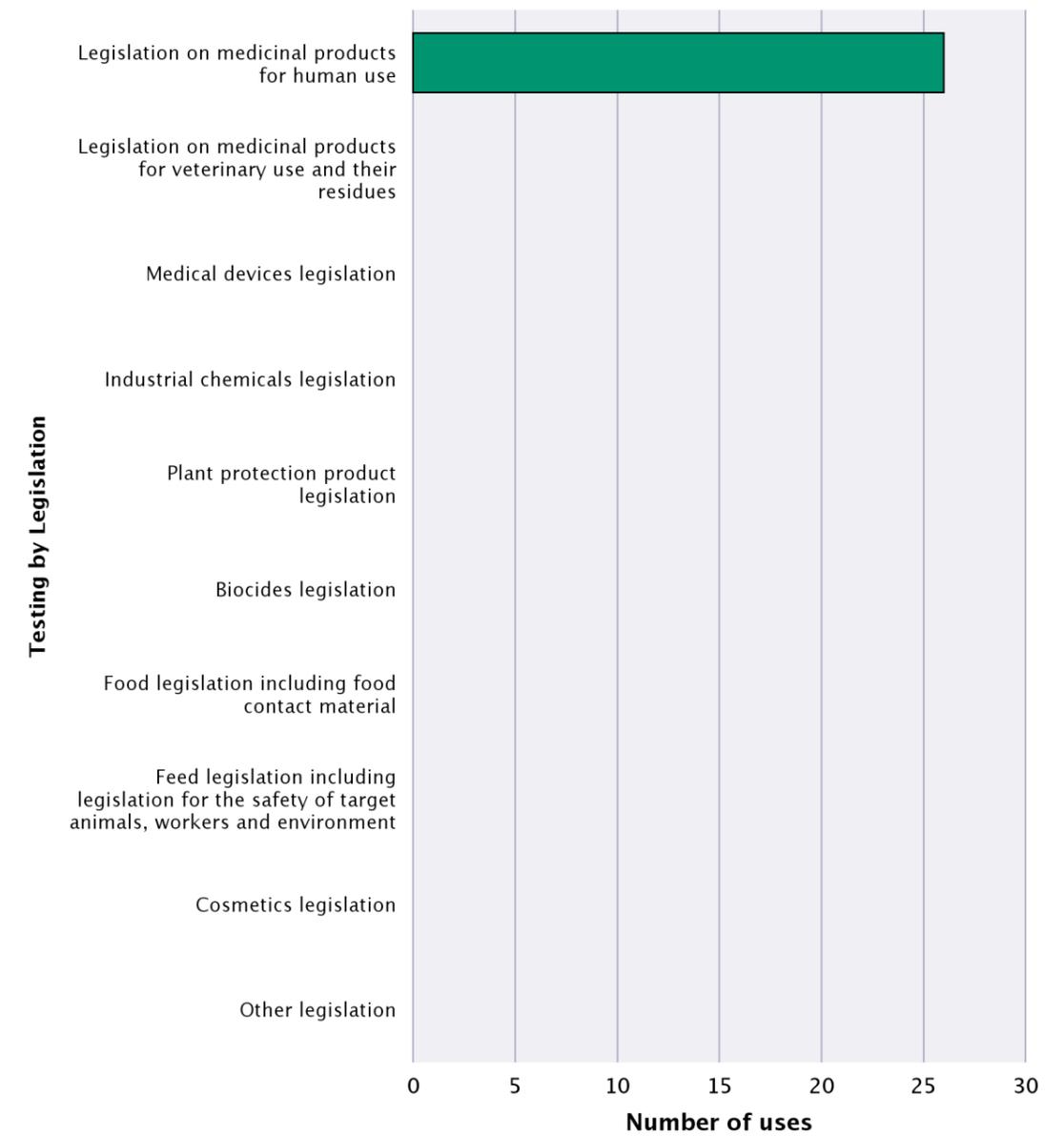
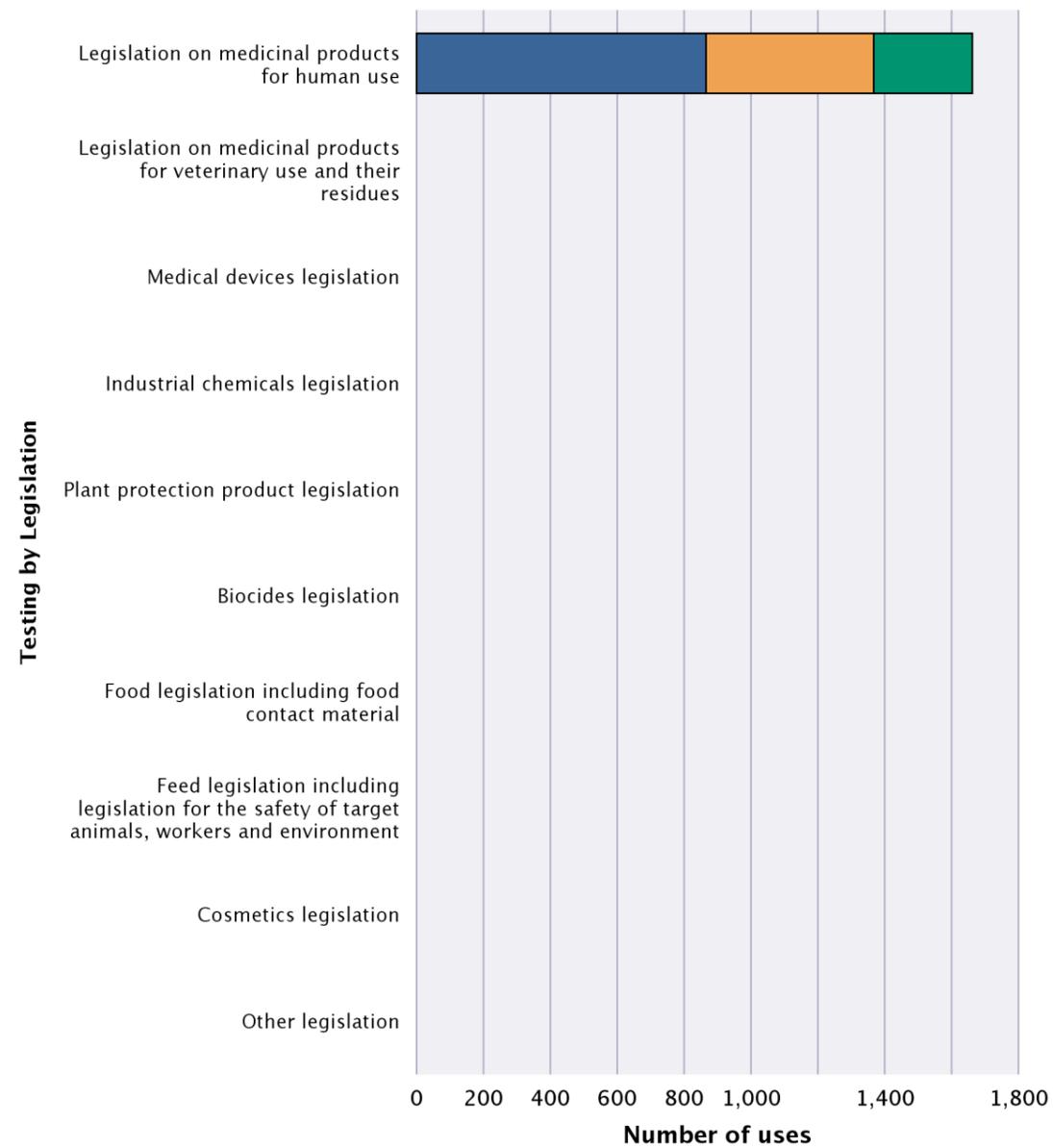
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Repeated dose toxicity purposes

	up to 28 days	29 - 90 days	> 90 days	Total of uses:
Legislation on medicinal products for human use	866	502	294	1,662
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:	866	502	294	1,662

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			26	26
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:			26	26



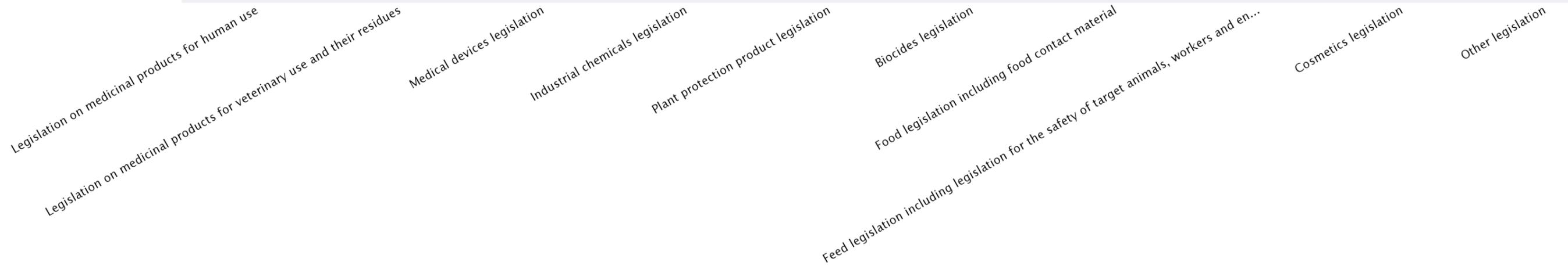
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Ecotoxicity purposes

	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							
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:							

Number of uses

- Acute toxicity
- Chronic toxicity
- Endocrine activity
- Bioaccumulation
- Other ecotoxicity



Testing by Legislation