

Norges bruk av forsøksdyr:

Hvordan går det?

Analyse av tallene for 2018 - 2023

Et prosjekt finansiert av Dyrevernalliansens Forskningsfond:

kr. 100.000 høsten 2021

kr. 100.000 høsten 2023

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(Excel, R, ulike former for datapresentasjon)

assistert av

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(KI)

Takk til Mattilsynet for diskusjoner og en gjennomgang

norecopa.no/statistics



Dyrevernalliansen

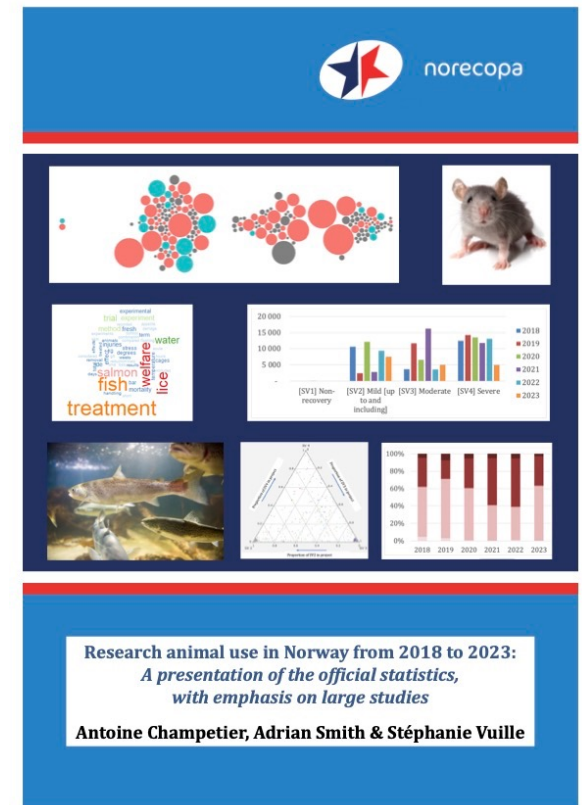
3 R Swiss 3R
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Basert på Mattilsynets offisielle tall som er levert til EU:

Det ble skrevet en preliminær rapport om bruken av forsøksdyr i Norge fra 2018 til 2021 (februar 2023)

Rapporten ble utvidet i med tallene fra 2022 og 2023 (mars 2025)



2018-2023

I snitt brukte Norge 1,5 millioner dyr i året, i totalt 3.104 forsøk



Det er ingen konsistente trender over de seks årene for det totale antallet dyr brukt

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I snitt brukte Norge 1,5 millioner dyr i året, i totalt 3.104 forsøk

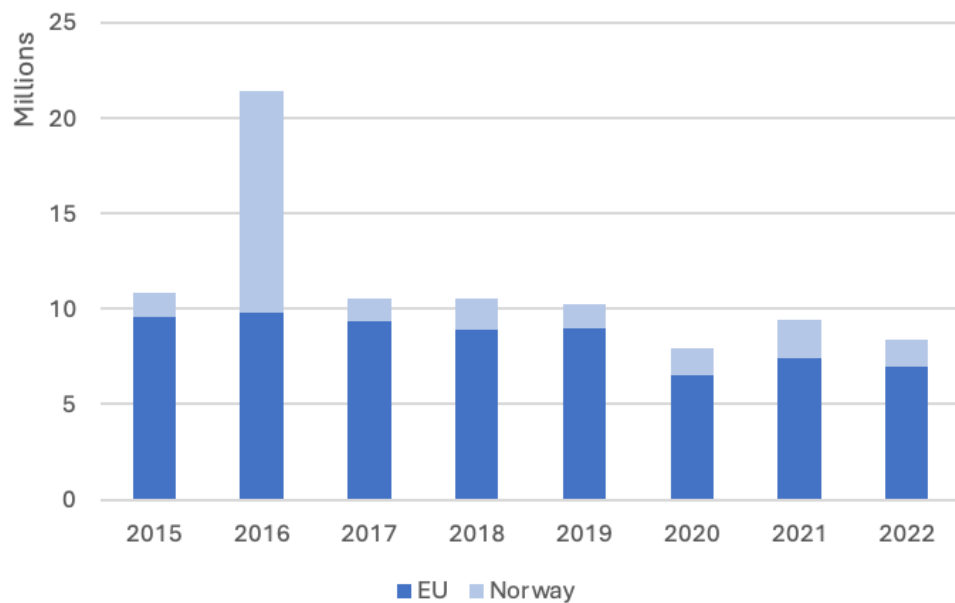
2018-2023

	2 0 1 8	%	2 0 1 9	%	2 0 2 0	%	2 0 2 1	%	2 0 2 2	%	2 0 2 3	%	Total	Average
Fish (other than Zebra fish)	1 554 973	92.2	1 165 641	91.0	1 313 565	92.4	1 903 937	94.8	1 312 835	92.8	1 470 451	93.0	8 721 402	92.7
Zebra fish	38 218	2.3	41 148	3.2	38 867	2.7	29 574	1.5	24 813	1.8	38 985	2.5	211 605	2.3
Birds	14 853	0.9	12 754	1.0	12 733	0.9	13 859	0.7	14 943	1.1	10 202	0.6	79 344	0.9
Mice	63 058	3.7	54 350	4.2	50 222	3.5	52 554	2.6	53 817	3.8	55 187	3.5	329 188	3.6
Rats	5 106	0.3	3 324	0.3	3 355	0.2	4 498	0.2	3 397	0.2	2 740	0.2	22 420	0.2
All other species	10 441	0.6	4 378	0.3	3 299	0.2	4 203	0.2	4 932	0.3	3 520	0.2	30 773	0.3
Total	1 686 649		1 281 595		1 422 041		2 008 625		1 414 737		1 581 085		9 394 732	1 565 788

Det er ingen konsistente trender over de seks årene for det totale antallet dyr brukt

Norge i forhold til EU

2018-2023

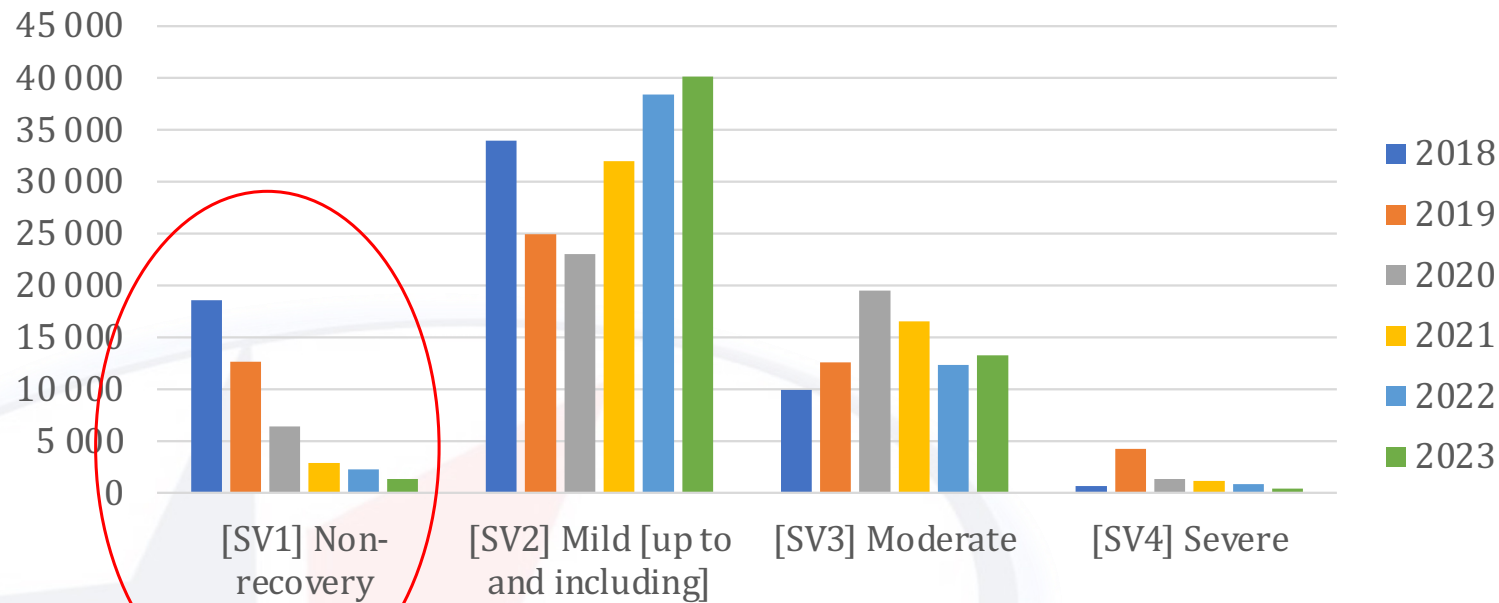


	Norway	EU	%
2015	1 230 832	9 590 379	12.8
2016	11 606 168	9 817 946	118.2
2017	1 159 667	9 388 162	12.4
2018	1 686 649	8 885 656	19.0
2019	1 281 595	8 979 227	14.3
2020	1 422 041	6 516 023	21.8
2021	2 008 625	7 397 608	27.2
2022	1 414 737	6 970 660	20.3

Belastningskategoriene:

terminal («non-recovery»), lett («mild»), moderat og betydelig («severe»)

2018-2023



Number of mice used by severity category by year

Belastningskategoriene:
terminal («non-recovery»), lett («mild»), moderat og betydelig («severe»)

2018-2023

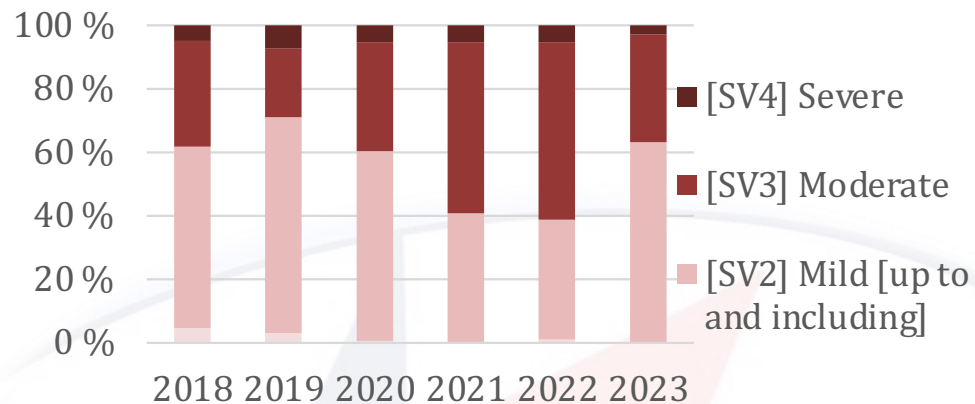
Table 3: Percentage of uses by severity in mice and zebra fish: average and ranges for 2018-2023:

		Mice			Zebra fish		
		Average	Range		Average	Range	
Terminal	[SV1]	13.4%	2.5%	29.5%	23.7%	0.3%	51.2%
	[SV2]	58.4%	45.8%	72.8%	44.6%	16.1%	63.7%
Lett	[SV3]	25.6%	15.7%	38.8%	20.4%	4.7%	32.8%
Moderat	[SV4]	2.6%	0.7%	7.7%	11.4%	2.0%	38.3%
Betydelig	Total	100.0%			100.0%		

2018-2023

Alle dyreartene:

Det er ingen konsistente trender over de seks årene for den relative forekomsten av de fire belastningskategoriene



	Proportion of total uses	Range	
[SV1] Non-recovery	1.6%	0.2%	4.7%
[SV2] Mild [up to and including]	53.5%	37.6%	68.2%
[SV3] Moderate	39.7%	21.4%	55.9%
[SV4] Severe	5.1%	2.9%	7.4%
Total	100%		

Det var store variasjoner fra år til år. Disse ble drevet av store forsøk med laks og annen fisk.

2018-2023

Batchtesting og andre regulativ- og kvalitetskontrollprosedyrer er blant bruksområdene hvor belastningsgraden er høyest for fisk.

En nedgang i absolutte tall, men ikke en relativ nedgang i belastningsgrad.

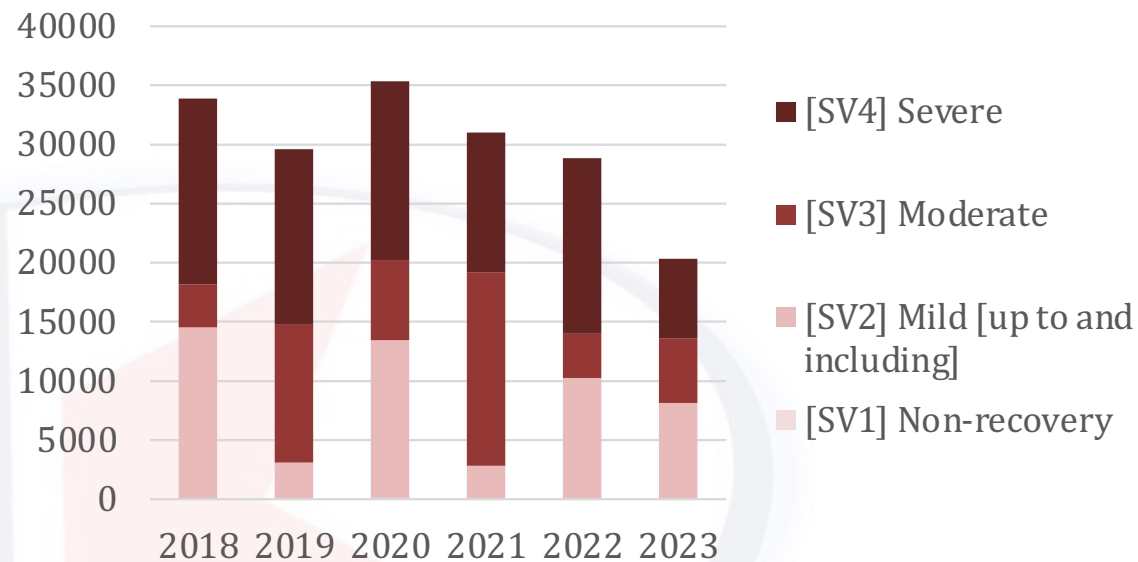


Figure 12: Severity categories in regulatory use and quality control for fish by year

2018-2023

Batchtesting og andre regulativ- og kvalitetskontrollprosedyrer er blant bruksområdene hvor belastningsgraden er høyest for fisk.

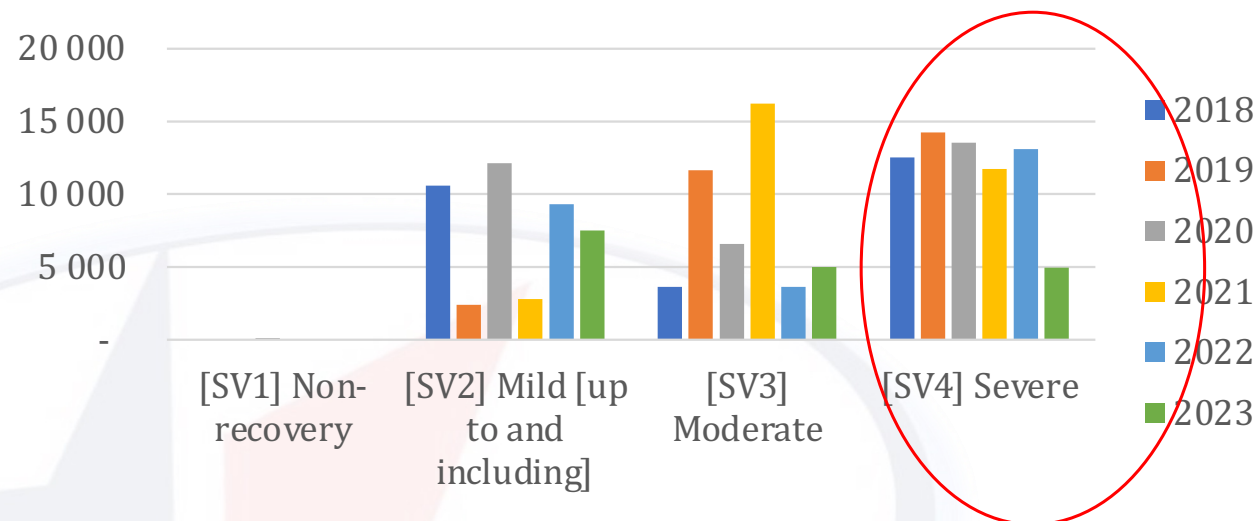


Figure 13: The number of Atlantic salmon used for regulatory purposes and quality control, by severity degree and year

2018-2023

Enkelte store forsøk på fisk er hovedfaktoren som påvirker den nasjonale statistikken, noe som gjør det vanskelig å identifisere reelle trender.

Variasjonene fra år til år på flere hundre tusen prosedyrer ble drevet av tidspunktet for forsøkene på Atlantisk laks, spesielt i forhold til håndtering av lus.

2018-2023

Gode nyheter:

Det er relativt få mus i den mest belastende kategorien.

Antallet mus som ble brukt til Lett/Mild eller Moderat belastende prosedyrer varierte, med en tendens de siste tre årene i retning Lett/Mild.

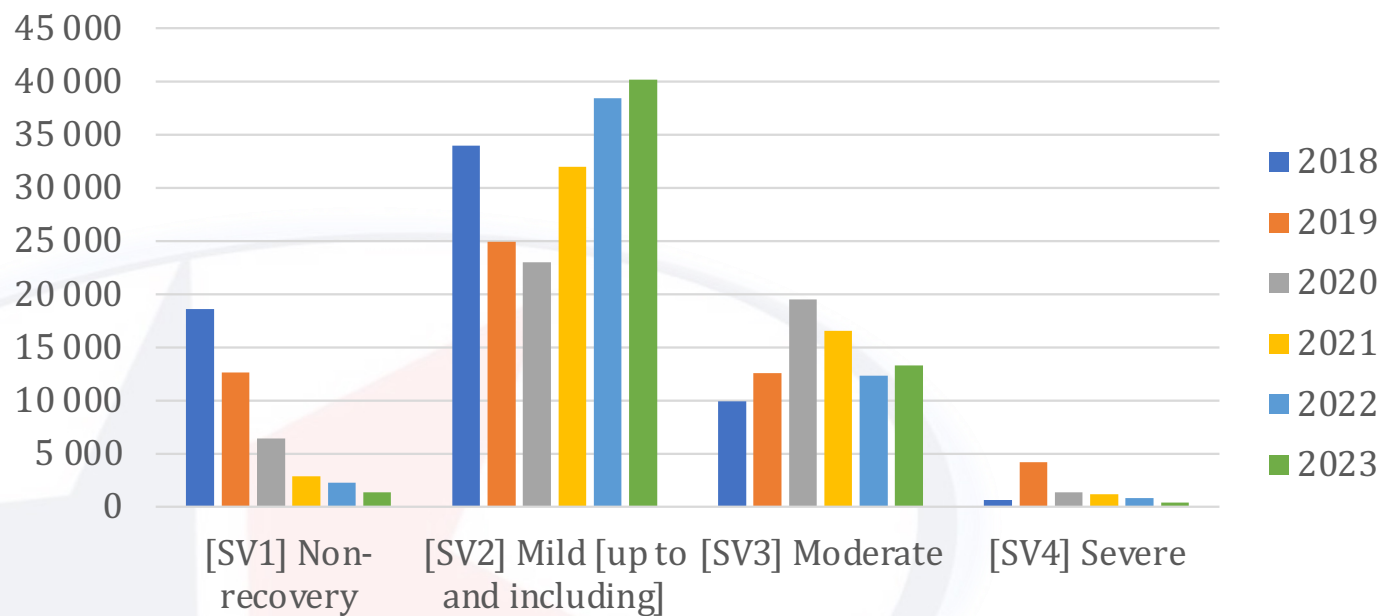


Figure 10: Number of mice used by severity category by year

Det har nok vært en del ***feilrapportering***

- terminale forsøk
- inndeling i EU-kommisjonens kategorier:
 - Basic research
 - Translational and Applied research
 - Preservation of species

og ***variasjon i rapportering***:

- oppfattelse av belastningsgraden

2018-2023

norecopa.no/severity

COMPILATION OF SEVERITY CLASSIFICATIONS ACROSS EUROPE

I Interventions on body systems and functions	II Induction of diseases	III Pharmacology, other external causes	IV Housing, environment and behaviour	V Fetuses and premature animals	VI Clinical signs
Substance administration	Heart & circulation	Physical impacts	Housing & Nutrition	1. Feeding 2. Surgical interventions 3. Reproductive toxicology	1. Condition of fur, grooming, body orifices 2. Breathing, heart rate 3. Body temperature 4. Behaviour & body posture 5. Reaction to artificial stimulation; handling behaviour; reaction to physical contact 6. Food & water consumption 7. Prostration 8. Self trauma 9. Body weight
Specimen collection	Infectious diseases	1. Irradiation & chemotherapy 2. Exposure to electricity 3. Exposure to heat 4. Exposure to cold 5. Exposure to acids & basis 6. Traumatization 7. Pressure change 8. Sound & ultrasound 9. Magnetic fields 10. Chronic hypoxia	1. Housing in general 2. Gnotobiology 3. Use of metabolic cages 4. Deprivation – water 5. Deprivation – food 6. Exposure to overstimulation		
1. Collection of body fluids 2. Tissue sampling	1. Infections in general 2. Gnotobiology 3. Bacterial infections 4. Viral infections 5. Mycotic infections	Generation of pain	Breeding & Reproduction		
Surgical interventions	Neurology & sensory organs	Pharmacological studies	1. Identification method and tissue sampling for genotyping 2. Germ cells		
1. Anaesthesia 2. Surgical interventions in general 3. Abdominal and chest cavity 4. Musculoskeletal system 5. Implantation of mini-pumps, transponders 6. Organ transplantation 7. Implanted probes 8. Others	1. Convulsions 2. CNS lesions 3. Ischaemias 4. Visual system	1. Toxicity studies - general 2. Acute toxicity 3. Sub-acute toxicity 4. Chronic toxicity 5. Reproduction toxicology 6. Pharmacokinetic studies 7. Batch testing	GA animals		
	Endocrine, nutritional & metabolic diseases		1. GA animal model in the experiment 2. Phenotype characteristics 3. Generation of GA animals 4. Tissue sampling for genotyping		
	1. Endocrinology 2. Bone metabolism 3. Glucose metabolism 4. Body weight loss		Behaviour		
	Neoplasms		1. Aversive learning, conditioned avoidance behaviour and conflict tests 2. Deprivation – social 3. Deprivation – sleep 4. Deprivation – motion & mobility 5. Pharmacologically induced behavior 6. Exercise 7. Specific behavior tests 8. External telemetry devices		
	Immunology				
	1. Transplantation 2. Cellular reactions 3. Autoimmune reactions 4. Immunisation 5. Immunity 6. Inflammation 7. Arthritis 8. Asthma				

Collection or body fluids

Source	Non-harmful / below threshold / severity degree 0	Mild / severity degree 1	Moderate / severity degree 2	Severe / severity degree 3
Directive 2010/63/EU, Annex VIII			Frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (> 10 % of circulating volume) in a conscious animal within a few days without volume replacement.	
Federal Food Safety and Veterinary Office FSVO (2018)	Sampling of blood, saliva or urine (non-invasive) without sedation, at intervals and frequencies or in volumes imposing no constraint on the animals (no prolonged restraining measures, no other interventions or previous administrations of test substances). Collection of body fluids, tissues, organs, or body parts under deep general anaesthesia directly followed by euthanasia in animals not previously subjected to any intervention. Examples: Collection of blood samples from the ear vein of the rabbit, twice with an interval of 14 days, 3 ml on each occasion. Single non-invasive swabs of body cavities.	Lege artis collection of blood, tissue, faeces or urine, with or without sedation, at intervals and frequencies imposing mild short-term constraint on the animals with non-toxic doses of test substances, slightly prolonged reduced housing conditions. Examples: Several blood samples from the tail vein, saphenous vein or sublingual vein in the mouse and rat within 24 hours. Skin biopsies. Perfusion of small rodents under terminal surgical anaesthesia.	Sampling of blood in volumes and at intervals and frequencies causing moderate short-term constraint on the animals; percutaneous urine collection, collection of tissue samples (cells or fluid), peritoneal washing of naive animals under general anaesthesia. Sampling of body fluids (in relatively large quantities, in relatively large numbers or at relatively short intervals) after administration of pharmacologically active substances (no toxic doses, no other interventions, no prolonged restraining measures). Examples: Repeated daily collection of blood samples from the tail vein in rats over five days to determine the course of hormone levels.	
Federal Food Safety and Veterinary Office FSVO (2018)		Collection of fluids or tissue resulting in mild impairment of the young animals' further development. Examples: Venous blood collection in premature calves	Collection of fluids or tissue resulting in moderate impairment of the young animals' further development.	Collection of fluids or tissue resulting in severe impairment of the animals' further development or death/abortion.
Working Group of Berlin Animal Welfare Officers (2010)		In small quantities and small numbers with only short-term compulsory measures and not combined with other procedures: Venipuncture, Foley catheter for larger animals.	In small quantities and small numbers with only short-term compulsory measures and not combined with other procedures.	With severe restrictions on motion and not combined with other procedures.



2018-2023

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2018-2023

96 % av de 9 millioner dyrene som ble brukt i perioden var ikke genetisk endret på noen måte.
 Totalt 332.949 dyr ble genetisk endret uten en skadelig fenotype
 54.207 dyr viste en skadelig fenotype

Table 7: Number of animals used for all species with genetically altered status (totals from all years)

Species	[GS1] Not genetically altered	[GS2] Genetically altered without a harmful phenotype	[GS3] Genetically altered with a harmful phenotype
Mouse	130 241	166 577	32 370
Zebra fish	72 408	120 831	18 366
Atlantic salmon	6 662 100	42 940	2 324
Rat	19 465	1 808	1 147
Japanese rice fish	876	590	
Lumpfish	224 380	181	
Pig	4 637	12	
Ballan wrasse	114 119	10	
All other species	1 779 350		
Total	9 007 576	332 949	54 207

2018-2023

Det er svært begrenset gjenbruk av forsøksdyr i Norge

	Severity	2018	2019	2020	2021	2022	2023	All years
Terminal	[SV1]	5 722	356	40		1	12	6 131
Lett	[SV2]	11 975	418	1 674	793	3 590	11 874	30 324
Moderat	[SV3]	67	80	140	65	341	284	977
	Total	17 764	854	1 854	858	3 932	12 170	37 432

Table 9: Number of animals reused by severity and year

The data does not track the severity of the initial use of the animals, so the severity indicated in Table 9 indicates the severity of the reuse. Over the six years of the dataset, 81% of the animal uses that were labelled as “reuses” were in the severity category “Up to and including Mild”. Very few animals (under 3%) were reused for moderately severe procedures, and none was reused for severe procedures.

Forsøk med kunstig intelligens

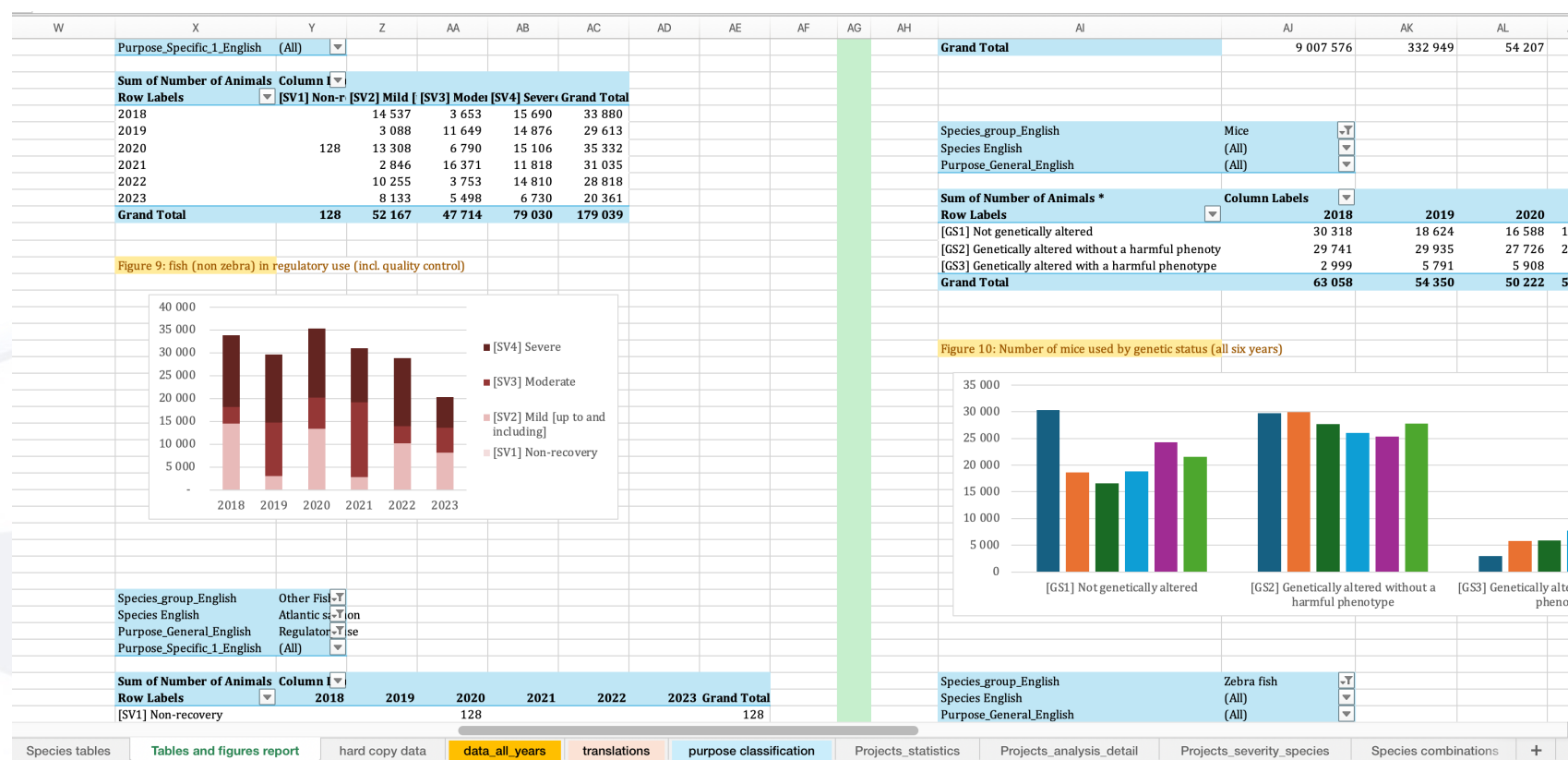
Vi forsøkte å analysere leg-sammendragene (Non-Technical Summaries) av alle de største forsøkene i perioden (minst 20.000 dyr) ved å samle emneord via ChatGPT.

Det viste seg å være av begrenset verdi.

Jeg hadde lignende erfaringer da jeg skulle analysere de britiske NTS – måtte gjøres manuelt.

2018-2023

Det er laget en samlefil i Excel av alle tallene fra Mattilsynet for de 6 årene og den er tilsendt Mattilsynet. Filen kan lett oppdateres med fremtidige års data.



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Konklusjoner (*husk at tallene dekker kun 6 år*)

- Store enkeltforsøk, særlig på laks og villfisk, påvirker tallene
- D.v.s. at oppdrettsnæringen påvirker tallene:
 - vaksiner (både til Norge og til utlandet), behandlinger, ny teknologi, forskning på fiskevelferd
- Den generelle forskningsaktiviteten i Norge påvirker tallene (finansiering, outsourcing)
- Feilrapportering forekommer:
 - hva som er terminalforsøk
 - tildeling av belastningskategorien
 - tildeling av EUs kategorier for målene med forskningen
- Vi har ikke studert effektene av COVID-19 lockdown og effektene av alternative metoder
- (og husk at definisjonen av dyreforsøk ble utvidet da Norge gjennomførte EU-direktivet i 2015)

Avsluttende kommentarer

‘Ansvar for korrekt rapportering ligger hos forskerne og deres institusjoner, ikke hos Mattilsynet’

Vi bør fortsette å diskutere inndelingen mellom de ulike belastningskategoriene, og bidra til internasjonal forståelse av disse.

Arbeidet bør være i nært samarbeid med brukerne, for å høste større innsikt i mulighetene for å fremme 3R.



Working Party Report

Guidance on the severity classification of scientific procedures involving fish: Report of a Working Group appointed by the Norwegian Consensus-Platform for the Replacement, Reduction and Refinement of animal experiments (Norecoba)

P Hawkins, (Convenor), N Dennison, G Goodman, S Hetherington, S Llywelyn-Jones, K Ryder, and A J Smith

Abstract

The severity classification of procedures using animals is an important tool to help focus the implementation of refinement and to assist in reporting the application of the 3Rs (replacement, reduction and refinement). The recently revised Directive that regulates animal research and testing within the European Union requires Member States to ensure that all procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’ or ‘severe’, using assignment criteria set out by the European Commission (EC). However, these are focused upon terrestrial species, so are of limited relevance to fish users. A Working Group set up by the Norwegian Consensus-Platform for the 3Rs (Norecoba) has produced guidance on the classification of severity in scientific procedures involving fish, including examples of ‘subthreshold’, ‘mild’, ‘moderate’, ‘severe’ and ‘upper threshold’ procedures. The aims are to complement the EC guidelines and help to ensure that suffering in fish is effectively predicted and minimized. Norecoba has established a website (www.norecoba.no/categories) where more information on severity classification for procedures using fish, including field research, will be made available.

Guidance on the severity classification of procedures involving fish

P Hawkins¹, K Ryder², N Dennison², G Goodman³, S Hetherington⁴, S Llywelyn-Jones⁵ and AJ Smith⁶



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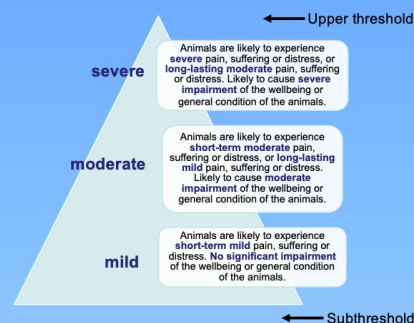
¹Research Animals Department, RSPCA, Wilberforce Way, Southwater, West Sussex, RH13 9RS, UK; ²Animals (Scientific Procedures) Inspectorate, Home Office, P.O. Box 6779, Dundee, DD1 9WW, UK; ³Biological Services, The University of Edinburgh, Chancellor Building, 49, Little France Crescent, Edinburgh, EH16 4SB, UK; ⁴CEFAS, Pakefield Road, Lowestoft, NR33 0HT, UK; ⁵King's College London, Biological Services Unit, 4th floor, Hodgkin Building, Guy's Campus, London, SE1 1UL, UK; ⁶Norecopa, c/o Norwegian Veterinary Institute, P.O. Box 750 Sentrum, N-0106 Oslo, Norway

Severity classification is an important tool in both implementing and monitoring the progress of refinement, including reporting the actual severity of procedures which is now part of the legislation on animal research and testing in some countries. Predictions of severity are also fundamental to the harm–benefit assessments undertaken by bodies such as regulatory authorities, and ethical committees, when deciding whether or not a project should be licensed or funded.

EU Directive 2010/63 requires signatories to ensure that the severity of all procedures is classified as 'non-recovery' (under terminal anaesthesia), 'mild', 'moderate' or 'severe', using assignment criteria set out by the European Commission (EC) – see diagram. 'Subthreshold' procedures are those that are expected to inflict less pain, suffering or distress than that caused by the introduction of a needle.

An EC Working Group produced a report in 2009 giving examples of procedures within these categories, but these are most relevant to research using terrestrial species.

A working group set up by the Norwegian Consensus-Platform for the 3Rs (Norecopa) has published a complementary document that gives guidance on severity classification in fish research, including examples of 'subthreshold', 'mild', 'moderate', 'severe' and 'upper threshold' procedures. This document will make it easier for fish researchers to implement the requirements of the Directive.



How would you categorise these procedures?



Behavioural studies



Handling out of water



Anaesthesia



Injection under anaesthesia

Examples from each category in Norecopa's guidelines (simplified):

Subthreshold

- Behavioural studies
- Feeding studies where food restriction does not cause any harm
- Marking using non-toxic and non-aversive dyes in the water
- Manipulations of photoperiod, temperature or water gases that do not cause significant harm

Mild

- Disease research where humane endpoints are applied at the first clinical sign of disease or earlier
- Gentle, brief handling of fish out of water
- Blood sampling under anaesthesia using recommended volumes and techniques
- Removal of a small part of one fin, where rapid healing and minimal dysfunction or pain are expected
- Toxicological studies where animals are humanely killed at or before the onset of clinical signs

Moderate

- Cannulation of blood vessels followed by successive blood sampling within recommended limits
- Intraperitoneal injection of substances known to cause adhesions
- Intramuscular or intraperitoneal implantation of telemetry devices by surgical procedures (under general anaesthesia)
- External attachment of telemetry devices with a risk of interference with normal activity and behaviour
- 'Shaking' in a net out of water to produce a stress response
- Removal of scales to promote fungal growth

Severe

- Saltwater/freshwater challenge for scientific purposes where it cannot be predicted that the fish will adapt without severe effects or mortality
- Disease studies likely to cause death where the study cannot be controlled to avoid mortality
- Vaccine potency testing with persistent impairment of the animal's condition, progressive disease leading to the animal's death, or associated with long-lasting moderate pain, distress or suffering
- Surgical interventions under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress

Upper threshold

- Pathophysiological studies where animals will experience substantial pain, suffering or distress which is long lasting
- Description of survival curves or similar tests where death is an endpoint and where death is preceded by prolonged and substantial pain, suffering or distress

Norecopa has set up a website with links to these guidelines and more information on severity classification:

<https://norecopa.no/categories>

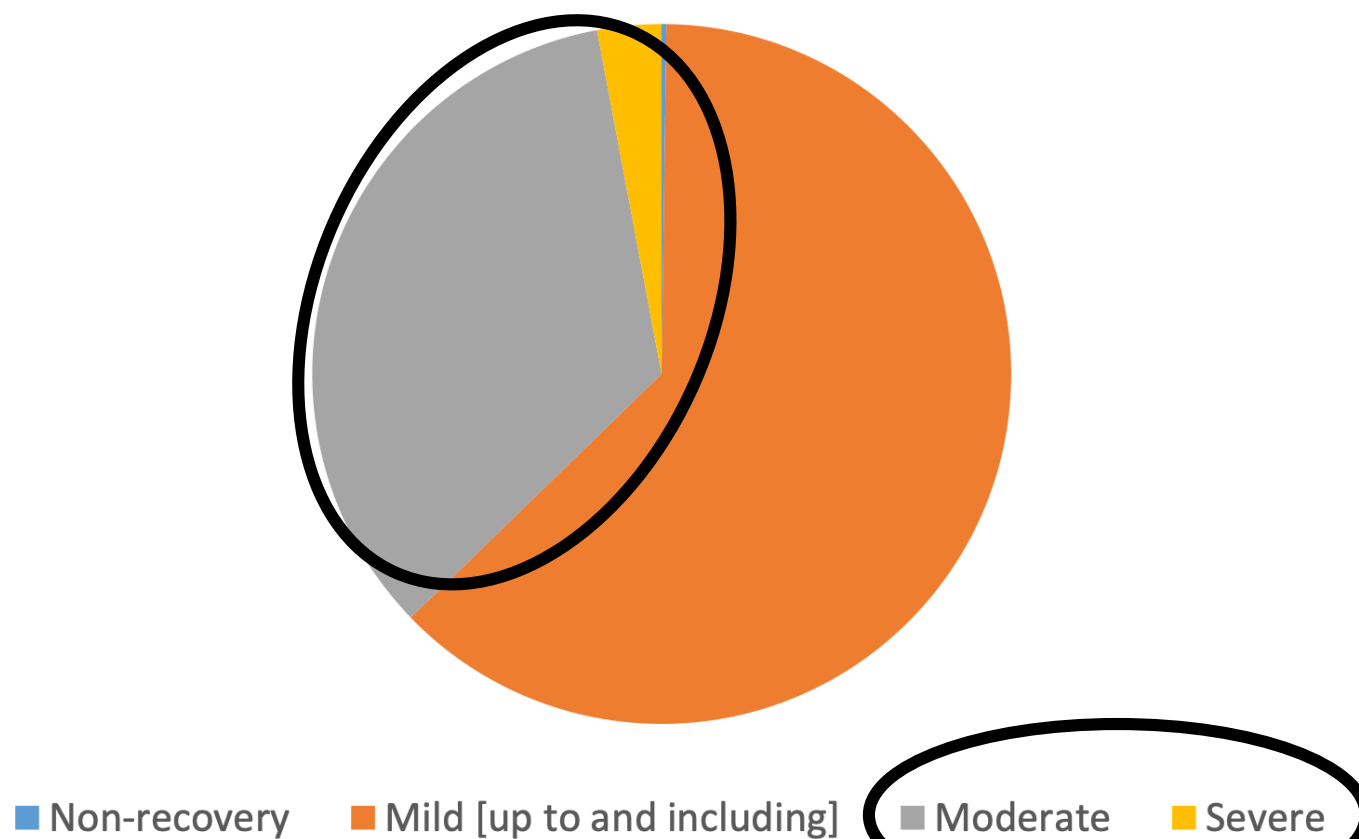
Correspondence to: Adrian Smith, Norecopa, (adrian.smith@norecopa.no)

Photos: Aurora Brønstad, Janicke Nordgreen & VESO Viken

Vi trenger flere situasjons- og artsspesifikke retningslinjer!

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Ca. 40% av dyreforsøkene i Norge er moderat eller betydelig belastende etter EUs definisjon

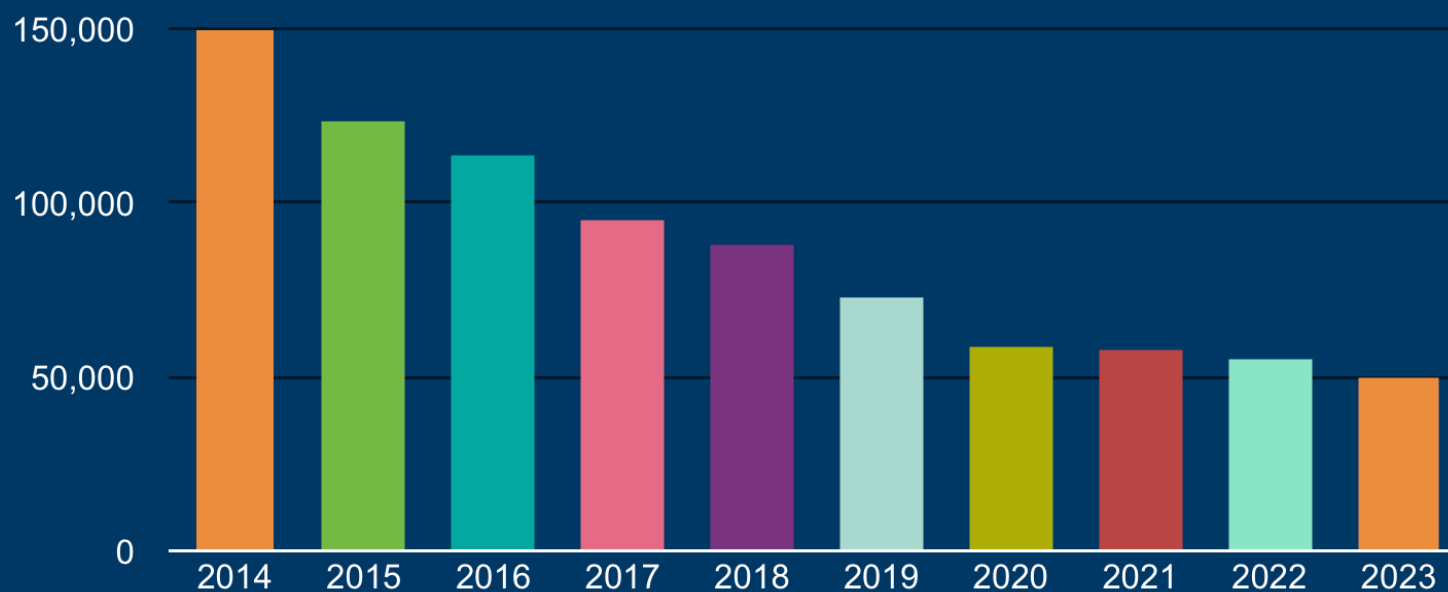


Mattilsynet, tall for 2023

Noen f.eks. Storbritannia arbeider systematisk for å redusere de mest belastende dyreforsøkene

67%
REDUCTION

IN EXPERIMENTAL PROCEDURES
CAUSING SEVERE SUFFERING IN
THE UK SINCE 2014



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