

Genetically Altered Animals – Legal Aspects

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Austrian State Prize – Staatspreis für Ersatzmethoden zum Tierversuch

Annual prize awarded for a peer-reviewed publication that describes outstanding and original work that has or could have major impacts on the 3Rs.

Deadline for submission: 30th June 2023



Prof. M. Ausserlechner (MUI) - 3D bioprinted, vascularized neuroblastoma tumor environment in fluidic chip devices for precision medicine drug testing

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Overview

- legal framework on the protection of animals used for scientific purposes
- project authorisation
- reporting animals used to create and maintain GA lines

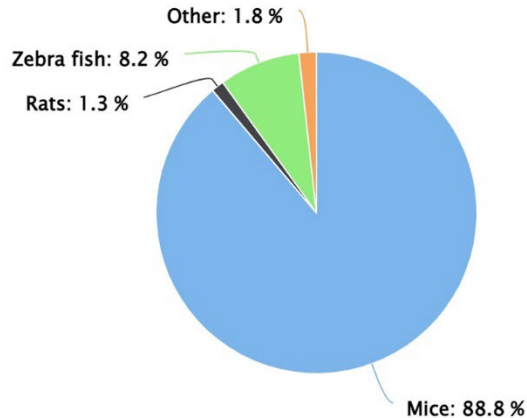
EU Statistical Report 2020 – Genetically Altered Animals

- ALURES – animal use reporting EU system
- 1,79 million genetically altered animals **used** in scientific research, testing, routine production and education and training purposes in the EU,
- the **creation and maintenance of GAA** amounted to appr. 303,000 animals

EU Statistical Report 2020 – Genetically Altered Animals

Uses by species

source : alures published data



Mice and zebrafish are the most common reported GAA species, followed by rats, rabbits and smaller numbers of other species such as Xenopus and other fish species

Important that attention is given to the techniques of creation and maintenance of GAA in order to **apply the Three Rs principles** in the creation, breeding, use and care practices of these animals.

Legal Framework

EU-Directive 2010/63/EU on the „protection of animals used for scientific purposes“
is transposed into **Austrian Legislation** by:

- Tierversuchsgesetz 2012 (TVG 2012)
- Tierversuchs-Verordnung 2012 (TVV 2012)
- Tierversuchsstatistik-Verordnung 2013 (TVSV 2013)
- Tierversuchs-Kriterienkatalog-Verordnung (TVKKV)

Procedure (§ 2 TVG 2012)

Procedure („Tierversuch“): any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which **may cause the animal a level of pain, suffering, distress or lasting harm** equivalent to, or higher than, that caused by the **introduction of a needle in accordance with good veterinary practice**.

This **includes** any course of action intended, or liable, to result in the birth or hatching of an animal or the **creation and maintenance of a genetically modified animal line in any such condition**, but excludes the killing of animals solely for the use of their organs or tissues;

Procedures

- Elimination of pain, suffering, distress or lasting harm shall not exclude the use of an animal in procedures (by the use of anaesthesia, analgesia or other methods)
- Breeding of GAA which retain a risk of the development of a harmful phenotype (e.g., risk of infection due to compromised immune system) regardless of the applied refinement (barrier/biosecure conditions), **requires** project authorisation as the application of refinement does not entirely eliminate the risk, but only reduces the risk in that context

Procedures

- the creation of a new GAA is in general considered a procedure since the consequences cannot always be determined fully in advance
- the maintenance of an established GA line is considered a procedure when the line carries a harmful phenotype

EU Guidance Documents

Guidance Document published by European Commission (EU-MS languages):

- Non-technical Project Summaries
- Animal Welfare Bodies
- Education and Training Framework
- Retrospective Assessment
- Severity Assessment
- Genetically Altered Animals ...

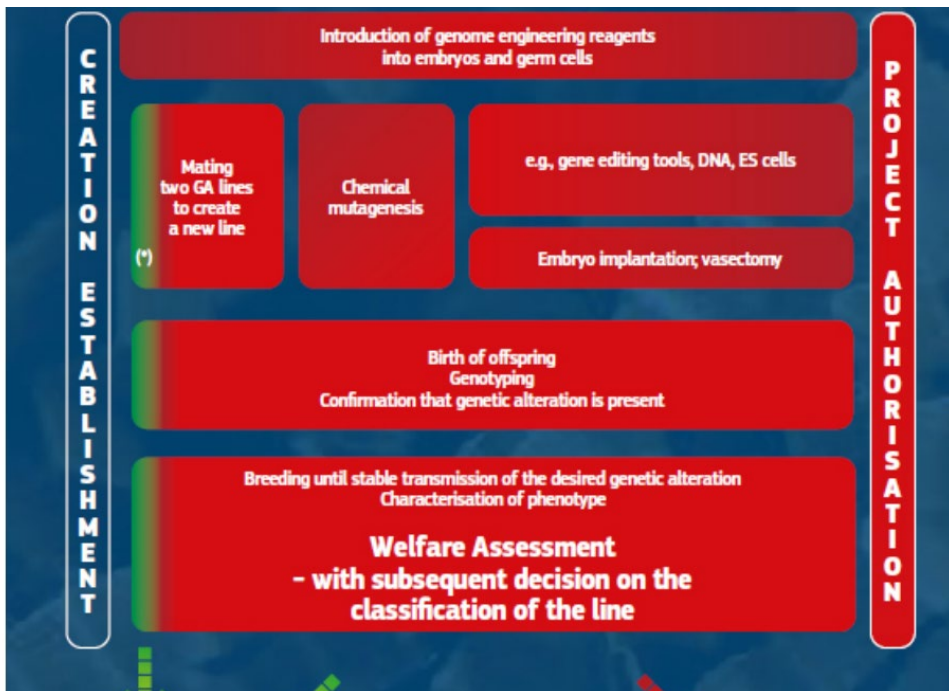
[Animals in science \(europa.eu\)](http://europa.eu)



EU Guidance Document – Genetically Altered Animals

- legal framework and formal obligations
- application of the Three Rs
- welfare assessment scheme for GA lines (including templates)
- legal reporting obligations related to GAA during creation and maintenance of lines

EU Guidance Document – Genetically Altered Animals



EU Guidance Document – Genetically Altered Animals



Statistical Reporting

Annual statistics

Information on animals used in procedures is collected EU-wide in a harmonized manner:

- species, numbers, origin, purposes, genetic status, actual severity, etc.
- user must report for each calendar year (by March 1, following year)
- Ministry collects data, to be published by Nov 10
- Statistical data are published in a central, open access, searchable EU database

Statistical Reporting

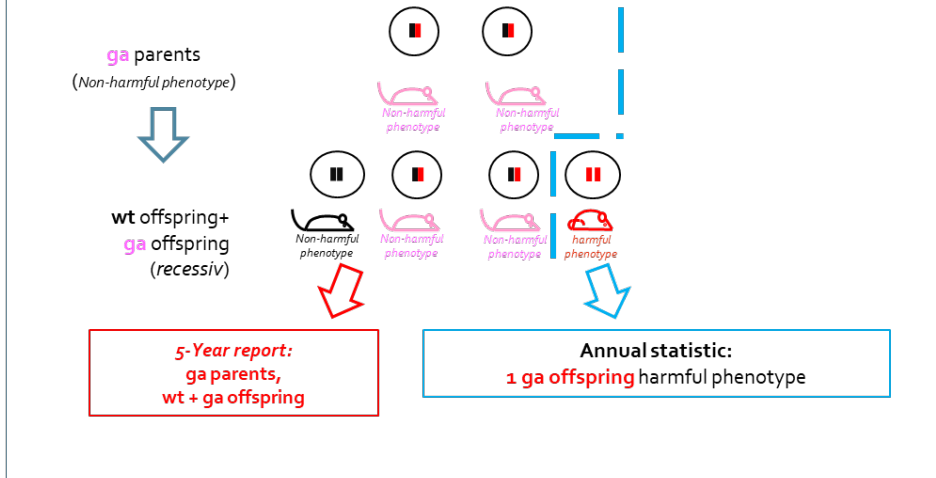
Implementation Report (5-jährlicher Bericht)

- every 5 years additional report (i.e. on top of the annual statistics) about animals specifically bred, but not used in procedures
- covers only the last year of the 5-year period (2022)

2nd Implementation report covering the years 2018-2022 will be published in May 2024 by the European Commission

Statistical Reporting

Beispiel: Maintenance of an established GA line, Project approval required, if harmful phenotype is known and documented



Further Information

Federal Ministry of Education, Science and Research <http://www.bmbwf.gv.at/tierversuche>

Empfehlungen für die Arbeitsweise von Tierschutzgremien gemäß § 21 TVG 2012, Ausfüllhilfe zum Formular 5-jährlicher Bericht, Erstellung der Unterlagen für die Rückblickende Bewertung

European Commission http://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm

Guidance documents, ALURES database etc.

European Commission, Directorate-General for Environment, Framework for the genetically altered animals under Directive 2010/63/EU on the protection of animals used for scientific purposes – , Publications Office of the European Union, 2022, <https://data.europa.eu/doi/10.2779/499108>

ECVAM (Eur. Reference Laboratory for Alternatives to Animal Testing) <https://eurl-ecvam.jrc.ec.europa.eu/about-ecvam/new-eurl-ecvam>

Austrian 3R Centre – The RepRefRed Society [Home](#) | [The RepRefRed Society](#)

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