

THE PROTECTION OF THE DIGNITY OF LABORATORY ANIMALS IN SWITZERLAND: DIFFERENT PROCEDURES? DIFFERENT STANDARDS?

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Abstract

The article discusses the question whether Swiss law offers an equal level of protection for animals being used in research projects and those being genetically modified and bred for these projects. To answer this question the article argues, first, that animal dignity has a sacrosanct core content which prohibits highly cruel treatments or killing methods, denial of an animal's essential natural needs as well as exclusive instrumentalization. However, a use that does not infringe the sacrosanct core can be justified by prevailing interests, as is the case within authorisation procedures of animal experimentation. During the approval procedure, the competent authority conducts a harm–benefit assessment to define, rate and evaluate the conflicting interests. Next, the article examines the issue of the breeding of genetically modified laboratory animals being subject to laxer requirements than other animal experiments. The projects are subject to a simplified procedure that does not include a “traditional” harm–benefit assessment. The article argues that the harm–benefit assessment is the key to a sufficient protection of laboratory animals and their dignity. Due to the purely “trailed” assessment as well as potential negligence in regard to reporting obligations regarding strains suffered by the animal, the application of the simplified procedure raises certain doubts as to whether it provides a sufficient protection of animal dignity. Moreover, it is argued that the breeding of genetically modified animals exclusively for test purposes constitutes an excessive instrumentalization of these animals. The article, therefore, weighs the instrumentalization against (human) interests, but holds that even if some prevailing interests are conceivable, the severe infringement of animal dignity cannot be justified.

Keywords: animal dignity, Swiss law, administrative procedures, animal protection, transgene animals, animal experimentation, laboratory animals

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1. Introduction

Switzerland is the only country worldwide laying down the concept of the dignity of living beings, which includes animal dignity, in its national constitution and statutory law. Although Swiss law accords dignity to all animals, the protection differs in regard to species or purpose. When it comes to animal experimentation, Swiss legislation subjects all experiments to the condition of obtaining approval. Therefore, the Animal Protection Act (AniPA)¹, in conjunction with the Animal Protection Ordinance (AniPO)², introduces two different authorisation procedures: first, as a rule, a “regular” authorisation procedure is applied when applying for a permission to perform animal experimentation. The heart of the “regular” procedure is a so-called harm–benefit analysis that serves to weigh the strain suffered by the animal in the course of an experiment against the possible benefit for human and animal health, society or the environment. Animal dignity is to be taken into account within the harm–benefit assessment as an independent criterion. Second, the simplified procedure, that only applies to the breeding of genetically modified animals using established methods³, takes animal dignity into account insofar as a (ex ante) harm–benefit assessment is conducted if there is reason to believe that the dignity of the transgenic animal is disregarded. Thus, the simplified procedure encompasses a so-called “trailed assessment” that prescribes a harm–benefit evaluation of the genetic modification only under certain circumstances. The question arises whether both procedures provide a sufficient level of protection of (transgenic) animals being used for scientific purposes.

To answer this question, the article first provides a brief overview of the concept of animal dignity in the Swiss legal system. In order to do so, it takes a glance at the constitutionally enshrined dignity of living beings (dignity of the creature) and the statutory animal dignity. In this context, the article examines whether animal dignity has a sacrosanct core. Based on this analysis, the article takes a look at the different authorisation processes of animal experimentation. The following section assesses the protection of animal dignity within the “regular” procedure. In this context, I point out that the harm–

¹ Tierschutzgesetz [Animal Protection Act; AniPA] (2010) SR 455.

² Tierschutzverordnung [Animal Protection Ordinance, AniPO] (2008) SR 455.1.

³ This article focusses only on animals modified genetically for experimental purposes. Modifications for other purposes, such as teaching or diagnostics, will be ignored. A genetically modified organism is every organism that has been altered in a way that does not occur under natural conditions by crossing or natural recombination (Art. 5 no. 2 Gentechnikgesetz; Gene Technology Act [GTA] (2009) SR 814.91).

benefit assessment is the key to a sufficient protection of the dignity of animals that are used for scientific purposes or those that are genetically modified for these purposes. Subsequently, the question arises whether the simplified procedure fails to guarantee a sufficient protection of animal dignity. Especially the fact that the simplified procedure only provides for a “trailed” assessment of dignity violations is analysed. Moreover, other risks in this regard, as the issue that the responsible person fails to comply with certain reporting obligations, will be addressed. Finally, an in-depth look will be taken at the issue whether the instrumentalization of test-tube animals is an unjustified encroachment on animal dignity. The article concludes that, in general, both licensing procedures provide sufficient protection of animal dignity, as various mechanisms and safety nets are put in place in order to prevent the disregard of animal dignity. However, the application of the simplified procedure may result in an unjustified excessive instrumentalization of transgenic animals being used for subsequent test purposes. The article, finally, presents an approach to a solution.

2. The concept of animal dignity in Swiss law

In the course of a constitutional amendment in 1992, the dignity of (non-human) living beings (*Würde der Kreatur*) was introduced into the Swiss Federal Constitution (Cst.).⁴ Art. 120 para. 1 Cst. (formerly Art. 24^{novies}) lays down that human beings and their environment shall be protected against any misuse of gene technology. For this purpose, the provision empowers (and obligates) the Swiss Confederation to adopt provisions about the use of reproductive and genetic material derived from animals, plants or other organisms, taking into consideration the dignity of living beings. Art. 120 para. 2 Cst. complements this mandate with an institutional guarantee of the protection of the dignity of (non-human) creatures.⁵ In fact, the Confederation shall be guided by this principle at all times within Swiss jurisdiction.⁶ However, the dignity of the creature is a relative principle, as the legislator may adopt restrictive

⁴ Art. 120 para. 2 Cst. [Bundesverfassung; Constitution, Cst.] (2009) SR 101.

⁵ Decision of the Federal Supreme Court (BGE) 135 II 384, 403 E. 4.6.1.; 135 II 405, 414 f. E. 4.3.4; BGer 2C_958/2014, E. 5.1.

⁶ Bernhard Waldmann, ‘Art. 120 Cst.’ in Bernhard Waldmann, Eva M Belser and Astrid Epiney (eds), *Schweizerische Bundesverfassung* (Basler Kommentar, 1st ed. Helbing & Lichtenhahn 2015), at 1929.

measures in order to protect other (preponderant) interests and rights.⁷ The Confederation enjoys considerable leeway with regard to implementation.⁸

Considering its fate as a rather vague constitutional concept, the dignity of the creature still needs – 25 years after its introduction – further clarification.⁹ Case law and legal scholars agree that the dignity of the creature introduces a legally acknowledged inherent value of animals, plants and other (non-human) organisms, which is permanent and not transitory.¹⁰ The scope of Art. 120 para. 2 Cst. encompasses exclusively individual creatures, which possess a value of their own as well as an ability to pursue individual objectives. They are to be treated with diligence, care and moderation by the human dealing with them.¹¹ However, the degree of protection may differ depending on the creature's evolutionary development.

With this constitutional amendment, the pathocentrism that had prevailed until then, according to which all animals are to be protected for their own sake if they are sentient beings, has been extended to a restrictive biocentrism in which animals (and plants as well as other organisms to a certain extent) have an inherent dignity and value, which can be benefited and harmed, regardless of their sentience.¹²

Animal dignity

In line with its legislative mandate, the Confederation revised the AniPA and the AniPO in 2008. Art. 1 AniPA defines as its main purpose the protection of the well-being and the dignity of the animal. Animal dignity, which is derived from the concept of the dignity of the creature, has become a guiding principle

⁷ Federal Food Safety and Veterinary Office, 'Dignity of the animal: Explanatory notes on the 'weighing of interest'' (1 May 2017), at 2; Waldmann (n 6), at 1929.

⁸ Providing detailed information to Art. 120 Cst. *ibid*; Gieri Bolliger, *Animal dignity protection in Swiss law: Status quo and future perspectives* (Schriften zum Tier im Recht volume 15, Schulthess 2016), at 36.

⁹ Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments, 'The dignity of animals' (Berne 2008) <http://www.ekah.admin.ch/fileadmin/_migrated/content_uploads/e-Broschüre-Würde-Tiere-2001.pdf>; Stefanie Schindler, 'The animal's dignity in Swiss Animal Welfare Legislation – challenges and opportunities' (2013) 84 (2) *European journal of pharmaceutics and biopharmaceutics*, 251; Christoph Errass, '20 Jahre Würde der Kreatur' (2013) 149 *ZBJV* 187, 202 *et seq.*

¹⁰ Christoph Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (Stämpfli 2006) at 79; Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9).

¹¹ Margot Michel and Eveline Schneider Kayasseh, 'The Legal Situation of Animals in Switzerland: Two Steps forward, One step back - Many Steps to go' (2012) VII *Journal of Animal Law* 1, 4 *et seq.*

¹² Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9), at 10; Administrative Court Zurich, decision of 5th April 2017, VB.2016.00048, at 61 E. 9.5.2.; Errass, '20 Jahre Würde der Kreatur' (n 9), at 205 *et seq.* (providing further references).

of Swiss animal welfare legislation.¹³ The term, as employed in the statute, is defined in its Art. 3 lit. a as the inherent value of each animal which is to be respected while dealing with the animal. Its dignity is disregarded if pain, suffering, anxiety or harm is inflicted on the animal, if it is made subject to humiliation or debasement, if it suffers major interference with its phenotype or abilities, or in the case of excessive instrumentalization. Such violations can be justified by prevailing public interests. As a result, the animal welfare legislation attributes an intrinsic value to each individual animal regardless of its having been born naturally or as the result of a scientific experiment. The animal is to be protected for its own sake, not merely for its use by human beings.¹⁴

The sacrosanct core of the dignity of the creature

As the Swiss Constitution does not specify the normative content of the concept of dignity of the creature, human dignity (Art. 7 Cst.) may act as a reference value to determine its meaning, since both the concepts are alike in many ways, as well as being dogmatically and terminologically comparable.¹⁵ The dignity of the creature, including animal dignity, is not an individual right but an obligation for humans to respect and protect living beings. Nevertheless, it shall not be interpreted in a way fundamentally different from human dignity, but regarded and valued similarly.¹⁶ According to the Swiss Federal Supreme Court, the values as protected in the constitution are comparable, but not identical.¹⁷

It is widely acknowledged that human dignity has a sacrosanct core.¹⁸ Yet, the core has not been conclusively defined. The idea is to guarantee the treatment of humans as subjects and sentient beings with a self-inherent value. Considering the absolute level of protection of the human dignity, a violation

¹³ Bolliger, *Animal dignity protection in Swiss law* (n 8), *passim*.

¹⁴ Margot Michel, 'Die Würde der Kreatur und die Würde des Tieres im schweizerischen Recht: Eine Standortbestimmung anlässlich der bundesgerichtlichen Rechtsprechung' (2012) NuR 102, 104; decision of the Federal Supreme Court 135 II 384, 403 E. 4.6.1.; 135 II 405, 414 f. E. 4.3.4.

¹⁵ Decision of the Federal Supreme Court 135 II 384, 403 E. 4.6.1., 135 II 405, 414 f. E. 4.3.4, 2C_958/2014, E. 5.1.; Praetorius Ina and Peter Saladin, 'Die Würde der Kreatur (Art. 25 novies Abs. 3 BV)' (Berne 1996). For information to human dignity see Eva M Belser and Eva Molinari, 'Art. 7 Cst.' in Bernhard Waldmann, Eva M Belser and Astrid Epiney (eds), *Schweizerische Bundesverfassung* (Basler Kommentar, 1st ed. Helbing & Lichtenhahn 2015).

¹⁶ Ulrich Häfelin and others, *Schweizerisches Bundesstaatsrecht* (9th ed. Schulthess 2016), at 28 *et seq.*; Gotthard M Teutsch, *Die "Würde der Kreatur": Erläuterungen zu einem neuen Verfassungsbegriff am Beispiel des Tieres* (P. Haupt 1995).

¹⁷ Decision of the Federal Supreme Court (BGE) 135 II 384, 403 E. 4.6.1.; 135 II 405, 414 f. E. 4.3.4.

¹⁸ See for instance Thomas Fleiner-Gerster, Alexander Misic and Nicole Töpferwien, *Swiss constitutional law* (Kluwer Law International 2012), at 214.

of human dignity is simultaneously a violation of its core content.¹⁹ As the dignity of the creature admittedly does not have the same weight as human dignity within the Swiss society and legal system, it is still under debate whether it has a sacrosanct core as well.²⁰ In consideration of the legislative principle that requires uniform interpretations of the same terminology, the Federal Supreme Court's case law as well as the alleged intention of the Swiss legislator not to formulate animal dignity as a paper tiger,²¹ a core content of the dignity of the creature can be assumed. This signifies that both dignities share a common or at least similar core content, which lies in the specific intrinsic value of all human and non-human living beings and their integrity.²² In conformity with human dignity, the core content of the dignity of the creature comprises, therefore, the prohibition of highly cruel treatments or killing methods, the denial of an animal's essential natural needs as well as exclusive instrumentalization.²³ An infringement of this core cannot be justified under any circumstances. From my point of view there is no human interest conceivable that might justify such a severe violation of the intrinsic value and integrity of a creature. An infringement of the dignity of the creature, that does not affect its core, can, however, be justified.²⁴ Therefore, the sacrosanct core is to be interpreted rather restrictively and thus only highly cruel treatments or killing methods, the denial of an animal's essential natural needs as well as exclusive instrumentalization cannot be justified by predominant interests.

3. The different authorisation procedures of animal experimentation

The carrying out of an animal experiment requires, without exception, a permission of the responsible cantonal authority (Art. 18 para. 1 AniPA). Therefore, every animal experiment is subject to an authorisation procedure. Arts. 17 ss. AniPA in conjunction with Arts. 139–142 AniPO entail the major details of animal experimentation law in general, as well as the authorisation procedures that the

¹⁹ *ibid.*, at 215; Gieri Bolliger, 'Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives' (2016) 22 *Animal Law* 311, 329 *et seq.* (providing further references).

²⁰ *ibid.*, 329.

²¹ Peter Kunzmann, 'Die "Würde des Tieres" - Grund oder Gegenstand einer Güterabwägung' (2011) *TIERethik* 56; Federal Council, 'Erläuterung zur Revision der Tierschutzverordnung'

<<https://www.admin.ch/ch/d/gg/pc/documents/1337/Bericht.pdf>> (accessed 15.12.2017).

²² Nils Stohner, *Importrestriktionen aus Gründen des Tier- und Artenschutzes im Recht der WTO: Dargestellt namentlich am Beispiel des Pelzhandels unter besonderer Berücksichtigung der Ausnahmebestimmung von Art. XX lit. a GATT sowie des schweizerischen Verfassungsgrundsatzes der Würde der Kreatur* (Abhandlungen zum schweizerischen Recht, Stämpfli 2006), at 121, 129 *et seq.* (providing further references).

²³ *ibid.*

²⁴ Cf. Art. 36 Cst.

researcher needs to go through prior to the performance of an animal experiment in detail. The detailed requirements may vary depending on the purpose and method of the experiment. The AniPO distinguishes between a regular procedure which applies to all projects intending to use laboratory animals, and the (less restrictive) simplified procedure that applies to the breeding of transgenic animals when using established methods.

The “regular” procedure is outlined in Chapter 6, Section 5 AniPO, which lays down the legal requirements according to which the cantonal authority decides on the approval of an animal experiment. The applicant must outline especially the anticipated benefits of the test and the severity of the strain the used animal is expected to suffer as the result of the experiment.²⁵ Thus, the researcher should explain the need for the experiment, the number and kind of laboratory animals required, the expected degree of severity and the anticipated outcome. The application should also establish the fulfilment of the requirements on the keeping and personal handling of laboratory animals.²⁶ The competent authority examines the application on a case-by-case basis and – provided that all the requirements are met – issues a license. The authority will, thus, have to conclude that the expected benefit overrides the strain on the animal and/or the violation of its dignity. The degree of severity is determined in accordance with the categories laid down in Arts. 24, 25 AniEO²⁷. Art. 137 AniPO provides criteria assisting in weighing harm and benefit. The provision stipulates that distressful animal experiments must be restricted to what is indispensable for the carrying out of the experiment. Criteria for determining the indispensability of a test are laid down in the provision. In general, an animal experiment shall not be approved if the harm–benefit analysis turns out to be to the disproportionate disadvantage of the animal’s well-being or dignity (Art. 140 Abs. 1 lit. b AniPO).

A variety of bodies is involved in the authorisation process. Next to the cantonal veterinary offices, cantonal commissions on animal experimentation examine every application of a distressful animal test

²⁵ Cf. information of the Federal Food Safety and Veterinary Office, ‘Application and Authorisation’, <<https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/antrag-bewilligung-tv.html#-589213524>> (accessed 05.03.2018).

²⁶ FSVO, *ibid.*

²⁷ Tierversuchsverordnung [Animal Experimentation Ordinance, AniEO] (2010) SR 455.163.

and provide a recommendation to the cantonal authorities (Art. 18 para. 3 AniPA; Art. 139 para. 4 AniPO).²⁸

Art. 11 para. 4 AniPA allows for the Federal Council to adopt exceptions or simplifications to the regular authorisation procedure when the breeding of genetically modified animals is concerned and the methods being used do not cause the animal any pain, suffering, harm or behavioural disorders (“established methods”). Moreover, animal dignity must be sufficiently respected and protected. All other methods of breeding transgenic animals qualify as regular animal experiment, subject to the regular procedure. The Federal Council made use of Art. 11 para. 4 AniPA by adopting a simplified procedure in Art. 142 AniPO. The provision introduces a procedure for the breeding of transgenic animals using an established method.²⁹ The procedure is governed by the provisions of the authorisation of husbandry of laboratory animals, “regular” breeding and trade with animals (Arts. 122, Art. 142 para. 3 AniPO). The provisions concerning distressful animal testing (Art. 136 AniPO), the criteria on the evaluation of the extent of indispensability (Art. 137 AniPO) and the procedural provisions for animal experiments (Arts. 139, 140 AniPO) do not apply. To qualify for the simplified procedure, the genetically modified animal must be bred using an established method (Art. 142 para. 1 lit. a AniPO). The Federal Food Safety and Veterinary Office defines the different methods in Art. 9 para. 1 and Annex 1 AniEO, which provide an exhaustive list of methods that are currently acknowledged as being “established”. These methods are frequently used within the praxis and are – compared to other methods – “animal friendly”. Furthermore, the method must be carried out using a standard protocol (Art. 9 para. 3) and be performed in an “animal friendly” way. Art. 142 para. 2 AniPO lays down certain further requirements of which the applicant needs to prove compliance with.

4. Protection of animal dignity within the regular procedure

The next sections examine if and to what extent the regular procedure provides for sufficient respect and protection of animal dignity. This sets the benchmark for the protection of animal dignity within the simplified procedure. I will argue that the key to an effective protection of animal dignity within the

²⁸ Arts. 148, 149 AniPO; Isabelle Häner, Gieri Bolliger and Antoine F Goetschel, *Geheimhaltungspflicht von Mitgliedern der Tierversuchskommissionen: (namentlich im Kanton Zürich)* (Schriften zum Tier im Recht volume 5, Schulthess 2011) discusses the role of the cantonal commission on animal experimentation within the Canton Zurich.

²⁹ Federal Council (n 21) (accessed 15.12.2017), at 53.

“regular” authorisation procedure lies in the harm–benefit assessment. I will also demonstrate that the consideration of animal dignity is a distinct criterion and independent of the harm–benefit assessment.

The harm–benefit evaluation

As outlined above, animal dignity is not an absolute concept. On this basis, the Swiss legal system does not prohibit animal experimentation in principle. However, there is no “right to animal experimentation” either. Instead, if the use of an animal conflicts with animal dignity, the conflicting interests need to be weighed. There, the violation of animal dignity has to be justified in order to go through with the experimentation. The definition in Art. 3 lit. a AniPA determines various violations of animal dignity. Such a violation does not have to cause physical injury to the animal, but the act must include certain types of activities affecting the animal, even if the animal itself does not perceive them as harmful.³⁰ If society’s interest is not apt to justify the particular violation, animal dignity is “impermissibly disregarded”.³¹

In this context, permitting an animal experiment is subject to a case-by-case assessment, in which the use of an animal for experimental purposes causing pain, suffering, harm or distress for the animal needs to be weighed against the expected outcome of the project. The cantonal veterinary office in cooperation with the cantonal commission for animal experiments perform this harm–benefit assessment within the licensing procedure (Art. 19 para. 4 AniPA; Art. 140 para. 1 lit. b AniPO).³² In the evaluation, first, the conflicting interests are determined, evaluated and rated. Then, they are weighed against each other.³³ If the infliction of pain, suffering, damage or anxiety weighs more than the expected interests, benefits and objectives, the authority declines the license.³⁴ To arrive at a well-founded (moral) decision, the authority

³⁰ Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9), at 8; Bolliger, ‘Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives’ (n 19), 338.

³¹ *ibid*, at 345; Samuel Camenzind, ‘Auf zu neuen Ufern: Rechtsphilosophische Überlegungen zur übermässigen Instrumentalisierung im schweizerischen Tierschutzgesetz’ in Margot Michel (ed), *Animal Law: Developments and perspectives in the 21st century = Tier und Recht ; Entwicklungen und Perspektiven im 21. Jahrhundert* (BWV Berliner Wiss.-Verl. 2012), at 186.

³² Ethikkommission für Tierversuche der Akademien der Wissenschaften Schweiz, ‘Ethische Grundsätze und Richtlinien für Tierversuche’ (2005); Katharina Friedli, ‘The Dignity of the Nibble Fish - Weighing the Benefits’ (2014) Animal Welfare Report 2014 21; Franz P Gruber, ‘Güterabwägung aus der Sicht des Tierschutzes’ in *Animalfree Research* (ed), *Gesundheit und Tierschutz - Güterabwägung bei Tierversuchen* (2008); Andrew Knight, *The costs and benefits of animal experiments* (2011), *passim*.

³³ Federal Food Safety and Veterinary Office, ‘Dignity of the animal’ (n 7).

³⁴ Cf. Art. 19 para. 4 AniPA; Bolliger, ‘Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives’ (n 19), at 347.

gathers additional empirical information, e.g. the number and kind of animals being involved, the amount of animals being killed and the intervention in their well-being. During the assessment, the authority pays further attention to the principle of proportionality.³⁵ This means that the infringement needs to be suitable and necessary for achieving the intended aim as well as proportional to the aim.³⁶ As a rule, “the more serious an interference in the dignity of animals and the more trivial, or even unnecessary, it is in terms of human interest, the more critically it must be evaluated. Conversely, however, the more negligible an intervention is for the affected animals and the more necessary it is in the interest of other living creatures, the more it must be considered tolerable.”³⁷ In other words, the more severe the strain is, the more restrictive are the licensing conditions.³⁸

The competent authority faces a major difficulty in carrying out the evaluation: the weighing of the contrary interests requires a moral judgement taking into account scientific considerations, which means that the assessment needs to be normative, not empirical. In other words, the decision concerns the way something should be, not the way it is.³⁹ Thus, the authority’s balancing is not based on quantifiable criteria, but on expectations and presumptions of the impact of the animal experiment on the particular animal and the expected benefit on humans, society or the environment. This leads to a significant degree of discretion on the part of the authority conducting the assessment. The uncertainty is amplified by the fact that neither the AniPA nor the AniPO specify the requirements of the assessment in general or the inclusion of the concept of animal dignity in particular. Even though Arts. 139–140 AniPO contain some requirements to be included in the decision-making process, in practice, the assessment is in large parts assigned to the competent authority.⁴⁰

³⁵ See in detail Friedli (n 32), at 22; Federal Food Safety and Veterinary Office, ‘Dignity of the animal’ (n 7), at 7 *et seq.*

³⁶ This well-known and acknowledged legal principle of Swiss administration law is guaranteed in Arts. 5 para 2 and 36 para. 3 Cst. See especially Fleiner-Gerster, Mistic and Töpperwien (n 18) (providing further references), at 231 *et seq.*; Thomas Fleiner, ‘Cantonal and Federal Administrative Law in Switzerland’ in F. Dessemontet and T. Ansay (eds), *Introduction to Swiss law* (2nd ed. Kluwer Law International 1995);

³⁷ Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9), at 8.

³⁸ *ibid.*, at 2 *et seq.*

³⁹ Vanessa Gerritsen, ‘Evaluation Process for Animal Experiment Applications in Switzerland’ (2015) ALTEX Proceedings 37, at 40.

⁴⁰ *ibid.*

Animal dignity as criterion in the harm–benefit assessment

The harm–benefit assessment allows the legislator and the authorities to apply animal dignity in practice.⁴¹ Yet, at the same time, the animal welfare legislation is silent on whether and how to include animal dignity into the assessment.⁴² However, the applicable provisions indicate that animal dignity is an additional assessment criterion within the harm–benefit ratio, which the competent authority always has to take into account when evaluating an application for a permission to perform animal experimentation.

Art. 1 AniPA identifies the act’s purpose as the protection of the animal’s well-being and its dignity. The nature and general scheme of the AniPA obliges the authority to respect and protect animal dignity in all areas regulated by the AniPA, including the licensing process of animal experiments (Art. 18 para. 1 AniPA). Hence, animal dignity has to be taken into account by the competent authority when conducting a harm–benefit assessment (Art. 19 para. 4 AniPA).

As was said already, animal dignity protects the inherent value of the animal from any kind of physical as well as psychological harm.⁴³ The harm–benefit ratio requires, however, for the harm to exceed a certain degree of severity (cf. Art. 24, 15 AniEO). A purely psychological constraint or an activity that the animal might not even perceive as harmful (e.g. humiliation or instrumentalization) is not sufficient in order to outbalance the benefits when evaluating the (potential) harm of an animal experiment.⁴⁴ Thus, the dignity is not included sufficiently in the harm–benefit assessment. In consequence, and to give practical effect to the dignity of the individual animal within the harm–benefit assessment, it must be considered as an additional (independent) criterion within the assessment, which stands equally alongside the strains inflicted on the animal and the expected outcome. This approach ensures that animal dignity is integrated within the harm–benefit assessment, especially when the infringement consists of a non-

⁴¹ Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9).

⁴² This discussion is still not completely resolved. The Swiss Academies of Art and Sciences advocate that the dignity itself is not part of the harm–benefit assessment, but the reason for the evaluation. A more differentiated view takes Kunzmann (n 21), at 56 *et seq.*

⁴³ *ibid.*, at 56 *et seq.*

⁴⁴ Kunzmann (n 21); Klaus P Rippe, ‘Güterabwägung im Tierversuchsbereich: Anmerkung zu einem ethischen Paradigmenwechsel’ (2009) ALTEXethik 1.

physiological harm. In this regard, the harm–benefit assessment is the key factor regarding the sufficient respect and protection of animal dignity within the authorisation procedure.

5. Protection of animal dignity within the simplified procedure

The simplified procedure is free from a “traditional” harm–benefit ratio, but obligates the regulator to perform an “abstract harm–benefit assessment” of the established methods. In the simplified procedure, the Federal Food Safety and Veterinary Office weighs the strain inflicted on the animal against the benefit in advance of the actual application. The regulator, therefore, assumes that these procedures and their implications on the animal have been sufficiently reviewed and examined, which, as a result, means that there is no need for further assessment – in contrast to the full-fledged harm–benefit evaluation mentioned above.⁴⁵ Hence, the methods in Annex 1 AniEO are not subject to another evaluation during the authorisation procedure.⁴⁶ The abstract harm–benefit assessment supplants a case-by-case evaluation in context of the regular procedure. Additionally, the applicant is obliged to ensure that the breeding of a transgenic animal does not follow an illegitimate purpose or disregards animal dignity (Art. 142 para. 2 lit. b AniPO).

The authority is, however, obliged to conduct a so-called “trailed assessment” (“*nachgezogene Güterabwägung*”)⁴⁷ in case the producer reports strains on the animal during the breeding. Art. 12 AniPA stipulates reporting obligations, namely that the head of the breeding facility frequently controls whether the modification or the breeding procedure cause pain, suffering, harm or anxiety or any other violation of animal dignity (“record of constraint”⁴⁸; *Belastungserfassung*; Art. 124 AniPO).⁴⁹ The different strains

⁴⁵ This is implied by Hermann Geissbühler, ‘Die Kriterien der Würde der Kreatur und der Menschenwürde in der Gesetzgebung zur Gentechnologie – Eine Übersicht über Grundsatzprobleme: Mit besonderer Berücksichtigung der Gen-Lex-Vorlage’ (2001) 137 ZBJV 229, at 247 *et seq.*

⁴⁶ Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (n 10), at 146 *et seq.*, Errass, ‘20 Jahre Würde der Kreatur’ (n 9), at 220.

⁴⁷ Federal Council (n 21), at 53.

⁴⁸ The Swiss legislator has translated the term “*Belastung*” as “constraint” rather than “burden”. This emphasises the different kinds of infringements of the animal’s well-being. Laboratory animals can suffer both physical and psychological harms (e.g. humiliation, instrumentalization), whereas the animal may not even discern the harm. In other words, it is of no relevance whether the animal realises the infringement of its dignity or well-being, but that an objective third party (e.g. the administration) considers it as a “*Belastung*” inflicted on the animal. Therefore, the term constraint (“*Belastung*”) requires an active participation in the infliction of harm on the animal by the human user. The legislator has chosen this broad translation in order to guarantee an extensive interpretation of the constraint. Cf. Federal Council (n 24), at 53 s.

⁴⁹ The record of constraint encompasses genetically modified animal lines as well as strained mutants. In the interest of simplification, the following sections refer to genetically modified or transgenic animals. The provisions addressed apply to both categories equally.

which need to be considered during this monitoring arise from Art. 3 lit a AniPA.⁵⁰ If the outcome of the record of constraint demonstrates a violation of animal dignity, the head of the facility is obliged to report the results to the competent cantonal authority, where he or she presents all information defined in Art. 126 para. 2 AniPO in order to initiate a trailed harm–benefit assessment. The provisions of the AniPO and AniEO define the details of the procedure.⁵¹ Based on this information the competent authority reviews the indispensability of the breeding and modification according to Art. 137 AniPO and conducts an ex ante harm–benefit evaluation.⁵² The competent authority thereupon transfers the matter to the cantonal commission for animal experimentation, which weighs the constraint against the benefit for research, therapy and diagnostics. Thereby, the commission gives special credit to the future purpose of the transgenic animal. Should the breeding be associated with strains amounting to the highest degree of severity, it needs to be closely evaluated whether the transgenic animal is suitable to be subject to (stressful) experiments afterwards.⁵³ However, the animal’s suffering during the different procedures cannot be accumulated.⁵⁴ The basic principle applies: the more severe the strain, the more restrictive the licensing conditions. At the end of the procedure the authority issues a decision, in which it defines the conditions for further breeding (Art. 127 AniPO). Although the animal welfare legislation does not explicitly provide for the duty to suspend further breeding during the ex ante assessment, it can be presumed that the breeding is on hold during the decision-making, as the competent authority has not yet issued a permission to breed transgenic animals that inflict (unexpected) strains on the animal. General principles of Swiss administrative law entail that the facility is not entitled to breed these animals until receiving a modified permission.⁵⁵ Regardless, it seems *de facto* unlikely that a facility would continue breeding transgenic animals if it is unclear whether it receives an approval, considering the very high costs of breeding transgenic animals.⁵⁶

⁵⁰ As a reminder, Art. 3 AniPA defines strain as pain, suffering or harm, anxiety or humiliation as well as major interference with the animal’s appearance or abilities and excessive instrumentalization.

⁵¹ Cf. Art. 12 para. 3 AniPA.

⁵² Art. 127 AniPO.

⁵³ Federal Council (n 21), at 53.

⁵⁴ Federal Food Safety and Veterinary Office, ‘Dignity of the animal’ (n 7), at 8. The Federal Food Safety and Veterinary Office clarifies that different strains cannot “add up to a total”.

⁵⁵ Ulrich Häfelin, Georg Müller and Felix Uhlmann, *Allgemeines Verwaltungsrecht* (5th ed. Schulthess; Dike 2006), at 348 *et seq.*

⁵⁶ Peter Krepper, ‘Tierwürde im Recht - am Beispiel von Tierversuchen’ (2010) AJP 303.

The following sections examine to what extent the simplified authorisation procedure effectively takes the protection of animal dignity into account, when transgenic animals bred for test purposes are concerned. I will first focus on the impact of non-physical violations of animal dignity and then discuss the risk of misuse of the reporting obligations within the simplified procedure.

Non-physical infringements of animal dignity

According to the preparatory works to the AniPO, every genetic modification – regardless of the method being used or its severity – infringes animal dignity.⁵⁷ Yet, under certain circumstances animal dignity can be restricted to protect prevalent public interests, as long as the activity does not encroach on its sacrosanct core.⁵⁸

The trailed assessment is initiated if the record of constraint displays “reasonable suspicion” that the strains on the animal exceed a certain degree of severity.⁵⁹ The severity inherently relates to physical harm and suffering. If a genetic modification entails no or only slight strains, there is no reporting obligation and subsequently no obligation to conduct a trailed assessment.⁶⁰ It appears, thus, that a genetic modification caused by the use of an established method needs to exceed a certain degree of severity in order to disregard animal dignity and, therefore, to initiate the assessment.

As a side note, the dignity of the used carriers – in other words the parent animals – is also subject to monitoring. The infringement of these animals’ dignity is “tolerated” until the first record of constraint is conducted. In contrast to the regular procedure, in which all potential infringements are considered before the license is issued by the competent authority, the simplified procedure in conjunction with the

⁵⁷ Federal Council (n 21), at 53.

⁵⁸ Praetorius Ina and Saladin (n 15), at 44; Margot Michel, ‘Instrumentalisierung und Würde der Kreatur - eine Annäherung an ein grundlegendes Verhältnis aus juristischer Sicht’ in Christoph Ammann and others (eds), *Würde der Kreatur: Ethische und rechtliche Beiträge zu einem umstrittenen Konzept* (Schulthess 2015), 265; Bolliger, ‘Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives’ (n 19), at 345 (providing further references).

⁵⁹ Cf. Arts. 124, 127 AniPO, Art. 25 AniEO; Regina Binder, ‘Würde erster und zweiter Klasse? : Überlegungen zur Forderung nach Anerkennung der Würde aus tierschutzrechtlicher Sicht’ (2011) 3 TIERethik 32, at 32 *et seq.*

⁶⁰ Federal Council (n 21), at 53; Federal Food Safety and Veterinary Office, ‘Explanatory notes on the data sheet’ (2016) <<https://www.blv.admin.ch/dam/blv/en/dokumente/tiere/publikationen-und-forschung/tierversuche/datenblatt-tv-erlaeuterungen.pdf.download.pdf/Explanatory%20notes%20on%20the%20data%20sheet.pdf>> (accessed 15.12.2017); cf. <https://www.blv.admin.ch/dam/blv/en/dokumente/tiere/publikationen-und-forschung/tierversuche/gm-data-sheet.doc.download.doc/GM-Data%20sheet%20EN_V1-0.doc/> (accessed 05.03.2018).

reporting obligation establishes a system in which constraints are assumed to be justified, as the animals are treated in an “animal friendly” way by using an established method that was safeguarded by the abstract evaluation.

The simplified procedure focuses exclusively on established methods to ascertain that only “animal friendly” methods are excluded from the regular procedure.⁶¹ Since the legislator has already carried out the abstract harm–benefit evaluation beforehand, it can be assumed that sufficient checks have been made as to whether the intended method and following use encroaches on the core content of animal dignity or not. By including the method in question into Annex 1 AniEO, the regulator assumes that the method does not affect the core content, which makes “another” weighing necessary solely in case “reasonable suspicions” arise that animal dignity, including its core, is unjustifiably infringed.⁶² As the abstract harm–benefit assessment is closely associated with the evaluation conducted during the “regular” procedure, I presume that animal dignity constitutes an indispensable aspect within the abstract assessment, too. Thus, the regulator and the competent authority ensure that non-physical violations of animal dignity are adequately taken into account. There seems to be no need for another assessment when the infringement does not exceed a certain degree of severity. On this basis, I conclude that sufficient protection of animal dignity is ensured within the simplified procedure.

Risk of misuse of the procedure

As was said, the record of constraint results in reporting obligations: the Federal Food Safety and Veterinary Office commits the manager of the breeding facility to analyse constraints inflicted upon the animal and to report burdened lines and mutants within two weeks after the determination of the strains to the competent authority, but at the latest when reported on five animals.⁶³ The final notification of strains must be made at the latest when 100 animals have been inspected (Arts. 14, 18 AniEO). In case no constraints appear, Art. 145 para. 1 lit. b AniPO stipulates an annual submission of information regarding the transgenic animals being bred and subsequently used for animal experimentation. The

⁶¹ See *supra*.

⁶² Federal Council (n 21), at 54.

⁶³ Cf. Arts. 126, 145 AniPO; Federal Food Safety and Veterinary Office, Announcement of constraint observed in animal lines (Form-M and data sheet), <<https://www.blv.admin.ch/dam/blv/en/dokumente/tiere/publikationen-und-forschung/tierversuche/fachinformation-form-m-datenblatt.pdf.download.pdf/Technical%20information%20-%20Form-M%20and%20data%20sheet.pdf>> (accessed 15.12.2017).

responsible person provides data about the number of animals, genetic modifications and subsequent use of the transgenic animals.

A certain risk arises that the manager of the breeding facility does not submit the record of constraint to avoid the trailed assessment and therefore bureaucratic efforts and production costs. However, the AniPO introduces some safety nets in this regard. First, when applying for a permit for an animal experiment the applicant needs to provide the data on the record of constraint, regardless of the fact whether constraints have actually been monitored. If not provided, the licence will not be issued.⁶⁴ Second, Art. 124 para. 3 AniPO obliges the head of the breeding facility to perform an annual animal inventory control, including the documentation of the number of animals being born and their potential strains, and provide the data upon request to the competent authority (Art. 143 para. 3 AniPO). Finally, the competent cantonal authority inspects the breeding facilities at least once a year. It is, however, free to carry out more inspections if considered necessary (Art. 216 para. 1 AniPO). As a rule, these inspections occur unannounced and entail the control of the compliance with the conditions possibly attached to the authorisation, the condition of the animals and the infrastructure, the personnel requirements, the inspection of livestock numbers and the data on the burden on genetically modified animals or lines (Art. 216 para. 2 AniPO). Furthermore, the cantonal authority annually inspects the performance of animal experiments of at least one fifth of the current permits (Art. 216 para. 3, 4 AniPO). The selection is made according to the extent of the burden on the animals, the number of animals and the technical complexity of the tests.

In conclusion, the risk of misuse is not to be underestimated, but there are a number of measures to mitigate it.

6. The instrumentalization of test-tube animals

Test-tube animals that are bred for a subsequent scientific use solely serve as laboratory test subjects and are “disposed” of if they do not exhibit the demanded features. This leads to the impression that the breeding of these animals qualifies as excessive or even exclusive instrumentalization. While Art. 3 lit. a AniPA prohibits any kind of excessive unjustified instrumentalization of animals, this article claims

⁶⁴ Art. 124 AniPO, Art. 23 para. 2 AniEO.

that exclusive instrumentalization is an encroachment on the sacrosanct core of animal dignity and thus never justifiable (cf. Art. 120 Cst.).⁶⁵ In case animals are genetically modified and bred solely for experimental purposes, one has to ask: is this activity to be classified as exclusive or excessive instrumentalization? Is this instrumentalization justified? I argue that the breeding and the modification of the animal's phenotype falls under the scope of excessive instrumentalization, which, however, cannot be justified by prevailing interests.

An impermissible infringement of animal dignity?

Excessive instrumentalization is constituted by every type of conduct aiming to use an animal solely as a "tool" without giving consideration to its interests or its physical and mental needs.⁶⁶ Such an animal's only purpose is to serve human interests; it is therefore objectified.⁶⁷ The exact threshold has not yet been exhaustively determined, since humans instrumentalize animals in various ways of varying severity (food, research, clothes etc).⁶⁸ However, an instance of exclusive instrumentalization is at hand when the animal is no longer seen as an independent living being with an inherent and intrinsic value, but only as a tool for human purposes.⁶⁹ Distinguishing between exclusive and excessive instrumentalization proves to be rather difficult. Art. 142 para. 1 lit. b AniPO emphasises that under the simplified procedure a license shall only be issued if animal dignity is respected. This means that the applicant at least has to consider the animal's inherent value and its dignity when breeding a genetically modified animal for test purposes using established methods. During its inspections, the competent authority monitors whether animal dignity is respected and protected. As the intrinsic value is an indispensable criterion of both the simplified as well as the regular procedure, the breeding of test-tube animals for experimental purposes is more aptly described as an instance of excessive than as of exclusive instrumentalization.

⁶⁵ See *supra*; Bolliger, 'Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives' (n 19), at 338 *et seq.*

⁶⁶ *ibid* (providing further references); Michel and Schneider Kayasseh (n 11), at 12 *et seq.*

⁶⁷ Camenzind (n 31), at 190; Michel, 'Instrumentalisierung und Würde der Kreatur - eine Annäherung an ein grundlegendes Verhältnis aus juristischer Sicht' (n 57), at 256; Philipp Balzer, Klaus P Rippe and Peter Schaber, *Menschenwürde vs. Würde der Kreatur: Begriffsbestimmung, Gentechnik, Ethikkommissionen* (Alber-Reihe Philosophie, K. Alber 1998), at 48.

⁶⁸ Cf. Bolliger, 'Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives' (n 19), at 342.

⁶⁹ *ibid*, at 341; Michel, 'Instrumentalisierung und Würde der Kreatur - eine Annäherung an ein grundlegendes Verhältnis aus juristischer Sicht' (n 57). Camenzind (n 31), at 191; Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9).

Justification of the instrumentalization

The Gene Technology Act (GTA), whose purpose is the protection of human beings, animals and the environment from abuses of gene technology, provides some insight regarding how acts that infringe upon transgenic animal dignity can be justified.⁷⁰ According to the preparatory works of the AniPA and the AniPO, provisions of the GTA, especially Arts. 8 and 9, complement the animal welfare legislation when animals are subjected to genetic modifications; this is due to the topical overlap of these provisions.⁷¹ Both the animal welfare legislation and the GTA apply in case of the application of breeding transgenic animals using established methods and, subsequently, when undergoing the simplified procedure. Whereas the AniPA and the AniPO lack precise directions on how to weigh the harms and benefits, Arts. 8 and 9 GTA provide a detailed framework of the substantive legal requirements regarding the aspects which are to be taken into account.⁷² Taken together, animal welfare legislation and the GTA provide almost complete directions on how to evaluate the excessive instrumentalization in the matter at hand.

Human and animal health as well as increasing knowledge as prevailing interests

Art. 8 para. 2 GTA provides a non-exhaustive list of overriding interests that may justify an act violating animal dignity: (a) human and animal health, (b) food security, (c) reduction of harm caused to the environment, (d) preservation and improvement of environmental conditions, (e) securing a substantial economic, social or environmental benefit for society, and (f) increasing knowledge. The violation of animal dignity must be directly justified by a prevailing interest.⁷³ An indirect or even collateral relevance is not sufficient; the excessive instrumentalization of the animal has to contribute directly to furthering the interest.⁷⁴ When breeding transgenic animals, the phenotype is genetically modified in order to breed suitable “models” for certain experiments. The breeder, as a rule, expects a certain outcome that can only

⁷⁰ Federal Council (n 21), at 51, 53; Federal Food Safety and Veterinary Office, ‘Dignity of the animal’ (n 7), at 5.

⁷¹ Art. 9 GTA states that genetically modified vertebrates may only be produced for purposes of research, therapy or diagnostics in human or veterinary medicine. If they are produced for any other purpose their dignity is not respected. This violation cannot be justified. Errass, ‘20 Jahre Würde der Kreatur’ (n 9), at 203, 225; Federal Food Safety and Veterinary Office, ‘Dignity of the animal’ (n 7), at 5.

⁷² Krepper (n 55), at 306 *et seq.*; Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (n 10), at 123 *et seq.*

⁷³ Errass, ‘20 Jahre Würde der Kreatur’ (n 9) 203.

⁷⁴ Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (n 10) 149, 156.

be ensured by modifying the animal's phenotype.⁷⁵ In this context two interests appear to be able to justify the excessive instrumentalization: the protection of human and animal health and the accumulation of knowledge.

Transgenic animals are bred in order to perform experiments that aim, among other things, at making progress in the protection of human and animal health (e.g. medical progress). However, the breeding of transgenic animals itself does not contribute directly to this goal, but is rather “a step along the way”. Human and animal health as laid down in Art. 8 para. 2 lit. a GTA, therefore, cannot justify the excessive instrumentalization, which transgenic animals suffer when being bred exclusively for experimental purposes. The basis of this reasoning also applies to the interest in the accumulation of knowledge. The modification of the phenotype of an animal could be subsumed as a pure interest in increasing knowledge in accordance with Art. 8 para. 2 lit. f GTA.⁷⁶ However, transgenic animals that are bred to be used in animal experiments – which are the focus of this article – do not contribute directly to the increase of general knowledge. Their purpose rather lies within the “production” of models for certain experiments. As a consequence, the interests laid down in Art. 8 GTA do not prevail over the harm the animal suffers due to the violation of its dignity.

Existential necessity of genetic modifications

What was said above raises the question whether unavailability or existential necessity alone constitute justifiable grounds for human interventions that seriously infringe upon animal dignity.⁷⁷ In other words, the necessity to exclude risks concerning the accuracy of test results by “modelling” the perfect laboratory animal seems to justify the excessive instrumentalization. This idea is hardly convincing. In general, the reasons for justification are to be interpreted in a rather restrictive way in order to avoid a dilution of the concept of animal dignity. Even if the justifications are not conclusively regulated, either in the animal welfare legislation or in the GTA, this does not result in an indiscriminate justification of an encroachment on animal dignity. It rather means that a justification must be evaluated on a case-by-case basis in accordance with the proportionality test. When applying the threefold proportionality test in this context, I hold that it turns out to be to the benefit of the animal. Whether the breeding of transgenic

⁷⁵ Geissbühler (n 45).

⁷⁶ Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (n 10) 155.

⁷⁷ Federal Ethics Committee on Non-Human Biotechnology/Swiss Committee on Animal Experiments (n 9) 8.

animals is, indeed, suitable as well as necessary to improve animal models and the subsequent research results can be a matter of debate. The breeder, as a rule, expects to use the modified animal for a particular experiment in order to improve the accuracy of the test results. Considering the fact that research in alternative methods has been developing rapidly, rendering the use of animals obsolete in some areas, the necessity could be challenged.⁷⁸ However, certain research fields exist where alternative methods cannot or are legally not allowed to replace animal experimentation – yet.⁷⁹ The measure is, therefore, at least in some areas suitable and necessary to reach the aim.

However, the instrumentalization is not proportionate. In order to justify the present excessive instrumentalization, the human user's interests (acquiring better "models") must prevail in the proportionality test. If the transgenic animal does not exhibit the required feature, it is "disposed of".⁸⁰ In other words, a great number of animals are killed to "produce" a few suitable models.⁸¹ The disposed animals are neither considered within the record of constraint within the simplified procedure, nor do they initiate any other reporting obligations.⁸² Even though the number of these animals is registered, and the head of the breeding facility is obliged to annually report the number of animals being born (and killed) within the facility,⁸³ it has to be emphasized that this is purely about passing on information. There is no evaluation of the breeding results. The regulator justifies this especially by the fact that animals suffering a possible severe constraint are killed painlessly. They, therefore, supposedly do not suffer any harm; yet, they suffer the greatest harm – death.⁸⁴ In addition, these animals are often simply killed because they do not exhibit the desired features. Also, the argument that fewer animals are used when

⁷⁸ Gill Langley and others, 'Replacing animal experiments: choices, chances and challenges' (2007) 29 *BioEssays* 918.

⁷⁹ Sarah Adler and others, 'Alternative (non-animal) methods for cosmetics testing: current status and future prospects - 2010' (2011) 85(5) *Archives of Toxicology* 367; Steven M Niemi, 'Alternatives to Animal Experimentation' 4 (1983) *Int J Stud Anim Prob* 241.

⁸⁰ Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (n 10), at 149, 156; ECNH, Stellungnahme zur Konkretisierung der Würde der Kreatur im Rahmen der geplanten Revision des Tierschutzgesetzes (1999); Regina Binder, 'Die "Schadenseite": Zur Erfassung der Belastung von Tierversuchen', *Borchers, Luy (Ed.)* 251 (2009).

⁸¹ Errass, *Öffentliches Recht der Gentechnologie im Ausserhumanbereich* (n 10), at 149, 156; Errass, '20 Jahre Würde der Kreatur' (n 9), at 203.

⁸² B. Salomon and others, *Erfassung und Bewertung des Leides sowie der Belastung transgener Tiere im Tierversuch im Vergleich zu konventionellen Tierversuchen: im Auftrag des Bundesministeriums für Bildung, Wissenschaft und Kultur und des Bundesministeriums für Soziale Sicherheit und Generationen//Endbericht zur Studie (Zentrum für Ersatz- und Ergänzungsmethoden zu Tierversuchen 2001)*, at 357; Gieri Bolliger, Michelle Richner and Andreas Rüttimann, *Schweizer Tierschutzstrafrecht in Theorie und Praxis* (Schriften zum Tier im Recht volume 1, Schulthess 2011) (providing further reference); Gerritsen (n 39), at 2.

⁸³ Cf. Arts. 23, 29, Annex 2 AniEO.

⁸⁴ Binder, 'Die "Schadenseite": Zur Erfassung der Belastung von Tierversuchen' (n 79) 251 (2009).

utilizing transgenic models appears to be untenable, since a high number of animals is killed in order to obtain only a few animals exhibiting the “correct” phenotype.⁸⁵ Finally, it is unclear whether the results of the subsequent conducted research can be transferred on human beings.⁸⁶ I conclude, therefore, that the excessive instrumentalization of transgenic animals based on unavailability or existential necessity alone is disproportionate.

As a consequence, the breeding of a genetically modified animal for test purposes using established methods constitutes an unjustified excessive instrumentalization. This tension could be resolved by not undergoing the simplified procedure, but the regular procedure, in which the instrumentalization and especially the expected amount of disposed animals can be assessed beforehand. As a result, the competent authority would have to refuse to issue a license for the breeding of transgenic animals which result in a high number of disposed animals.

7. Conclusion

Swiss law knows of a globally unique principle: it enshrines the dignity of the living beings, including animal dignity, within its constitutional as well as statutory law. Animal dignity is interpreted similarly as, yet not identically with, human dignity. This supports the conclusion that animal dignity has a similar inviolable core content as human dignity.

The core content of animal dignity is of particular interest when examining the authorisation processes of animal experiments. In addition to the regular procedure, the legislator has introduced a simplified procedure, which is used when breeding genetically modified animals using established methods. This article analyzed the following central questions: Does the simplified procedure

⁸⁵ Due to the lack of data it is difficult to say how many animals are killed when they do not exhibit the required features. A study from Taylor et al. from 2005 indicates an additional use of animals of a range between 32%–80% if counting all surplus animals, Katy Taylor and others, ‘Estimates for Worldwide Laboratory Animal Use in 2005’ (2005) 36 ATLA 327, at 332. Considering technical development the number is probably much higher nowadays. According to some news reports and to animal protection NGOs, 90–95% of transgenic animals are estimated to be killed as surplus animals. Cf. Pallab Ghosh, ‘Experiments with genetically modified animals increase’ *BBC News* (27 July 2010) <<http://www.bbc.com/news/science-environment-10774409>> (accessed 19.12.2017); Ärzte gegen Tierversuche, ‘Millionen verschwiegene Tieropfer bei Tierversuchen’ <<https://aerzte-gegen-tierversuche.de/de/projekte/stellungnahmen/1499-millionen-verschwiegene-tieropfer-bei-tierversuchen>> (accessed 19.12.2017).

⁸⁶ Andrew Knight, ‘Systematic Reviews of Animal Experiments Demonstrate Poor Human Clinical and Toxicological Utility’ (2007) 35 ATLA 641; Hope R Ferdowsian and Nancy Beck, ‘Ethical and Scientific Considerations Regarding Animal Testing and Research’ (2011) 6(9) PLoS One 1, at 2 *et seq.*

sufficiently protect animal dignity? Does the breeding of genetically modified animals for experimental purposes disproportionately instrumentalize these animals?

I demonstrated, first, that animal dignity is to be considered as an independent criterion within the harm–benefit assessment to give practical effect to animal dignity. I then analysed whether the simplified procedure – by solely introducing a trailed assessment – provides an equal or at least sufficient level of protection as the regular procedure. I came to the conclusion that even if the simplified procedure comes with certain risks, it still provides a sufficient degree of protection. The risk that the strains inflicted on the animals are not reported has to be taken seriously, but the animal welfare legislation provides several reporting and information provisions to ensure the conduction of a harm–benefit assessment. Also, the fact that the weighing is only carried out after the strains have occurred raises doubts whether the simplified procedure provides a sufficient protection of animal dignity. However, the simplified procedure only applies if the researcher uses established methods that are “animal friendly”. The regulator ensures the harmlessness of these methods by conducting an abstract harm–benefit assessment. In addition, the record of constraint guarantees the initiation of the trailed assessment in case strains appear on the animal.

The excessive instrumentalization of transgenic animals being bred for a subsequent laboratory use causes serious doubts about adequate animal dignity protection within the simplified procedure. The instrumentalization does not yet exceed the threshold of an infringement of the sacrosanct core of animal dignity. This entails that prevailing interests can, in principle, justify the resulting infringement of animal dignity. Yet, convincing justifications do not appear to arise from the interests listed within the GTA. Moreover, a justification based on pure necessity and unavoidability fails at the last hurdle – the threefold proportionality test. Even though genetically modifying an animal to use it for test purposes afterwards is suitable and (to a certain extent) necessary, it is not proportionate. The high number of animals being disposed of during the processes due to their lack of the sought-after features is disproportionate in relation to the excessive instrumentalization of these animals. This is especially the case, as they are not the subject of any (ex ante) harm–benefit assessment. The application of the simplified procedure is, as a consequence, not sufficient to protect their dignity. However, this conflict could be resolved by excluding animals being bred for scientific purposes from the simplified procedure and ascribing the authorisation to the regular procedure.

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