

## Letter

# Applications for Animal Experiments are Rarely Rejected in Germany

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According to the German Animal Protection Law, an application to perform an animal experiment may only be approved in case it is found to be indispensable for the specified purposes and if the expected pain, suffering, or harm caused to the animals during the experiment is ethically justifiable (Germany, 2018). In Germany, permits to perform animal experiments are issued by the licensing authority of the respective federal state. The authority may either approve or reject applications, or set conditions for approval. The authority is advised by a commission, which is generally composed of two thirds scientists and one third representatives of animal protection organizations.

However, in 2014 the authorities' competence to assess submitted proposals was reduced to a mere plausibility check by a decision of the German Federal Administrative Court, which means that the actual assessment is now left to the project applicant. In practice this means that the authority has to approve an application as long as the applicant argues the indispensability and the ethical justification in a scientific manner. This procedure is in conflict with the demands of the EU Directive on the use of animals for scientific purposes (EU, 2010), according to which this assessment must be made by the competent authority.

In order to determine the rejection rate of applications in Germany, data on the number of applications, retractions, and rejections in the years 2015 to 2017 was requested in writing from the respective licensing authorities of the federal states of Germany between December 2016 and March 2019. Related information sources, i.e., official printed matter and an interview statement, were also consulted but not included in the calculations. The rejection rate for each federal state was calculated based on the number of proposals submitted to the licensing authorities and the number of rejections issued by that authority. Applications that had been retracted by the applicants, i.e., no decision had been reached on the application by the authority, were omitted

from the calculation. Thus, only the number of applications on which the licensing authorities had reached a decision were included. The state-wide rejection rate of applications to perform animal experiments was calculated based on the sum of applications submitted to the individual federal states and the sum of rejected applications.

The number of applications to perform animal experiments, the number of rejections and the respective rejection rates are listed in Table 1.

No data were provided by the government of Lower Franconia, part of Bavaria, for any of the years requested, however, according to parliamentary printed matter regarding Bavaria, the rejection rate was 0% in 2014 and 0.21% in 2013. The rejection rates in Bavaria in previous years were similar<sup>1</sup>. The Office for Nature, the Environment and Consumer Safety of North Rhine Palatinate provided no information for 2017. The licensing authority for Lower Saxony rejected data requests for all years. However, a rejection rate of 0.3% for 2016 can be assumed based on a statement by the Minister for Science and Culture in Lower Saxony, Gabriele Heinen-Kljajić, made in an interview<sup>2</sup>.

Our analysis of the available data on applications submitted to German licensing authorities during 2015 to 2017 shows that less than 1% of applications to perform animal experiments were rejected by the authorities in any of the years analyzed: In 2015, a total of 2,534 applications for animal experiments were made in Germany, of which 18 were rejected (0.71%). In 2016, 23 of 2,567 applications were rejected (0.9%) and in 2017, 12 of 1,995 applications were rejected (0.6%). The range of rejection rates of the individual federal states averaged 0.75% over the three years (range of 0 to 3.32%).

The low number of rejected animal experiments across all federal states of Germany shows that animal experiment pro-

<sup>1</sup> <https://bit.ly/2x7PNIW>

<sup>2</sup> <https://bit.ly/31ResQ5>

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**Tab. 1: Number of applications to perform animal experiments, number of rejections and rejection rate (%) of German federal states in 2015-2017**

	2015			2016			2017			Average (2015-2017)
Federal state	total	rejected	%	total	rejected	%	total	rejected	%	%
Baden-Württemberg	675	10	1.48	737	5	0.68	681	7	1.03	1.05
Bavaria (Government of Upper Bavaria only <sup>a</sup> )	245	1	0.41	218	2	0.92	219	0	0	0.44
Berlin	192	5	2.6	257	3	1.17	255	4	1.57	1.70
Brandenburg	43	0	0	35	0	0	46	1	2.17	0.81
Bremen	11	0	0	4	0	0	4	0	0	0.00
Hamburg <sup>b</sup>										
Hesse	322	2	0.62	292	2	0.68	314	0	0	0.43
Mecklenburg-West Pomerania	67	0	0	85	1	1.19	69	0	0	0.45
Lower Saxony <sup>c</sup>										
North Rhine-Westphalia <sup>d</sup>	574	0	0	494	1	0.2				0.09
Rhineland-Palatinate	100	0	0	88	0	0	85	0	0	0.00
Saarland	67	0	0	50	0	0	52	0	0	0.00
Saxony <sup>e</sup>										
Saxony-Anhalt	70	0	0	68	0	0	45	0	0	0.00
Schleswig-Holstein	113	0	0	118	0	0	130	0	0	0.00
Thuringia	55	0	0	121	9	7.44	95	0	0	3.32
<b>Germany (total)</b>	<b>2,534</b>	<b>18</b>	<b>0.71</b>	<b>2,567</b>	<b>23</b>	<b>0.9</b>	<b>1,995</b>	<b>12</b>	<b>0.6</b>	<b>0.75</b>

<sup>a</sup> The government of Lower Franconia, part of Bavaria, did not answer the request for data. <sup>b</sup> Data were not requested on account of the cost of access to the information. <sup>c</sup> The data requests for all years were rejected. <sup>d</sup> The data request for 2017 was rejected. <sup>e</sup> Only the number of applications received but not the number of rejections were provided. Further data were not requested on account of the cost of access to the information.

posals are very rarely rejected. One main reason for this could be that the German Animal Protection Law provides a generous definition of the purposes for which an animal experiment may be performed. This, together with the limitation of the competence of the licensing authority to a mere plausibility check, gives the authorities a limited handle on rejecting an animal experiment, which in practice reduces the approval process to a matter of form.

## References

- EU (2010). Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. *OJ L276*, 33-79.
- Germany (2018). *Tierschutzgesetz in der Fassung der Bekanntmachung vom 18. Mai 2006 (BGBl. I S. 1206, 1313), das zuletzt durch Artikel 1 des Gesetzes vom 17. Dezember 2018 (BGBl. I S. 2586) geändert worden ist.*