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Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit
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Via e-mail: ulf.klaass@lavg.brandenburg.de

Dear Dr. Klaaß,

We are writing on behalf of PETA Deutschland e.V., the largest animal rights organization in the country, with 1.5 million supporters, and our affiliate PETA U.S., which has more than 6.5 million members and supporters worldwide. We understand that the Landesamt für Umwelt, Gesundheit und Verbraucherschutz in Potsdam approved a permit (number V3-2347-A-6-14-2013) for the use of live pigs in deadly live tissue training (LTT) drills in the context of trauma training conducted for Bundeswehr personnel, despite the widespread availability of superior and economical non-animal training methods.¹ Similar permits for LTT may have been issued in subsequent years.

Based on the detailed information presented in the enclosure, we urge you to reject and prohibit all current and future permit approvals for LTT in accordance with Directive 2010/63/EU and the German Animal Welfare Act, as animal use is not indispensable in LTT in the context of trauma training.

We look forward to your response regarding this important issue. Thank you.

Best regards,



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¹ Back DA, Waldmann K, Hauer T, *et al.* Concept and evaluation of the German War Surgery Course—Einsatzchirurgie-Kurs der Bundeswehr. *J R Army Med Corps.* 2017;163(3):206-210.
<https://militaryhealth.bmj.com/content/163/3/206.short>.

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Enclosure: Justification for Prohibiting Live Tissue Training (LTT) in the Context of
Trauma Training

Justification for Prohibiting Live Tissue Training (LTT) in the Context of Trauma Training

LTT Appears to Violate Directive 2010/63/EU and the German Animal Welfare Act

Article 4(1) of Directive 2010/63/EU on the protection of animals used for scientific purposes states, “Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.”²

The German Animal Welfare Act states, “When deciding whether an animal experiment is indispensable and when carrying out animal experiments, the following principles must be observed: [...] It must be checked whether the intended purpose can be achieved by other methods or processes.”³

Animal experiments cannot be justified as indispensable on the basis of saving time, money, or effort.⁴ If experimenters don't wish to carry out several non-animal experiments in order to avoid a single animal procedure, the study should be redesigned.⁵

Both EU Directive 2010/63/EU and the German Animal Welfare Act require the explicit assessment – *prior* to the approval of an animal experimentation protocol – of whether the intended purpose can be achieved using a non-animal method achieves satisfactory results or other methods or processes are required.

PETA Germany and PETA U.S. have been in contact with the Ministry of Defence and the Bundeswehr for years about this troubling matter. Meanwhile, the Defence Committee of the Bundestag, which we have also asked for assistance, reported that the Bundeswehr Medical Service Command has stated, “A possible replacement for training on living animals (live tissue training) is currently being intensively examined at various levels.”⁶ It is important to view this statement in the context of applicable European and German regulations.

Since the Bundeswehr Medical Service Command acknowledges that it is currently still in the process of intensively examining a possible replacement for LTT, this review has not yet been completed. As such, there is no substantive and comprehensive evidence that a scientifically satisfactory method or experimental strategy that does not use live animals for trauma training is unavailable at the moment. We therefore ask you to

² 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. *Official Journal of the European Union* . L 276 / 33-79. <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32010L0063&from=EN>.

³ Animal Welfare Act (TierSchG), Section 7a, Art. 2. <https://www.gesetze-im-internet.de/tierschg/BJNR012770972.html>.

⁴ VG Hanover ruling, September 30, 2013, Az.: 11 A 3671/11.

⁵ Hirt/Maisack/Moritz, Commentary on the Animal Welfare Act, 3rd edition, 2016, § 7a TierSchG, Rn. 11.

⁶ Bundeswehr Medical Service Command. Letter to the Bundestag Defence Committee, September 10, 2020.

reject or, at the very least, suspend all LTT permits until the current review has been completed.

Proven Animal-Free Trauma Training Methods Are Available

As explained above, according to EU and national regulations, animals may be used only as a last resort, i.e., if the intended purpose cannot be achieved by other methods or processes. This is not the case for LTT in trauma training. Please allow us to give you a brief overview of the latest findings regarding innovative, animal-free processes:

- Researchers at the Bundeswehr Hospital Berlin openly admitted in a 2018 study that “training technically demanding maneuvers that require an exact human anatomy ... can currently ... be achieved by [human cadavers].”⁷
- The Human Worn Partial Task Surgical Simulator (Cut Suit) is a “realistic surgical training tool that allows for the simulated performance of actual surgical procedures. In addition to perfused extremities, the Cut Suit also has perfused internal organs that may be accessed through the abdominal wall and can be incised to bleed and repaired or excised to control hemorrhage.”⁸
- High-fidelity human cadaver models are used in the Major Incident Surgical and Trauma Teams (MISTT) Trauma Course held at the Queen Elizabeth Hospital Birmingham in the U.K.⁹ and are mentioned in a 2018 study from the U.S. Navy Trauma Training Center, which states, “Preliminary data highlights the utility for open vascular, thoracic and other high acuity/low volume procedures critical to combat casualty care.”¹⁰
- High-fidelity simulation models include the surgical anatomy model (SAM), whose use was described by representatives of the U.K.’s Royal Army Medical Corps and Royal Navy in a 2016 study: “During damage-control surgery using the SAM, the materials and anatomical details have simulated human blast injury with fidelity that may be superior to cadaveric and animal models.”¹¹

⁷ Schneider K, Willmund G, Back DA, Maaz A, Peters H, Lieber A, Hauer T. Technische Simulationsmodelle in der notfallchirurgischen Ausbildung—eine Alternative zu Live Tissue Training und humanen Präparaten? *Wehrmedizinische Monatsschrift*. 2018. <https://wehrmed.de/article/3582-technische-simulationsmodelle-in-der-notfallchirurgischen-ausbildung-eine-alternative-zu-live-tissue-training-humanen-praeparaten.html>.

⁸ Kirkpatrick AW, LaPorta A, Brien S, *et al.* Technical innovations that may facilitate real-time telementoring of damage control surgery in austere environments: A proof of concept comparative evaluation of the importance of surgical experience, telepresence, gravity and mentoring in the conduct of damage control laparotomies. *Can J Surg*. 2015;58(3 Suppl 3):S88-S90. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467498/>.

⁹ Major Incident Surgical and Trauma Teams. The MISTT trauma course. <https://www.mistt.co.uk/index.html>.

¹⁰ Polk TM, Grabo DJ, Minneti M, Inaba K, Benjamin ER, Demetriades D. Initial report on a damage control surgery course for military forward surgical teams utilizing a novel perfused cadaver model for training and evaluation. *J Am Coll Surg*. 2018;227(4 Supp 2):E40. [https://www.journalacs.org/article/S1072-7515\(18\)31238-9/fulltext](https://www.journalacs.org/article/S1072-7515(18)31238-9/fulltext).

¹¹ Naumann DN, Bowley DM, Midwinter MJ, Walker A, Pallister I. High-fidelity simulation model of pelvic hemorrhagic trauma: The future for military surgical skills training? *Mil Med*. 2016;181(11):1407-1409. <https://www.ncbi.nlm.nih.gov/pubmed/27849473>.

Studies Underscore the Advantages of Using Non-Animal Simulation Models

- A 2018 study found that “[h]igh-fidelity simulation offers many advantages, including broad exposure to procedures, their complications, and the opportunity for repetitious learning in a non-clinical setting” and that “[s]ynthetic models can produce a stress response equivalent to that of live tissue during simulation training.” At that time, this was the largest study indicating that “synthetic models produce a sufficient immersive and realistic experience for trainees.”¹²
- A 2020 study published in *Trauma Surgery & Acute Care Open* examined the training of U.S. Navy and U.S. Army surgical teams involving the above-mentioned Cut Suit. The authors found that simulation training enhances team performance, i.e., “improves surgical procedures and processes.” The paper concludes, “High fidelity surgical simulation equipment such as the ... “Cut Suit” combined with highly realistic replicated settings will allow surgical trauma teams to improve their life-saving skills and teamwork communication to maximize successful patient outcomes. High fidelity, highly realistic, immersive and stress-provoking surgical trauma training is now an option to improve the readiness and capabilities of trauma teams.”¹³
- A 2016 study in the *Journal of the Royal Army Medical Corps* states that the Danish LTT course (which is similar to the Bundeswehr’s course) uses pigs, whose anatomy differs from that of humans: “Training courses based on animal models (Exercise Surgical Training Denmark) and cadavers (the Military Operational Surgical Training course) have been used extensively to prepare surgeons for deployment in recent conflicts. However, they are expensive and provide a one-off opportunity to practice advanced techniques in models that are either anatomically incorrect (pigs) or have altered tissue characteristics with no vascular perfusion (cadavers). [Instead, a]bdominal multivisceral organ retrieval [in clinical settings] is the ultimate laparotomy and takes the surgeon to parts of the retroperitoneum and thorax otherwise not seen during standard surgical training. ... From April 2012 to April 2013, there were 2748 retrievals carried out by the 8 UK abdominal retrieval teams. The number of retrievals has increased by 50% between 2010 and 2014, and it is predicted to increase by a further 50% by 2020.”¹⁴ The use of this approach in Germany as an alternative to LTT for training and maintaining the skills of military surgeons is feasible.
- In addition, a 2019 study in the *Journal of Surgical Education* states that the purported benefits of LTT to patient outcomes are unsubstantiated: “[N]o published evidence from prospective controlled trials exists suggesting that surgical skills training courses change trauma patient outcome, or improve performance of the skills taught, when performed in the real-world operating room. ... Published evidence of course training benefit was not

¹² Keller J, Hart D, Rule G, Bonnett T, Sweet R. The physiologic stress response of learners during critical care procedures: Live tissue vs synthetic models. *Chest*. 2018;154(4):229A. [https://journal.chestnet.org/article/S0012-3692\(18\)31402-8/fulltext](https://journal.chestnet.org/article/S0012-3692(18)31402-8/fulltext).

¹³ Hoang TN, LaPorta AJ, Malone JD, et al. Hyper-realistic and immersive surgical simulation training environment will improve team performance. *Trauma Surg Acute Care Open*. 2020;5(1):e000393. <https://tsaco.bmj.com/content/5/1/e000393>.

¹⁴ O’Reilly D, Lordan J, Streets C, Midwinter M, Mirza D. Maintaining surgical skills for military general surgery: The potential role for multivisceral organ retrieval in military general surgery training and practice. *J R Army Med Corps*. 2016;162(4):236-238. <https://pubmed.ncbi.nlm.nih.gov/26243807/>.

identified for many established courses including: Definitive Surgical Trauma Skills, Emergency Management of Battlefield Injuries, Endovascular Skills for Trauma and Resuscitative Surgery, Emergency War Surgery Course (EWSC), Military Operational Surgical Training, Specialty Skills in Emergency Surgery and Trauma, Surgical Training for Austere Environments, or Surgical Trauma Response Techniques”—all of which, according to the paper, “used live tissue (usually porcine).”¹⁵ Article 4(1) of Directive 2010/63/EU on the protection of animals used for scientific purposes calls for scientific judgment on whether a given method or testing strategy will achieve results in a satisfactory manner. The lack of substantive and verifiable evidence that LTT improves patient outcomes means that it fails the standard set by the Directive of using a “scientifically satisfactory method.”¹⁶

Classification of LTT as Ethically Unjustifiable

An independent, peer-reviewed study published by German scientists has shown that the use of animals in such trauma training is ethically unacceptable. The researchers concluded, “A close examination of the evidence base for the presumed advantages of LTT showed that it is not superior to simulation-based methods in terms of educational benefit. Since credible alternatives that do not cause harm to animals are available, we conclude that LTT on animal models is ethically unjustified.”¹⁷

Regulatory, Political, and Legal Precedents in Germany for Opposing LTT

- A plenary report by the Christian Democratic Union Thuringia describes LTT as the “mutilation of living animals without there being any scientific need for this.”¹⁸
- PETA U.S. successfully persuaded German regulators to block repeated applications by U.S. Army Europe to conduct LTT with US service members stationed in Germany, on the grounds that such invasive and lethal exercises would violate the German Animal Welfare Act.¹⁹
- Gera Administrative Court declared in 2012 in case 1 K 584/11 Ge that it is legally forbidden to train medical personnel who are deployed in warzones and other crisis areas using “anesthetized pigs that were previously supposed to have been inflicted with typical war injuries.” In addition, the competent licensing authority, the Thuringian State Office

¹⁵ Mackenzie CF, Tisherman SA, Shackelford S, Sevdalis N, Elster E, Bowyer MW. Efficacy of trauma surgery technical skills training courses. *J Surg Educ.* 2019;76(3):832-843.

<https://www.sciencedirect.com/science/article/abs/pii/S1931720418305506?via%3Dihub>.

¹⁶ 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. *Official Journal of the European Union.* L 276/33-79. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>.

¹⁷ Rubeis G, Steger F. Is live tissue training ethically justified? An evidence-based ethical analysis. *Aging Lab Anim.* 2018;46(2):65-71. <https://www.ncbi.nlm.nih.gov/pubmed/29856644>.

¹⁸ Kowalleck M. Current plenary report of the CDU parliamentary group: An overview of all topics and debates. Maik-Kowalleck.de. October 14, 2011. https://www.maik-kowalleck.de/lokal_1_1_203_Aktueller-Plenarbericht-der-CDU-Fraktion-Alle-Themen-und-Debatten-im-Ueberblick.html.

¹⁹ Montgomery N. Germany again shoots down U.S. Army Europe’s live-tissue training. *Stars and Stripes.* October 28, 2010.

<https://www.stripes.com/news/germany-again-shoots-down-u-s-army-europe-s-live-tissue-training-1.123395>.

for Consumer Protection, was of the opinion that “such animal experiments are not necessary within the meaning of the Animal Welfare Act. In particular, there are alternative training options, such as on dummies, i.e., training dummies on which the treatment of injuries can easily be practiced in a realistic manner. This was confirmed by the experts questioned by the Chamber.”²⁰

- Animal-free methods are available and are already used by almost three-quarters of all NATO countries in their military medical training programs.²¹ This represents independent assessments by various experts worldwide underscoring that non-animal training methods can replace the use of animals in LTT. (You’ll see that Germany was originally included in this study as a nation that does not use animals for military medical training, based on written statements that the Bundeswehr made to PETA U.S. in 2010. However, in 2017, Lieutenant General Dr. Michael Tempel in the Bundeswehr Medical Service Command wrote to PETA U.S. at the direction of former Minister Ursula von der Leyen to “formally apologise for the misunderstandings in [the military’s] communication so far with regard to this particular form of training,”²² acknowledging that the Bundeswehr does, indeed, participate in LTT.)
- The Polish military replaced its use of animals in trauma training drills in 2013 with modern, superior simulation models after hearing from PETA U.S.²³
- The U.S. Coast Guard became the first branch of the U.S. military to end all use of animals in LTT – a practice that then-Commandant Adm. Paul Zukunft described before a U.S. House of Representatives committee as being “abhorrent” – after the agency reviewed available non-animal training methods.²⁴

Request for Action

In 2018, the Ministry of Defence responded to a communication from PETA U.S., stating, “The training of 18 surgeons per year for the entire Bundeswehr requires a maximum of twelve pigs. ... [It] is our ultimate goal to abandon live tissue training entirely as soon as suitable simulation models are available. ... We are open to a further exchange of ideas and conversations regarding this topic.”²⁵

²⁰ Amelung B. Gera Administrative Court. Press release from October 2, 2012, on case 1 K 584/11

Ge. [http://www.thovg.thueringen.de/webthfj/webthfj.nsf/6C447206B6A89D0FC1257A8D003148C1/\\$File/28803840.pdf?OpenElement](http://www.thovg.thueringen.de/webthfj/webthfj.nsf/6C447206B6A89D0FC1257A8D003148C1/$File/28803840.pdf?OpenElement).

²¹ Gala SG, Goodman JR, Murphy MP, Balsam MJ. Use of animals by NATO countries in military medical training exercises: An international survey. *Mil Med.* 2012;177(8):907-910. <https://www.piscltd.org.uk/wp-content/uploads/2014/10/use-of-animals-by-nato-countries-in-military-medical-training-exercises-military-medicine-aug-2012-gala-et-al.pdf>.

²² Ministry of Defence. Letter to PETA U.S., March 17, 2017.

²³ PETA U.S. PETA campaign prompts Polish military to end deadly animal labs. Press release, November 20, 2013. <https://www.peta.org/media/news-releases/peta-campaign-prompts-polish-military-end-deadly-animal-labs/>.

²⁴ Hodge Seck H. Coast Guard puts permanent end to wounding animals for training. *Military.com.* March 20, 2018. <https://www.military.com/daily-news/2018/03/20/coast-guard-puts-permanent-end-wounding-animals-training.html>.

²⁵ Ministry of Defence. Letter to PETA U.S., March 17, 2017.

It is unacceptable for any animal still to be used and killed by the Bundeswehr for LTT, given the information presented above and considering that German and EU regulations mandate the use of non-animal methods that are already widely available and in use by peer nations.

The Ministry of Defence has not shown that its use of animals in LTT in the context of trauma training is indispensable. As such, we urge your office to reject and prohibit all current and future permit applications for LTT, in accordance with Directive 2010/63/EU and the German Animal Welfare Act.