

LINZ 2012 17th European Congress on Alternatives to Animal Testing

EUSAAT 2012 14th Annual Congress of EUSAAT

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European Society for Alternatives to Animal Testing



5th – 8th September 2012 – University of Linz, Austria

Transposition of Directive 2010/63/EU: Missed opportunities in Germany

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Background

Current German legislation

**Animal Welfare Act from 1972 covering all areas of animal use
(also including their developmental stages)**

Major revision 1986

**Chapter on experimentation on vertebrates, cephalopods, decapods
includes**

- 3Rs principle
- Authorisation system including an ethical evaluation
- Simplified procedure for regulatory animal tests
- Bans on animal experiments for the development or safety evaluation of weapons, ammunition, tobacco products, cosmetics, detergents



Background

Legal obligation resulting from Constitution

2002 animal protection has been included into the German Constitution.

Article 20a:

„Mindful also of its responsibility toward future generations, the state shall protect the natural foundations of life and animals by legislation and, in accordance with law and justice, by executive and judicial action, all within the framework of the constitutional order.“

This means

1. New legislation should not lead to a worsening of the situation of the animals
2. Animal protection should be improved wherever possible

Two legal opinions were published that strongly support our demands



Background

Public opinion

Representative EU opinion survey, 2009 (YouGov Plc)

German results:

- **85%** - The new law should prohibit all experiments causing pain or suffering to primates.
- **82%** - The new law should prohibit all experiments on animals which do not relate to serious or life-threatening human conditions.
- **89%** - The new law should prohibit all experiments causing severe pain or suffering to any animal.
- **84%** - All information about animal experiments should be publicly available, except information which is confidential and information which would identify researchers or where they work.



Timetable of transposition in Germany

Directive 2010/63/EU came into force in Nov 2010

Publication of first German drafts (by Ministry) in January 2012

- Proposal for the revision of the German animal welfare act
- Proposal for a new regulation on the welfare of animals used for scientific purposes – partly identical with 2010/63/EU

In June, July, October discussions in Bundesrat (German Federal Assembly) and Bundestag (German Federal Parliament)

Directive 2010/63/EU has to be transposed by November 2012



Transposition in Germany

Introduction of new measures

- Publication of project summaries
- Retrospective assessment for selected projects
- Establishment of so called animal-welfare bodies
- Establishment of a national committee for the protection of animals used for scientific purposes
- Some additional measures for the use of primates, e.g. retrospective assessment for all projects
- Extension of protection of fetuses in the third trimester of pregnancy



Transposition in Germany

Maintenance of stricter national rules

Stricter national rules that will be maintained:

- In principle the law covers not only vertebrates and cephalopods, but all animals
- Experiments on animals for the development or testing of weapons, ammunition and related equipment, as well as for the development of tobacco products and detergents will be prohibited
- “Ethical committees” that advise authorities on animal experimentation applications



Critique on the transposition in Germany

Shortfalls

Some animal welfare friendly regulations are in danger:

- Scope will be expanded to include experiments for the production conditions for agricultural animals or forensic inquiries
- The use of stray and feral animals of domestic species was only allowed if the species could not be purpose bred, now possibility for broad exemptions
- Project evaluation process shortened from 3 months to 2
- Project authorisation for regulatory tests extended from 3 to 5 years



Critique on the transposition in Germany

Shortfalls

Opportunities for stronger national rules have not been taken:

Art. 55 of the Directive would have allowed unconditional bans on

- experiments that involve severe pain, suffering that are likely to be long-lasting
- the use of Great Apes
- the use of monkeys for applied research not undertaken with regard to debilitating or life-threatening clinical conditions



Critique on the transposition in Germany

Further missed opportunities

- Introduction of a consistent authorisation procedure for ALL animal projects instead of clinging to the simplified administrative procedure for projects to satisfy regulatory needs and others
- Increasing transparency by publication of project summaries and retrospective assessments of ALL animal projects – now most of the regulatory testing will not be transparent and only a very small proportion of projects will be subjected to retrospective assessment
- Establishment of a national committee for the protection of lab animals: specifications on the structure, management, appointment of its members or the interaction with other institutes/authorities



Critique on the transposition in Germany

Missing structures for 3Rs advancement

- One of the main issues of the EU-Directive: promotion of alternative approaches with the ultimate aim of ending animal experiments.
 - MS shall contribute to the development and validation of alternative approaches, promote and disseminate alternative approaches.
- No corresponding measures in the German drafts
Danger that ZEBET will be occupied with administrative tasks (e.g. publication of project summaries) and will not be able to fulfill its original tasks e.g. developing and validating 3R methods or giving advise on 3Rs methods to authorities and others.



Critique on the transposition in Germany

Legal uncertainty remains

According to the Directive the project evaluation by the authority consists of a cost-benefit analysis and shall be performed in an impartial manner.

There has been disagreement in the past if the German animal welfare act allows granting authorities to make their own ethical assessment or if they can only follow the statements of the applicant (→ “plausibility check”).

In the proposals the wording has not been changed, therefore there is still no clarification whether authorities have the right/duty to make their own ethical evaluation.



Critique on the transposition in Germany

“Translation errors”?

Directive prohibits in Art. 15(2) procedures involving severe pain, suffering or distress that are likely to be long-lasting.

Draft of the new German regulation on laboratory animals only prohibits such procedures if that pain or suffering is permanent.

As to the information of the German Federal Ministry the EC has already promised not to prosecute Germany for not implementing the Directive correctly.



Critique on the transposition in Germany

Long lasting vs. permanent

2010/63/EU	2010/63/EU (German)	Draft German Regulation
<p>Art. 15 (2)</p> <p>... Member States shall ensure that a procedure <i>is</i> not performed if it involves severe pain, suffering or distress that is likely to be <i>long-lasting</i> and cannot be ameliorated.</p>	<p>Art. 15 (2)</p> <p>...gewährleisten die Mitgliedstaaten, dass ein Verfahren nicht durchgeführt wird, wenn es starke Schmerzen, schwere Leiden oder schwere Ängste verursacht, die voraussichtlich <i>lang anhalten</i> und nicht gelindert werden können.</p>	<p>§ 26</p> <p>(1) Tierversuche ..., die bei den verwendeten Tieren zu voraussichtlich länger anhaltenden oder sich wiederholenden erheblichen Schmerzen oder Leiden führen, dürfen nur durchgeführt werden, wenn....</p> <p>(2) Tierversuche nach Absatz 1 dürfen nicht durchgeführt werden, wenn die erheblichen Schmerzen oder Leiden <i>dauerhaft</i> anhalten und nicht gelindert werden können.</p>



Demands

Where the Directive allows a degree of freedom to national implementation, this has to be used for the benefit of the animals

- experiments on Great Apes and procedures involving severe suffering have to be banned without exceptions
- all experiments must undergo a strict project authorisation process.

Projects summaries of **all** projects and their retrospective assessment should be published.

Present exceptions, like continuing a simplified procedure, e. g. for regulatory required animal tests, should be abandoned.

Promotion of the 3Rs has to be enshrined.



Thank you for your attention!

Questions, more info?

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