

Genome Editing. Use in Animals – A German Perspective

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- I. Introductory remarks: „In Europe, perhaps the majority“**
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I. Introductory remarks : „In Europe, perhaps the majority“

- background: CRISPR-Cas9 and its potential wide fields of application with regard to animals
- strength of the opposition: only a – albeit very vocal – „sizeable minority“?
- education vs. regulation?
 - differences between plants and animals?

1. Animals as food source

a) Legal requirements for genetically modified organisms

→ Gentechnikgesetz/Directive 2001/18/EC

→ applies to both plants and animals

→ if applicable → specific obligations

- pre-market assessment and authorisation
- labelling requirements
- GMOs must be identifiable using detection methods → practical problem

b) "Stuck in a legal limbo": Does genome editing produce genetically modified organisms?

Europe's genetically edited plants stuck in legal limbo

Scientists frustrated at delay in deciding if GM regulations apply to precision gene editing.

BY ALISON ABBOTT

including the popular CRISPR-Cas9 method. "Projects hit a dead end," he says.

→ ongoing debate whether GMO regulation is applicable to genome editing; both on the national (→ Kahrmann) and supranational level

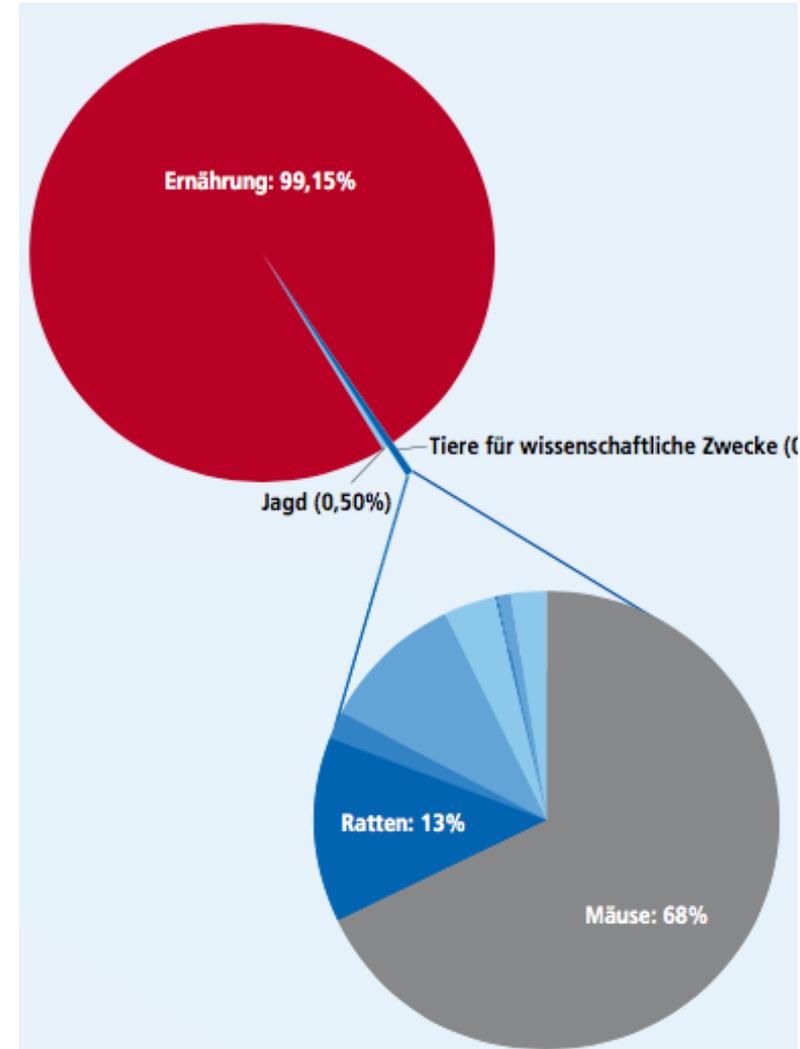
II. Legal (and moral) challenges

- legal interpretation by the Commission to issue guidance on the regulatory status of „products“ generated using the new techniques
- yet: 'sole prerogative of the ECJ to render a final and binding opinion on the interpretation of EC law'.
- two major problems:
 - regulatory uncertainty as a cause for concern
 - legitimacy scope of administrative interpretation

II. Legal (and moral) challenges

2. Animal testing

a) The (limited) relevance of animal testing from an animal welfare point of view



Source: DFG

S. Augsberg

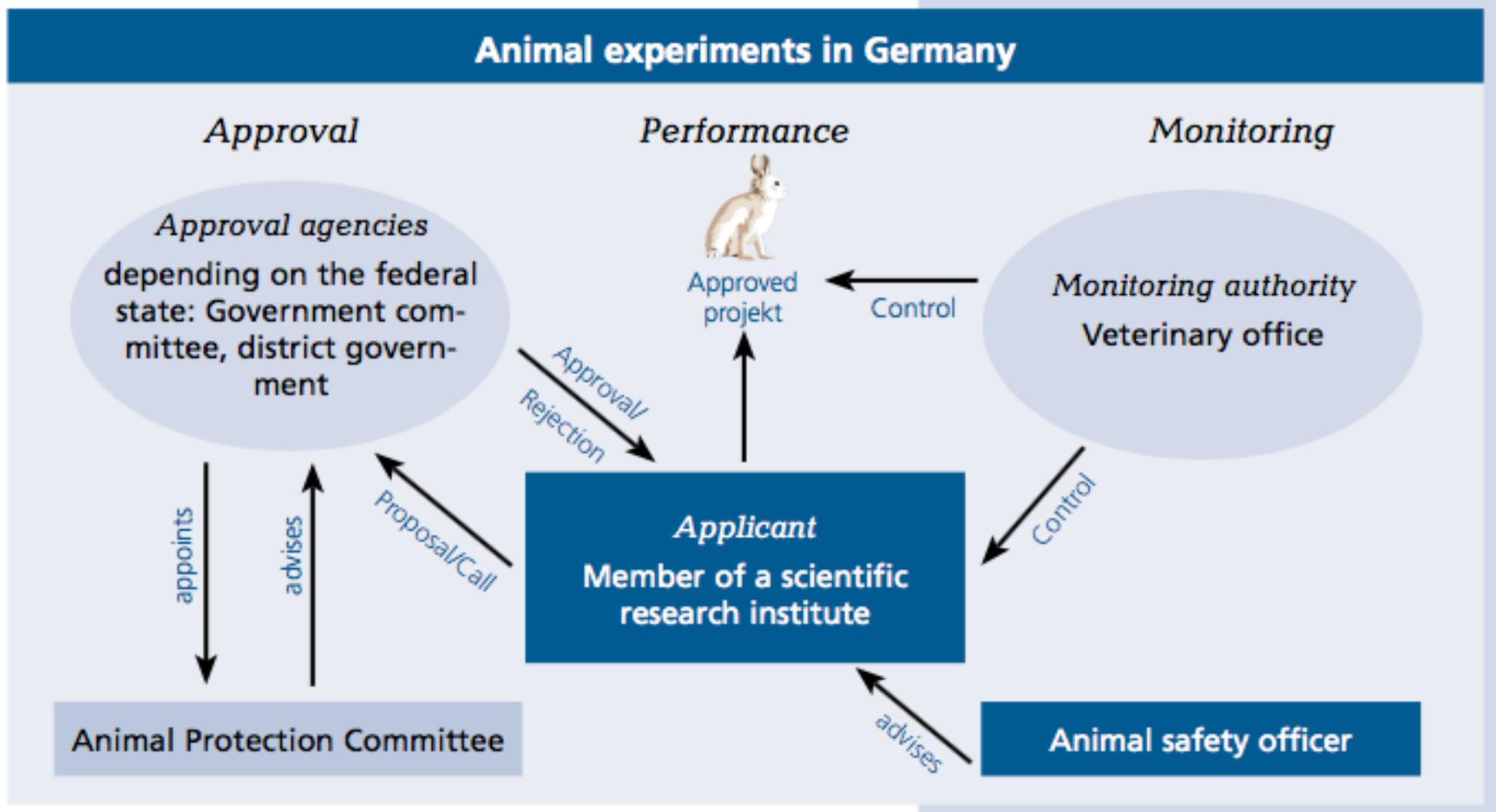
II. Legal (and moral) challenges



b) Vertebrate animals and cephalopods

- new technologies are highly likely to result in more animal testing
- important differentiation on the EU and national level → rather complex regulatory arrangements:

II. Legal (and moral) challenges



Source: DFG

II. Legal (and moral) challenges

c) Insects and "parasites"

- importance of genome editing in fundamental research as well as in practical applications
- animal testing is not per se legal, but state approval is not needed
- material rather than procedural standards

II. Legal (and moral) challenges

3. „Torture breeding“

- according to Sec. 11b of the Animal Welfare Act, vertebrate animals must not be bred or biotechnically altered in a way that harms the species-appropriate use of their bodies:



II. Legal (and moral) challenges

- the consequences of this prima facie strict norm on the industrialised agricultural sector are underappreciated and need further analyses
 - e.g.: turkeys, but also cattle („polledness”)



III. A tentative conclusion/prognosis

- general regulatory function and ideological relevance of the cautionary principle
- “supercharged“ topic unlikely to find the solution to its problems in administrative interpretation; regulatory (legislative) and didactic efforts needed
- ethical reflection not only on the product and the methods of production, but also on the underlying developments (demographics, social and cultural expectations)