



# EUROPÄISCHE AKADEMIE

zur Erforschung von Folgen wissenschaftlich-technischer Entwicklungen  
Bad Neuenahr-Ahrweiler GmbH

Direktor: Professor Dr. Dr.h.c. Carl Friedrich Gethmann

## NEWSLETTER

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### EDITORIAL

■ Recently, various developments and activities took place in the field of medical ethics at the Europäische Akademie. From the beginning of October 2008, the “Advanced Master’s Degree Course in Medical Ethics” will move from the FernUniversität in Hagen to the Institute of History, Theory, and Ethics in Medicine at the Johannes Gutenberg-Universität Mainz. The Europäische Akademie will continue to organise the course in cooperation with Mainz and will contribute to the course in medical ethics by providing teaching material originating in various interdisciplinary studies resulting from the work of its project groups.

On 24<sup>th</sup> September 2008 the working group on medical ethics organised an evening event in the course of which Stephan Schleim, M.A., (Abteilung für Medizinische Psychologie, Zentrum für Nervenheilkunde, Universitätsklinikum Bonn) gave a lecture on “Ethical challenges of brain sciences” which was discussed afterwards by invited participants and members of the scientific staff of the academy.

On 6<sup>th</sup> and 7<sup>th</sup> November 2008 an expert meeting will be held at the academy on ethical questions of public health policy comprising themes, beyond others, on the question if there are or if there could be any moral or psychological obstacles while implementing this policy. Contributions of invited experts are planned to be prepared didactically and to be used as teaching material for students in the study course (see above).

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Further information: [www.medizinethik.eu](http://www.medizinethik.eu) and  
[www.ea-au.de](http://www.ea-au.de)

### FOCUS

#### Transgenic animals in the fields?

Kristin Hagen

Transgenic animals have hitherto primarily been realised in laboratories, the most common application being biomedical models. However, animal biotechnology has steadily developed, and there is an increasing availability of genome data for many species. In 2006, there was a breakthrough for the use of transgenic animals outside laboratories when a pharmaceutical made from transgenic goats’ milk gained market approval. Thus, transgenic animals and their products may be on the way into the fields and markets with potential applications within the whole range of animal use, e.g. production of medical and industrial compounds, food production, and entertainment. Nevertheless, there is a big leap from research and development to commercial application and public acceptance, as transgenic animals are associated with benefits but also with reservations and risks related to the welfare of the animals, the environment, the sustainability of agricultural production, and consumer safety.

#### In the laboratories

■ Molecular biology allows combining DNA molecules from different sources into a gene construct which can be inserted into an organism. A transgenic animal, also referred to as derived from recombinant DNA technology, has integrated such a foreign gene construct in its genome. The modification changes the kind of proteins which are produced in the animal, and thereby its physiological processes, and ultimately its looks, behaviour, health, etc. In a wider sense, the term “transgenic” also refers to animals in which such changes have been brought about by deletion of specific genes (“knock-out”) or by inactivation, replacement, and other biotechnological interventions.

The first transgenic animals were mice produced in the mid-1970s, and by the early 1980s, experiments had shown that the recombinant genes could integrate in the germ line and be passed on to the transgenic animals’ offspring by normal reproduction. Transgenesis in species other than mice

has increasingly been accomplished – including other rodents, large farm animals, birds, fish, non-human primates, frogs, insects, and nematodes. A range of different techniques for gene transfer were developed, and they were refined to make possible, for example, targeted insertion and deletion of genes. Transgenic technology has been of particular importance for the generation of animal models of human diseases: strains of animals developed with genetic defects mirroring those seen with human patients. Over the past 30 years, these have significantly contributed to the understanding of disease mechanisms and associated pathology, and, consequently, to the development of diagnoses and therapies.

Throughout, transgenic mice have been the most commonly used animal models in biomedical research: The techniques for generating transgenic mice are well understood, mice have short generation times, and they are inexpensive. Customized strains can relatively easily be created for specific research purposes.

es, and specific strains are well characterised and can be bought from commercial suppliers. There is increasing demand for animal models from non-rodent species, e.g. non-human primates, as physiological parameters like metabolism, life span, and brain physiology may be less different compared with humans. There are also other biomedical applications for transgenic animals: pigs' organs can be made more suitable for transplantation to humans (xenotransplantation), and transgenic farm animals can be used for the efficient production of medical compounds, including biopharmaceuticals. The latter type of animal use, also known as "pharming", has already brought one product to market: a pharmaceutical based on a recombinant human protein expressed in the milk of transgenic dairy goats. (Readers interested in more details are referred to the forthcoming publications, see footer.)

#### Outside the laboratories?

Transgenic animal production projects that are close to market approval include a strain of salmon that grow more quickly than their relatives, as well as cattle with increased resistance against udder inflammations and pigs with the ability to digest plant phosphorus more efficiently. So far, the only transgenic animals that are used outside laboratories apart from the pharming goats are pet fish that glow, and an arts project: the "Green Fluorescent Bunny". Arguably, pharming goats, while used in a biomedical context, could also be seen as agricultural production animals: They are kept in ways very similar to conventional dairy goats, and they are used to provide raw material for a marketed product (as opposed to experimental animals). In this sense, their regulatory approval in the EU and the USA was a breakthrough for the use of transgenic animals and their products outside laboratories. Transgenic animals may, thus, now be on their way into animal production, and onto the markets.

Historically, transgenic animals were expected outside the laboratories much earlier, particularly in animal husbandry, but these expectations were not met. In the late 1980s, attempts, for example, to produce faster-growing pigs, were infamous: The "Beltsville pigs" which had human growth hormone genes suffered from very serious health problems. They exemplified a number of problems in early transgenic farm animal projects, including lack of specificity of transgene expression, and the inadequate goal to achieve further increase in the production of breeds already pushed to the limit. Other breeding aims of transgenesis may be more adequate, like improving disease resistance and resistance to pain and suffer-

ing which could be transgenic animal applications with production benefits as well as animal welfare benefits. However, it should be taken into account that animal welfare is a complex concept which relates to the whole animal: Reducing diseases is beneficial in principle, but the net effect on welfare could be negative if, for example, decreased susceptibility to disease permits animals to be more closely confined.

#### Risks and reservations

This takes us to risks and reservations regarding transgenic animal production where animal welfare considerations play a role among a number of other concerns. Transgenic biomedical model animals in the laboratories did already open for new moral topics: Should humans mix species, is this natural? Does genetic engineering make use of excessive numbers of animals? Does it violate animal integrity or animal dignity? Are there any risks of escape and environmental damage? In addition to such more general concerns about (animal) biotechnology, there are a number of concerns specifically associated with transgenic animals outside laboratories:

- **Food or other product safety:** Are food or other products of transgenic animals substantially different from others, and could they create any hazards for consumers? This is an area in which ample research will be needed in the future. The Codex Alimentarius Commission is currently in the process of preparing a guideline for food safety assessments of foods derived from transgenic animals.
- **Environmental issues:** Is there a risk of ecosystem disturbance in the case of deliberate release or escape? Is there a risk of interbreeding, or of horizontal gene transfer, making possible that an engineered modification could become integrated into the DNA of unintended organisms, and thereby create a hazard? In many instances, especially with large animals, the environmental risks might well be less compared with those associated with transgenic plants. However, it should be kept in mind that horizontal gene transfer is not yet well understood, and that transgenic animals outside laboratories may include species that are difficult to keep contained, such as insects and fish.
- **Animal welfare and sustainability of animal breeding:** Most production and behavioural traits and livestock are polygenic, and despite our increasing understanding of livestock genomes, few traits can be engineered reliably and predictably. Therefore, transgenic production animals will need to be

bred selectively and scrutinized for generations after the introduction of gene constructs into the founder generation to ensure that the animals display the desired phenotypes without undesirable side effects, including such that may lead to poor health and welfare. Further, as each founder animal is genetically unique, if only one founder is used to found a transgenic strain, the result could be loss of diversity, unless genetic variability is restored by backcrossing a transgenic strain to a large number of distinct mates.

#### Conclusions and outlook

In the light of insecurities regarding regulatory approvals and public acceptance realisation of practical animal applications of transgenesis outside the laboratories rather stagnated before the turn of the millennium. As the techniques have now been further refined, genome sequencing projects have yielded ample new data, and one transgenic animal product has reached market, it is possible that genetic engineering may become one breeding tool among others in the medium-term future. Such a possible development would need to go hand in hand with a broad consideration of associated risks and reservations as well as expected benefits, and statutory tools of various agencies involved would need to be developed to cope with the new technologies. The empirical data that is available with regard to public attitudes to gene technology in animals suggests that there could be even more reservations and controversies in the public in reaction to products derived from transgenic animals than with regard to plants. Conflicts similar to those over genetically modified crops could easily arise, and policy development in this area should consider a climate of openness from the start.

*Kristin Hagen, Ph.D., is scientific staff member of the Europäische Akademie gGmbH where she is member of the project group "Pharming". The final report "Pharming. Promises and risks of biopharmaceuticals derived from genetically modified plants and animals" by E. Rehbinder, M. Engelhard, K. Hagen, R. B. Jørgensen, R. Pardo-Avellaneda, A. Schmieke and F. Thiele (vol. 35 of the book series "Ethics of Science and Technology Assessment", Springer, Berlin; in press) will be presented by the project group at the Berlin-Brandenburgische Akademie der Wissenschaften on 30<sup>th</sup> October 2008. Concurrently, the symposium proceedings volume "Genetic Engineering in Livestock. New Applications and Interdisciplinary Perspectives" by M. Engelhard, K. Hagen and M. Boysen (vol. 34 of the same book series; in press) will also be published.*

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## WORKING GROUPS

■ Project Group “Deep Brain Stimulation in Psychiatry. Guidance for Responsible Research and Application”: 20–21/10/2008 in Bad Neuenahr-Ahrweiler

**Book presentation on fuel cells**

■ The results of the study on “Fuel Cells and Virtual Power Plants as Elements for a Sustainable Development. Innovation Barriers and Implementation Strategies” will be presented at the Berlin-Brandenburgische Akademie der Wissenschaften, Berlin, on 9<sup>th</sup> December 2008. The authors will present the main aspects of their study “Brennstoffzellen und Virtuelle Kraftwerke. Energie-, umwelt- und technologiepolitische Aspekte einer effizienten Hausenergieversorgung” to the public, politicians and scientists and will be ready for discussion.

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**New study on sustainability in schooling was presented**

■ On 25<sup>th</sup> September the newly released study “Nachhaltigkeit und Gerechtigkeit. Grundlagen und schulpraktische Konsequenzen” (by G. de Haan, G. Kamp, A. Lerch, L. Martignon, G. Müller-Christ and H.G. Nutzinger), Springer-Verlag, was presented to the public at the Sekretariat der Ständigen Konferenz der Kultusminister der Länder in der Bundesrepublik Deutschland (KMK) in Bonn. After the welcoming address by the director of the Europäische Akademie, Professor Dr. Dr. h.c. C. F. Gethmann, Staatssekretär Michael Ebling (Ministerium für Bildung, Wissenschaft, Jugend und Kultur Rheinland-Pfalz) gave a short survey of the importance of education for sustainability and passed on to Senatsdirigentin Dr. Angelika Hüfner (KMK) who introduced the topic. After this introduction, two of the authors gave an overview of the work. The study focuses on the goals of the education for sustainable development and analyses the obstacles pupils or other actors have to overcome in order to act according to the requirements of sustainability and justice. Subsequently, in its school practical part the study discusses the competences that enables the actor to cope with these obstacles and that therefore should be conveyed in schooling.

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## CONFERENCES

**Facing the regulatory challenges of nanotechnology**

■ From 31<sup>st</sup> August to 2<sup>nd</sup> September 2008 the Institut für Umwelt- und Technikrecht (IUTR) of the Universität Trier invited to its 24<sup>th</sup> annual colloquium on environmental and technology law. This year's topic was both a very sensitive and controversial issue, scilicet the regulatory challenges posed by nanotechnology. Whereas in the areas of applied ethics and technology assessment nanotechnology has been attracting close attention for several years by now and has even led to the eventual establishment of “nanoethics” as a new field of ethical inquiry, this seems to be a subject so far neglected (or avoided?) by legal scientists. Now legal scholars and practitioners working in the area of environmental and technology law took up the challenge and discussed strategies to adequately regulate the technological advances brought about by nanotechnology. After an introduction by Professor Dr. jur. Peter Reiff, managing director of the IUTR, the first talk was given by Professor Dr. rer. nat. Günter Schmid of the Universität Duisburg-Essen, who gave an overview of the chances and risks of nanotechnology from a scientific and technological perspective. From 2003 to 2006 Professor Schmid chaired the project group of the Europäische Akademie gGmbH on nanotechnology (see publication below). In his conference contribution Günter Schmid explicated the new, recursive definition of nanoscience and nanotechnology devised by his project group which focuses not on substances but applications of nanotechnology. According to this definition, nanoscience is “dealing with functional systems either based on the use of sub-units with specific size-dependent properties or of individual or combined functionalized subunits” (Schmid et al., p. 11 and 62, s. below). The following talks given by Professor Dr. jur. Christian Callies (Berlin), Dr. Martin Kayer (toxicologist and head of product safety at BASF AG Ludwigshafen) and Professor Dr. jur. Eckard Pache (Würzburg) examined the legal implications of the precautionary principle on nanotechnology, the application of the new EU chemicals legislation (“REACH”) to nanoparticles and nanotechnologies, and the regulatory requirements of environmental law for the production of nanomaterials in industrial plants. Furthermore, current trends and developments in tort and insurance law were discussed by Professor Dr. jur. Gerald Spindler (Göttingen) and Professor Dr. jur. Christian Armbrüster (Berlin). Finally, Dr. Thomas Epprecht of the Swiss Reinsurance Company presented the insurance industry's perspective on risk assessment of nanotechnology. In the discussions moderated by Professor Dr. jur. Meinhard Schröder (IUTR and member

of the Council of the Europäische Akademie) and Professor Dr. jur. Peter Marburger (IUTR and chair of the Scientific Advisory Board of the Europäische Akademie) consensus emerged as to the applicability of existing environmental and chemical law to nanotechnology. No speaker or participant to the conference called for a specialized “Nanotechnology Act”. However, disagreement persisted as to the need for revision of the REACH regulation to better capture nano-scale substances. Currently, the European Chemical Agency's “Guidance for identification and naming of substances under REACH” of June 2007 does not provide for any particular treatment of substances in the nanoform.

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*Publication: G. Schmid et al.: Nanotechnology. Assessment and Perspectives. Springer-Verlag Berlin 2006 (series: Wissenschaftsethik und Technikfolgenbeurteilung, vol. 27).*

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**Expert talk on renewable energies**

■ An expert discussion on renewable energies and their potential to mitigate the climate change was held in Karlsruhe on 30<sup>th</sup> September (“Klimaerwärmung entschärfen mit Erneuerbaren Energien aus Wüsten und Steppen”); the intention of the shop talk was to depict the fundamental feasibility of the concept to provide Europe with “clean” electricity from suitable southern countries in large scope with a centre-fed HVDC system and to invoke the competences of the plurality of persons concerned to start the necessary measures in societal and political fields for a contemporary realisation.

The meeting was arranged by the following institutions: “Ausschuss für Gerechtigkeit, Frieden, Bewahrung der Schöpfung” (Stadtsynode Evangelische Kirche Karlsruhe), working group “Energie und Klima” (Lokale Agenda 21 Rastatt), “Karlsruher Initiative zur nachhaltigen Energiewirtschaft” (Hochschulgruppe Kine), Regenerative Energie Mittelbaden (REM) and TERRA Arbeitskreis “Energiewende”, Karlsruhe. More than twenty specialists from the energy sector and energy management, the power supply industry and representatives of politics and finance participated and discussed about the implementation of a preferably fully regenerative energy supply for Europe.

Dr. Gregor Czisch from the Universität Kassel presented a scenario of harnessing solar and wind energy in North Africa and West Asia together with the storage power stations of Scandinavia to account for an economically priced power supply and to break the climate

change. Then various political, technical and financial aspects were evaluated by the attendants on how to install appropriate solar and wind power stations and the required low-voltage, direct current electric power transmission systems (HVDC) to transport the electricity in Europe's congested areas.

Within the scope of political basic conditions and measures to convert the described concept, Dr. rer. nat. Ruth Klüser presented the results of the recently published study of the Europäische Akademie on the regulation of electricity networks (publication: U. Steger et al.: Die Regulierung elektrischer Netze – Offene Fragen und Lösungsansätze", Springer-Verlag, Berlin 2008, series: Ethics of Science and Technology Assessment, vol. 32). The commensurability of the existing network and its appropriate future extension are the foundation for the transport of electricity from renewable energy resources far away to Europe and Germany via HVDC transmission systems.

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## NEWS

### Ahrtal Talk

■ On Wednesday, 19<sup>th</sup> November 2008, 7.30 pm, the Sponsors' Club of the Europäische Akademie gGmbH invites to this year's Ahrtal Talk at the town hall of the city of Bad Neuenahr-Ahrweiler, Hauptstraße 116, 53474 Bad Neuenahr-Ahrweiler.

Professor Dr. Klaus Heinloth (Physikalisches Institut, Universität Bonn) and Professor Dr. Thomas Ziesemer (Economic Research Institute of Innovation and Technology, University of Maastricht) will dispute on the topic "Renaissance of nuclear power?". Following a short introduction by Professor Dr. Dr. h.c. Carl Friedrich Gethmann, director of the academy, there

will be a disputation between the two speakers. Finally, they will discuss with the audition.

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## PUBLICATIONS

### Carl Friedrich Gethmann

■ "Klimaforschung und Politik", in: *Forum des Instituts der Deutschen Wirtschaft*, Nr. 20 (2<sup>nd</sup> October 2008)

## LECTURES

### Carl Friedrich Gethmann

27/10/2008

■ "Der Eurozentrismus und das abendländische Vernunftprojekt"  
Universität Bayreuth, Semester opening of the study course "Philosophy and Economics"

### Thorsten Galert

16/9/2008

■ "Die Bedeutung des Authentizitätsbegriffs für die Ethik des Neuroenhancements"  
XXI. Deutscher Kongress für Philosophie, Essen

3/10/2008

■ "Pharmaceutical Neuroenhancement and the Ideal of Authenticity"  
Workshop "On the Ethical and Philosophical Relevance of Neuroscience", Universität Bonn, 3/10–5/10/2008

10/10/2008

■ "Eine narrative Theorie der Persönlichkeit und ihre Anwendung auf Probleme der Neuroethik"  
Workshop of the Graduiertenkolleg Bioethik of the Eberhard-Karls-Universität Tübingen, Freudenstadt

## PERSONALITIES



■ Dipl.-Kff. Margret Heyen began her career training with a travel agent in 1997. After three years with the travel agency, she entered the Rheinische Friedrich-Wilhelms Universität in Bonn. There, she studied economics. Heyen transferred her university studies to the Universität Bielefeld in 2002 and continued studying economics and business with an emphasis on operational tax, economic policy and business computer science. She graduated in 2006 with a Business Diploma.

Heyen began her professional career with the Europäische Akademie GmbH where she is responsible for administrative and financial affairs. She is coordinating all matters of administration and finance and is the contact person for all business and legal matters concerning the corporation, especially for the shareholders and sponsors of the company. Heyen is also assistant to the director. Therefore, she is liable for the personal belongings of the director concerning the Europäische Akademie and reports directly to him.

Furthermore, she is responsible for the Sponsors' Club "Verein der Förderer der Europäischen Akademie" and, thus, she is in charge of organising the private viewings, the Ahrtal Talks and the Medical Ethics Working Group. She is also in charge for the administrative and financial affairs and reports directly to the executive committee.

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Dipl.-Kff. Margret Heyen has been staff member of the management of the Europäische Akademie gGmbH since 2006.  
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