



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

■ In 2009 the Europäische Akademie continues its interdisciplinary projects, establishes new ones (cf. Editorial Nr 85) and will arrange a variety of events as every year. The project group “Clinical research in vulnerable populations” (in collaboration with the Berlin-Brandenburgische Akademie der Wissenschaften), for example, took up its work in December 2008. Clinical research in vulnerable populations – such as minors, elderly, and the mentally ill – is an increasingly urgent problem and its state is far from satisfying. The project, thus, aims at developing recommendations for the improvement of clinical research and consequently an improvement of the therapeutic situation of vulnerable populations.

Besides, two conferences will take place (both in Bad Neuenahr-Ahrweiler). On 26/27 March the academy will invite to the conference (held in German) “Transformation von Menschenbildern im Informationszeitalter” (transformation of the philosophy of man in the age of information sciences) to discuss consequences of technology-guided developments for the transformation of the concepts of man. On 8/9 October the (English speaking) conference “The concept of animal welfare: interdisciplinary perspectives” will take place. The symposium will address animal welfare issues on a broad basis, aiming to substantiate reasons and inspire work plans for a philosophical reconstruction of the scientific terminology, concepts and theory of animal welfare science.

The Newsletter will regularly report on projects and events of the academy.

KM

FOCUS

Do we need a “Nano Act”? How (not) to regulate nanotechnology

Katja Stoppenbrink

Nanosciences and nanotechnology have been greatly promoted and heavily subsidized over the last decade. While the debate on “nanoethics” as a separate branch of applied ethics has displayed the demand for normative reflections on nanotechnology, law has exercised considerable restraint with respect to nanotechnology so far. Calls neither for a new field of “nano law” nor for a “nano act” have been ventilated from within this discipline. Debate on the regulatory forefront has become invigorated only recently. This Focus explores the legislative status quo and the range of regulatory proposals in the EU and in Germany.

1 Persistent definitional problems

The quest for clear-cut definitions of nanotechnology tends to provoke the rhetorical question of who needs them. Definitions are not given concepts to be “discovered” but purpose-related conventions which may be relevant in certain contexts. One of these contexts is regulation. While many policy documents on nanotechnology refer to the 1–100 nm range of particles as the relevant defining characteristic, the nanotechnology project group of the Europäische Akademie has established a definition based on functional systems. This gives a hint at the regulatory problem of how to address nanotechnology adequately, for a function- or property-related approach is transversal to the substance-based approach adopted in existing chemical law. Considerable effort is being devoted to taxonomical and metrological issues. The first standard on nanotechnology adopted by the International Standard Organisation was published in September 2008 and refers to practices for the prevention of adverse health and safety consequences during the production, use and disposal of manufactured nanomaterials in occupational settings. For regulatory purposes, it is important to distinguish unintentionally/“naturally” generated nanoparticles (such as

soot from chimneys or diesel engines) from intentionally/synthetically engineered nanomaterials. The standard addresses the latter.

2 Legislative status quo and case-law

While there is no nano-related *lex specialis* in either the EU or Germany, it has to be made plain that nanotechnology is not an unregulated technology. Chemical substances which in their nanoscale may be integrated into “nanomaterials”, and engineered “nanoproductions” are addressed by a number of sectoral regulations such as environmental law (e.g. the German Federal Immissions Control Act), chemical law, occupational health and safety law, food, cosmetics, medicines and medical devices law, product liability law and the duties of care in tort law.

• **Chemical substances regulation:** On 1 June 2007 the new EU Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) entered into force. Its substance definition applies to substances irrespective of their size (art. 3 s. 1). Although there has been some discussion, nanoparticles are, thus, covered, too. The physicochemical, toxicological and ecotoxic-

cological information requirements are tonnage-dependent (art. 12). A Chemical Safety Report (CSR) documenting the Chemical Safety Assessment is only required if a threshold of 10 tonnes per annum is exceeded. In its 2008 report the German Advisory Council on the Environment (SRU) recommends a revision of the quantity-based approach to allow for an early risk detection. The test requirements currently prescribed by the technical guidance documentations for hazardous substances are criticised as inadequate to capture the specific exposition-effect-relations of nanomaterials. The question is whether chemicals legislation is a suitable instrument for regulating nanotechnology, since it codifies an assumption of a direct relationship between volume and exposure. However, for nanomaterials, toxicity is presumed to be related to surface area rather than weight or volume.

- **Food, cosmetics, medicines, etc.:** Specific legislation applies in these particularly sensitive areas. However, not all products require a pre-market notification or authorisation in which the manufacturer's risk assessment is subject to control. There is some uncertainty as to the applicable legislative regime at the respective sectoral intersections. Since industry is very vague about this, it is unclear to what extent nanoparticles are actually being used e.g. in food and cosmetics. The SRU hence called for labelling and registration requirements for nanomaterials in any products.

- **Aspects of liability:** The EU environmental liability regime (translated into the German Environmental Damage Act (USchadG) in 2007) provides strict liability for plant operators carrying out "hazardous activities". They can be held strictly liable for not preventing or restoring any damage to land, water, protected habitats and species. "Hazardous activities" refer to classified substances under the EU chemicals legislation. Other damage, personal injury and damage to personal goods and property, is not covered by the USchadG. For such damage, the "traditional" liability regimes, e.g. the German Environmental Liability Act, product liability and tort law apply. Neither of them has a specific provision for nanotechnology. However, in combination with industrial self-regulation indicating the respective standards of care they may present a considerable incentive of avoiding law-suits on the basis of harmful products. In the present regulatory state, nanotechnological applications are not likely to have been specifically authorised, hence the defence a manufacturer would have to raise relates to the impossibility of anticipating the damaging effect on the basis of the scientific knowledge at that time.

- **Nanospecific case-law:** One example of nano-specific case-law is the 2003 "Nano-

pulver" decision of Germany's Federal Administrative Court. The court explicitly establishes that the Federal Immissions Control Act could "provide the due protection of human health and environment and [that] no explicit authorisation of industrial plants for the manufacturing of nano powder by means of a specific sectoral law" was needed. If there is a "cause for concern" under s. 5 para 1 no. 2 Federal Immissions Control Act, precautionary measures which have to be proportionate in kind and degree may be taken. An extra immission load of below one per cent of recognized thresholds is regarded as irrelevant. The court has recourse to a twelve-year-old study on cancerogenous effects of air pollution through soot particles. These criteria are chosen, because "scientifically detectable thresholds" are lacking. Irrespective of the question of whether such normative analogies from soot particles to other nanoparticles may be appropriate, the court, thus, walks into a naturalistic trap: Threshold values have to be defined and justified, they cannot just be "discovered".

3 Regulation in situations of epistemic uncertainty

The apparent legal limbo with regard to nanotechnology originates in the current lack of specific norms specifying acceptable quantities and thresholds. The applicability of environmental law depends in some respect on the definition of such standards. Sanctions and liability derive their operationalisation from threshold values (limits on measurable quantities) and the establishment of duties of care such as indicated, e.g., by the regulatory guidance documents of the chemical industry. At this stage, hardly any statements on potential environmental, health or safety risks can be made, because, apart from some pioneer work, studies on relevant nanoparticle expositions, human toxicity and ecotoxicity are still missing. This situation of epistemic uncertainty is being prolonged by the fact that recognized testing methods have not yet been developed so that the few toxicological studies presently available are mostly contested. The main challenge is to consider surface structure, size and composition of each type of nanoparticles in order to assess their risks adequately. In the absence of a standardised detection of nanoparticles their risks cannot be quantified so as to allow 'ordinary' risk assessment and management to take place.

4 The role of the precautionary principle

On the European level, the precautionary principle is codified in art. 174 s. 2 of the EC Treaty; its application was specified in a 2000 Communication by the European Commission. Accordingly, the implementation of REACH represents itself a precautionary strategy in accordance with the Commission Communica-

tion (cf. art. 1 s. 3 REACH). For the application of the precautionary principle a two-tier test is required: a cause for precaution (i) may give rise to a precautionary measure (ii). Whilst it is uncontested that with respect to nanotechnology the first requirement, a cause for precaution, is given, there is still considerable disagreement on the appropriate precautionary measures, thus revealing a deep-seated discord on the interpretation and function of the precautionary principle. Without going into details, two different stances can broadly be distinguished.

- **A prohibitionist, strict approach:** This has led to calls for a moratorium on further research into nanoparticles and nanomaterials and for a *pro tempore* ban on the sale of certain nano-based products such as cosmetics and food. However, research activities are fundamental rights and cannot be outlawed altogether on constitutional grounds. Such impractical policy recommendations may be dismissed as "attention-getting devices". To quote a commentator: "[...] a research moratorium would more likely keep us in the dark than keep us safe." (Reynolds, *Harvard Journal of Law & Technology* 17 (179) 2003, 192)

- **An incrementalist, soft (law) approach:** Against a comprehensive nanotechnology regulation at this stage, many commentators have raised a plea for normative incrementalism: a continuous monitoring and evaluation of new research results and a strong focus on safety research which may be described as a regulatory approach of vigilance.

5 Conclusion: Small-sized particles – great regulatory qualms?

Neither have any nano-specific norms been adopted so far nor is there a recognized need for such regulation. As a state of epistemic uncertainty is prevailing, projects to define threshold values for nanoparticles in, for instance, environmental and occupational health and safety law are being frustrated. In the EU the precautionary principle is supposed to apply in such situations. Whereas action groups have called for a moratorium on (certain) research and commercialisation of nanotechnology, the existing legislative framework in the EU is mostly regarded as an adequate application of the precautionary principle. The (possibly self-regulatory) establishment of best practices in risk research and manufacturing and the definition of threshold values for nanoparticles in sub-statutory regulations are required to operationalise the laws in force, to determine duties of care and, thus, allow for manufacturers' civil liability. Abstention from regulatory activity also being normative decisions, an incrementalist approach is being adopted. In June 2008 the European Commission pub-

lished a review of the legislation applicable to nanomaterials. While no demand for immediate regulatory changes was identified, a need of continued and constant market surveillance was expressed. Vigilance and the promotion of further research into toxicity and ecotoxicity of nanoparticles seem to be the order of the day. We do not need a "Nano Act".

Katja Stoppenbrink, LL.M., M.A., Maître en Droit, is scientific staff member of the Europäische Akademie and currently working on a doctoral thesis on the "Foundations of Negligence in Action Theory and Philosophy of Law" (working title).

WORKING GROUPS

New Project Group on Radioactive Waste

■ The project group "Radioactive Waste. Technical and Normative Aspects of its Disposal" joined for its first meeting in Zurich on 18 December 2008. The members closer defined the agenda for its working period up to September 2010 and elected Professor em. Dr. rer. nat. Dr. med. h.c. Christian Streffer (Essen) their chairman. Further members hitherto are Professor Dr. Dr. h.c. Carl Friedrich Gethmann (Europäische Akademie GmbH), Professor Dr.-Ing. Wolfgang Kröger (ETH Zürich), Professor em. Dr. em. jur. Eckard Reh binder (Frankfurt) and Professor Dr. rer. nat. Klaus-Jürgen Röhlig (Technische Universität Clausthal).

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New study group on crucial infrastructure (SKRIBT)

■ On 18 November 2008 the study group "Ethical Evaluation – SKRIBT (Joint Research Project 'Protection of crucial bridges and tunnels of road traffic')" met for a kick-off at the premises of the "Bundesanstalt für Straßenwesen (BASt)" in Bergisch-Gladbach near Cologne. BASt is prime contractor of the BMBF-funded joint research project. Main topics of the meeting were the exchange of information about the capabilities and expectations of the partners with respect to the academy's ethical evaluation task within the project and a report upon its current status as well as upon the further timeline. The next meeting within the whole consortium of ten partners is scheduled to take place at the Universität Bochum on 10 March 2009.

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CONFERENCES

Spring Conference 2009

■ This year's spring conference will take place in Bad Neuenahr-Ahrweiler from 26 to 27 March. The title is "Transformation von Menschenbildern im Informationszeitalter". The German speaking symposium will explore topics in the field of the transformation of the philosophy of man in the age of information sciences: As there is reason for technology-guided transformations of the concepts of man, further consequences have to be evaluated. Speakers will cover research branches from areas such as informatics, biology and philosophy. The conference refers to the academy project "The Research-Guiding Function of Metaphors from the Information Sciences and their Relevance to the Transformation of the Philosophy of Man" (funded by the Federal Ministry of Education and Research (BMBF)). It is organised by the project coordinators Dipl.-Päd. Ulrike Henkel and Thomas Engel, M.A.

 Registration (until 20 March):

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Ethical Questions of Public Health Policy

■ On 6 and 7 November 2008 an expert meeting was held at the academy on "Ethical Questions of Public Health Policy" involving participants from the fields of medicine, jurisprudence, sociology, and philosophy. Discussions focused on ethical, socio-political, and juridical questions of public health policy. Participants were Professor Dr. rer. phil. S. Geyer (Medizinische Hochschule Hannover), Dr. phil. A. Mielck (GSF-Neuherberg), Professor Dr. phil. M. Quante (Universität Köln), Professor Dr. rer. medic. N. W. Paul (Universität Mainz) and Professor Dr. phil. St. Huster (Universität Bochum). A further meeting is scheduled for spring 2009 (19–20 March).

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NEWS

Ahrtal Talk 2008: A Renaissance of Nuclear Power?

■ What will our source of energy in the future be? Is nuclear energy obsolete? Or can it help reduce the greenhouse effect? To what extent does it influence political security on

a national and international level? The latest Ahrtal Talk was hosted by the Europäische Akademie's sponsors' club in conjunction with the city of Bad Neuenahr-Ahrweiler on 19 November 2008. Radiation biologist Professor em. Dr. rer. nat. Dr. med.h.c. Christian Streffer and economist Professor Dr. rer. pol. Thomas Ziesemer engaged in a controversial debate headed by Professor Dr. phil. Dr. phil. h.c. Carl Friedrich Gethmann, director of the Europäische Akademie. Streffer believes that nuclear energy cannot be avoided; without it, it would be impossible to guarantee an energy supply for the coming decades consisting of an "energy mix" of fossil fuels and renewable energy resources.

Economist Ziesemer, from the Economic Research Institute of Innovation and Technology at Maastricht University, countered Streffer's views mainly with economic objections and questions regarding unresolved issues of cost and security. He called for political and industrial decision-makers to continuously invest in new technologies in the fields of biomass energy, hydropower, solar and wind energy as well as geothermal energy.

Gethmann finally led a lively debate with the audience in the course of which the pros and cons of nuclear energy were extensively discussed.

Students visited academy

■ On 17 December 2008, Heinz-Wilhelm Schaumann, M.A., visited the Europäische Akademie GmbH together with his students of the RheinAhrCampus Remagen of FH Koblenz, University of Applied Sciences. In the course of his lectures on "International Studies", Schaumann had chosen the academy as one example of an international approach on science. The students showed great interest in the variety of topics of the academy and discussed with the scientific staff. Schaumann and the academy staff both agreed to continue the mutual communication on technology assessment.

Humans in Outer Space

■ On 28 October 2008, the European Science Foundation and the European Space Policy Institute presented a book publication on "Humans in Outer Space" on the occasion of a meeting of the International Council of Science in Paris. The book compiles the results of the last year's conference of the publishers on this issue. Multi-disciplinary contributions of international experts – also from the Europäische Akademie – focused on the human quest for exploration beyond the terrestrial atmosphere with respect to current plans of space-faring nations.

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PUBLICATIONS

Bert Droste-Franke

■ Together with H. Berg, A. Kötter, J. Krüger, K. Mause, J.-C. Pielow, I. Romey, T. Ziesemer, *Brennstoffzellen und Virtuelle Kraftwerke. Energie-, umwelt- und technologiepolitische Aspekte einer effizienten Hausenergieversorgung*, vol. 36 of the series 'Ethics of Science and Technology Assessment', ed. C. F. Gethmann, Berlin: Springer 2009

■ Together with H. Berg, A. Kötter, J. Krüger, K. Mause, J.-C. Pielow, I. Romey, T. Ziesemer, *Fuel Cells and Virtual Power Plants. Energy, Environmental, and Technology Policy Aspects of an Efficient Domestic Energy Supply. Executive Summary*, vol. 47, Graue Reihe, 11/2008

Thorsten Galert

■ "Wie mag Neuro-Enhancement Personen verändern?", in B. Schöne-Seifert, D. Talbot, U. Opolka, J. S. Ach (Hgg.) *Neuro-Enhancement. Ethik vor neuen Herausforderungen*, Paderborn: Mentis 2008, 159–187

Carl Friedrich Gethmann

■ "Wunscherfüllende Medizin?", in: D. Grönemeyer, Dietrich, Th. Kobusch, H. Schott (Hgg.) *Gesundheit im Spiegel der Disziplinen, Epochen, Kulturen*, Tübingen: Niemeyer 2008, 333–343

Georg Kamp

■ Together with G. de Haan, A. Lerch, H. G. Nutzinger, L. Martignon, G. Müller-Christ, *Nachhaltigkeit und Gerechtigkeit. Grundlagen und schulpraktische Konsequenzen*, vol. 33 of the series 'Ethics of Science and Technology Assessment', ed. C. F. Gethmann, Berlin: Springer 2008

■ "Wenn man sich im gemeinsamen Handeln wirklich eine Sprache aufbaut..." Logische Propädeutik als Mittel zur lebensweltlichen Störungsbewältigung", in: J. Mittelstraß (Hrsg.) *Der Konstruktivismus in der Philosophie im Ausgang von Wilhelm Kamlah und Paul Lorenzen*, Paderborn: Mentis 2008, 63–91

■ Art. 'Gebrauchstheorie der Bedeutung'; Art. 'Gehirn im Tank'; Art. 'Genius Malignus'; Art.; 'Handlungslogik'; Art. 'Handlungstyp/Handlungstoken'; Art. 'Humesches Gesetz'; Art. 'Implikatur'; Art. 'indem-Relation'; Art. 'Interventionismus'; Art. 'Jørgen Jørgensen'; Art. 'Jørgensens Dilemma', in: J. Mittelstraß (Hrsg.) *Enzyklopädie Philosophie und Wissenschaftstheorie*. 2nd, updated and extended version. Stuttgart, Weimar: Metzler, 2005ff.

LECTURES

**Margret Engelhard/Kristin Hagen/
Felix Thiele**

16/10/2008 and 3/11/2008

■ Radio Features on "Pharming": "Impfbananen und Medizin-Mais. Pharmapflanzen mit Zukunft?", SWR 2, Feature "Die Milch macht's. 'Pharming' erzeugt Arzneien in gentechnisch veränderten Tieren", DLF, *Forschung Aktuell*

Thorsten Galert

9/12/2008

■ Radio Interview on "Ritalin": "Wissenschaftler arbeiten am Braindoping", DLF, *Informationen am Morgen*

Carl Friedrich Gethmann

15/1/2009

■ "Der Mensch handelt mittels seines Gehirns (und nicht dieses in ihm). Sprachpragmatische Überlegungen zu einigen Amphibolien in der gegenwärtigen Diskussion" ETHOS. Mariazeller Dialog 2009 "Gehirnforschung und Ethik" (Mariazell, Österreich)

PERSONALITIES



■ Professor Dr. med. Thomas E. Schläpfer received his medical training at the Universität Bern, Switzerland. His residency training in psychiatry began at the Universitätsklinik Bern and was completed at the Johns Hopkins Hospital in Baltimore, MD, USA. After a fellowship in psychiatric neuroimaging he joined the departments of psychiatry and mental health at Johns Hopkins. In 1997 he returned to the department of psychiatry of the Universitätsklinik Bern as associate professor; since 2003 he has been professor of psychiatry and psychotherapy and the vice-chair of the department of psychiatry and psychotherapy of the Universität Bonn, Germany. Since 2006 he has been dean of medical education at the Universität Bonn. In Switzerland and the USA he was trained in cognitive-behavioural therapy, contextual family therapy, and interpersonal therapy. Schläpfer has authored and co-authored over 100 peer-reviewed research reports and reviews; his areas of interest are brain stimulation methods (ECT, rTMS, MST, VNS and DBS) in the treatment of refractory major depression and functional neuroimaging methods in affective disorders. He is member of the editorial boards of *Neuropsychopharmacology*, *Journal of ECT*, *CNS Spectrums* and *International Review of Psychiatry*. He is a fellow of the *American College of Neuropsychopharmacology (ACNP)* and serves on the programme committees of the *Society of Biological Psychiatry (SOBP)* and the *Collegium Internationale Neuro-Psychopharmacologicum (CINP)*. Furthermore, he is member of the board of the *Association for Convulsive Therapy* and the *International Society for Transcranial Stimulation*.

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Professor Dr. med. Thomas E. Schläpfer, Universität Bonn, is chair of the project group "Deep Brain Stimulation in Psychiatry. Guidance for Responsible Research and Application" at the Europäische Akademie GmbH.

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