'degenerate research', and allowing persecution of practitioners of certain intellectual approaches, such as the use of the most precise and predictable techniques for genetic modification, the stridency and absolutism of the activists' pronouncements—and their violent tendencies—will only increase. It is not hard to draw parallels with some of the excesses of intellectual persecution in the 1930s, when the regime's objections to *Entartete Kunst,* or 'degenerate art', drove out such great minds and innovators as Albert Einstein, Emil Nolde, Max Beckmann, Marc Chagall, Vincent van Gogh, Henri Matisse, Edvard Munch and Pablo Picasso. Those who ignore the mistakes of history are destined to repeat them.

But Herr Hormuth has a different take on Germany's past. In an e-mail to me, he wrote: "If we look at history then we should have also learned that we have to act responsibly with the results and possibilities of scientific research and are accountable to society." A quite extraordinary statement. Given the existing achievements of recombinant DNA–modified plants—economic benefits to farmers, less use of chemical pesticides, more environment-friendly farming practices—he appears to have a peculiar view of what constitutes acting "responsibly with the results and possibilities of scientific research" and being accountable to society. Could anyone argue seriously that delaying or abandoning a demonstrably safe technology that is environmentally friendly and enhances food (and potentially, biofuel) production is beneficial to society?

This time around, the German government is not directly culpable for the current situation, but it certainly has failed to protect freedom of expression and the personal safety and property of plant scientists against assaults by antitechnology activists. (In the United States, such groups have been officially designated as terrorist organizations.) How have we arrived at a position in the 21st century where thugs and vandals dictate the research and syllabus of the academic institutions of a major Western European democracy?

One reason is that policy makers in both the European Union (EU) and in individual European countries like Germany have consciously and purposefully chosen not to apply scientific and risk-based regulatory policies to the oversight of recombinant DNA–modified plants. Flying in the face of the scientific consensus—including the EU's own risk assessments—current EU and national regulations cast a veil of suspicion over agbiotech by requiring case-by-case government environmental assessments for field testing with recombinant DNA–modified plants. In contrast, plants with similar or even identical traits that were created with less precise techniques, such as hybridization or mutagenesis, are subject to no government scrutiny or requirements (or publicity or vandalism) at all. And that applies even to the numerous new plant varieties that result from 'wide crosses' with embryo rescue, hybridizations that move genes from one species or genus to another; that is, across what used to be thought of as natural breeding boundaries.

If recombinant DNA–modified plants were treated appropriately—that is, no differently from other new varieties—their testing would not need special warning signs or public announcements of test sites. There would be no way for the vandals to target and disrupt field research that they deem unacceptable.

There are important lessons here. First, you don't conciliate thugs by capitulating to them. Second, the problem would have been avoided entirely, had public policy been crafted intelligently in the first place. And third, when universities permit intimidation to compromise academic freedom and the safety of their faculty and students, they become part of the problem.

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Trace and traceability—a call for regulatory harmony

To the Editor:

Genetically modified (GM) crops were grown commercially in 23 countries in 2007, with a further 29 allowing the import of GM crops for food and/or feed use and release into the environment[1]. Despite encouraging evidence concerning the positive socioeconomic and environmental benefits brought about by the adoption of GM technology[1,2], we wish to highlight the fact that further development is being hampered by a lack of harmonization among national regulatory frameworks relating to research, biosafety and to the trade and use of GM crops. Nowhere is this more apparent than in the laws and regulations governing the tolerance levels for GM material in non-GM food and in the labeling and traceability of GM products.

The definition of what is considered GM and non-GM food varies from country to country, with some nations enshrining precise tolerance targets in their GM regulations and some overlooking this important criterion. The European Union (EU; Brussels) follows the 'precautionary approach' and the consumers' 'right to know', with stringent approval, labeling and traceability standards on any food produced from or derived from GM ingredients[3]. In contrast, US regulations are based on differences in the end product, and include a voluntary safety consultation and voluntary labeling guidelines for GM food[4]. Most other developed countries, including Japan, Canada, Australia and New Zealand, have introduced regulations that share features of both the EU and US systems[4]. Developing countries often base their regulatory frameworks on models promoted by developed nations without considering the potential socioeconomic impact of such decisions, and the negative consequences of an overcautious regulatory environment on the health and well-being of their populations. The regulatory frameworks of selected countries are compared in **Table 1.**

In the United States and Canada, as well as Japan and Taiwan, food and feed can be classed as non-GM, even if they contain up to 5% GM material. In contrast, other countries set much lower limits (e.g., 0.9% in the EU or 1% in Australia, New Zealand, South Africa, Brazil and China). The EU actually has a two-tier tolerance policy, with the 0.9% limit applied to approved GM organisms, and a stricter 0.5% limit applied to GM organisms that have yet to be approved, but which have received favorable risk assessments. In many developing countries, there appears to be no established tolerance limit, which calls into question how such countries will distinguish GM and non-GM food and feed. Similarly, this global regulatory discord begs the question of how nominally GM-free food and feed imported from countries with high tolerance will be handled in stricter countries when it may breach local regulations concerning GM tolerance. This inevitably will

lead to disputes and the impounding of food and feed.

The potential confusion caused by these conflicting tolerance levels will only become worse as more countries join the 'GM club'. It is projected that the number of countries growing GM food and feed commercially will double over the next 10 years in line with the amount of land given over to GM crops[1]. The potential for conflict is compounded by disharmonious regulations concerning the labeling and traceability of GM food. The USA, Canada, Mexico, Argentina, The Philippines and South Africa have voluntary labeling practices, whereas the EU, Australia, New Zealand, China, Chile, Brazil and Taiwan require the mandatory labeling of GM produce. Still other countries, including Bangladesh, Egypt and Kenya, have no requirements for labeling at all.

As the prevalence of GM crops continues to grow, we foresee real problems with the trade and use of food and feed if the regulations are not harmonized on a global level. US food exporters and biotech companies have already complained about the EU's slow and obscure approval process, and bans by individual EU countries on GM products approved by the EU as a whole[5]. This ongoing dispute has been intensified by

Table 1 Current GM biosafety regulations for selected countries

Country	Governing bodies/agencies	Regulations/laws	Product/ process based	Transparency	Labeling and traceability	Tolerance levels
Argentina	Comisión Nacional Asesora de Biotecnología Agropecuaria, Servicio Nacional de Sanidad y Calidad Agroalimentaria, Instituto Nacional de Semillas, Direccion Nacional de Mercados Agroalimentarios	Law 18284 on Argentine Food Codex, Decree 1585/96, Decree 4238, Decree 815/99, Resolution 289/97, Resolution 511/98, Resolution 1265/99	Product	Yes	Voluntary	n.d.
Australia	Office of the Gene Technology Regulator, Food Standards Australia New Zealand	Gene Technology Act 2000, Standard 1.5.2- Food Produced Using Gene Technology	Process	Yes	Mandatory	1%
Bangladesh	Ministry of Agriculture, Ministry of Science and Information & Communication Technology, Ministry of Environment & Forest	Draft Biosafety Guidelines	Product	n.d.	No labeling regulation	n.d.
Brazil	Conselho Nacional de Biosegurança, Comissão Técnica Nacional de Biossegurança	Biosafety Law Number 11.105	Process	n.d.	Mandatory	1%
Burkina Faso	National Biosafety Agency	Decree 2003-208-/PRES/PM/MAECR/ MFB/MECV	Process	No	n.d.	n.d.
Canada	Canadian Food Inspection Agency	Consumer Packaging & Labeling Act, Feeds Act, Fertilizers Act, Food & Drugs Act, Health of Animals Act, Seeds Act, Plant Protection Act	Product	Yes	Voluntary[a]	5%
	Health Canada	Food & Drugs Act, Canadian Environmental Protection Act, Pest Control Products Act				
	Environment Canada	Canadian Environmental Protection Act				
Chile	Advisory Committee for the Release of Transgenics (Ministry of Agriculture, Agricultural and Livestock Service, National Agricultural Research Institute, National Commission on Scientific and Technical Research)	Resolution of exemption 1927/93 Decree-Law 3554/81	n.d.	n.d.	Mandatory	n.d.
China	Administration for Quality Supervision, Inspection and Quarantine State Environmental Protection Administration, Ministry of Science and Technology, Ministry of Commerce, Ministry of Health	Under discussion	Process	n.d.	Mandatory	1%
Egypt	National Biosafety Committee	No proper biosafety regulation but Ministerial decree No. 1648 (1998) is for commercialization of imported products; National Biosafety Committee guidelines occur, however, not legally binding	Process	n.d.	No labeling required (no framework)	Not established
EU	Member states' competent authorities and European Commission	EU Directive 2001/18/EC (2001), EC Regulation 258/97 (1997)	Process	Yes	Mandatory[b]	0.9%; 0.5% food and feed
India	Ministry of Environment & Forests, Department of Biotechnology	EPA 1986 &1989 Rules	Process	Yes	Proposed legislation for mandatory labeling occurs	n.d.
Japan	Ministry of Agriculture, Forestry and Fisheries, Ministry of Health, Labor and Welfare, Ministry of the Environment, Ministry of Education, Culture, Sports, Science and Technology	Law Concerning the Conservation & Sustainable Use of Biological Diversity through Regulations on the Use of LMOs, Food Sanitation Law, Feed Safety Law	Process	Yes	Mandatory for selected products	5%

(continued)

Table 1 Current GM biosafety regulations for selected countries (continued)

Country	Governing bodies/agencies	Regulations/laws	Product/ process based	Transparency	Labeling and traceability	Tolerance levels
Kenya	National Biosafety Committee, National Environmental Management Authority, Kenya Bureau of Standards, Kenya Animal Plant Health Inspectorate Services, Kenya Standing Committee on Imports and Exports, Public Health Department, Department of Veterinary Services, Pest Control Products Board	Kenyan Draft Biosafety Bill of 2003, EMCA Act	Process	Yes	No labeling addressed in draft bill	Not established
Mexico	Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion, Secretaría de medio ambiente y recursos naturales, Secretaria de Salud, Comision Federal para la Proteccion contra Riesgos Sanitarios, Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados	Biosafety Law of Genetically Modified Organisms (2005)	Process	Yes	Mandatory	n.d.
New Zealand	Environmental Risk Management Authority, New Zealand Food Safety Authority, Food Standards Australia New Zealand, Ministry of Agriculture and Forestry	The Hazardous Substances & New Organisms Act 1996 (HSNO Act)	Process	Yes	Mandatory	1%
Nigeria	Federal Ministry of Environment, National Biosafety Committee	Nigeria Biosafety Guidelines, Draft biosafety bill	Process	Yes (planned in draft bill)	Mandatory as planned in draft	n.d.
South Africa	Executive Council of Genetically Modified Organisms, Department of Agriculture, Department of Environment and Tourism, Department of Health	GMO Act, 1997 (Act No. 15 of 1997), amended 2007; National Biodiversity Act	Product	Yes	Voluntary	1%
Taiwan	Taiwan Department of Health; Council of Agriculture	Article 14 of the Law Governing Food Sanitation	Product	Yes	Mandatory	5%
The Philippines	National Committee on Biosafety of the Philippines (Departments of Agriculture, Science and Technology, Health, and Environment and Natural Resources), Institutional Biosafety Committee	E.O. 430 (1990) DA-A.O. No. 8 (2002)	Product	Yes	Voluntary	5%
UK	Health and Safety Executive, Department for Environment, Food, and Rural Affairs	Directive 2001/18/EC	Process	Yes	Mandatory	[c]
	Food Standards Agency, Advisory Committee on Releases to the Environment	Regulation (EC) No 1829/2003				
USA	US Department of Agriculture	Federal Plant Protection Act	Product	Yes	Voluntary[a]	5%
	Environmental Protection Agency	Federal Insecticide Fungicide and Rodenticide Act, Federal Food Drug and Cosmetic Act, Toxic Substances Control Act				
	Food and Drug Administration	Federal Food Drug and Cosmetic Act				
Zambia	National Biosafety Authority, Scientific Advisory Committee[d]	National Biotechnology & Biosafety Bill	Process	Yes	n.d.	n.d.

[a]Labeling required if safety concerns (allergenic, change in nutritional composition) exist. [b]Labeling required at a 0.9% threshold for approved GM organisms or 0.5% for GM organisms given a favorable risk assessment but not yet approved (called 'adventitious presence') and 0% for unapproved GMOs. [c]To be established by the biosafety bill, however, the Parliamentary Committee on Education, Science and Technology currently is in rule. [d]Labeling is required of seeds used for planting—the characteristics of the acquired genetic combination, implications with regard to special conditions and growing requirements, and changes in reproductive and productive characteristics should be stated. n.d., not disclosed.

the EU's introduction of mandatory labeling. The role of the World Trade Organization's (Geneva) legal framework regarding trade in GM products (the Sanitary and Phytosanitary Agreement, and the Agreement on Technical Barriers to Trade; http://www.wto.org has played a significant role in stifling the opportunities offered by GM products. Strict labeling, identity preservation and import requirements impose additional costs and reduce public confidence, which in turn affects trade. The decline in US corn exports to the EU has been blamed on the EU's strict approval and labeling requirements, with some EU countries banning GM products all together, even after they have been approved as safe by European Food Safety Authority (Parma, Italy), the EU's own regulatory agency on GM[6]. Developing countries have also been drawn into this dispute as both sides try to win their support. Many developing countries have banned GM products owing to consumer and environmental concerns, only to find themselves excluded from markets and refused financial support from industrialized nations to conduct research and build human capital for biotech activities.

In the decade since GM crops were first adopted, it is estimated that farmers have earned $27 billion from the technology, split almost equally between developed and developing countries[2]. As well as direct economic benefits, GM crops reduce pesticide use, and reduce the use of fossil fuels in agriculture[2]. These benefits could be lost, or curtailed, if the regulations in different parts of the world are not brought into line, or at least made mutually compatible. It is also important to base the global regulations on scientific principles rather than unrealistic expectations of risk avoidance. Currently, many countries have in place regulations that erect unnecessary hurdles to the further development of the technology, especially

developing countries where the benefits are most needed[7].

Several policy tools have been used to accommodate, reduce or eliminate international regulatory diversity[8]. One realistic approach is 'mutual recognition', where countries agree to recognize each other's regulations; for example, the US and EU could agree to allow imports of each other's products (GM and conventional) produced and marketed under home regulations, giving consumers on both sides of the Atlantic the choice. Perhaps if Europe and the US were to show such leadership, this type of compromise could be rolled out globally. Whatever the case, as more and more countries cultivate GM varieties, and national and international bodies continue to promulgate diverging regulatory approaches, there is little doubt that a more harmonious future for GM food and feed regulation would be in the interests of all.

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Do-it-yourself (DIY) pathology

To the Editor:

An exchange of correspondence in your November issue highlighted the importance of precise terminology for pathology data and terminology in scientific research and literature[1]. In the past few decades, several developments in technology have significantly increased the use of pathology in basic and translational research. For example, the development of genetically engineered mice has resulted in the creation of an ever-increasing variety of murine disease models. And more recently, availability of new technologies, such as mRNA expression arrays and tissue microarrays, has allowed basic researchers to work with patient tissue samples. Even so, the application of these technologies appears to have outpaced our ability to properly evaluate the resulting data[2].

The systematic analysis of disease phenotypes in mice, and their correlation with human disease, requires expertise in 'comparative pathology', encompassing training both in mouse and human gross anatomy, microscopic analysis of tissues (histopathology and immunopathology) and disease mechanisms (pathobiology), which even the most accomplished basic or clinical scientists frequently lack[2]. Formal training in one field of pathology might prepare one to become a self-taught expert in another field of pathology. However, we find it unlikely that one can become an expert pathologist with no prior formal training.

Those of us with comparative pathology expertise have collectively noted that numerous tissue-based research studies have been published over the past decade without a pathologist among the authors, collaborators or consultants[2]. Furthermore, based on the frequently inaccurate use of pathology terms and misinterpretation of data in many of these studies, it appears that not only the authors but also the reviewers and editors often have neglected to consult a comparative pathologist during the evaluation of such manuscripts. One must wonder whether such a practice would be allowed if a submitted manuscript contained complex statistical analyses and no statistician was involved during the preparation or review of the manuscript, or crystallography was used to resolve a molecular structure but no expert was asked to check the X-ray diffraction data. Yet, it appears that when it comes to evaluation of human tissues and genetically engineered mouse (GEM) phenotypes, which is no less complex than statistics or X-ray diffraction, unvalidated DIY pathology' has become common—and frequently accepted—practice[2].

We have previously noted the dwindling number of comparative pathologist-scientists who are qualified to coordinate and critique the pathological interpretation and the basic science in a manuscript[3,4]. There is an urgent need to make use of existing experts and encourage the growth of this discipline[5]. We recognize that a qualified expert may not be available for journal editors in some instances. However, when a pathologist-scientist who can review the entire manuscript is not available, both journal editors and grant study sections should, at least, seek the expert opinion of a pathologist to perform a fact and/or quality check of the pathology data, without necessarily commenting on the basic science. Implementing such a policy routinely during manuscript reviews in *Nature* journals would have an immense positive impact for the future health of scientific research. We, a group of concerned investigator-pathologists, have formed a nonprofit educational foundation, Center for Genomic Pathology (CGP; Davis, CA, USA; http://www.ctrgenpath.org/) to address these issues. We invite others who are interested in this issue to participate in a comprehensive debate to develop standards for the manuscript and the grant review process involving human and genetically engineered mouse tissues and use of pathology in research. We note that this letter represents a consensus opinion of the faculty of CGP and other cosigners below.

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