

Assessing the Security Implications of Genome Editing Technology

Report of an international workshop

Herrenhausen, Germany
11-13 October 2017

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This report has been prepared and published by IAP.
The views expressed in these proceedings of the workshop do not necessarily represent those of the individual academies of science, workshop funders, or any other organizations that provided support for the project.

About the InterAcademy Partnership

The InterAcademy Partnership (IAP) was formally launched in South Africa in March 2016, bringing together three established networks of academies of science, medicine and engineering, now re-named as IAP for Science, IAP for Research and IAP for Health.

Under the new InterAcademy Partnership, more than 130 national and regional member academies work together to support the special role of science and its efforts to seek solutions to address the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals.

The work of the world's academies of science, medicine and engineering has resulted in lives saved, better education, and more effective policy approaches to a range of issues. Academies are typically independent and highly committed institutions that recognize and promote excellence and achievement. By definition, they are merit-based, with members selected from among the leading scientific minds within a country or region. In addition to their honorific roles, academies are vital civil society institutions that have the credibility to inform the public and policy-makers about problems and potential solutions. Their credibility comes not only from the scientific excellence of their members, but also from the fact that they are free of vested political and commercial interests. Indeed, although many academies were established by national governments and tasked with serving their countries by, among other things, bringing scientific perspectives to bear on national and international issues, they were also constituted as independent bodies.

Just as each IAP member academy represents an authoritative voice nationally, this unified voice of academies under IAP aims to have great impact at the international level. Now, as international attention has turned to the 2015 Sustainable Development Goals, IAP provides a collective mechanism and voice for science academies to further strengthen their crucial roles as providers of evidence-based policy and advice. IAP will also continue to produce evidence-based statements and reports examining major priorities for sustainable development, and provide independent and authoritative advice to national governments and inter-governmental organizations, including the UN, on critical science-based issues.

Foreword

This report, the proceedings of a workshop “Assessing the security implications of genome editing technology” is published by the InterAcademy Partnership (IAP). IAP is the global network of more than 130 national academies of science, medicine and engineering, together with four regional networks of academies in Africa, the Americas, Asia and Europe. These academies work together to support the role of science in seeking solutions to the world’s most challenging problems.

In organising this workshop, IAP joined with the US National Academies of Science, Engineering and Medicine (NASEM), the European Academies Science Advisory Council (EASAC) and the German National Academy of Sciences Leopoldina, to review the latest advances in genome editing and their societal implications. Potential benefits span medicine, plant and animal breeding, microbial production systems and gene drives, systems that could potentially transform an entire population of a selected animal or plant species. In addition to discussing potential benefits, the workshop was designed to explore potential safety and security – associated with intended misuse – implications, and ways to prevent or mitigate those potential security concerns. The workshop recognised the importance of an open and inclusive discussion with stakeholders and the promotion of a research culture that builds trust through responsibility and integrity.

As with any other new technology, a lack of communication about uncertainties may undermine public confidence in science. Scientists and security experts should listen to concerns regarding the potential misuse of genome editing and provide their expertise on what is, and is not, likely. The scientific community must ensure that younger researchers and researchers worldwide also have a voice in this ongoing dialogue.

Genome editing offers tangible benefits. There should be balanced discussion of the benefits and any potential safety or security issues, particularly where they relate to consumers. More widespread use of genome editing does not necessarily mean that there will be increased risks of misuse. Indeed, it was noted in the workshop that genome editing could also help to tackle security challenges for health and food.

A variety of approaches to prevention and mitigation – via technical, legal, regulatory and policy initiatives – were highlighted in the workshop as important ways to tackle potential security concerns. There are already a wide range of governance options that are important for integrated management of research and its outputs. According to the workshop participants, many current regulatory frameworks already in place for research and its applications can also be applied to genome editing. There is a need to share good practice in research, policy and regulation worldwide and to continue monitoring developments to ensure that there is flexibility to enable and manage innovation.

Our workshop and this report are intended as first steps in catalysing and supporting further debate. It was agreed in the workshop that it would be highly desirable to develop a sustainable network encompassing the scientific and security communities and others, to share perspectives, facilitate information exchange, identify priorities for further study, and serve as a basis for extending the engagement more widely. IAP has a history of interest in the issues for emerging technologies and responsible science and experience in engagement with policy makers on security issues, for example in discussions about the Biological and Toxin Weapons Convention. We in IAP will continue in our follow-up on the points emerging from this workshop and will distribute these proceedings to all our academies and key contacts. We will encourage our academy members and their networks to support their scientific communities through their convening, evidence-gathering and advisory functions. This includes:

- **Continuing to provide their expertise to set these issues in context;**
- **Promoting interdisciplinarity and collaborative work;**
- **Explaining the potential significance of research outputs and facilitate sharing of knowledge to raise awareness with other stakeholders;**
- **Contributing independent assessment of developments in innovation to inform policy options.**

Further effort in all these areas is required at national, regional and global levels: IAP greatly welcomes feedback on this report to discuss any of the points we have raised or any others that require attention.

This has been a pioneering collaborative initiative and I thank: the co-organisers of this workshop and the members of the Planning Committee for their considerable support and commitment; all presenters for their contribution to the workshop and for their review of the draft of this report; all other workshop participants for their active involvement in the discussion; the Volkswagen Foundation and Gordon and Betty Moore Foundation for their financial support and the Volkswagen Foundation additionally for their local organisation of the workshop; and Robin Fears for preparing the draft of this report.


Volker ter Meulen
President, IAP

CONTENTS

Foreword	5
Report of the Workshop	7
Welcome from the Organisers	7
Keynote Lectures: A New Age of Biology	8
Advances in Genome Editing: Promise and Readiness	9
Assessing the Security Dimensions Associated with Specific Applications of Genome Editing Technologies	11
Breakout Discussions – Assessing the Security Dimensions Associated with Specific Applications of Genome Editing	12
Summary of Breakout Sessions as contributed by Rapporteurs, and Plenary Discussion	12
• Human cell editing	13
• Editing in agriculture (plants and animals)	13
• Gene drive applications	14
• Microbial applications	14
Strategies for Addressing Potential Security Risks of Genome Editing	15
Legal, Regulatory and Policy Strategies for Genome Editing: General	15
Legal, Regulatory and Policy Strategies: Security-Specific	16
Norms of Responsible Behaviour and Voluntary Guidelines	16
Scientific and Technical Strategies	17
Breakout Discussions: Addressing and Mitigating Potential Security Risks Associated with Specific Applications of Genome Editing	18
Summary of Breakout Sessions, Contributed by Rapporteurs, and Plenary Discussion	18
• Human cell editing	18
• Editing in agriculture	19
• Gene drive applications	19
• Microbial applications	20
Public Communication and Engagement on Potential Security Risks of Genome Editing Applications	21
Panel discussion	22
The Way Ahead	22
Workshop Agenda	24
List of Participants	29

Report of the Workshop

Academies of science, comprising the InterAcademy Partnership (IAP), the European Academies' Sciences Advisory Council (EASAC), the US National Academies of Science, Engineering and Medicine (NASEM), and the German National Academy of Sciences Leopoldina, convened an international workshop of experts in genome editing, security studies and public policy. International dialogue is particularly important because of the rapid development and widespread use of genome editing tools in countries with various, sometimes divergent, regulations and governance of research. The workshop organisers thank the Volkswagen Foundation and the Gordon and Betty Moore Foundation for their support. This report has been prepared and published by IAP. The views expressed in these proceedings of the workshop do not necessarily represent those of the individual academies of science or workshop funders.

Welcome from the Organisers

In welcoming participants, **Volker ter Meulen** (IAP) described the broad interests of the workshop organising committee in examining issues for emerging technologies – exemplified by genome editing – their potential benefits and concerns. Previous work by individual academies and their networks, IAP and EASAC, has already helped to lead discussion on the manifold implications of the new tools and on responsible science more broadly. Researchers cannot dissociate themselves from the uses of the new knowledge they generate and they must take into consideration the reasonably foreseeable consequences of their activities. Through engagement with broader society, researchers also have the opportunity to help promote policies that are intended to support both improved security and continued scientific progress.

A major goal of the workshop was to enable members of the research, security, and policy communities to discuss the potential benefits and security implications – associated with intended misuse – of these technologies, and what might be done to prevent or mitigate potential harm. The workshop was organised with breakout sessions to facilitate inclusive discussion with wide geographical, sectoral and disciplinary representation. In the time available, it was not possible to resolve all the issues but the aim was to bring greater clarity to concerns that had been raised elsewhere.

¹IAP and IAC 2012, *Responsible conduct in the global research enterprise*, <http://interacademies.net/file.aspx?id=19789>

²EASAC 2017, *Genome editing: scientific opportunities, public interests and policy options in the European Union* (<http://www.easac.eu/home/reports-and-statements/detail-view/article/genome-editi.html>)

³For example, US National Academies 2016, *Genetically engineered crops: experiences and prospects* (US National Academies 2016, *Genetically engineered crops: experiences and prospects*); 2016, *Gene drives on the horizon: advancing science, navigating uncertainty, and aligning research with public values* (<https://www.nap.edu/catalog/23405/gene-drives-on-the-horizon-advancing-science-navigating-uncertainty-and>); 2017, *Human genome editing: science, ethics, and governance* (<https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance>)

In adding a personal welcome from IAP, ter Meulen observed that previous IAP work had assisted in clarifying the implications of scientific advance, fostered understanding of governance mechanisms – including responsible research conduct – and encouraged links with policy-makers for example in discussion of the Biological Weapons Convention (BWC). IAP regards proactive international dialogue as vital to support and inform public engagement. Sharing of evidence and good practice is also highly important to the IAP objective to build academy capacity at the science-policy interface.

Wilhelm Krull (Volkswagen Foundation) noted that scientific advances may have many socio-economic implications. For example, as seen recently, the opportunities inherent in genome editing may help to drive corporate merger plans and political coalitions. Recognition of the importance of molecular biosciences is not new but genome editing may be perceived as a tipping point with many potential consequences. This international consortium had worked hard to construct a stimulating and intensive programme to generate ideas and identify priorities in a fast-moving field and, thereby, inform and lead subsequent discussion and action.

Thierry Courvoisier (EASAC) introduced the EASAC European report, published earlier in the year, on *Genome Editing* that had included discussion of safety and security aspects, the latter primarily in the context of responsible science and self-regulation. EASAC supports the continuing international discussion of the issues: to better understand the global environment, to set potential security concerns into the broader context of the potential societal benefits, and to reflect on how the scientific community can play its part in the wider engagement with stakeholders and publics, recognising that science moves rapidly and society also changes.

Diane Griffin (NASEM) observed that the involvement of the US national academies in these issues began in 2001 and has continued up to a recent report on dual-use research of concern in the life sciences, encompassing also a series of published studies on specific aspects of genome editing. These are complex global issues, involving many disciplines. The workshop is timely and relevant in its objectives to clarify what is uncertain and to lead to a common understanding of the scientific norms for genome editing.

Jörg Hacker (German National Academy of Sciences Leopoldina) added that the Leopoldina also had significant interests in the area of genome editing, whose developments may lead to expansion of research outside of the conventional laboratory setting. There is a general tension between researchers' freedom and research responsibility, and previous debates about dual use have indicated that research findings and methods have a potential to be misused. In the view of the Leopoldina, formal legal instruments offer only limited protection against misuse and research progress can be difficult to predict. Therefore, the research community has to accept its responsibility and develop mechanisms of self-governance in handling security-relevant research issues. Work by the Leopoldina and others to be discussed later in the workshop has underpinned the establishment of committees throughout Germany to manage responsible research guidelines, review opportunities and risk, and minimise unintended consequences.

Keynote Lectures: A New Age of Biology

This session, chaired by Indira Nath (All India Institute of Medical Science), was designed to provide high-level overview of genome editing technologies within the broader contexts of biotechnology and communication about new technologies with the public.

Sir Venki Ramakrishnan (Royal Society) introduced A New Age of Biology by observing that, although genetic technologies might seem new, selective breeding of domesticated crops and animals has been underway for a very long time. But the new tools are very powerful, in dramatically decreasing the cost of DNA sequencing and synthesis and allowing the increasingly precise, cheap and easy editing of entire genomes. The relationship of the researcher and the natural world may be changing: from observing, preserving and controlling, to creating and directing evolution. Genome editing tools have potential uses in:

- **Tackling human disease – e.g. to treat single or multi-gene disorders but also to make cosmetic changes and, perhaps, to enhance human abilities. Controversy regarding some of these applications is magnified by the future possibility to edit the germline and change future generations.**
- **Developing gene drives – e.g. to control insect vectors of diseases such as malaria. This application raises questions about the consequences of eliminating entire species, and how to test those consequences, although there may also be applications to correct previous**

human disturbances of vulnerable ecosystems (for example, to reverse the introduction of a rodent pest on an island).

- **Food security – e.g. to generate crops with higher yield, greater nutrient content and resistance to drought, pests, pathogens or herbicides.**

Previous use of genetic technologies in crop breeding had sometimes been controversial, possibly because of the perception that commercial priorities were different from societal priorities. There is need to catalyse debate on what technology can do and on the distribution of risks and benefits, acknowledging that views on risk depend on context and culture. The Royal Society is currently initiating public dialogue to explore views on which genetic technology applications should be developed, why, and under what conditions. Professor Ramakrishnan advised that regulatory systems should focus on the characteristics of an organism, rather than on how it is created, should be adaptable and "future-proof" (expecting new technology to emerge), and should contribute to a web of protection to guard against abuse, which might include, for example, ethical guidelines, constraints on purchasing DNA, and other checks. Also, of great importance, there must be global cooperation to reap and spread the benefits of the new age of biology, and to agree on how to regulate risks.

Robin Lovell-Badge (The Francis Crick Institute) reviewed The Latest Advances in Genome Editing: Between Promise and Alarm. The recent advances in genome editing, comprising zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and now CRISPR-Cas9 (Clustered Regularly Interspaced Short Palindromic Repeats-CRISPR associated protein 9), have stimulated extensive research expansion. As part of the rational design of improved editing components, there are now many CRISPR effector nucleases varying, for example, in on- versus off-target specificity, or ease of expression by viral vectors. Among very recent research advances with the objective to improve targeting further are new variants such as HypaCas9, where enhanced proofreading governs targeting accuracy. The mechanisms relying on endogenous repair using CRISPR-Cas9 systems, all now used in early human embryo research, can be classified as:

- **Non-homologous end joining (NHEJ) to make an inactivating mutation, or allow protein synthesis if promoting the skipping of an exon with a nonsense mutation.**
- **Homology-directed repair (HDR), which leads to a precise exchange of sequences and has many uses to alter gene coding or regulatory regions, or to insert markers.**

⁴For example, Leopoldina and others 2015, *The opportunities and limits of genome editing* (<https://www.leopoldina.org/en/publications/detailview/publication/chancen-und-grenzen-des-genome-editing-2015/>)

- **Base editing, to alter a single base pair C:G to T:A, to create a mutation in coding or regulatory region, including induction of STOP codons, an efficient way to inactivate eukaryotic genes.**

Among other recent research advances are:

- **Cas9 nickase to induce a single-stranded break, e.g. in an application in transgenic cattle for increased resistance to tuberculosis.**
- **Changing gene expression by using Cas9 with inactivated nuclease activity linked to a transcriptional activator or repressor. Epigenetic modifiers can also be used to affect how and when genes become active, and some epigenetic traits can be inherited.**
- **Modifying RNA instead of DNA, e.g. using CRISPR-Cas13a, and thereby affecting gene expression.**
- **Diverse methods to regulate Cas9 activities – in terms of targets, level, location and time – to avoid high or persistent levels of Cas9 that might induce off-target effects.**
- **Multiplexing, to target more than one gene at a time. This has many conceivable applications, such as inactivation of porcine endogenous retrovirus in pigs (to facilitate xenotransplantation), development of screens for biological processes or disease, recreating extinct species, and building synthetic DNA for applications as molecular machines or in data storage.**

Professor Lovell-Badge concentrated on promise rather than alarm, but noted one concern: security depends on detection and it may be hard to ascertain what changes in an organism were due to the use of an editing tool.

Dominique Brossard (University of Wisconsin-Madison) focused on The Importance of Public Engagement for Discussions about Emerging Technologies, examining objectives and models for public engagement. Many models have been proposed along the spectrum of inform/consult/deliberate/co-create, variously reconciling the objectives to promote dialogue and exert influence. There are numerous practical issues, including how to increase involvement of groups that are often relatively neglected.

It has been clearly established that the provision of science information does not, in most cases, lead to increasing support for science (as the knowledge deficit model had suggested), and that information means different things to different people. Attitudes are also determined by many variables, including values such as religion, ideology and the degree of deference to scientific authority. As far as attitudes toward human gene editing are concerned, a recent survey of the US population

concluded that there is little difference in attitudes toward somatic and germline human cell editing, but that there is more public support for the objectives of therapy than of enhancement. The majority of US respondents agreed that scientists needed to consult with the public before applying gene editing to humans. Public views do need to be taken into account: as remarked in the NASEM 2016 report on genetically engineered crops, “a purely technical assessment of risk can result in an analysis that accurately answered the wrong questions and will be of little use to decision-makers.”

Professor Brossard concluded by emphasising that the way different stakeholders are thinking about technologies may differ from the way the scientific community thinks about them, so scientists must engage to help develop better policies for communicating complex issues. This is particularly important online, where many of the audiences now reside, and when engaging with groups voicing conflicting opinions. These points were elaborated further in a subsequent session.

Among issues raised in general discussion with the audience were:

- **When should regulation be applied, e.g. before translation of research to practice? Speakers re-emphasised that various approaches to regulation should be embraced within the web of protection but that the focus should be on regulating the final product, not the technology.**
- **Should all information be shared publicly? There may be exceptions, e.g. if a journal limits publication on a modified pathogen sequence, but there should be a general presumption of openness (discussed further in subsequent sessions).**
- **How should editing be monitored? Assessment can be made by full genome sequencing but if sample size is small (e.g. the early embryo), then accuracy is harder. New technologies to sequence DNA or amplify the signal may help. New methods may also improve targeting, by reducing mosaicism in early embryos or by increasing efficiency in delivery of viral vectors.**

Advances in Genome Editing: Promise and Readiness

Bärbel Friedrich (Alfred Krupp Institute of Advanced Studies) chairing, introduced the session, designed to outline the latest developments in genome editing applications and their readiness for use in different fields. The focus would be on function, discussed with regard to potential societal value and timelines for delivery, taking account of differences between alternative genome editing research approaches.

Duanqing Pei (Chinese Academy of Sciences) in reviewing Genome Editing in Medicine, reinforced points made by Professor Lovell-Badge, noting the successive advances represented by ZFNs, TALENs and CRISPR-Cas9, both in understanding biology and in expanding potential applications. Opportunities in medicine include:

- **Better understanding of disease and faster development of more detailed animal models for drug discovery.**
- **Somatic therapy, either ex vivo, e.g. editing blood cells for treatment of cancer or thalassemia, or in vivo, e.g. editing liver cells for haemophilia and muscle cells for muscular dystrophy. In vivo editing currently has more challenges, associated with targeted delivery, but probably has the greater potential once barriers are resolved.**

Heritable genome editing requires significant further R&D and strengthening of ethical review before clinical trials can be contemplated, but the tools are improving. Among major issues to be considered are risks for future generations who cannot consent; the need for long-term follow-up; consequences for societal acceptance of children with genetic disorders; and concerns that this may become a step towards biological enhancement.

Embryo editing uses a precious resource and there must be international cooperation, inclusive of stakeholders.

Dan Voytas (University of Minnesota, Calyxt) addressed Genome Editing in Agriculture and highlighted twin motivations, namely to understand the biological function of plant genes and to confer enhanced traits. Recent advances were exemplified in case studies of differing methodology:

Using the transgenic strategy to make targeted gene knockouts, with no foreign DNA in the genome of subsequent generations – TALEN-edited soybean to increase the content of mono-unsaturated fatty acids. The purpose is to improve storage life and cooking properties but this route to modified soybean oil also avoids the disadvantage of the alternative, hydrogenation, route (where an increase in trans-fatty acids brings health concerns). Proof-of-principle has been achieved and the US Department of Agriculture (USDA) pronounced that this product was not a regulated article and could proceed to field trials to determine whether it would be appropriate for commercialisation (expected in 2018).

Using homologous recombination to introduce a wide variety of modifications. Many research projects are underway, e.g. editing corn to fix atmospheric nitrogen or enhancing photosynthesis by converting plants from the C3 to C4

pathway. These are complex ambitions and there are technical challenges, e.g. in delivering editing into cells and developing stable translation methodology, but proof-of-principle has been achieved for herbicide-tolerant cassava. This may become a significant advance in combatting weed problems faced by small farms that rely mainly on family labour (with societal benefits, e.g. in allowing children to attend school rather than weeding fields). The question as to how such products will be regulated is not yet answered because the USDA had never previously considered genome-edited crops of this type. It is anticipated that there will now be rapid increase in these research approaches worldwide.

Fred Gould (North Carolina State University) considered Gene Drives: From Species Eradication to Species Preservation. Historically, there have been two general approaches to genetic control of insects: replacing strains (e.g. *Aedes aegypti* that cannot transmit dengue virus) or suppressing/eradicating them (e.g. use of irradiated sterile male release to control screwworm fly). However, in the early work, the tools to spread genes were inadequate. Site-specific selfish genes were proposed as a tool for the control and genetic engineering of natural populations but progress was slow until the advent of CRISPR-Cas9. Using gene drive for eradication, the genome editing construct converts heterozygous individuals to homozygotes, such that the altered gene is almost always inherited, e.g. targeting female reproduction in the malaria mosquito vector *A. gambiae*. However, there is evidence that resistance to suppression drives can develop due to NHEJ. In addition, when using gene drive for replacement, the possibility of gene drive failure due to mutation in the effector gene remains a significant concern. Another concern surrounds what happens when moving from the laboratory to the wider environment – what may be the consequences of transforming or eradicating an entire species (a point previewed by Professor Ramakrishnan)? Thus, it is necessary to consider the management framework required to achieve a stable gene drive and to avoid over-promising benefits in the eventuality that gene drives are found to be unstable. These concerns will be discussed in subsequent sessions, but it is worth noting that there may be opportunities to reverse or otherwise locally restrict gene drives and that, because of extending research timelines, demonstration of the potential may be further into the future than initially predicted.

Lennart Randau (Max Planck Institute for Terrestrial Microbiology) describing Genome Editing in Microbes, showed that there is considerable diversity of CRISPR-Cas systems, with identifiably different functions. Classification of this diversity provides an expanding toolbox for editing in support of innovation. It can reasonably be assumed that most, if not

⁵Proposal for an international consortium for research, building on previous academy discussions: D Pei et al. "Human embryo editing: opportunities and importance of transnational cooperation" *Cell Stem Cell* 2017 **21**, 423-426.

all, editing tools have now been identified in those microbial genomes that have been sequenced but, of course, there are many microbes yet to be discovered or sequenced. There has also been significant progress in understanding the efficiency of editing in different microbes to select model strains for engineering, e.g. applying CRISPR-Cas9 in recombinering *E. coli* strains. Research on cascade type I CRISPR-Cas effector complexes has helped to clarify the relationship between size of complex, stability and efficacy of genome targeting. Some viruses have evolved anti-CRISPR proteins that specifically block Cas nuclease activity. These anti-CRISPR proteins may be of value in regulating genome editing by decreasing off-target effects. The increasing understanding of bacterial biology is also revealing new opportunities to tackle pathogens, including the major therapeutic goal to avoid development of microbial resistance to antibiotics.

General discussion of these presentations explored the extent to which genome editing research can expand outside of the traditional laboratory settings – such expansion might be difficult to regulate and, thereby, increase security concerns. Although some reagents can be obtained online, all applications currently depend on significant research skills. Other aspects of the regulatory framework were also raised. For example, for crop breeding applications, review by the US Food and Drug Administration (FDA) could require testing of plant metabolite profiles but FDA guidelines are currently reasonably clear on the boundaries defining which mutations would be acceptable, e.g. if they could have occurred naturally.

Assessing the Security Dimensions Associated with Specific Applications of Genome Editing Technologies

This session was designed to explore potential security concerns – specifically intentional misuse – for different applications, and how plausible these concerns may be. Are there biological, technical, expertise- or infrastructure-related constraints on the security risks?

In introducing the session, Chair **David Relman** (Stanford University) called for clarification of which concerns are most relevant, for whom (within the scientific community and also for those with responsibility to anticipate or respond to adverse outcomes), and over what timeframe. How might consequences with a long lag-time for appearance be mitigated? It is important to avoid making assumptions about those who intend harm or are irresponsible, and more needs to be done to analyse the intersection of capability and intent.

Piers Millet (Future of Humanity Institute, Oxford University) presented on *Assessing the Security Implications of Emerging Technologies: What Do We Need to Know?* based on a background paper circulated to participants. Concern grew in 2016, when the US Director of National Intelligence labelled genome editing a security threat and, although he provided no detail, the concern seems to persist in the US national intelligence community. It might be postulated that the concern about misuse could include: altering pathogens, application of gene drives, influencing future human generations, new types of neurological weapons, and enhancement of military capabilities (“super soldiers”). Reports by IAP, EASAC and NASEM have all alluded to potential dual use/security concerns evoked by emerging technologies in the biosciences (these and other academy documents are discussed in detail⁶). More broadly, the scientific community has identified guidelines for working with dual use materials and the type of activities that may pose concern. Responsibilities for scientists, their institutions and the regulatory authorities have all been discussed in the literature. It should also be emphasised that genome editing could boost the ability to deal with disease threats and develop counter-measures to biological weapons.

However, it is important to reflect more widely about what is meant by the term security. In addition to considering the potential misuse in biological weapons, national security would cover, e.g. the security of resources, energy, manufacturing and data. It is also vital to take account of the changing risk environment, such that products that might otherwise be safe/secure may pose higher risks in unqualified hands. The pace of change brings various challenges that might undermine traditional security frameworks:

- Could the expansion of research overwhelm regulatory capacity?
- Might regulatory controls be circumvented, e.g. if research turned to making hitherto non-pathogenic organisms pathogenic?
- Will international norm setting be outpaced?

There was wide-ranging general discussion about the issues, including:

- Is there anything unique about genome editing and its security concerns? Many scientists regard it as an extension of previous methodologies and related security concerns as a continuation of previous concerns.
- Has genome editing been discussed in the meetings of the Biological Weapons Convention? Yes, together with other advances in science and technology, covering the

⁶<http://nas-sites.org/dels/files/2017/05/Biosecure-GeneEditingBiosecurity-Report-170925.pdf>

benefits as well as the concerns. It is important to keep informing the State Parties to the BWC about scientific and technological advances, and potential implications. It is also important to ensure that the global ban on biological weapons does not damage objectives for other applications of the bioeconomy.

- Are scientists well prepared to predict security implications? To reiterate, the issues are not unique for genome editing, and scientists are well placed to stimulate the broader, continuing debate. This international workshop is just the beginning.

- Do we understand what, in particular, the US national intelligence community is worried about? There may be other relevant dimensions, e.g. for national competitive advantage – the concern that other countries are capitalising on advancing science to compete with US technological advantage.
- What is the better plan to prevent misuse – keep information secret or disclose it? Although there may not be a lot of evidence to inform this choice, a culture of openness and transparency is considered to promote efforts to counter misuse.

Breakout Discussions – Assessing the Security Dimensions Associated with Specific Applications of Genome Editing

Breakout Group	Chair	Speaker	Rapporteur
Human cell editing applications	Anthony Perry (University of Bath)	Jonathan Moreno (University of Pennsylvania)	Johannes Fritsch (Leopoldina)
Applications in agriculture	Fred Gould (North Carolina State University)	Joachim Schiemann (German Federal Research Centre for Cultivated Plants) and Angelika Schnieke (Technical University of Munich)	Christiane Diehl (EASAC)
Gene drive applications	Zachary Adelman (Texas A&M University)	Todd Kuiken (North Carolina State University)	Sarah Carter (Science Policy Consulting LLC)
Microbial applications	Iqbal Parker (University of Cape Town)	Bert Rima (Queen's University, Belfast)	James Revill (University of Sussex)

The goals of the breakout sessions were to differentiate between security concerns associated with particular applications of genome editing, and to map the scientific evidence supporting those concerns. Breakout groups were asked to discuss the state of the science, the technical skills and equipment required to develop the application, and the biological plausibility of suggested uses and misuses.

Question 1 What are the major security risks that have been identified or postulated for this application?

Question 2 How much consensus or disagreement is there about these potential risks with regard to:

- **Timeframe** – current, near-, medium- or long-term.
- **Feasibility of using this application in this way.**
- **Accessibility to a range of potential nefarious actors.**

Question 3 What is the evidence base for identifying these risks? What additional evidence would assist in analysing and assessing the potential risks?

Question 4 Are there other risks, such as safety, that are of particular concern for this application? If so, what are they?

Summary of Breakout Sessions as contributed by Rapporteurs, and Plenary Discussion

Initial feedback by the rapporteurs from the breakout sessions to the plenary sessions is listed as bulleted items. These then served as a basis for discussion of other perspectives and collective review of the issues during general debate and subsequent sessions, as reported later in this text.

Chair **Diane Griffin** (NASEM).

Human cell editing

Q1

- It can be difficult to avoid mixing safety and security issues or to consider all issues appertaining to human health separate from other applications (e.g. pathogen manipulation in microbial production systems). It is important to differentiate between somatic and germline applications, as discussed in the keynote presentations.
- Issues for delivery systems may also need to be taken into account, e.g. the evidence that aerosol/viral vectors may be engineered to induce lung cancer.
- There might be misuse potential for off-label use, e.g. employing a medical product registered to treat a muscle or cognitive disorder for enhancement in military use, or by individuals for their own gain. Attitudes to the optimisation of normal biology (and what might be covered by the doctor-patient relationship) probably varies between countries. It is also worth noting that biological enhancement could serve as a counter-measure against biological weapons, which can raise its own ethical and perhaps security issues, a point repeated throughout the workshop.

Q2

- Significant basic research is conducted in animal models but this is not yet close to human embryo application. Germline editing in human embryos may be possible in the longer-term. Somatic gene therapy is likely to be available in the near-medium term (1-10 years).
- Accessibility by nefarious actors would probably be different in different countries. A significant amount of regulation governs germline editing, e.g. the Oviedo Convention and national embryo protection Acts. The do-it-yourself (DIY) biology community is probably unlikely to do human genome editing in the near future. Regulation of military research and development is more challenging. There is a general point to be made that deliberations within the academic community may be irrelevant to those who wish to pursue nefarious purposes, and this point was addressed further in subsequent discussions.

Q3

- There is need to understand the conditions that may repurpose this technology for hostile use – intent as well as accessibility. Current evidence for security concerns is weak and it is difficult to quantify the threat,

in part because research to gather evidence might itself not be permitted.

Q4

- It is important to take into account differing cultural views, e.g. on biological enhancement or germline interventions. It is also essential to consider the global as well as domestic dimensions of security – economic competitiveness issues may be more pronounced in the latter.
- Stakeholders to be engaged include: scientists, citizen scientists, NGOs, ethicists, patient groups, policy makers and the media, as well as the public-at-large.

Editing in agriculture (plants and animals)

Q1-2

- Many consider that nothing is completely new in this application but rather that genome editing facilitates agricultural research. However, genome editing may have no footprint and a lack of traceability challenges regulation and enforcement.
- The knowledge base for potential malfeasance is growing and research locations are expanding (into the DIY community, for example, as discussed subsequently). However, better access to knowledge may also help to counteract misuse. Food security might be endangered if genome editing were to be regulated too strictly: better access to technology and education ultimately reduces risks. There may also be an increased risk from conflict between different regulatory systems.

Q3

- There is little evidence available for defining the threat from DIY science; subsequent discussion explored how to engage better with the DIY community.
- Regulation in low- and middle-income countries can draw on established models elsewhere: e.g. biosecurity and safety councils and other advisory groups.

Q4

- A broader range of voices globally – especially from low- and middle-income countries - must be captured to clarify perceived risks.
- Dialogue between stakeholders in food systems must be maintained and civil society engaged to the fullest extent possible.

Gene drive applications

Q1

- Risks can be associated with intended as well as unintended use, including, potentially: the escape of drives from one location to another; transfer of the drive to non-target species, and continued evolution of the drive into a new, harmful, construct. However, as noted previously, because of extending research timelines for this application, there is now more time available for examination of, and debate about, these implications than had been initially assumed.
- There is a potential for threat to human health (e.g. if malaria transmission were increased), agriculture (e.g. increasing insect pests and plant damage), and ecology.
- There could be significant economic impact if there were loss of public confidence in science – undermining the broader research enterprise – even in the absence of physical harm.

Q2

- As mentioned above, the practical use of gene drive lies further in the future than some other genome editing applications. As there has been no successful deployment yet, all risks would be long-term. Nonetheless, information generated now may be useful for the future.
- Generally, accessibility is perceived as difficult, there are significant infrastructure requirements, and there would be easier ways to cause physical harm. For gene drive, there are no Select Agents used or DNA sequences that might be flagged as a basis for regulation. The US military (Defense Advanced Research Projects Agency, DARPA) is funding gene drive research and there is concern that this might provoke other States to do the same.

Q3

- The evidence base for use or misuse of gene drives is limited, e.g. in terms of genetics, target population effects and ecology. Information may not be generalisable between different vectors and pests. Useful information might, however, be obtained from natural gene drives and from modelling studies on effectiveness.
- National laws will determine regulatory requirements but it should be recognised that guidelines for public funding would probably be irrelevant to those using other sources of support.

Q4

- Gene drive researchers have a good track record in being proactive and responsible. There is continuing need to create a culture of responsibility encompassing researchers, funders, publishers and others (e.g. vendors of DNA sequences). But what would be effective in constraining those with malign intent, a point discussed further in subsequent sessions?
- Media hyperbole may lead to involvement of nefarious others – but we are not sure who we are worried about.

Microbial applications

Q1

- Again, probably nothing is completely novel in the use of genome editing tools for this application but there is transformative potential for organisms other than bacteria, e.g. yeast. The technique could be used to construct pathogens, and pathogens could be weaponised. The categories of concern identified in the initial US academies' work (Fink report, 2004) are still relevant.
- Information flows (digitalisation of DNA data) are becoming increasingly important in widening access.
- However, as emphasised previously, benefits can mitigate security concerns.

Q2

- During this data accumulation phase of research, the timeframe for any potential risk is difficult to estimate.
- States remain a particular concern as nefarious actors. There may be minor changes in accessibility by non-State actors but no certainty that this change is significant.

Q3

- Scientific evidence has an important role in monitoring risk but different stakeholders – including the security community – have different expectations about the type of evidence needed to make an assessment, this point was again addressed in subsequent discussion.

Q4

- Stakeholders, including scientific, law enforcement, intelligence, and policy communities, and the public,

should be engaged, but this is not easy (various approaches to engagement are discussed in a subsequent session). Is there political will to enact any proposals, nationally or internationally?

- It is essential to continue educating scientists, including the DIY community, about codes of conduct.

After the Breakout sessions had reported, discussion emphasised various common points:

- Generally, genome editing has made applications more accessible but has also depended on many other advances (e.g. decreasing cost of gene sequencing and synthesis). Thus, genome editing should be viewed as part of the new era of biology rather than compartmentalised as something unique.
- Commentators should avoid generalising about the DIY community or any other group – it is the intent that is important in misuse, although there may also be risks arising from error. Unintended (safety) concerns as well as intended (security) concerns must both be taken into account in risk assessment. There is also risk in overstating what can be achieved outside of the conventional laboratory setting.
- Among the benefits that may result is a timely contribution to counter-measures to mitigate security concerns: discussion of the balance of risks and benefits needs to be cognisant of the rapid pace of science and technology.
- Countries may vary in their attitudes to valuing outcomes, e.g. one country may judge the eradication of a mosquito species to be a benefit whereas a neighbouring country may consider it a potential harm. Different national interests may be reconcilable by international conventions and there should be proactive collective deliberation on the issues.
- In summary, it was difficult to identify whether, and what, misuse would be likely for different applications of editing. For microbes, the misuse of natural pathogens (e.g. anthrax) seems more probable than an edited organism. For gene drive, the point was reiterated that the greatest concern may relate to the undermining of public confidence in research rather than to specific physical harm. Impact on public confidence was also seen as the greatest concern in agriculture. For human germline editing, there would be concern if the technology were used inappropriately, in unregulated clinics. That this would be a health, but not necessarily a security concern, illustrates the pervasive point

that issues for bioethics, security and safety, and for deliberate/accidental risks are easily conflated.

Strategies for Addressing Potential Security Risks of Genome Editing

Chair **Pilar Ossario** (University of Wisconsin-Madison) introduced the session by observing that governance has many tools and that the session would range widely in drawing on the diverse experience of participants, encompassing legal, regulatory and policy strategies, norms of responsible behaviour and voluntary guidelines, together with scientific and technical strategies.

Legal, Regulatory and Policy Strategies for Genome Editing: General

Michele Garfinkel (EMBO) reviewed how governance encompasses: the processes variously leading to e.g. legislation, norm-setting, self-regulation; policy development (expanding the options) and politics (narrowing the options); the tensions between individual stakeholders, groups and governments; the trade-offs, compromises and development of trust; and, as discussed earlier in the workshop, the implications of technology changing faster than governance processes can accommodate. Governance tools include treaties, laws, soft law (e.g. standards, guidelines, self-regulation) and strategic intelligence, which is learning lessons from what had been done previously.

A case study on synthetic biology, which explored the incremental differences between the new technology and previous technologies, illustrated the issues for developing a governance framework and for identifying objectives in mitigating risks. Governance is the responsibility of governments, science administrators and funders, but also of scientists. Emphasising the point made earlier in the workshop, scientists need training, e.g. on what is dual use.

SR Rao (Ministry of Science and Technology, Government of India) also provided an experienced perspective on legislation and regulation, drawn from involvement with various genetic technologies, especially GMOs, new breeding techniques and gene therapy.

Countries vary in their definition of what is a DNA technology, in their attitude to what should be covered by law relating to biosafety and biosecurity, and in their oversight by particular ministries. Risk assessment systems tend to be more similar between countries and there are opportunities for global consensus in governance. It was recommended that public policy on genome editing should guide debate and

development of the field, toward the goal of dynamic and flexible international harmonisation that will address security issues. Supervision of basic research should continue as under current systems with their focus on safety and ethical review, accompanied by product-specific assessment of benefits and risks, and management approaches.

Legal, Regulatory and Policy Strategies: Security-Specific

Daniel Feakes (Biological Weapons Convention, Implementation Support Unit) described the history of the BWC (www.unog.ch/bwc) and the norm against using disease as a weapon, its scope (applying to all science and technology developments in the life sciences) and its weaknesses, namely that it has no institutional basis or in-built verification mechanism. IAP initiated significant effort on the BWC, advising on the necessity of taking account of the benefits of bioscience technologies as well as the risks. Convergence of technologies may present new challenges for policy instruments. For example, if artificial intelligence is coupled with genome editing to optimise the power of the latter, then the pace of advance may accelerate further.

The BWC is relevant to the UN Sustainable Development Goals (SDGs) in multiple respects: not just SDG 16 (just, peaceful and inclusive societies), but also e.g. SDG 3 (healthy lives), SDG 4 (education), SDG 9 (resilient infrastructure) and SDG 17 (global partnership). There are continuing opportunities for the scientific community to engage with BWC policy makers, e.g. during the annual meeting of the State Parties.

Catherine Rhodes (Centre for the Study of Existential Risk, University of Cambridge) contributed additional insight on institutional security structures as part of the science-policy interface. It is possible to learn lessons from previous activities – in terms of how to share informative experience, how to manage complementary activities and how to avoid the cost of duplicating effort. In addition to the BWC, there are various mechanisms whereby the scientific and security communities can engage: via standing advisory boards (e.g. for the OIE biological threat reduction strategy) or ad hoc advisory and consultative processes (e.g. for the CBD synthetic biology initiative); laboratory networks (e.g. WHO Reference laboratories); through online fora (e.g. FAO); journals and collaborations; and as expert rosters during crisis events. There are additional routes outside of formal institutional structures where expert communities can raise awareness, model scenarios and disseminate good practice, to support capacity building and engage with the public. Academies and their networks can play an increasingly valuable role.

Norms of Responsible Behaviour and Voluntary Guidelines

Indira Nath (All India Institute of Medical Sciences) reviewed the IAP's work on research integrity and scientific responsibility, based on global values of honesty, fairness, objectivity, reliability, scepticism, accountability, and openness. The 2012 IAP report I with recommendations for researchers, their institutions, sponsors, and journals was followed by an educational guide in 2016. Among key themes in the report, relevant to the workshop, were: challenges from research trends; responsibility of science to global society (preventing misuse and exercising global stewardship); preventing and tackling irresponsible research behaviour; and global harmonisation of practices.

In developing these themes further with regard to genome editing, Professor Nath remarked that it is difficult to predict the consequences of basic research, however, the research community is responsible for creating institutions and practices to address possible risks of both existing and emerging technologies. Fostering mentorship was identified as a core part of developing responsible conduct. To attain global harmonisation in research standards and practices requires: improving the quality and accessibility of research data at the global level; improving the environment for inter-disciplinary and international collaboration; standardising approaches where possible (e.g. on embryonic research, clinical trials); introducing global peer review; education to promote research integrity; and encouraging stakeholders to exercise leadership.

Ulrich Sieber (Max Planck Institute for Foreign and International Criminal Law) described the recent approach of the Max Planck Society (MPS), the Leopoldina and the German Research Foundation (DFG) to ethical issues and risks of research. The starting point for dealing with these questions was the recognition of a conflict between the "principles of free research" and the "prevention of research risks" (whether arising from the researcher's own conduct or misuse by others). The solution to this conflict had to answer a number of fundamental questions: What are the limits of risky or unethical research? How and by whom are these limits determined? How can adherence to these limits be enforced?

Analysis of these questions led to the identification of two normative options: legal regulation by the state and self-regulation by researchers themselves. Legal regulation by the state has the advantages of clear legitimacy and enforceability but the disadvantages of being time-consuming, inflexible and nationally limited, and of representing regulation by politicians rather than by experts. Self-regulation has the advantages of being managed by experts and their peers – leading to a high motivation of the affected researchers – and of having a high transnational potential. The disadvantages of self-regulation are its questionable legitimacy, lack of a concretising institution (comparable to the courts in the state legal system) and of

being mostly sector-specific, with a plurality of norms that are non-binding and difficult to enforce.

In its attempt to achieve an optimal solution the MPS developed an effective set of self-regulatory rules with attributes similar to those of the state legal system. The main features of this initiative were:

- Clear distinction between legal and ethical norms as a starting point.
- Legitimation and acceptance of a set of self-regulatory norms – agreed upon by all scientific members of the Max Planck Institutes.
- Coverage of all types of research risks in all disciplines (general approach).
- Development of a basic guiding principle for balancing the freedom and benefits of scientific research with the responsibility to protect essential values.
- Specification of this principle and ethical rules for key activities, e.g. risk analysis and risk minimisation, research moratoria, training and education.
- Procedural determination of principles in individual cases by ethics committees.

The Leopoldina and the DFG are now using the MPS initiative as a basis for its development of model rules on scientific freedom and scientific responsibility for all research institutions, with the creation of joint committees for the handling of security-relevant research and the dissemination of good practice throughout research organizations in Germany.

Scientific and Technical Strategies

Ursula Jenal (Jenal & Partners) described the work of the Swiss Academies on a code of conduct to address the misuse potential in academic settings, as part of a concerted governance mechanism. The aims were to: raise awareness and broaden discussion; give incentive for assuming responsibility for one's own research as a matter of course; anticipate or pre-empt regulatory requirements; and foster public confidence. Proposals for a code of conduct were sometimes met with reluctance because of the uncertainties relating to risk assessment of misuse potential of biological research and the difficulties in establishing an effective enforcement mechanism. This SCNAT project proceeded as a series of workshops with researchers, and the outcomes covered issues for awareness, responsibility, misuse potential, training, publishing, and public engagement. Principal investigators have to be role models for their students, who come from varied backgrounds. Furthermore, a scientific culture has to be encouraged, where researchers can say if something is wrong: this requires a basis of research in collaboration rather than competition.

Owain Edwards (Commonwealth Scientific and Industrial Research Organisation) presented on scientific and technical strategies for mitigating gene drive research, based primarily on studies in Australia. The previous history of safeguarding gene drives has concentrated on the laboratory research phase, e.g. in terms of molecular, ecological and reproductive barriers. These same principles could be applied to field-scale research:

- **Reducing off-target effects:** which could be managed as in other genome editing applications, most such effects would not be propagated by gene drive systems.
- **Containing gene drive systems:** this could be geographic (e.g. if tackling island rodent infestation); might use target population-specific alleles, reversal drives or engineered kill switches; or by self-limiting systems (e.g. if resistance alleles are naturally present or introduced by NHEJ) or threshold drives – changing the level of selective disadvantage changes dissemination throughout the population.
- **Preventing unintended ecological consequences,** however, consequences are not always predictable, e.g. the target population may not be as isolated as assumed, with consequences for neighbouring territories, or vacant species' niches resulting from eradication may be filled (perhaps by something worse).
- **Tackling bioterrorism:** there are mitigation opportunities associated with diagnostics, to detect edited material, and therapeutics, e.g. capitalising on discovery of anti-CRISPR proteins (or equivalent small molecules) to inhibit gene drive spread.

In summary, there are molecular, geographical and ecological options to contain gene drive systems but they require modelling and more information about target systems. There may also be opportunities to refine gene drives to balance efficiency and risk, according to context.

General discussion returned to some of the issues raised by use of codes of conduct and other research frameworks:

- Some participants expressed concern about the potential for an excessively bureaucratic burden on the academic researcher in terms of compliance and auditing, particularly if there is duplication of procedures for assessment and monitoring. However, rather than using compliance as a “box-ticking” exercise, there is value in instilling awareness of security issues and the conduct of responsible science as part of the obligations inherent in being, and being recognised as, a good researcher. This recognition should extend to activities involved in mentoring and whistle-blowing.
- Codes of conduct are relevant, and are used, in private sector research but it was also noted that companies may already be using other research management frameworks such as ISO standards for biorisk management and externally verified Quality Management Systems for recombinant DNA. Such systems would also be relevant in academic settings

but would, again, necessitate a change in the research culture and reward systems that are currently dominated by the activities to obtain grants and generate publications.

- Voluntary codes of conduct are important but not sufficient to enhance public trust. There must also be mechanisms to monitor and enforce – funders can enforce standards through their commitment to support research. While codes of conduct have value

in academic research, it may seem paradoxical to focus on this as a mitigation approach to security if academics are not engaged in misuse. Codes of conduct and other governance mechanisms are unlikely to work equally well for those with nefarious intent. There is concern that additional governance would hamper responsible research without diminishing the risks on intentional misuse and these issues are discussed further subsequently.

Breakout Discussions: Addressing and Mitigating Potential Security Risks Associated with Specific Applications of Genome Editing

Breakout Group	Chair	Speaker	Rapporteur
Human cell applications	Duanqing Pei (Chinese Academy of Sciences)	Abhimanyu Veerakumarasivam (Sunway University)	Johannes Fritsch (Leopoldina)
Applications in agriculture	Sarah Hartley (University of Exeter)	René Custers (VIB (Flanders Institute for Biotechnology))	Christiane Diehl (EASAC)
Gene drive applications	Elizabeth Heitman (University of Texas Southwestern Medical Center)	Ary Hoffman (University of Melbourne)	Sarah Carter (Science Policy Consulting LLC)
Microbial applications	Herawati Sudoyo (Eijkman Institute for Molecular Biology)	Filippa Lentzos (Kings College London)	James Reville (University of Sussex)

The goal of the breakout session was to explore the range of mitigation strategies that could be applied to address potential security risks, including the role of scientists in promoting awareness and developing norms and practices for responsible conduct of science.

Question 1

Given the potential security risks associated with this application, what are the primary legal, regulatory and policy approaches that could be applied to address and mitigate them? In addition, are there technical approaches for specific applications that are being or could be developed to address these risks?

Question 2

Are there approaches that seem particularly appropriate for this application? Particularly inappropriate?

Question 3

If safety emerged in the previous breakout session as a major source of potential risk, how would addressing that risk affect the potential security risks associated with this application?

Summary of Breakout Sessions, Contributed by Rapporteurs, and Plenary Discussion

Chair **Peter Mills** (Nuffield Council on Bioethics)

Human cell editing

Q1

- It is questionable whether new technologies always require new legislation, although some of the imaginable security issues, e.g. somatic cell editing enhancement for “super soldiers” are subject to no specific regulations at present.
- As discussed previously, it is important to strike a balance to prevent misuse of research while not preventing research.
- Media initiatives are important to promote awareness of issues and the public should be informed of progress,

⁷Swiss Academies of Arts and Sciences 2017, *Misuse potential and biosecurity in life sciences research*

e.g. in encouraging whistle-blowing. Educational initiatives, including those encompassed in codes of conduct, may mitigate risks associated with nefarious intent. Other soft governance options, e.g. by research funders, can also address safety and security issues. Alongside funding of genome editing, there should be funding for counter-measures, e.g. to reverse editing and gene drives, to develop methods of detection and to improve public health preparedness and responsiveness.

Q2

- Many consider that restrictions on access to genome editing technology are inappropriate and probably unworkable. Reiterating previous points, many scientists advise that regulation should focus on the product not the process. It is important to engage with the commercial community, including SMEs and venture capitalists, with a view to incentivising compliance with governance.
- Also, as noted previously, current regulatory frameworks seem likely to be inappropriate for institutions operating beyond their reach, e.g. unregulated clinics performing IVF or providing unapproved stem cell treatments, although it is not clear whether this could translate into a security issue. International oversight does not have sufficient capacity (and ways to enhance international frameworks are discussed subsequently) but current governance measures seem unlikely to be always able to prevent nefarious misconduct.

Q3

- There is a low risk of genome editing aerosols/viral vectors reaching unintended recipients but a case might be made for more effective containment measures.
- There is scope for further development of internationally accepted standards for clinical trials on genome editing though there is sometimes scepticism about western-driven initiatives for global harmonisation.
- Disproportionate public fear may impede innovation and, again, it is important for the scientific community to inform public expectations about risk and to avoid over-promising benefits. It is improper to be anything but open and transparent: these points are discussed further in subsequent sessions.

Editing in agriculture

Q1-3

- To reiterate, no new types of risks were discerned in agriculture genome editing: traits are already regulated and no new forms of governance were proposed. There are opportunities to share established good practice in governance worldwide. There was also concern expressed that too onerous regulation in some countries may drive research elsewhere with potential consequences for innovation and competitiveness.
- As discussed previously, it is difficult to determine how legislation could best contribute to lowering the motivation for malpractice. There might be opportunities to strengthen the stringency of requirements for purchasing reagents and equipment. The DIY community is aware of the regulatory requirements for responsible research.
- Opportunities for education and the application of consistent quality standards during training should be pursued.

Gene drive applications

Q1

- It is not yet obvious who may have malign intent or how they might be deterred.
- Broader legislative approaches may apply only after damage is done and may lack clarity in terms of what is covered, e.g. ecological changes. In Germany, research facilities need to be licensed for genetic engineering and this form of legal governance should be considered for other countries where it does not already exist.
- Institutional biosafety committees may not have appropriate expertise to assess gene drive research and the options for adding expertise should be considered. Laboratories working on gene drive, but with no intention to release, still generate data that could be misused by others. There is a tension in controlling the flow of knowledge – transparency is generally important for users and the public.
- International treaties and conventions, e.g. CBD, may help to resolve competing interests among countries.
- Technical and monitoring capabilities are still major barriers. Perhaps gene drive systems should not be developed unless they can be detected, alongside the variety of containment methods discussed previously.

Q2

- There is more to be done both to map legal and other governance systems worldwide and to build collaboration between the scientific and security communities to understand nefarious motivations.
- Training, access control and standards should be implemented consistently in research facilities, and security requirements should be extended elsewhere, e.g. in establishments for breeding mosquitoes.
- Natural gene drive systems can provide guidance on risks and mitigation strategies.

Q3

- A major risk is the loss of public confidence – the scientific community must demonstrate that it is paying attention to the issues.

Microbial applications

Q1-2

- Misuse concerns must be addressed through hard law (statutory regulations, licensing, export controls, reporting requirements), soft law (guidelines, codes of conduct, research funder review) and peer pressure (mentoring, ISO standards, insurance, role models).
- In many national contexts, many of these elements are already in place. Any new measures introduced would therefore not operate in isolation, and thought must be given to how measures operate together and how they would work in different contexts geographically.
- There are particular opportunities: to co-design research project protocols (researcher and risk assessor); to integrate education on security into initiatives on responsible research; to find ways to support expansion of ISOs worldwide; and to test institutional capacity and public health systems in crisis exercises. Caution should be exercised in prescribing EU and US models for adoption worldwide.
- Consideration of misuse and security risks must be embedded into careers structures and rewards for professionals to ensure it does not only become a 'tick box' exercise.

Q3

- Safety may be more generally understandable than security – sometimes safety encompasses security, sometimes it does not.
- There is a concern that research perceived as risky could be outsourced to countries with lower standards of regulation. International harmonisation of security controls is difficult because it requires a high level of international trust, open discussion, and information exchange about studies and concerns.

Alexander Kagansky (University of Edinburgh) reported back from the Policy Mini-Hackathon satellite event involving the Global Young Academy, exploring potential security concerns and their mitigation relevant to the DIY community. This event (to be reported in detail elsewhere) covered four topics:

- How to achieve safety by design – addressing safety and security issues at the time of the project's inception, building governance, considering standards as the basis for subsequent formal regulation.
- How to deal with technology that could pose biological or cultural existential threats – requiring researchers to work with their institutions in updating requirements for research review, including ethical review.
- How to address risk and responsibility – to foster a culture of responsible science, requiring training, again involving the wider community (including DIY scientists).
- Restrictions on germline genome editing research and how to reassess current limits – continuing efforts for international agreement on guidelines that allow for cultural or other differences, without compromising global security.

In the general discussion, it was noted that many of the points emerging in the second round of breakout sessions were closely related to those from the first, with many commonalities in the issues raised between different applications. Other pervasive points were highlighted:

- Are we indulging in genome editing exceptionalism – does this focus add anything to previous considerations about emerging technologies?
- The concern that countries might outsource research risk is not confined to genome editing but funders enforce regulatory standards on research they support worldwide, including clinical trials.
- Much of the discussion was about safety and its mitigation. What more should be done about security, to clarify what we are securing against? Does the lack

of a credible scenario/risk framework indicate our lack of imagination? There is no previous reference point to frame the potential impact of biosecurity concerns (unlike misuse of nuclear or chemical agents). It may be counter-productive, it is certainly controversial, to imagine extreme scenarios, but scenarios can be compared in education efforts and as part of the proposed crisis exercises.

- Discussions about genome editing have not concluded that there is no risk, rather that there is no extra risk. Participants acknowledged that uncertainty, at a time of rapid pace of advance in science and technology, itself causes public concern. To tackle this concern requires ongoing and inclusive dialogue.

Public Communication and Engagement on Potential Security Risks of Genome Editing Applications

This session was designed to explore evidence-based, culturally-relevant considerations and practices for communicating about the risks and benefits, and the role of the media and scientific community in the dialogue about security implications with society.

Chair **Dietram Scheufele** (University of Wisconsin-Madison) observed that academics and others in the scientific community are already active in engaging with society on the issues of responsible research and innovation. There was widespread agreement in the workshop on the necessity of broad engagement; this session covered some of the ways to do it.

Volker Stollorz (Science Media Center Germany) discussing Science Journalism in a Changing World, described the role of professional science journalism as not only to communicate science but also to confront scientists and science-policy makers with public expectations. "What concerns all of us can only be solved by all of us". Public trust increases if scientists are perceived as knowledgeable, as acting with integrity and for the public good. Public concerns about genome editing security risks are heightened by:

- An increase in the number of actors that will soon be able to create organisms with traits that, to date, did not result from natural evolution.
- The possibility of manipulation of living organisms without leaving detectable traces
- Scenarios with low likelihoods (but non-zero probabilities of occurrence) but high impact, e.g. modified pathogens causing a potential pandemic. This concern is compounded by difficulties in identifying and calculating the risk.
- The immaterial character of modification – electronic transmission of genetic information is in fact not

susceptible to traditional Dual Use Research of Concern control methods.

- For the emerging biosecurity issues in the life sciences in the new age of non-state terrorism, we only have regulations so far that do not match the possible threats we face in the 21 century.

Dominique Brossard (University of Wisconsin-Madison) presenting the Science of Communicating Risks and Benefits: When, Why and How? proceeded from the starting point that concerns about genome editing and bioterrorism are already widespread in the media, so how do we restore public trust? Mitigating the problem is related to increasing trust. Professor Brossard advised that risk analysis needs to imagine the worst-case scenario in order to identify how to manage the problem. The worst-case scenario may include the DIY community or hacking concerns. These points would be addressed further during the subsequent panel discussion.

Jason Delborne (North Carolina State University) reviewing Public Engagement: Rationales, Methods and Intended Outcomes, built on the previous discussion of the typology of engagement mechanisms, also taking into account other points that had arisen during the workshop. The most important engagement with the public occurs when information flows in both directions and each participant can modify their position in response to the views of the other participants. If we want our own decisions to be impacted by engagement and if engagement is accorded the potential to influence policy, then engagement has to be integrated into existing decision networks. Professor Delborne returned to the question of what are we trying to secure: different interests will define security in different ways, and they may compete. As noted previously, whenever engagement is undertaken, certain design decisions need to be made based upon analysis of the landscape – what and whose are the interests? There is a history of stakeholder engagements becoming polarised, but this likelihood is reduced if stakeholders are also collectively involved in the design of the engagement model that can then be enacted in broader public engagement.

Elizabeth Heitman (University of Texas Southwestern Medical Center) reviewing Lessons from Engaging Global Communities of Science, returned to who should be involved in engagement from the institutions, including: scientists and the users of science, legal experts, research administrators, funders (including philanthropic and private sector funders) and industry. In addition, it is necessary to reflect further on where the nefarious actors might come from – it might include those who think they are doing good. Discussions on research with dual use potential have recently become part of science education programmes, and other activities on research integrity are exemplified by IAP's leadership on responsible science. Part of the continuing difficulty experienced between

different groups and countries is ascribed to the different use of terms like risk (variably used to denote harm or probability) and stewardship, often interpreted as synonymous with administration, losing its culturally-specific moral connotations. There are also challenges in promoting research integrity amidst a more general culture of corruption. Moreover, NASEM has shown that many biomedical researchers themselves know little about security. When engaging with the public, it is prudent to ensure that the researcher is familiar with the issues.

Reiner Korbmann (Wissenschaft Kommuniziert) in advising on Connecting with Publics in a World of Twitter, Blogs and Online News Environments, reminded participants about the need to improve on connecting with the public on the societal implications of genome editing compared to previous technologies, e.g. on GMOs. Media are competing for sensation, social media have transformed the spread of information and its amplification, whether true or not. Hierarchies in communication have vanished and all arguments are equivalent in social media. Most scientists are not familiar with this environment, there are no markers for orientation and they are exposed to audiences they have never met before. But there are also advantages – direct access to audiences, the potential to influence many publics and to create communities with common interest. How, practically, should scientists connect with this complex world:

- Be open in speaking and listening.
- Cooperate with communication professionals from the beginning.
- Realise that not every recipe works in all circumstances.
- Use social media actively.
- Security and safety issues are obviously important but there are many factors involved in framing and understanding the issues.
- Do not underestimate the activities of NGOs and established communities.
- Do not rely on reasoning, talk about values.
- Be aware that you are talking to all of us, not them – we are one society.

Panel discussion

Various points raised in this and earlier sessions were discussed further with the audience:

- Costs of public engagement – how can these be afforded by developing countries? Engagement exercises can be conducted at smaller scale while still capturing diversity.
- It is important to articulate benefits: how should the balance between benefits and concerns be valued?

There are significant issues here: the public (in reality, multiple publics) may regard “safety” issues as a proxy label, substituting for other concerns (e.g. dislike of modern agriculture or big business); benefit has to be assessed in terms of what the public perceive as benefits, and other values will need to be taken into account (in particular, whether the innovation is regarded as based on integrity and openness). Scientists often impose technical distinctions on what the public should think but the public may use other mental frameworks. The problem is compounded by differing perception of terms. In addition to the examples provided by Professor Heitman, some languages use the same word for biosafety and biosecurity, so a distinction between the two becomes difficult.

- To reiterate, it is imperative to build public trust in social media and elsewhere, for scientists and for regulatory authorities. There is a role for other trusted parties such as religious or community leaders in catalysing engagement but significant risk if scientists are suspected of co-opting other voices.
- Standards of evidence are crucially important. Scientists also need to build trust in the security community -- who have differing perceptions of threat, acknowledge that there are few data points for assessment and, consequently, rely on expert opinion.

The Way Ahead

This session was designed to reflect on themes and lessons from the workshop, and to outline next steps in building relationships to examine the security implications of genome editing and to foster engagement with others. In chairing the session, Robin Lovell-Badge highlighted priorities to communicate about benefits, create openness, and extend current public engagement exercises. Final perspectives were provided by the chairs of previous sessions:

Bärbel Friedrich outlined the Leopoldina’s conclusion that risk assessment and mitigation are intrinsic to all scientific developments. Although in Germany there is constitutive freedom of research, it is vital to demonstrate integrity and build trust at a time of rapid change, and this requires monitoring and flexible responsiveness. The Leopoldina’s initiative with the MPS and DFG to form ethics committees to review security-relevant research also helps to educate younger scientists without expanding bureaucracy. This may be a model to consider in other countries but, in addition, public engagement must be improved.

Diane Griffin gave NASEM’s perspective, concluding that this international workshop was a great start to an ongoing process. NASEM will continue its work on all the issues, including holding a meeting on life sciences governance in 2018, and IAP will publish its report from this workshop. A consensus strategy is required to develop recommendations, and ideas on how to do this are welcome.

Piers Millet agreed that this should now be the starting point for further activity: some of the identified concerns could be developed as narratives to expand the scope and scale of inquiry into security implications, and to feedback to the broader discussions on genome editing. In terms of future

security, it would be useful to progress thinking from the “weaponisation of disease” to “how biosciences may be able to manipulate what it means to be well”. There are good prospects to educate the future generation of researchers, e.g. the International Genetically Engineered Machine (iGEM) Foundation’s safety programme is now reaching out on security issues.

Peter Mills described the relevant recent and ongoing work of the Nuffield Council on Bioethics, including the examination of whether there is anything substantially new about the moral issues raised by genome editing – or if the arrival of genome editing can help to prioritise moral issues? There is still ambiguity on whether genome editing can be seen to constitute a new technology. Much work on issues of genome editing has been done by other bodies and it is important to integrate these different discussions, and to seek global consensus. Whether or not this can be achieved for security remains to be established.

Indira Nath, agreeing with the importance of continuing discussion, highlighted aims for global harmonisation in standards (both technical and for responsible conduct), governance frameworks and the monitoring of guidelines that already exist. The global work of IAP and others such as ICSU helps in this regard but regional cooperation is also needed, e.g. on how to handle human cell editing, gene drives, and trans-border procedures. Public inclusiveness must extend to young people and marginalised groups.

Dietram Scheufele re-emphasised three challenges for the scientific community:

- If scientists remain silent and leave the deliberative space to others, we cannot assume there won’t be public conversation – it will happen without us.
- We think that we know what the benefits of genome editing are, but they may not be regarded in the same way by the public. It is vital to frame benefits in a meaningful way that appeals to consumers.
- We say that there are no additional risks but then we describe genome editing as a transformative technology. Scenarios will be imagined by others – we need to communicate that we understand the problem, we are making an effort to engage, and we are acting with integrity.

The final question from the audience identified a new aspect of security. Is there also genetic security – a societal value held that the human genome should not be altered? Researchers know that the genome is undergoing continual natural change so may find it difficult to comprehend the public value of an inviolable genome, but this, too, is an issue for wider engagement.

In closing the meeting, Volker ter Meulen noted that the

workshop’s intensive and diverse discussions had amply satisfied the expectations of the planning committee.

Work will be needed subsequently to develop consensus recommendations for action, but from the perspective of IAP there are some key messages:

- **Recent evidence confirms that genome editing will be an important tool to drive innovation in pursuit of societal priorities.**
- **As with other tools, it could be misused, inadvertently or deliberately. While the advantages of genome editing lead to its widespread use, this does not in itself directly promote intent to misuse. There must be balanced discussion about benefit and risk, valuing benefits in ways that are relevant to the public. Benefits may include increasing security for human health and agriculture.**
- **Our workshop discussions represent significant progress in bringing together members of the science, security and policy communities to clarify if, where and how intentional misuse can be expected and what we might do to prepare for and mitigate such eventualities. We must listen to concerns about misuse while also making clear what is, or is not, scientifically feasible. We must continue building a culture of research responsibility and integrity, knowing that uncertainty may undermine public confidence in science and that other stakeholders may have different expectations of evidence.**
- **The voices of countries worldwide are essential in our collective efforts to assess value and harmonise procedures for risk assessment and management. It is highly desirable to build on the evidence shared and the links formed in our workshop to develop a sustainable network encompassing the scientific and security communities as a basis for extending the engagement more widely. IAP is ready to continue playing its part in doing this.**



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International Workshop Assessing the Security Implications of Genome Editing Technology

11-13 October, 2017

Herrenhausen Palace • Hanover, Germany

WORKSHOP PROGRAM

WEDNESDAY, 11th OCTOBER

09.00 A.M.- 1:00 P.M. REGISTRATION

Satellite Event:

**09.00 A.M. - 1:00 P.M. POLICY MINI-HACKATHON SATELLITE EVENT, GLOBAL
YOUNG ACADEMY (Invitation Only)**

12.30 P.M. LUNCH

01.30 P.M. WELCOME

Chair: Volker ter Meulen, InterAcademy Partnership

Wilhelm Krull, Volkswagen Foundation

Volker ter Meulen, InterAcademy Partnership

Thierry Courvoisier, European Academies Science Advisory Council

Diane Griffin, U.S. National Academies of Sciences, Engineering, and Medicine

Jörg Hacker, German National Academy of Sciences Leopoldina

02.00 P.M. KEYNOTE LECTURES: A NEW AGE OF BIOLOGY

Chair & Introduction: Indira Nath, All India Institute of Medical Sciences, New Delhi

Presentations (20 min each):

A New Age of Biology

Sir Venki Ramakrishnan, Royal Society

The Latest Advances in Genome Editing: Between Promise and Alarm

Robin Lovell-Badge, The Francis Crick Institute

**The Importance of Public Engagement for Discussions about Emerging
Technologies**

Dominique Brossard, University of Wisconsin-Madison

Questions & Answers

03.30 P.M. COFFEE BREAK

04.00 P.M

SESSION 1
ADVANCES IN GENOME EDITING: PROMISE AND READINESS

Chair and Introduction: Bärbel Friedrich, Alfried Krupp Institute of Advanced Studies, Greifswald

Presentations (20 min each):

Genome Editing in Medicine
Duanqing Pei, Chinese Academy of Sciences

Genome Editing in Agriculture
Dan Voytas, University of Minnesota, St. Paul

Gene Drives: From Species Eradication to Species Preservation
Fred Gould, North Carolina State University

Genome Editing in Microbes
Lennart Randau, Max Planck Institute for Terrestrial Microbiology, Marburg

Questions & Answers

05.45 P.M.

SESSION 2
ASSESSING THE SECURITY DIMENSIONS ASSOCIATED WITH SPECIFIC APPLICATIONS OF GENOME EDITING TECHNOLOGIES

Chair & Introduction: David Relman, Stanford University

Assessing the Security Implications of Emerging Technologies: What Do We Need to Know?
Piers Millett, Oxford University

Questions & Answers

Introduction to the Breakout Groups
David Relman, Stanford University

06:30 P.M.

APERITIF

07:00 P.M.

DINNER

THURSDAY, 12th OCTOBER

**09:00 A.M. SESSION 2
BREAKOUT DISCUSSIONS: ASSESSING THE SECURITY DIMENSIONS
ASSOCIATED WITH SPECIFIC APPLICATIONS OF GENOME EDITING**

Breakout Group 1: Potential Security Concerns Arising from Human Cell Editing Applications (Auditorium)

Chair: Anthony Perry, University of Bath

Speaker: Jonathan Moreno, University of Pennsylvania

Rapporteur: Johannes Fritsch, German Academy of Sciences Leopoldina

Breakout Group 2: Potential Security Concerns Arising from Applications in Agriculture (Seminar 2)

Chair: Fred Gould, North Carolina State University

Speakers: Joachim Schiemann, German Federal Research Centre for Cultivated Plants

Angelika Schnieke, Technical University of Munich

Rapporteur: Chistiane Diehl, European Academies Science Advisory Council

Breakout Group 3: Potential Security Concerns Arising from Gene Drive Applications (Seminar 5)

Chair: Zachary Adelman, Texas A&M University Speaker:

Todd Kuiken, North Carolina State University Rapporteur:

Sarah Carter, Science Policy Consulting LLC

Breakout Group 4: Potential Security Concerns Arising from Microbial Applications (Seminar 6)

Chair: Iqbal Parker, University of Cape Town, Cape Town

Speaker: Bert Rima, Queen's University Belfast

Rapporteur: James Revill, University of Sussex

10.30 A.M. COFFEE BREAK

**11.00 A.M. SUMMARY OF SESSION 2
BREAKOUT GROUPS AND PLENARY DISCUSSION**

Chair: Diane Griffin, U.S. National Academies of Sciences, Engineering, and Medicine

Report Out from Human Cell Editing Group

Report Out from Agriculture Group

Report Out from Gene Drive Group

Report Out from Microbe Group

Discussion of Breakout Group Reports

12.30 P.M. LUNCH (Ceremony Hall)

**01.30 P.M. SESSION 3, Part I
STRATEGIES FOR ADDRESSING POTENTIAL SECURITY RISKS OF GENOME
EDITING**

Chair and Introduction: Pilar Ossorio, University of Wisconsin-Madison

Panels

01.35 P.M. Legal, Regulatory, and Policy Strategies for Genome Editing: General

Michele Garfinkel, EMBO

S.R.Rao, Ministry of Science & Technology, Government of India

- 02.00 P.M.** **Legal, Regulatory, and Policy Strategies: Security-Specific**
Daniel Feakes, Implementation Support Unit, Biological Weapons Convention
Catherine Rhodes, University of Cambridge
- 02.25 P.M.** **Norms of Responsible Behavior and Voluntary Guidelines**
Indira Nath, All India Institute of Medical Sciences, New Delhi
Ulrich Sieber, Max Planck Institutes for Foreign and International Criminal Law
- 03.00 P.M.** **BREAK**
- 03.30 P.M.** **SESSION 3, Part II**
STRATEGIES FOR ADDRESSING POTENTIAL SECURITY RISKS OF GENOME EDITING
- Scientific and Technical Strategies**
Ursula Jenal, Jenal & Partners
Owain Edwards, Commonwealth Scientific & Industrial Research Organisation
- 03.55 P.M.** **Discussion with Session 3 Speakers Followed by Questions & Answers**
- Introduction to the Breakout Groups**
Pilar Ossorio, University of Wisconsin-Madison
- 04.45 P.M.** **COFFEE BREAK**
- 05.15 P.M.** **SESSION 4**
BREAKOUT DISCUSSIONS: ADDRESSING AND MITIGATING POTENTIAL SECURITY RISKS ASSOCIATED WITH SPECIFIC APPLICATIONS OF GENOME EDITING
- Breakout Group 1: Human Cell Editing Applications** (Auditorium)
Chair: Duanqing Pei, Chinese Academy of Sciences
Speaker: Abhimanyu Veerakumarasivam, Sunway University
Rapporteur: Johannes Fritsch, German Academy of Sciences Leopoldina
- Breakout Group 2: Applications in Agriculture** (Seminar 2)
Chair: Sarah Hartley, University of Exeter
Speaker: Rene Custers, Vlaams Institute for Biotechnology
Rapporteur: Chistine Diehl, European Academies Science Advisory Council
- Breakout Group 3: Gene Drive Applications** (Seminar 5)
Chair: Elizabeth Heitman, University of Texas Southwestern Medical Center
Speaker: Ary Hoffman, University of Melbourne
Rapporteur: Sarah Carter, Science Policy Consulting LLC
- Breakout Group 4: Microbial Applications** (Seminar 6)
Chair: Herawati Sudoyo, Eijkman Institute for Molecular Biology
Speaker: Filippa Lentzos, Kings College London
Rapporteur: James Revill, University of Sussex
- 06.45 P.M.** **APERTIF AND POSTER SESSION**
- 07.30 P.M.** **DINNER**

FRIDAY, 13th OCTOBER

**09.00 A.M. SUMMARY OF SESSION 4
BREAKOUT GROUPS AND PLENARY DISCUSSION**

Chair: Peter Mills, Nuffield Council

Report Out from Human Cell Editing Group
Report Out from Agriculture Group
Report Out from Gene Drive Group
Report Out from Microbe Group

Report-Out from Policy Mini-Hackathon Satellite Event: Alexander Kagansky, University of Edinburgh

Discussion of Breakout Group Reports

10.30 A.M. COFFEE BREAK

**11.00 A.M. SESSION 5
PUBLIC COMMUNICATION AND ENGAGEMENT ON POTENTIAL SECURITY
RISKS OF GENOME EDITING APPLICATIONS**

Chair & Introduction: Dietram Scheufele, University of Wisconsin-Madison

Commentaries (7 min each):

Science Journalism in a Changing World
Volker Stollorz, Science Media Center Germany

The Science of Communicating Risks and Benefits: When, Why, and How?
Dominique Brossard, University of Wisconsin-Madison

Public Engagement: Rationales, Methods and Intended Outcomes
Jason Delborne, North Carolina State University

Lessons from Engaging Global Communities of Science
Elizabeth Heitman, University of Texas Southwestern Medical Center

**Connecting with Publics in a World of Twitter, Blogs, and Online News
Environments**
Reiner Korbmann, Wissenschaft Kommuniziert

Panel Discussion Followed by Questions & Answers

**12.30 P.M. SESSION 6
THE WAY AHEAD**

Chair: Robin Lovell-Badge, The Francis Crick Institute

Bärbel Friedrich, Alfred Krupp Institute of Advanced Studies, Greifswald
Diane Griffin, U.S. National Academies of Sciences, Engineering, and Medicine
Piers Millett, Oxford University
Peter Mills, Nuffield Council
Indira Nath, All India Institute of Medical Sciences, New Delhi
Dietram Scheufele, University of Wisconsin-Madison

Panel Discussion Followed by Questions & Answers

01.15 P.M. CLOSING REMARKS

Volker ter Meulen, InterAcademy Partnership

01.30 P.M. END OF WORKSHOP / REFRESHMENTS

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