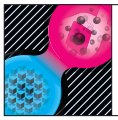
DAVID AUSSERHOFER/LEOPOLDINA

Time to settle the synthetic controversy

If synthetic biology is to thrive, the world needs to decide now how the field should be regulated and supported, says **Volker ter Meulen**.



BEYOND DIVISIONS
The future of synthetic biology
nature.com/synbio

The creation of an artificial yeast chromosome shows that synthetic biology is getting closer to what most scientists want: to be able to deliver benefits to society. The field has already found cheaper ways to produce medicines, and is making progress in applications from water purification to materials design.

The topic is, however, controversial, and that is jeopardizing its promise. Environmental groups argue that it poses risks to health and the environment and have called for a global moratorium. We have been here before: exaggerated fears and uncritical acceptance of claims of the risks of genetic modification led to excessively cautious regulation and a block on innovation that not only slowed the development of new products, but also deterred basic science.

The debate over synthetic biology is now entering a critical phase. The Conference of the Parties to the Convention on Biological Diversity (CBD) — the global framework that governs the protection of biodiversity — is currently exploring possible restrictions and will clarify its position at meetings next month and in October. But given the precedent of how the issue of genetically modified crops was handled, many scientists are worried that some policy-makers will take unsubstantiated concerns of environmental groups at face value and impose cumbersome and unnecessary rules. To prevent that, we need an objective, evidence-based and balanced assessment of the risks and benefits, both within and beyond the CBD. And that means that the voice of science must be heard.

FUNDING BODIES ACROSS THE WORLD MUST ANTICIPATE THE POTENTIAL OF SYNTHETIC BIOLOGY.

To kick-start the necessary dialogue, the IAP — the Global Network of Science Academies — has published a position statement (see go.nature.com/tmvhf8), drawn from the work of member institutes across Europe and the United States. We (I am co-chair) hope that the statement will spur debate on how best to feed scientific evidence that emerges from peer-reviewed research into the development of policy. This includes the regulations for overseeing research and innovation, as well as, for instance, investment in relevant infrastructure and training.

The IAP represents 106 academies worldwide and wants to have a more active role in global policy issues; last year, for instance, we published a similar position statement on antimicrobial-drug resistance.

In the case of synthetic biology, the world needs to commit to addressing several priorities. First, the scope of synthetic biology needs be determined. We describe it as the construction of customized biological systems to perform new and improved functions, through the application of principles from engineering and chemical synthesis.

The goal might be new, but many of the techniques are borrowed from existing fields, such as genetic modification. This means that the work is not proceeding entirely without regulation, as some claim; much of it is, in fact, governed by existing rules. The use, release and movement across borders of genetically modified organisms, for instance, are covered by the application of the Cartagena Protocol on Biosafety.

The recognition that key methods are already controlled is crucial, because it should defuse some of the public controversy about risk. Also important is striking the right balance between statutory regulation and self-governance by scientists and scientific bodies. (The IAP and others have published recommendations on how to develop individual and institutional codes of conduct.)

A second aspect that must be considered more broadly is how the results of synthetic biology are owned and shared. The current situation reflects its mixed parentage from both the biosciences (with its tradition of patenting) and engineering and software development (which embrace open sourcing and sharing). The announcement of how researchers worldwide worked to produce a synthetic yeast chromosome shows how openness can pay off in academia.

As synthetic biology progresses, techniques and tools will inevitably be developed that are not covered by existing regulations. It is reasonable to assume, the IAP argues, that these will allow the research to be done with greater precision. More-controlled modifications to genetic sequences, cells and organisms will facilitate characterization and bring the prospect of reducing unexpected and unwanted side effects. Future synthetic-biology techniques and products should therefore be easier to regulate, manage and audit than earlier, less controlled genetic-modification techniques.

Finally, the IAP says that funding bodies across the world must anticipate the potential of synthetic biology and invest in the research, and in the researchers involved. The investment should also incorporate projects in the social sciences and the humanities, which can, for instance, look at concerns about biologists 'creating life' and find better ways to communicate the issues.

Together, these steps should help to ensure that policies on synthetic biology set out sensible practices to mitigate the risk that is inherent in any major advance, yet are flexible enough to encourage research and innovation. ■

Volker ter Meulen *is co-chair of the IAP — the Global Network of Science Academies in Trieste, Italy, and past president of the German Academy of Sciences Leopoldina.*
e-mail: volker.termeulen@mail.uni-wuerzburg.de