

THE IASB: QUESTIONS & ANSWERS

What is the IASB?

The Industry Association Synthetic Biology (IASB) is a consortium of leading companies in synthetic biology. Founding members include ATG:Biosynthetics GmbH, Biomax Informatics AG, Entelechon GmbH, febit synbio GmbH, MWG Biotech AG and Sloning BioTechnology GmbH. The main focus of the association is the advancement and future development of synthetic biology. For more information on the IASB please visit the IASB website at www.ia-sb.eu.

What is synthetic biology?

Synthetic biology means the artificial construction of biological components and systems. Fueled by the rapid progress of DNA synthesis techniques, synthetic biology offers unprecedented opportunities for the advancement of biological research. This powerful technology has a broad spectrum of applications, e.g. in vaccine development, optimization of drugs and renewable energy sources, among many others.

Where lies the most promising potential of this new area of research?

Synthetic biology releases life science from the limitations imposed by the use of preexisting genetic material. The targeted design of biological systems opens up a new dimension in basic research and applied sciences.

Which are the advantages of synthetic biology versus conventional cloning approaches?

Experiments based on synthetic DNA are much faster and allow for very flexible adaptation to changing requirements. Functional investigations based on classical cloning involve tissue sampling, isolation of specific cell types and preparation of messenger RNA which is then reverse transcribed into a cDNA library. Tedious screening and sequencing of clones finally yields the desired DNA. Using the comprehensive information of existing genomic databases to synthesize selected genes and study their effects in a biological system is a significantly faster approach to gain insights in gene function. The resulting information can be used immediately to address further questions in subsequent experiments.

Besides the modification of natural biological systems synthetic genes may be used in the stepwise de novo construction of artificial biological systems with defined properties and enhanced resilience. These biotechnologically constructed systems may e.g. be used in cleantech (e.g. for removal of pollutants), renewable energies (fuel-producing microorganisms) or medicine (drug-producing bacteria).

Could you describe current examples of research using synthetic genes?

Since a number of years, synthetic genes are used in the development and production of vaccines and therapeutic proteins, also known as biologicals.

In January, a team lead by US researcher Craig Venter published the artificial reconstruction of the complete genome of the bacterium *Mycoplasma genitalium*. Multiple synthetic gene building blocks were assembled to form the complete genome of *Mycoplasma genitalium* JCVI-1.0, an identical copy of the natural example. In summer 2007, Venter had already succeeded in replacing the whole genome of living microbial cells by another specimen.

By serial omission of single genes, the researchers now define the essential set of genes required for the survival of a bacterium, which is a valuable piece of information for the construction of novel microorganisms producing fuels or pharmaceuticals. An example for the latter application is the effort aimed at the production of artemisinin (an antimalarial drug found in plants which is available in limited quantities) by transplantation of a delicately tuned set of 15 genes in yeast cells.

Which are the risks of synthetic biology? For example, could terrorists buy viral genes and assemble a killer virus?

Building such a synthetic viral weapon would be an extraordinarily demanding project, certainly much more difficult than employing conventional threats, e.g. explosive devices. In principle, however, such an attack may be feasible, and therefore rapid implementation of comprehensive controls is of cardinal importance. The IASB actively supports these efforts and has already initiated the first steps in close communication with the relevant authorities.

All members of the IASB monitor incoming orders for their potential hazards and check their compliance with gene technology legislation and export regulations. Therefore, it is highly unlikely that any order of a gene associated with a significant biosafety hazard goes unnoticed.

Which biosecurity measures are envisaged by the IASB?

Acting on these insights, the IASB has already taken the first steps: an anonymized survey of industrially produced and delivered genes will rapidly establish the current data status and provide a solid basis for the further development of biosecurity provisions.

In addition, we plan to establish a sequence database accessible for all companies involved in gene synthesis that will help to identify orders requiring closer scrutiny. A panel of experienced researchers and representatives from relevant authorities will be involved in the establishment of the database and the resulting reviews.

In addition, the IASB advocates an industry-wide harmonization of security measures in close cooperation with its members and other international companies involved in synthetic biology.

How about accident protection?

In all areas of science improperly conducted experiments may lead to undesired sequelae. Since synthetic biology has the potential to booster basic biological research in an unprecedented manner and because it is a rather new technology, accidents are a relevant risk. However, compliance with the existing safety regulations on the handling of biological systems provided, the consequences are confined to the laboratories themselves. Still, the IASB has already ventilated these issues. Sources of error may be eliminated by systematic cataloguing and effective user information as well as expert consulting via a dedicated internet portal. Concerning these matters, the IASB e.g. plans a cooperation with the University of Berkeley, CA, USA.

When will the planned measures of the IASB become effective? When will legislation and protection by state authorities be established?

Of course, the German gene technology act, similar existing legislation in other countries and the harmonized export restrictions of the Australia Group already provide strict safety regulation of genetic experimentation.

Nonetheless, it appears crucial to update these regulations and adapt them to the novel potential of synthetic biology. In a workshop held by the IASB and its US counterpart ICPS at the Analytica 2008 early in April, a panel of experts made a comprehensive risk assessment and discussed potential risk management strategies. The first steps towards a database for sequence screening and identification of suspicious orders have been taken. By comparison, the authorities proceed in a somewhat slower pace regarding financial support and legislation. The IASB will focus on acceleration of these processes and continue to point out the urgency of the matter, particularly because synthetic biology as a technology is still in its early days.

Is an industry association an appropriate body to take care of these issues? How will you ensure that commercial interests do not prevail over the concerns of environment and society?

The companies involved in gene synthesis are genuinely interested in the prevention of any discrediting through the misuse of their technology by individuals—which may entail a complete ban of synthetic biology by European authorities. This would be clearly against the interest of the industry and those of corporate and academic research that expect to gain new momentum from the extraordinary potential of synthetic biology. Thus, all players in the field have the same interest: establish appropriate controls to provide maximum safety and enable optimal use of this highly promising technology.

What does your company do today to ensure maximum security in synthetic biology?

Currently, we compare all ordered gene sequences with the relevant databases of the Robert-Koch Institute to identify potentially hazardous sequence elements in advance. In addition, we verify the shipping addresses of customers to ensure that artificial DNA is exclusively delivered to established companies and academic

institutions. In addition, we are actively engaged in the work of the IASB to provide optimal conditions for a safe and secure use of synthetic biology.

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