FIFTH REVIEW CONFERENCE OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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DEVELOPMENTS IN NON-PROFIT AND INDUSTRIAL APPLICATIONS OF GENETIC ENGINEERING, BIOTECHNOLOGY AND OTHER AREAS OF LIFE SCIENCES

Since the Fourth Review Conference in 1996 major developments have taken place in biotechnology and other areas of the life sciences. These developments have not only opened new avenues in research, with increasing importance attaching to emerging areas such as genomics, proteomics, bioinformatics, to name but a few, but have also broadened the basis for non-profit and industrial applications of biotechnology.

Beyond giving a description of the scientific progress made in the fields of biology, biotechnology and genetic engineering, a consideration of the national capabilities of non-profit and industrial applications of biotechnology and other life sciences provides additional information on the spread and accessibility of these technologies.

The following description of developments in Germany also reflects similar developments in other countries where appropriate.

Genetic engineering

The German Genetic Engineering Act requires a thorough risk assessment before any genetic engineering installation or genetic engineering operation can start working. The risk has to be evaluated to include the properties of the donor organism, the receiving organism and the genetically modified organism, as well as the possible impact of the modified organism on human health and the environment. The aim of the risk assessment is to classify a genetic engineering operation as having one of four levels of biological safety. Depending on the biosafety level, the genetic engineering operation must be declared or requires authorization by an appropriate agency of a federal state. For biosafety level 3 and 4 experiments, the state agencies themselves request expert advice from the Central Advisory Committee for Biological Safety (Zentrale Kommission für Biologische Sicherheit; ZKBS), which is an independent body located at the Robert-Koch-Institut (www.rki.de/GENTEC/ZKBS/ZKBS.HTM).

From 1990 to spring 2001 a total of 6,139 genetic engineering operations were either declared to or

authorized by the federal states in Germany. 3,754 were classified as biosafety level S1, 2,247 as biosafety level S2 and 138 as biosafety level S3. No biosafety level S4 operations have been requested or authorized in Germany to date. Of the total number of 6,139 operations, more than 5,000 were executed in public research, the remainder in private research and commercial applications. However, the number of executed S1 operations is much higher than the figure given above, as a S1 operation has to be declared only when executed for the first time by an installation. Follow-up S1 operations by declared or authorized facility do not require an additional declaration.

For this reason the number of genetic engineering operations represents only a vague picture with regard to the development of genetic engineering. A better indicator is the number of authorized genetic engineering installations. These installations are subject to mandatory registration by agencies of the federal states. 3,931 facilities have been authorized from 1990 till now, of which approximately 3,200 are in the public domain. With regard to biosafety levels, more than 3,000 belong to level S1, more than 800 to level S2 and around 50 to level S3. To date no installation authorized for genetic engineering operations on biosafety level S4 exists in Germany.

Since 1992 the annual reports of the Central Advisory Committee for Biological Safety have provided more detailed information on organisms used in biosafety level S3 experiments. According to the data the majority of operations are related to HIV research.

All the above data are accessible at www.rki.de/GENTEC/GENENG/GENTEC_E.HTM and are updated with the annual reports of the ZKBS (www.rki.de/GENTEC/ZKBS/ZKBS.HTM).

Biotechnology-related medicines

With the beginning of the last decade genetic engineering left the field of pure research to become increasingly important in commercialization, especially of biotechnology-related medicines. In June 2000 in Germany, 53 different genetically engineered proteins as part of 80 registered medicines were authorized, as well as 8 genetically modified antibodies.
(www.i-s-b.org). The fifth edition of the *Editors' and Reporters' Guide to Biotechnology* of the *Biotechnology Industry Association* reports that in the first half of the last decade five to seven substances were approved in the USA annually as new biotech drugs or vaccines. In the second half of the decade, the number of substances approved annually climbed to 32 in 2000. To date more than 110 biotech pharmaceutical products approved by the FDA are on the market (www.bio.org/er/statistics.asp).

The *2000 survey Biotechnology* of *PhRMA* names for the USA 369 medicines in the pipeline to meet the definition of 'biotechnology medicines'. Approximately half of them fall into the category cancer and cancer-related, 39 into the category infectious diseases and 28 into the category neurological disorders. Most of the substances are in the development status of phase II or phase III testing (www.phrma.org/searchcures/).

For the same period *Ernst & Young's Eighth Annual European Life Sciences Report 2001* counts 278 pipeline products for Europe, most of them in preclinical or phase I testing. Leaders in the development of biotech medicines in Europe are the United Kingdom and as a cluster the Nordic countries Denmark, Sweden, Norway and Finland. (www.ey.com/global/vault.nsf/uk/integration_report_2001/$file/european_life_sciences_report_01.pdf)

The development and authorization of genetically engineered medicines is not restricted to industrialized countries in Europe and North America. The group of countries developing and authorizing biotech medicines includes Australia, China, Cuba, India, Israel and Japan - to name but a few (www.i-s-b.org). At the meeting of the 5th Session of the United Nations Commission of Science and Technology for Development in May 2001, China mentioned 18 bio-pharmaceutical products commercialized and 30 more at the clinical trial stage (www.china-un.ch/eng/14947.html). China is also the world's leading producer of antibiotics.

Field releases of genetically modified organisms (GMOs)

Since 1991, European Union member states have authorized 1,726 field releases of genetically modified organisms. The majority of releases took place in France, followed by Italy, the United Kingdom, Spain and Germany. The organisms are headed by maize, rape seed and sugar beet (www.rki.de/GENTEC/GENENG/GENTEC_E.HTM). Data on more than 10,000 field trials are available at http://binas.unido.org/binas/ and www.isb.vt.edu/cfdos/globalfieldtests.cfm.

However, the release of GMOs into the environment is in the meantime no longer restricted to experimental trials. A series of modified agricultural products have been approved for placement on the market in the EU (www.rki.de/GENTEC/INVERKEHR/INVKLIST_E.HTM). In the period 1996 to 2000, the area of genetically modified crops increased from 1.7 to 44.2 million hectares globally. The number of countries planting GMOs rose from 6 to 13 to include the USA, Canada, Argentina, Chile, South Africa, Mexico and Uruguay. The predominant GM crops are soy beans, maize, rape seed and cotton. The genetically changed properties of the crops are mostly related to resistance against herbicides and insects (www.isaaa.org/kc).

Biotechnology facilities

Reviewing and comparing the number of biotechnology facilities in different countries is not an easy task. For a lot of countries information on biotechnology facilities is available on the Internet. However, the mix of fermentation facilities in traditional food processing, pharmaceutical and bio-pesticide production and emerging so-called Entrepreneurial Life Science Companies (ELISCOs) makes it difficult to compare countries' biotechnology capabilities. Another problem is the difference in economic and organizational structures. ELISCOs are defined as small and medium-sized companies that use modern biological techniques to develop products or services to serve all areas of the life sciences. (www.ey.com/global/vault.nsf/uk/integration_report_2001/$file/european_life_sciences_report_01.pdf)

The abovementioned *Ernst & Young's Eighth Annual European Life Sciences Report 2001* counts 1,570 small and medium-sized ELISCOs in Western Europe in 2000. The comparable figure for 1998 was 1,178. The leader in Europe in 2000 was Germany with 332 companies, followed by the United Kingdom; however, if the financial data and the number of employees are compared, the United Kingdom ranks ahead of Germany. The same report gives 1,273 companies in the United States which have financial revenues and employee numbers three times higher than the comparable figures in Europe.

ELISCOs reflect the fast expansion of commercializing biotechnology, but describe only a portion of the biotechnology infrastructure of a country, as they do not include big companies which dedicate only part of their business activities to biotechnology. For instance, a website of the German *InformationsSekretariat Biotechnologie* supported by the German Federal Ministry for Education and Research contains a map with more than 500 companies which are active in different fields of modern biotechnology. The survey does not include companies that conduct no research activities in Germany. All companies in Germany are named, with their full address, a description of their activities and the number of employees, as well as additional statistical data on German biotechnology industries. The web site is updated continuously (www.i-s-b.net/firmen/sme.htm).

The Internet is an interesting and valuable source of figures on biotechnology facilities world-wide. Compiled data on biotech companies and research institutions are available on the Internet not only from the web sites of individual companies but also from the web sites of national chemical, biotechnology, pharmaceutical and related associations. In addition, government institutions - similar to the German Federal Ministry of Education and Research (see above: www.i-s-b.org) or the German federal-owned Robert-Koch-Institut (see above: www.rki.de) - support or operate web sites to inform the public about biotechnology and life science activities and institutions. This form of information is not restricted to government organizations in Europe or North America as the Internet shows. The web site www.i-s-b.org also includes summary sheets on the biotech capabilities of several countries. Most of the data available in the summaries are based on figures from 1998 and 1999 and compiled from different sources.

Summary

When dealing with BWC issues and the benefits and risks of modern biotechnology and other areas of life sciences, the focus should be not only on scientific and technological progress but also on the spread and accessibility of these technologies through the increase of non-profit and industrial applications. Increased world-wide transparency of national capabilities combined with stringent national legal regimes to control and safeguard these technologies would be a major contribution towards strengthening the Biological Weapons Convention.
