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Biotechnology for Sustainable Growth and Development

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT 2004

BIOTECHNOLOGY FOR SUSTAINABLE GROWTH AND DEVELOPMENT

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To achieve the highest sustainable economic growth and employment and a rising standard of living in member countries, while maintaining financial stability, and thus to contribute to the development of the world economy.

To contribute to sound economic expansion in member as well as non-member countries in the process of economic development; and

To contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

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EXECUTIVE SUMMARY

Life science research and biotechnology are delivering on better outcomes for health, the environment, and for industrial, agricultural and energy production.

Working together, OECD countries have the opportunity to optimise the contribution that life sciences and biotechnology can make as a driver for sustainable growth and development.

Growth must meet the economic, environmental and societal needs of countries. Concerted efforts, involving public and private sectors, are required to remove inappropriate barriers and provide opportunities for the transition to a more biobased economy.

Continued investment is required by the public and private sectors in the basic research and development that will underpin innovation, as well as on delivery of clear and consistent policy signals to innovators.

A strong scientific infrastructure is necessary to underpin the contribution that biotechnology can make and high-quality biological resource centres (BRCs) will be an essential element of such an infrastructure.

Appropriate safeguards to society must keep pace with scientific and technological advances in biotechnology.

Continued international effort is necessary to deliver on the full potential for life sciences and biotechnology to help drive sustainable growth and development.

The OECD should strengthen its contribution to work on biotechnology as a driver for sustainable growth, focusing on the issues identified and conclusions reached in this paper.

BIOTECHNOLOGY FOR SUSTAINABLE GROWTH AND DEVELOPMENT

Introduction

1. The recent and continuing advances in the life sciences are making a reality of the prediction that this will be the century of biotechnology. Capturing the economic, environmental, health and social benefits of biotechnology will challenge government policy, public information, law, education and the scientific and technological infrastructure, and will affect our societies and many aspects of our life as profoundly as information technologies have already done.

2. Such scientific advance has the potential to enable better outcomes for health, the environment, and for industrial, agricultural and energy production. Successful capture of these will provide significant opportunities for sustainable growth in the OECD area and beyond, partly through transformation of industries. By increasingly interacting with information and communication technologies, bioinformatics and nanotechnologies, the potential is even greater.

3. Innovative products and services with improved economic and environmental performance will draw on renewable resources and biological processes to meet the needs of society. If delivered successfully, they have the potential to help decouple industrial growth from environmental degradation and deliver a more resilient, more biobased economy[1], less susceptible to uncontrollable global events and less dependent on large-scale distribution systems.

4. Life science research and biotechnology also promise more effective and efficient products to help deliver better health, whether in developed or developing countries, that are based on a fuller understanding of the human body and its ailments and diseases and of the interventions required to deal with them. These products can deliver on two vital and inextricably linked goals - improved health and more sustainable growth and development.

5. This paper thus focuses on three areas of biotechnology where there is both a particular need for international action and great potential for early contribution to sustainable growth. First, establishing a Global Biological Resource Centre Network as part of the necessary international infrastructure underpinning successful research. Second, the contributions that industrial biotechnology can make to a more biobased economy. And third, enabling innovation in health biotechnology. Achieving optimal contributions to sustainable growth and development through health and industrial biotechnologies will rely on R&D spill-over between the two sectors as well as on a successful infrastructure such as that envisaged for biological resource centres.

6. Working together on these issues, OECD countries have the opportunity to optimise the contribution that life sciences and biotechnology can make to sustainable growth that meets the economic, environmental and societal needs of countries.

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1. A biobased economy is defined as an economy that uses renewable bioresources, efficient bioprocesses and eco-industrial clusters to produce sustainable bioproducts, jobs and income.

I. Scientific infrastructure: biological resource centres

7. A sustainable international scientific infrastructure is necessary to underpin successful delivery of the benefits of biotechnology, whether within the health, industrial or other sectors, and in turn assure that these advances will help drive growth.

8. High-quality biological resource centres (BRCs) will be a vitally important element of such an infrastructure. They are fundamental to the harnessing and preservation of the world's biodiversity and genetic resources. They are part of the key infrastructure supporting biotechnology, bioprocessing and the development of new approaches in prevention, diagnosis and treatment of disease. They also have a vital role in ensuring the safe, regulated use of organisms that are known pathogens to humans, plants or animals.

9. BRCs must meet the standards of quality and expertise demanded by the international community of scientists and industry for the delivery of biological information and materials that will enable research. Adequate funding is required to achieve these standards and assure sustainability. It might be difficult for any single entity to supply the full financial support necessary and so international co-operation on this issue might be required.

10. Steps need to be taken to secure an international infrastructure for the proper maintenance and exchange of biological resources since they represent the fundamental starting material for all biological science. The OECD report *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*[2] sets out the key requirements but the detail of what needs to be done, and how to do it, rather than simply the intention, needs to be made clear and a way forward laid out that takes account of stakeholder interests and delivers on what is required.

11. The OECD Working Party on Biotechnology has been addressing these issues over the past two years and has concluded that a Global Biological Resource Centre Network (GBRCN) should be established and that collections of biological resources should be encouraged (though not obliged) to join. The focus of the GBRCN would be to improve international access to high-quality biological materials and data.

12. The Working Party on Biotechnology has concluded that in establishing a GBRCN, common international operational standards should provide the framework for the network. Nationally designated independent third-party approval systems should be agreed to assure compliance with GBRCN standards and should operate in line with the agreed guidance set out in OECD documents.[3]

13. The GBRCN should aim to assist collections that are candidates for BRC status to take appropriate steps to meet necessary GBRCN standards.

14. The Network will improve international access to biological materials and data. Appropriate security measures will need to be taken to safeguard against unauthorised or undesirable access to certain sensitive material.

15. The GBRCN should be open to collections from all countries, whether OECD members or not, provided the required operational standards and third-party approval mechanism are met.

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2. OECD (2001), *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*, Paris, ISBN 92-64-18690-5.

3. Guidance set out in OECD documents DSTI/STP/BIO(2003)12/REV2 and DSTI/STP/BIO(2003)13/REV2.

16. It should be established as an international body independent of OECD, with its own small secretariat, governing council and scientific advisory apparatus, possibly under the aegis of an appropriate existing universal international governmental organisation or other body with the necessary expertise. It should seek to complement but not duplicate existing international effort.

17. A Global Biological Resource Centre Network will in particular complement the existing Global Biodiversity Information Facility (GBIF). A GBRCN is likely to concern itself primarily with the collection and maintenance of high quality biological materials. GBIF provides access to data on biological diversity but does not concern itself with the collection and maintenance of the biological material itself. Nonetheless, care needs to be taken to ensure that in establishing a GBRCN there is not duplication of the work of GBIF or other existing international bodies.

18. A number of countries, both members and non-members of OECD, have already recognised the need and taken substantive steps to establish national biological resource centres. These countries should be congratulated and others encouraged to follow their lead.

Next steps

19. The OECD should recognise that biotechnology is a key driver for sustainable economic growth and that a GBRCN will provide vitally important infrastructure for reaching this goal. The OECD should complete its development of the instruments required to bring the GBRCN into being, including common operational standards, standards for information linkage and exchange, appropriate security arrangements, guidance on institutional architecture management and on funding, and any necessary interim measures, by 2006 at the latest. In particular, the OECD should:

i. Propose a mechanism to facilitate the development of a high quality network by setting out the means by which collections which are candidates for BRC status might be assisted in taking appropriate steps to meet necessary GBRCN standards.

ii. Take further steps to agree common general principles to provide an appropriate basis for the development of appropriate security measures to safeguard against unauthorised or undesirable access to certain sensitive material in BRCs.

iii. Finalise guidance on the development of sustainable plans for BRCs.

iv. Initiate a transparent process, involving stakeholders and appropriate national and international bodies, to complete work to bring the GBRCN into being.

20. Other countries, relevant international bodies, and public and private sector entities should consider taking steps to assist in the development of a GBRCN.

II. Industrial biotechnology and sustainability

21. There was much attention paid in the early days of the technology to what biotechnology might do to benefit the environment. A quarter of a century on, some of the claims made remain conjecture. However, there is now no doubt that biotechnology applied in many industrial products and processes brings with it significant environmental as well as economic benefits, in areas as diverse and important as climate change, water conservation and reduction in the production of toxic pollutants.

22. The OECD report *The Application of Biotechnology to Industrial Sustainability*[4] describes practical case studies where biotechnology has been introduced in industrial processing or manufacturing as an alternative technology for more traditional physico-chemical means. The case studies come from a broad range of industrial sectors and countries, and in each case the use of biotechnology resulted in lower costs and a reduced environmental footprint.

23. This OECD report was the first to bring together systematic evidence that biotechnology, used appropriately, can contribute to improved industrial eco-efficiency. In the private sector, industrial biotechnology continues to produce more versatile chemicals and materials with significantly lower environmental impact than physico-chemical methods.

24. Advances in areas such as genomics, proteomics, metabolomics and pathway engineering are delivering new generations of bio-transformation technologies opening up real potential for using renewable biomass as feed-stock for industrial products and processes across a broad range of economic sectors.

25. Moving towards the use of more biobased products and processes offers the prospect of reducing reliance on finite resources of fossil fuels and developing an economy that is increasingly based on renewable resources, produces much lower carbon emissions, and so has the potential to make a significant contribution to mitigating climate change. There is also great potential for creating new industries that use biotechnology applications for environmental protection, for example, in waste management, bioremediation, and the control of pests.

26. While environmental benefits are a strong motivator for a biobased economy, alone they are not a sufficient incentive for adopting biotechnology. Industry decisions will be influenced by economic considerations, company strategy and products. Biotechnology may not always provide the best solution but when it does economic gains and environmental friendliness can go hand in hand.

27. A transition towards a biobased economy could bring with it sustainable industrial transformation, improved quality of life and revitalisation of rural economies. Though the OECD member countries are at the forefront of developing the technologies that might deliver a more biobased economy, there is substantial potential too for direct and technology transfer benefits to economies in transition and developing economies, which could benefit from revived economic interest in agrarian resources.

28. Such an economy offers a range of solutions that could service the needs of different countries according to their technological capabilities and the availability of renewable bioresources. It could enhance security of supply for energy and chemical feedstock and deliver health benefits through reduced pollution and exposure to toxic substances.

29. The potential economic and environmental gains through use of these technologies across appropriate industry sectors both in OECD member and non-member economies are substantial. In some areas the competitive advantage of industrial biotechnologies is already apparent.

30. It is not realistic, however, to assume that a new "green revolution" will sweep spontaneously over existing industries. Though a number of governments have developed or are considering policies to encourage the use of biobased products and processes, a transition to a biobased economy will require policy co-ordination and convergence across various sectors of the economy, including agriculture, industry and energy.

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4. OECD (2001), *The Application of Biotechnology to Industrial Sustainability*, Paris, ISBN 92-64-19546-7.

31. A positive transition will require stakeholders to develop a consensus. Both the public and private sectors will need to work together. They have essentially complementary roles, with the private sector largely delivering on the technology and the public sector assuring scientific infrastructure and supportive policies. Both will be faced with strategic choices in any future transition and considerable effort will be required to maximise benefits for all parties and discourage the emergence of entrenched positions on the basis of a narrow perception of self-interest.

32. There is a need to remove inappropriate barriers to the development of a more eco-efficient, more biobased, economy and address opportunities to leverage transition, through the private sector as well as broader societal interests. It is necessary to evaluate frameworks, tools and indicators so as to deliver coherent policies to enable a move towards a biobased economy through public/private sector collaboration. It is also necessary to develop indicators that will help determine the long term contribution that biotechnology can make to sustainable growth and development.

Next steps

33. The OECD Working Party on Biotechnology is developing country-based scenarios that are intended to identify the policy challenges, as well as the likely impact of existing policy frameworks, for a transition to a biobased economy. This work should be completed by 2005. It will provide a foundation for subsequent action that the OECD should take to identify inappropriate barriers and address opportunities to leverage the transition to the use of sustainable industrial biotechnologies.

34. The OECD should develop evaluation frameworks, statistics, tools and indicators to help deliver coherent policies in OECD economies to enable a move towards a biobased economy. Analysis should be undertaken of how better to develop links between, and ensure adequate provision of trained human resources for, R&D activities and commercial exploitation of bioprocesses and products.

35. Further consideration should be given by the OECD to how to broaden the debate on a biobased economy to non-member economies.

III. Biotechnology, innovation and health

36. The third broad area in which life sciences and biotechnology are making significant and rapid contributions to sustainable growth is the health-care sector. A better understanding of the underlying biology of disease, gleaned through the human and other genome projects and elsewhere, is providing researchers and health professionals with the opportunity to employ safer, more effective interventions based on biotechnological products and processes that promise a better match between the supply of effective health interventions and increasing societal expectations for good health and better quality of life, in OECD countries and beyond.

37. An increasing share of R&D in OECD countries is health related. But, though the promise is great, delivery of innovative health-related products and processes can be heavily influenced by a very wide range of public policies. It is in the interests of all that the OECD countries – where most health-related research is carried out and where most of it is paid for – make informed choices when developing policy to assure a continued flow of biotechnology-based health innovation.

38. Many OECD countries actively support health-related biotechnology innovation. However, there is a growing recognition that it is very difficult to determine the most appropriate public policy measures to effectively provide accessible, high-quality, effective and safe health-related innovation. There is a concern that these may cost more than currently available interventions, where these exist. There is also substantial public debate about the provision of appropriate safeguards to society as medical science mines the human and other genomes for clues to better health.

39. OECD economies have recognised that more needs to be done, including at the international level, to ensure that the remarkable advances in the biosciences can contribute fully to improving the health of society and to sustainable growth. There is a particular need for progress in enabling the continued flow of innovation in the health sector to help deliver improved health outcomes.

Human genetics

40. The information coming from the study of human genetics, and the identification of genes associated with disease, can make a significant contribution to the knowledge that will help drive innovation in health. But, if the fruit of such labour is to be used optimally, with the approval of society, a balance needs to be struck between access to and use of individuals' genetic information. Whether or not that balance is achieved in public policy will affect how successful genetic science is as a driver for innovative products and processes and delivery of better health.

41. OECD countries came together to discuss these challenges in Vienna in February 2000, and the report of that meeting[5] recommended a number of specific further actions. One such action has been to take stock of how those laboratories that offer molecular genetic testing ensure quality assurance and proficiency testing of genetic tests. This work needs to be completed although there is already enough evidence to suggest that OECD countries should explore what steps might be taken internationally to ensure good practice.

42. The second action has been to address the policy challenges associated with the development, maintenance and use of human genetic research databases. Such databases can make a significant contribution to advancing knowledge. The OECD economies are working together to foster empirical comparison of human genetic research databases and assess the need for development of good practices in their management and governance. The report of this work, expected during 2004 following a seminal workshop in Tokyo, will make a significant contribution to international consideration of the role of such databases in helping translate scientific advance into sustainable growth and will provide a solid basis for countries to evaluate possible future action in this area.

43. The third and final action taken so far has been to determine empirically at a workshop[6] in Berlin in 2001 the impact of the current intellectual property regime on dissemination of and access to genetic inventions. The workshop concluded that it remains important to foster intellectual property protection of, and access to, inventions in biotechnology. Good licensing guidelines can facilitate the use and diffusion of innovation in biotechnology. The OECD should aim to complete such guidelines by 2005.

44. As the number of genetic inventions continues to increase, it is likely that novel access mechanisms will be required to assure continued access for better health outcomes. More work will be required to evaluate such novel access mechanisms, many of which have already been successful in other high-technology areas, such as information technology. Examples of novel access mechanisms include patent pools, clearing houses and open access agreements.

45. Advances in human genetics will continue to challenge public policy making in as yet unforeseen ways. The OECD offers a useful forum where these challenges should continue to be discussed and targeted collective action taken to meet them and to turn science through technology into growth.

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5. OECD (2000) *Genetic Testing: Policy Issues for the New Millennium*, Paris, ISBN 92-64-18304-3.

6. OECD (2002) *Genetic Inventions, Intellectual Property Rights and Licensing Practices*, which can be downloaded from www.oecd.org/sti/biotechnology.

Enabling health innovation

46. The second set of major challenges for getting the most out of biotechnology for health is how to deliver and capture innovation consistently and rapidly for the issues that really matter – delivering both better health outcomes and sustainable economic benefits.

47. The OECD has carried out some work on this. For example, in 2002, OECD economies came together in Lisbon to address how biotechnology might contribute to the fight against infectious diseases, particularly neglected and emerging diseases. A report from that workshop, produced in April 2003[7], concluded there is much to be done to improve the policy signals for innovators to encourage them to bring products that address such diseases to the market.

48. But getting the signals right to innovators is not just a challenge for policy makers who are addressing neglected diseases – it is a common challenge for all.

49. It is essential to recognise that private sector research and development is necessary to realise the full benefits of biotechnology. Options need to be analysed for mechanisms that could deliver proper incentives for R&D into health priorities and assure appropriate subsequent returns on innovation.

50. Analysis also needs to be carried out to determine which mechanisms most affect the rate of introduction of new biotechnologies. Some such mechanisms are likely to speed introduction and others to impede introduction. The decision on how to respond to any such analysis will be for individual countries, but OECD economies could come together to share experience on the likely effects – intended and/or unintended – of different mechanisms.

51. There is a need to develop a better understanding of the factors that enable biotechnology innovation in areas of high health-care needs, and how to encourage diffusion and facilitate uptake of health-related biotechnology products.

52. Ways also need to be found to facilitate the effective development of multi-sector partnerships between public, private, NGO and/or academic sectors that can provide important means to fill in research gaps, spread financial burdens, and reach acceptable balances between public health needs and incentives for innovation.

53. Finally, closer scrutiny is necessary of the opportunities afforded by biotechnology for reduction of risk associated with health interventions as well as risk detection. In determining impacts on risk, for example, through the use of pharmacogenomics, further efforts are required to broaden the framework of assessment of technologies to include the full range of issues that affect society.

54. Analysis of pathogen genomics offers opportunities for issues such as surveillance and early detection of threats to public health. The OECD might analyse measures that might facilitate the development, deployment and interoperability of systems for health security that build on such advances.

Next steps

55. The OECD should complete its existing work on appraising international measures for quality assurance of genetic tests and good practice in the management and governance of genetic databases. It

7. OECD (2003) *Biotechnology and Sustainability: The Fight Against Infectious Disease,* which can be downloaded from www.oecd.org/sti/biotechnology.

should aim to deliver good licensing practices for biotechnology patents that facilitate the use and diffusion of innovation in biotechnology by 2006.

56. OECD should maintain a forum where the ongoing challenges to public policy arising as a result of increasing understanding of the genetics of disease should continue to be discussed and targeted collective action taken.

57. The Organisation should analyse measures that might facilitate development, deployment and interoperability of systems for health security that build on advances in the analysis of pathogen genomics.

58. The OECD should also take steps to develop a better understanding of the factors that enable biotechnology innovation in health, as well as how to encourage diffusion and facilitate uptake and should report on this by 2006.

IV. Summary of conclusions and next steps

59. Integrating the advances made possible by biotechnology based on the rapid advances in biology, genetics and informatics offers OECD member and non-member countries sustainable economic growth comprising improved economic, environmental and health performance in a way that can meet the expectations of society.

60. International co-operation will accelerate the rate at which life sciences and biotechnology can benefit society and contribute to sustainable growth. So, too, will a truly multidisciplinary approach and OECD is well placed to provide an appropriate supportive forum for countries to move forward together.

61. Focusing effort on establishing a Global Biological Resource Centre Network as well as on industrial and health-related biotechnology is likely to bring early benefit.

62. OECD should strengthen its contribution to work on biotechnology as a driver for sustainable growth and development. In particular, the Organisation should:

i. Complete its development of the instruments required to bring a Global Biological Resource Centre Network (GBRCN) into being, including common operational standards, standards for information linkage and exchange, appropriate security arrangements, guidance on institutional architecture management and on funding, and any necessary interim measures, by 2006 at the latest.

ii. Complete work on country-based scenarios and policy challenges for a biobased economy by 2005. Identify inappropriate barriers and address opportunities to leverage the transition to the use of sustainable industrial biotechnology.

iii. Complete work on appraising international measures for quality assurance of genetic tests and good practice in the management and governance of genetic databases. Deliver good licensing practices for genetic inventions by 2006.

iv. Take steps to develop a better understanding of how to enable biotechnology innovation in health, as well as how to encourage diffusion and facilitate uptake, and report on this by 2006.

v. Develop appropriate frameworks, data and measuring methods, as well as best practice and guideline instruments to enhance the contribution that biotechnologies can make to global sustainable growth.

vi. Advance a multidisciplinary approach to the analysis of strategic challenges for translating scientific advances through biotechnology into sustainable growth.

vii. Bring together the expertise in biotechnology of the respective parts of the Organisation with appropriate internal co-ordination.

63. The OECD offers a forum under the auspices of CSTP's Working Party on Biotechnology (WPB) that can help OECD member countries meet these challenges.