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**DSTI/STP/BIO/M(2008)7**

Organisation de Coopération et de Développement Économiques  
Organisation for Economic Co-operation and Development

**29-Oct-2009**

**English - Or. English**

**DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY  
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY**

Cancels & replaces the same document of 18 March 2009

**Working Party on Biotechnology**

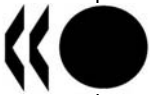
**SUMMARY RECORD OF THE 24TH SESSION OF THE WORKING PARTY ON BIOTECHNOLOGY  
(WPB)**

**Held at the OECD Headquarters  
on 19-21 November 2008**

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OF THE WORKING PARTY ON BIOTECHNOLOGY (WPB)**

**Held at the OECD Headquarters on 19 – 21 November 2008**

**ITEM 1: STATEMENT BY THE CHAIRMAN**

1. The Working Party on Biotechnology Chairman (Mr. G. Jimenez-Sanchez) welcomed delegates, reminded them of the main activities and reports completed since their last meeting, and identified the most important items for decision on the Agenda including the Accession process and the discussion on Global Challenges.

**ITEM 2: STATEMENT BY THE SECRETARIAT**

2. The Secretariat (Mr. I. Gillespie) made introductory remarks on behalf of the Director (Ms. S. Huttner) who was not able to attend the opening of the WPB due to her participation in a joint OECD/World Bank seminar on Innovation. Mr. Gillespie announced the appointment of two new deputy Directors (Mr. H. Yoshikawa and Mr. A. Wyckoff) in the Directorate for Science, Technology and Industry. He identified a number of high profile horizontal projects at the OECD, including the OECD Innovation Strategy, OECD responses to the financial crisis and work on food security.

**ITEM 3: ADOPTION OF THE DRAFT AGENDA** DSTI/STP/BIO/A(2008)10/REV1

3. The Working Party adopted the Draft Agenda.

**ITEM 4: APPROVAL OF THE SUMMARY RECORD OF THE 23RD SESSION** DSTI/STP/BIO/M(2008)2

4. The Summary Record of the WPB's 23rd Session was adopted.

**ITEM 5: SECRETARIAT REMARKS**

5. The Secretariat (Ms. S. Peric) presented recent administrative changes at the OECD. In particular she noted that: *i*) the Secretariat will be required to formally report on progress in meeting output results each year; *ii*) accountability will be for delivery of outputs rather than for inputs; and *iii*) that Committees will have more flexibility to make modifications to their PWB for output results with budgets under 250 K Euro. Council approval is required for 250 K Euros or higher amounts. It was noted that the relevant OECD documents are C(2008)92/REV1 and C(2008)93/REV2.

6. The Secretariat (Mr. Gillespie) also reviewed progress of the WPB in meeting its output results for the 2007-2008 biennium and identified a number of changes in its Programme of Work and Budget. Mr. Gillespie also reported on voluntary contributions made to date by countries for 2009-2010.

7. The Secretariat also noted progress toward responding to the recommendations by Council in its In-Depth Review of the Committee for Scientific and Technological Policy. The WPB has: *i*) become more policy focussed; *ii*) broadened the breadth of its work beyond health issues, however, the WPB still

needs *iii*) to carry out a review of its relationship with the European Commission. The WPB agreed that the Secretariat should carry out such a review and report back in writing. Also, the CSTP was asked to carry out a review of stakeholder needs in biotechnology. The WPB agreed to develop a targeted questionnaire about the relevance of its work for stakeholders. It also agreed to create a small virtual steering group to guide this process.

#### **ITEM 6: ELECTION OF THE BUREAU**

8. For 2009, the Working Party on Biotechnology re-elected Mr. G. Jimenez-Sanchez (Mexico) as Chairman. Mr. M. Bale (United Kingdom), Ms. A. Eisenstadt (United States), Mr. M. Hirsch (Australia), Mr. R. Main (Canada) and Mr. H. Yoshikura (Japan) were elected as vice chairs.

#### **GLOBAL ISSUES DISCUSSIONS - BIOSECURITY**

9. The Secretariat (Mr. Gillespie) outlined the recent activities of the Secretariat related to the promotion of OECD Guidelines on Biosecurity and next steps as defined by the 2009-2010 Programme of Work and Budget. Two guest speakers made presentations about the current policy challenges for biosecurity and the potential role of the OECD in addressing these issues. Mr R. Atlas, University of Louisville, United States, spoke to the challenges of balancing scientific freedom and regulation and the need to meld a legally binding top down approach with a bottom-up approach to responsible conduct of science. Mr. H. Rubin, University of Pennsylvania, United States raised the question of whether there is “forbidden knowledge” and the enormous difficulty of deciding what knowledge should not be published. He argued for the need for a Global Compact to combat the communicable diseases crisis, which would link national commitments to develop basic research centers; harmonised regulatory and best laboratory practice; surveillance and reporting; and expanded capabilities for manufacturing capacity for vaccines and therapeutics.

10. Following the question and answer session between WPB delegates and speakers, it was agreed that OECD had an important role to play in furthering awareness of its Guidelines and in addressing further issues of biosecurity. Specific possibilities for future work included: sharing of experiences and decision making amongst countries; practical approaches to dealing with uncertainties; drawing together WPB tools for combating disease and easing vaccine research; exploring the one-health model; developing future frameworks for biosecurity.

#### **ITEM 7: BIOSECURITY**

DSTI/STP/BIO(2008)27

11. The Secretariat (Mr. Gillespie) provided an update on work recently undertaken on the implementation and promotion of OECD Guidelines on Biosecurity for BRCs. The next steps of the project will consider risk assessment methodologies for dangerous pathogens and emerging technologies in the biosciences as a first step toward the development of biosecurity principles.

12. In discussion, delegates agreed to set up a steering group to organise a workshop which would address the issues of biosecurity risk assessment. Delegates agreed to provide any comments and to nominate participants to the steering group by 14 December 2008. Work would go ahead once resources were in hand (the US once again indicated their willingness to provide voluntary contributions in support of this work).

13. Delegates also agreed that the Secretariat will produce a report that draws together the body of biosecurity-related work completed by the WPB and addresses the issue of how biosecurity can help deliver innovation in the biosciences.

**ITEM 8: INNOVATION STRATEGY**

DSTI/STP/BIO(2008)4  
SG/INNOV(2008)2  
SG/INNOV(2008)2/ANN1

14. The Director of DSTI (Ms. S. Huttner) gave an update on progress for the OECD Innovation Strategy. In particular she noted: recent Workshops and events designed to feed in external perspectives on changes in the innovation process; and as recent committee discussions across the OECD. She noted an interim report will be presented at the 2009 Ministerial Council Meeting.

**ITEM 9: KNOWLEDGE MARKETS WORKSHOP**

DSTI/STP/BIO(2008)8  
DSTI/STP/BIO(2008)21  
DSTI/EAS/IND/WPIA(2008)11  
DSTI/STP/IND/WPGI(2008)9

15. The Secretariat (Ms. B. Callan) presented the outcomes of the expert Workshop on Knowledge Markets in the Life Sciences held on 16-17 October 2008 in Washington DC. The Workshop explored: *i)* what is meant by “Knowledge Markets”; *ii)* what are the business, economic and policy incentives behind the creation of knowledge markets in the life sciences; *iii)* what types of health data, information, and know-how could create greater added-value if more easily exchanged or traded; *iv)* what impacts knowledge markets might have on biomedical innovation and health outcomes; *v)* new business models and opportunities that open up due to the use of knowledge markets; and *vi)* the factors that influence their development. She noted that a Chairmen’s Summary of the workshop discussion was available for comment and that a Policy Report will be developed for early 2009 based on the Rapporteur’s Report.

16. Two other presentations of OECD-related work on knowledge markets were made by Mr. T. Hatzichronoglou on the globalisation of R&D in multinational corporations and Mr. D. Guellec on a recent licensing survey of Japanese and US firms.

17. Delegates discussed the outcomes of the workshop and possible future work within the WPB. They noted that the workshop was of high quality and allowed very interesting cross disciplinary discussions about emerging models for knowledge diffusion. Countries discussed the extent to which governments should use different policy levers to encourage access and use of biomedical data.

18. Countries noted their preferences for future work to focus on: Regulatory modernisation; Knowledge management; Next generation networking of biomedical infrastructures; Safe sandboxes where governments can play a catalytic role in bringing diverse parties together to discuss knowledge markets.

19. Delegates were asked to send in comments on options for future work in writing by 14 December 2008. It was agreed that the Secretariat would organise a meeting of the steering group and selected experts to work up possible follow on work proposals. Moreover, the policy report from the October 2008 workshop should be cleared through written procedure once it is finalised.

**ITEM 10: COLLABORATIVE MECHANISMS**

DSTI/STP/BIO(2008)20

20. The Secretariat (Ms. C. Sampogna) presented progress on this initiative, particularly on the work carried out by the Steering Group and the outcome of the June Steering Group meeting at which the Steering Group members refined the programme for the workshop and identified the work to be undertaken to develop the case studies.

21. WPB delegates noted the progress on the planned workshop and the case studies and welcomed the United Kingdom’s offer to host it. Dates should be fixed as soon as possible for Spring 2009. Clarity was required quickly on whether new voluntary contributions would be made available to support the

workshop. The principal purpose of the workshop should be to identify where guidance to countries on the establishment and operation collaborative mechanisms might be developed. The Secretariat should provide delegates with a revised agenda and rationale for the workshop, within available resources, as soon as possible. WPB asked that this work is coordinated with follow-on for knowledge markets work.

**ITEM 11: BIOMEDICINE AND HEALTH INNOVATION**

DSTI/STP/BIO(2008)24  
DSTI/STP/BIO(2008)24/ANN1  
DSTI/STP/BIO(2008)25  
DSTI/STP/BIO/M(2008)5

22. The Chairman of the Task Force on Biomedicine and Health Innovation (Mr. M. Bale) presented the work of the TFBHI. The TFBHI met in June of 2008 and developed a Synthesis Report as well as a paper on options for future work in the 2009-2010 PWB.

23. Delegates agreed to send comments on the draft Synthesis Report as well as possible next steps for the TFBHI **by 14 December 2008**. The WPB agreed that the Synthesis Report should be declassified by written procedure once comments have been taken on board. The WPB also agreed the Secretariat should produce a short Policy Brief pamphlet based on the messages of the Synthesis Report but written for a broader non-technical audience.

24. Delegates expressed particular interest in future work on regulatory mechanisms, patient's needs and demands, personalised medicines as well as human capital management.

**ITEM 12-13d: DISCUSSION ON ACCESSION TO THE OECD OF CHILE, ESTONIA, AND ISRAEL**

DSTI/STP/ACS(2008)2  
DSTI/STP/BIO/ACS(2008)4  
DSTI/STP/BIO(2008)15  
DSTI/STP/BIO(2008)16  
DSTI/STP/BIO(2008)17  
DSTI/STP/BIO(2008)18  
DSTI/STP/BIO(2008)19  
DSTI/STP/BIO/ACS(2008)2  
DSTI/STP/BIO/ACS(2008)5  
DSTI/STP/BIO/ACS(2008)6  
DSTI/STP/BIO/ACS(2008)6/ANN1  
DSTI/STP/BIO/ACS(2008)6/ANN2  
DSTI/STP/BIO/ACS(2008)6/ANN3  
DSTI/STP/BIO/ACS(2008)7  
Room Document 2

25. Three Accession Candidate Countries were formally reviewed by the Working Party on Biotechnology: Chile, Estonia and Israel. These three countries had submitted to the WPB completed Questionnaire responses with regard to the biotechnology related OECD Instruments and best practices. In a closed session discussion with OECD member countries, the three Accession candidate countries made presentations about their questionnaire responses and the state of biotechnology in their country. The WPB then asked questions to elicit further information with regard to their willingness and ability to implement the WPB's instruments and best practices.

26. In a closed session, the OECD member countries of the WPB discussed each Accession candidate country's willingness and ability to assume the obligations of membership related to biotechnology. A full account of the discussions is provided in document DSTI/STP/BIO/ACS/M(2008)1.

**ITEM 13e: EXCHANGE OF VIEWS WITH THE RUSSIAN FEDERATION AND SLOVENIA**

27. Two Accession candidate countries were invited to an informal exchange of views with the WPB member countries about the implementation of WPB instruments. The Russian Federation has not submitted an initial memorandum to the OECD and Slovenia has not submitted completed questionnaire responses to the WPB. For these reasons, the exchange of views with these two countries is not considered part of the formal assessment process. In a closed session, each of the two countries made a brief presentation about biotechnology in their country. The WPB then engaged in a short question and answer session with them. Both countries will be invited at a later date to discuss with the WPB in order for it to make a formal assessment as part of the Accession candidate country review process.

**ITEM 13f: ACCESSION PROCESS – NEXT STEPS**

28. WPB agreed the process for developing their assessments of the Accession candidate countries to be submitted to the CSTP. The Secretariat would revise the assessment of each Accession candidate country based on any additional material submitted prior to the end of 2008.

**ITEM 14: ENVIRONMENTAL BIOTECHNOLOGY**

ROOM DOC

29. The Secretariat (Mr. A. Bartsev) outlined the main outputs of an expert consultation held on 29 October 2008 to scope out the main challenges for environmental biotechnology R&D and define options for work under the 2009-2010 Programme of Work and Budget of the WPB. WPB noted the recommendations of the expert consultation and set up a steering group to discuss in greater depth the options for future work on environmental biotechnology R&D. Japan and the European Commission agreed to participate in a Steering Group. Further nominations of experts for the steering group and comments on Room Document 6 were to be sent to Secretariat **by 14 December 2008**.

**ITEMS 15: TASK FORCE ON INDUSTRIAL BIOTECHNOLOGY**

Room Document 3  
DSTI/STP/BIO(2008)32  
DSTI/STP/BIO(2008)32/ANN1  
DSTI/STP/BIO(2008)32/ANN2  
DSTI/STP/BIO(2008)32/ANN3  
DSTI/STP/BIO(2008)32/ANN4  
DSTI/STP/BIO(2008)32/ANN5  
DSTI/STP/BIO(2008)32/ANN6  
DSTI/STP/BIO(2008)33  
DSTI/STP/BIO(2008)35

30. Mr M. Duncan (United States) presented a summary of the 16<sup>th</sup> meeting of the Task Force on Industrial Biotechnology (TFIB). He noted the Task Force had successfully delivered two main output results under the 2007-2008 PWB: i) a policy report on supply side issues for industrial biotechnology; and ii) a case study on the evaluation of sustainability of bio-based products and processes. The Task Force recommended to the WPB that the policy report be submitted for declassification by written procedure once editing recommended by the TFIB is taken on board. It also recommended that the WPB submit the case study for declassification by written procedure in January 2009. It was agreed by the WPB that both documents be submitted for declassification by parallel written procedure.

31. Mr. Duncan also reported on progress in developing two projects the TFIB will undertake under the 2009-2010 Programme of Work and Budget, namely: output result 2.1, the development of “Best Practices in Assessing Sustainability of Bio-based Products and Processes;” and output result 2.4, the development of an “OECD Outlook for Industrial Biotechnology in the Economy.” In 2009 the TFIB will

hold two workshops to advance work on these two projects, under the guidance of two separate steering groups. The Best Practices in Assessing Sustainability workshop will be held back-to-back with the 6<sup>th</sup> World Congress on Industrial Biotechnology and Bio-processing in Montreal in July. The workshop on developing an OECD Outlook on Industrial Biotechnology will be held in Vienna on 23-25 September 2009, following a proposal by Austria. The WPB agreed to the TFIB work plan.

#### **ITEM 16: SYNTHETIC BIOLOGY**

DSTI/STP/BIO(2008)26

32. The Secretariat (Ms. M-A. Baucher) presented progress in delivering the synthetic biology project and on the Bellagio planning meeting, organised jointly with the US National Academies of Science and the UK Royal Society. She presented a draft of the themes to be included on the Agenda of the April 2009 Symposium on Synthetic Biology in Washington DC. In addition, some options for future work on Synthetic Biology by the WPB were suggested. Mr. J. Conolly (United Kingdom) provided further insight into the Bellagio planning meeting discussions and outcomes.

33. Delegates were supportive of further OECD work on synthetic biology. The WPB agreed the proposed themes for the Symposium. Japan and the United States indicated their intent to nominate experts to speak at the Symposium. Delegates agreed to hold a short steering group meeting back to back with the Symposium. They noted that developing issues papers in advance of the Symposium would be helpful in defining what sort of future work the OECD might usefully explore for issues such as biosecurity; intellectual property rights; and the barriers to the industrial applications of synthetic biology applications.

#### **ITEM 17: HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES – DRAFT GUIDELINES**

DSTI/STP/BIO(2008)22

DSTI/STP/BIO(2008)23/REV1

DSTI/STP/BIO(2008)31

DSTI/STP/BIO(2008)34

34. The Secretariat (Ms. Sampogna) presented the progress of the expert group on developing the draft *Recommendation on Human Biobanks and Genetic Research Databases* and on the feedback received from the public consultations carried out in mid-2008.

35. WPB delegates commended the experts on the progress made in developing the draft Guidelines. WPB delegates considered that as square brackets remained in the draft Guidelines, the text should undergo another round of comments, at their level, before being finalised by the Secretariat. The WPB delegates determined that outstanding aspects, including in regards to scope, broad consent and pre-established HBGRDs, needed to be resolved as soon as possible and prior to the transmission of the draft Guidelines to the Committee for Scientific and Technological Policy (CSTP). Moreover, delegates agreed that the Secretariat streamline the text of the draft Guidelines including to reduce redundancies and to ensure consistent use of terminology.

36. WPB delegates agreed to submit comments on the draft Guidelines in writing by 16 December 2008. Based on the comments, the Secretariat would produce a revised version of the draft Guidelines which would be sent to WPB delegates for approval. WPB delegates agreed with the objective of submitting the finalised draft Guidelines to the CSTP at its March 2009 meeting. WPB delegates strongly expressed the view that the draft Guidelines be finalised and presented to Council as soon as possible.

**ITEM 18: BIOMARKERS AND TARGETED THERAPIES**

DSTI/STP/BIO(2008)30  
DSTI/STP/BIO(2008)36  
DSTI/STP/BIO(2008)37  
DSTI/STP/BIO(2008)38  
DSTI/STP/BIO(2008)39  
DSTI/STP/BIO(2008)40  
DSTI/STP/BIO(2008)42  
DSTI/STP/BIO(2008)43

37. The Secretariat (Ms. Baucher) presented progress in delivering the biomarker project. Seven analytical papers had been delivered and a workshop was held in Hinxton, Cambridge, United Kingdom on 6-7 October 2008. The main workshop messages were presented. An outline for the Policy Report was suggested as well as options for follow-on work. The Netherlands (Mr. J. Hulleman) provided further insights into the biomarkers workshop outcomes.

38. Countries commented on the workshop outcomes. WPB agreed the policy messages identified in the Chairman's Summary and the proposed outline for the Policy Report. Delegates noted that future work on biomarkers should be included as part of broader topics being developed for the 2009-2010 PWB, for example, under the Knowledge Market project or the TFBHI. Delegates identified their interest in issues linked to: the management of intellectual property models for biomarkers, the development of new business models, the management of human capital as well as the development of policies for regulation of diagnostic tests. They also emphasized that the work ongoing in other international groups regarding regulatory issues should not be duplicated when developing any future work on biomarkers.

**ITEM 19: REVIEW OF THE GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS**

DSTI/STP/BIO(2008)4  
DSTI/STP/BIO(2007)33

39. The Secretariat (Ms. Sampogna) described the elements on which the WPB would need to report back to Council in 2010 for the *Recommendation on the Guidelines for the Licensing of Genetic Inventions* [C(2006)149/REV1]. The Secretariat indicated that through the Committee for Scientific and Technological Policy (CSTP), WPB would need to report back to Council in regards to: (i) implementation and dissemination of the Guidelines; (ii) review of the principles and best practices contained in the Guidelines; and (iii) further work on the issue of "addressing 'unmet and urgent health needs' in both developing and developed countries, including providing examples".

40. Delegates agreed that the Secretariat should develop a methodology for carrying out the assessment and review to be presented to the WPB in June 2009. The aim would be to carry out this process over the second half of 2009. The inputs from this assessment and review would form the basis for a report back to Council in 2010.

**ITEM 20: GLOBAL FORUM ON THE KNOWLEDGE ECONOMY (BIOTECHNOLOGY)**

ENV/JM(2008)55

41. The Secretariat (Mr. Gillespie) presented a room document explaining changes to the funding of the Global Forum on the Knowledge Economy and proposed changes to its name and governance structure. Delegates discussed the origin and the implications of the proposed changes. The WPB agreed that the title should be changed to the Global Forum on Biotechnology and that it should be formally recognised that the funds are to be split between the biotechnology programmes supported by the Environment and Science, Technology and Industry directorates.

**ITEM 21: BIOECONOMY 2030**

42. The Secretariat (Mr. M. Osborne) discussed the process for finalising the *Bioeconomy 2030* report and the expected Spring 2009 publication date for the report.

**ITEM 22: REPORT FROM THE OECD'S INTERNAL CO-ORDINATION GROUP ON BIOTECHNOLOGY (ICGB)**

43. This item was postponed to the next WPB session in June 2009.

**ITEM 23: DATES AND LOCATION OF FUTURE MEETINGS**

44. The 25<sup>th</sup> Session of the WPB will be held on 8-10 June 2009 at the OECD Headquarters in Paris. Dates for the Task Forces would be agreed separately.

**Final Participants list for the 24th Session of the Working Party on Biotechnology**

**19-21 November 2008**

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