

STRATEGIC ISSUES

AGENDA ITEM 7 COUNCIL TASK FORCE ON BIOTECHNOLOGY

1 Background

As requested under Council Resolution 28/2008, the Secretary-General, through a circular letter dated 13 November 2008, invited Council members to indicate their interest to participate in the Task Force on Biotechnology and to nominate one expert as representative from their organization in the Task Force, whose terms of reference were finalized by CSC/STRAT by correspondence.

Nominations were received from nine Council members and the Task Force was set-up in early January 2009. (The terms of reference and the list of members of the Task Force are attached at Annexes 1 and 2 respectively.)

The Task Force worked electronically and held one meeting on 29-30 April in Geneva.

The Task Force focused on analysing the priority areas of interest to ISO, concerning the application of biotechnology in the fields selected by Council (as indicated in the Task Force terms of reference, the fields of *Terminology, measurement and characterization for biotechnology/bioscience* and of *Industry/environment*).

The outcome of the analysis has been organized in a matrix (attached at Annex 3), highlighting the fields for which International Standards are potentially desirable. The matrix includes a reference (for each proposed subject matter) to those organizations considered as the most relevant for ISO to cooperate with.

To validate the draft list of priority areas highlighted in Annex 3, the Task Force considers it preferable to adopt an integrated approach, combining the consultation of stakeholders (to be conducted through the ISO member bodies) with the organization of a focused workshop.

2 Recommendations from the Council Task Force on biotechnology

The Task Force recommendations to Council are the following:

- 2.1 to undertake a **stakeholder consultation** among the selected ISO members, to validate, refine and complement the priority areas proposed by the Task Force and
- 2.2 in parallel, to organize a **focused workshop** (tentatively to be held no later than mid-2010), taking advantage of the consultation process and involving a variety of key stakeholders, representatives from the most relevant ISO/TC/SCs and from selected partner organizations.

Regarding item 2.1 (consultation of stakeholders), the Task Force recommends to focus attention on a manageable set of ISO members with potential interests in standardization of Biotechnology (to be determined e.g. on the basis of secretariats of and P-memberships in ISO/TC/SCs dealing with related issues).

Regarding item 2.2 (workshop), the Task Force recommends to identify a limited number of high priority issues, by refining the preliminary list of fields of interests provided at Annex 3 (taking e.g. advantage of the consultation of stakeholders). The workshop should be by invitation only, open to qualified experts to be designated by the concerned ISO/TC/SCs, the selected partner

organizations and the ISO member bodies involved. The structure of the workshop on Documentary Standards for Measurement and Characterization in Nanotechnologies, organized in February 2008 by ISO, IEC, NIST (USA) and OECD, was considered a possible model.

COUNCIL ACTION

Council is invited:

- a) to consider the recommendations of the Council Task Force on biotechnology under item 2 above with a view to their approval;
- b) to disband the Council Task Force on biotechnology.

COUNCIL TASK FORCE ON BIOTECHNOLOGY – TERMS OF REFERENCE

finalized by CSC/STRAT by correspondence

- to analyze information received from ISO members and ISO technical bodies concerning standardization in the biotechnology field;
- to provide advice and guidance concerning the most appropriate modalities for addressing ISO work in the domain of *terminology, measurement and characterization for biotechnology/bioscience* (including the possibility of developing a specific ISO project);
- to provide advice and guidance concerning the priority areas of interest to ISO concerning the application of biotechnology in the *industry/environment field*, with a view to prepare a consultation with relevant groups of stakeholders as well as ISO TC/SCs potentially concerned (e.g. through an international workshop on the subject);
- to provide advice concerning the cooperation with relevant international organizations (such as OECD, FAO, WHO, IUBMB – international Union of Biochemistry and Molecular Biology, IUPAC – International Union of Pure and Applied Chemistry, and others).
- to develop proposals for future actions and possible further study.

NOTE – Definitions

- a) *Biotechnology*: The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services (*source: OECD*).
- b) *Terminology, measurement and characterization for biotechnology/bioscience*: a horizontal field providing a basis for the measurement infrastructures, whose development is needed to ensure consistency of biomeasurement capabilities at national and international levels.
- c) *Applications of Biotechnology*: Biotechnology is not one discipline, but instead represents the use of a range of specific applications in a number of sector areas. It has been found useful to categorize and consider Biotechnology applications in three major areas (*source: ANSI presentation to CSC/STRAT, January 2008*):
 - **Industry/Environment**
Applications of life sciences to traditional manufacturing and chemical synthesis; using micro-organisms (bacteria, fungi) and enzymes (specialty proteins) to improve manufacturing processes, make new “biobased” fuels, industrial raw materials, intermediates and consumer goods.
 - **Agriculture/Aquaculture**
Applications are focused on the designing of transgenic plants which will help meeting increasing global food and fuel needs with increased crop yields, decreased crop inputs (e.g. water and fertilizer) and pest control methods, and with improved environmental impacts.
Whether or not “green biotechnology products” such as these are ultimately more environmentally friendly, is a topic of considerable debate.
 - **Medical/Healthcare**
Applications seek to capitalize on the attributes of cells, such as their manufacturing capabilities, and put biological molecules, such as DNA and

proteins, to work to improve human health in areas such as cell/tissue/gene therapies, Novel vaccines, RNA interference, innovative molecular diagnostics, research tools and reagents, imaging and biosensors, regenerative medicine and “personalized medicine.

COUNCIL TASK FORCE ON BIOTECHNOLOGY – LIST OF MEMBERS

Chairman

Dr. George Arnold
 Vice-President (policy)

Council member	Representative and title
ABNT (Brazil)	<i>Mr. Wanderley de Souza</i> Programme Director, INMETRO (National Institute of Metrology, Standardization and Industrial Quality)
AFNOR (France)	<i>Dr. Jean-Baptiste Finidori</i> Project manager, AFNOR
ANSI (USA)	<i>Dr. Kristin Moore</i> Director, Technical Services, Renewable Fuels Association
BIS (India)	<i>Dr. J. Gowrishankar</i> Director, Centre for DNA Fingerprinting and Diagnostics
DIN (Germany)	<i>Dr. Norbert Gerbsch</i> Bundesverband der Pharmazeutischen Industrie e. V. (BPI), Biotechnologie/F&E
DSM (Malaysia)	<i>Dr. Ahmad Hazri b Abdul Rashid</i> Programme Head for the Bioprocess Technology Programme in the Environment and Bioprocess Technology Centre, SIRIM Berhad
JISC (Japan)	<i>Dr. Noboru Yumoto</i> Vice President, National Institute of Advanced Industrial Science and Technology (AIST)
SABS (South Africa)	<i>Dr. E Jane Morris</i> Director, African Centre for Gene Technologies
SAC (China)	<i>Dr. Wang Jing</i> Deputy Director of biological, energy and Environment metrology measurement, National institute of metrology (NIM).

Secretariat: *Dr. Daniele Gerundino*
 Strategic Advisor to the Secretary-General, Secretary of CSC/STRAT

OUTCOME OF THE ANALYSIS OF THE COUNCIL TASK FORCE ON BIOTECHNOLOGY

The items presented below highlight selected areas of potential interest for ISO work in the field of biotechnology. They have been identified on the basis of the outcome of the Task Force meeting held on 29-30 April 2009 and of comments received from the Task Force members further to the meeting.

It is useful to recall that the TF members were asked to provide – in rather general terms – advice and guidance concerning the most appropriate modalities for addressing ISO work in the domain of terminology, measurement and characterization for *biotechnology/bioscience* and priority areas of interest to ISO concerning the application of biotechnology in the *industry/environment field*, with a view to prepare a consultation with relevant groups of stakeholders as well as ISO/TC/SCs potentially concerned.

The items listed in the tables below must not be considered as proposals for initiation of standards work, but as a first set of recommendations to be validated and discussed through consultation with relevant groups of stakeholders. In particular, a number of high-level suggestions (regarding e.g. broad spectra of techniques) need to be refined and specialized through stakeholders' input.

Finally, the organizations referenced as potential “main partners” in the tables below (and listed at the end of this document) represent a preliminary selection – there was no attempt to develop, at this stage, a comprehensive or exhaustive list.

A) Terminology, measurement, characterization and other horizontal matters

A.1 Terminology¹

Field	ISO standards - work found	Main Partners	Recommendations
Terminology	N/A	BIPM OECD-WP Biotech	→ Harmonized international terminology for biotechnology would be desirable

¹ The OECD definition of biotechnology is considered a valid starting point.

A.2 Techniques of analysis (horizontal)²

Field	Techniques	ISO standards - work found	Main Partners	Recommendations
Genomics	- mRNA – RT/PCR - DNA Microarrays - High-Throughput sequencing* - Mass spectrometry - Chromatography - Fluorescence	None <i>(some published standards and WIs of TC 215 need to be checked)</i>	BIPM MIBBI MIAME PSI	→ Standards for data representation and management are a high priority (to support capture of large data sets, use of data by different applications, data exchange and archival) → Statistical methods and guidelines providing standard ways of calculation and presentation of results → Methods of analysis: description of methods and guidance
Proteomics	- 2-D Gel electrophoresis - Mass spectrometry (and specific techniques e.g. Matrix assisted laser desorption/ionization Time of Flight (MALDI-TOF) - Protein arrays - CD spectrometry - Chromatography - Fluorescence	None	As above	→ As above
Metabolomics	- Chromatography - Mass spectrometry - NMR spectroscopy	None	As above	→ As above

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- A standard methodology enabling the integration of data (covering the DNA/Protein/Cell levels) would be highly desirable. It should be considered if and, in case, how, ISO might contribute to facilitating such development.
 - One of the TF members suggested to include Glycomics in the list of fields to be covered, considering techniques such as SDS Page, Mass spectrometry, NMR spectroscopy and Sugar arrays.
 - The notion of standardization related to horizontal methods of analysis has been questioned by one TF member -- noting that a general presentation of the different techniques available (a sort of technical report) together with general principles related, such as Data management, might be a better approach.

Field	Techniques	ISO standards - work found	Partners	Recommendations
Molecular imaging	- MRI - PET - SPECT - Confocal microscopy - Nanoscopy (such as TIRF, AFM)	None	? <i>SNM's</i> Molecular Imaging Center of Excellence ? <i>EMIL</i> Excellence assembling European Molecular Imaging Laboratories	→ Description of methods of analysis (for images of cells, tissues, etc.) and guidance

Field	Techniques	ISO standards - work found	Partners	Recommendations
Stem Cells Analysis	- Surface analysis - Gene expression - Proteomics	None	→ ?	→ Standards for the definition and characterization of stem cells

A.3 Validation and calibration

- Guidelines for validation and calibration
- Reference data
- Reference database
- Reference materials: the possible need for reference materials *for horizontal applications* should be investigated (including information on activities underway in the ISO/REMCO (Committee on Reference Materials))

A.4 Risk Management

- General principles for risk/benefit analysis and risk management (with possible specialization by sector/application area)

In this field, the upcoming ISO standards (ISO/FDIS 31000 *Risk management – Principles and guidelines*) should be considered.

A.5 Management System Standards

- MSS for organizations operating in the biotechnology field

Possible ISO activities in this area should be coordinated with other initiatives (e.g. through the Joint technical Coordination Group on MSS).

B) Industry/Environment field**B.1 Methods of analysis**

Field	Techniques	ISO standards - work found	Partners	Recommendations
Enzyme Analysis	- Color spectrometry - Chromatography - Mass spectrometry - Fluorescence	N/A	<i>BIO</i> <i>EuropaBio</i> <i>DECHEMA</i> <i>ETA</i> <i>IUBMB</i> <i>STREND</i>	Standards for methods of analysis covering i.a. → Insoluble substrates → Activity of immobilized enzymes → Activity of enzymes in organic solvents Standards for the evaluation of the performance of biocatalysts under different conditions

Field	Techniques	ISO standards - work found	Partners	Recommendations
Characterization of proteins (Applicable for antibodies, protein therapeutics, biofuel enzymes, etc)	Chromatography Crystallography Sedimentation ...	N/A	<i>BIO</i> <i>EuropaBio</i> <i>DECHEMA</i>	Beyond biophysical parameters: standards for characterization of proteins allowing to compare products manufactured through different methods by different companies, covering e.g. → Analysis of aggregated state → Analysis of Glycosylation → Analysis of protein folding

B.2 Industrial processes

Field	Techniques	ISO standards - work found	Partners	Recommendations
Industrial fermentation procedures	- Liquid fermentation - Solid state fermentation	N/A	<i>BIO</i> <i>EuropaBio</i> <i>DECHEMA</i>	Standards for operating procedures covering e.g. → Disposal of biomass → Disposal of Waste → Aerosols...

				<p>Different levels of standards may be needed depending on the nature of the fermentation required</p> <p>On-line analysis of the concentration of products in fermentation processes</p>
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B.3 Containment³

Field	Techniques	ISO standards - work found	Partners	Recommendations
Biosafety and Biosecurity containment	N/A	N/A	OECD WP Biotech European Biosafety Association	Standards for physical facilities and operating procedures covering e.g. → Laboratory level → Industrial operations level → Classification of biological agents

B.4 Bioremediation

- To be further analyzed

Field	Techniques	ISO standards - work found	Partners	Recommendations
Bioremediation	Microorganism bioremediation	N/A		→ Standards for the evaluation of the performance of bioremediation under different conditions

³ One of the TF members has underlined that appropriate containment standards should be defined in line with existing regulations. Considering that standards in this field may influence the work of research institutions, these should be involved in the process along with other categories of stakeholders (industry, government agencies).

B.5 Biofuels⁴

Field	Techniques	ISO standards - work found	Partners	Recommendations
Energy balance and sustainability	N/A	N/A	Roundtable on Sustainable Biofuels	
Production processes	N/A	N/A		Technical standards for biodiesel Determination of degradation rates of cellulosic substrates for biofuel production

⁴ The TF members have expressed different opinions in relation to this item.

One member has noted that the main items of interest are included in the tables B.1 (enzyme analysis) and B.2 (industrial fermentation procedures).

Another member has underlined the importance of having international standards allowing to compare the “true” energy efficiency of biofuels produced through different processes and techniques (first, second and third generation biofuels), taking into account the complete production chain and energy consumption at each step of the process.

In any case, should this field be confirmed as a viable candidate for ISO work in the domain of biotechnology, allocation of work to or collaboration with existing ISO TC/SCs covering biofuels should be pursued (ISO/TC 28/SC 7 “Liquid Biofuels”, ISO/TC 238 “Solid Biofuels” and the newly approved ISO/TC on “Sustainability criteria for bioenergy”).

C) Emerging fields to be monitored

(Very preliminary list to be better described and extended at a later stage)

- 1 Biosensors (by domain of application)**
- 2 Synthetic biology**
- 3 Use of plants for industrial products**

ORGANIZATIONS/INITIATIVES REFERENCED IN THIS DOCUMENT

BIO – Biotechnology Industry Organization <http://www.bio.org/>

BIPM – Bureau International des Poids and Mesures <http://www.bipm.org/>

DECHEMA – Society for Chemical Engineering and Biotechnology http://www.dechema.de/en/start_en.html

EBSA – European Biosafety Association <http://www.ebsaweb.eu/>

EMIL – European Molecular Imaging Laboratories www.emilnet.org

ETA – Enzyme Technical Association <http://www.enzymetechnicalassoc.org/>

EuropaBio – European Association for Bioindustries <http://www.europabio.org/index.htm>

IUBMB – International Union of Biochemistry and Molecular Biology <http://www.iubmb.org/>

MIAME – Minimum Information About a Microarray Experiment (an initiative of the MGED society)
<http://www.mged.org/Workgroups/MIAME/miame.html>

MIBBI – Minimum Information for Biological and Biomedical Investigations www.mibbi.org

PSI – HUPO Proteomics Standards Initiative (an initiative of the Human Proteome Organization, HUPO) <http://www.psidev.info/>

OECD WP Biotech – OECD Working Party on Biotechnology http://www.oecd.org/topic/0,3373,en_2649_37437_1_1_1_1_37437,00.html

RSB – Roundtable on Sustainable Biofuels <http://cgse.epfl.ch/page65660.html>

SNM – Society of Nuclear Medicine <http://www.snm.org/index.cfm?PageID=4551&RPID=10>

STREND A – Standards for Reporting Enzymology Data <http://www.strenda.org/>