ROOM DOCUMENT 3

AUSTRALIAN FRAMEWORK FOR BIOTECHNOLOGY STATISTICS – EXECUTIVE SUMMARY – DECEMBER 2006

Workshop on Biotechnology Impacts and Outputs

OECD, Paris, 11 December 2006

This document is submitted by Kate Le Strange, Department of Industry, Tourism and Resources, Australia. It is presented for information and discussion under item 5.1 of the Agenda.

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Executive Summary

Section 1 - Introduction

This Information Development Plan (IDP) has been developed by the Biotechnology Statistics Users Group (BSUG) which is co-chaired by Biotechnology Australia (BA) and the Australian Bureau of Statistics (ABS).

The concept of an IDP involves the development of a collaborative work plan with stakeholders and other data custodians to achieve agreed outcomes for a field of statistics that meet the needs of data users.

Biotechnology has received a large, and increasing, amount of policy attention in Australia in recent years. In November 2005, Premiers and Chief Ministers from the States and Territories endorsed the development of a National Biotechnology Statistical Framework noting that quality data to support biotechnology policy development is of the utmost importance. This need is already high given the amount of policy attention given to biotechnology compared to the low level of consistent, high quality data currently available.

Section 2 – Concepts, Definitions and Key Classifications

The BSUG agreed to adopt the OECD definition of biotechnology for statistical purpose, including both the single and list based definitions set out by the OECD.

The OECD single definition is as follows[1]:

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.

The OECD Framework recognises that this definition covers

"all modern biotechnology but also many traditional or borderline activities".

Australia has consistently supported the use of this single definition at OECD meetings. It does however have a preference for the exclusion of traditional biotechnology from the scope of any statistical collections. Thus any Australian definition should be accompanied by an instruction to that effect.

The OECD lists the following techniques to be included in the definition:

- *DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling and use of antisense technology.*

[1] A Framework for Biotechnology Statistics, OECD, 2005

- *Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signalling, identification of cell receptors.*
- *Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.*
- *Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.*
- *Gene and RNA vectors: Gene therapy, viral vectors.*
- *Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.*
- *Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.*

It is important to note that the OECD Framework points out that this

> *"list is indicative rather than exhaustive and is expected to change over time as data collection and biotechnology activities evolve".*

Australia has supported the expansion of the list referred to above at the relevant OECD meetings and it is proposed that the expanded list, including the addition of environmental biotechnologies, should be included within this IDP and used in future Australian surveys. Thus the proposed list of techniques to be included in future surveys is as follows:

- DNA/RNA
- Proteins and other molecules
- Cell and tissue culture and engineering
- Bioremediation
- Biosensing
- Biological control
- Other process biotechnology techniques
- Gene and RNA vectors
- Bioinformatics
- Nanobiotechnology
- Metabolomics/metabonomics
- Systems biology
- Synthetic biology
- Biodiscovery
- Other

While adopting the OECD definition of biotechnology, the BSUG also recognised a considerable policy interest in activities which fall outside the definition. In response, this IDP recognises the existence of **biotechnology-related activities**, about which information is needed if policy makers are to get a more complete measure of the importance of biotechnology products and processes to the Australian economy. These are activities which do not necessarily fall within the OECD definition of

biotechnology, but are often considered to be part of, or closely associated to, biotechnology activity in Australia.

Biotechnology-related activities include activities which, while not strictly biotechnology (according to the OECD definition), build on knowledge about biological systems or have an interaction with a biological system or organism. Some key activities proposed to be included within the biotechnology-related definition are as follows:

- medical devices;
- pharmaceuticals;
- diagnostics;
- nutraceuticals and functional foods; and
- biofeedstocks for energy, chemicals and materials production.

In Australia, it is thought that companies undertaking these activities are likely to provide outputs of about the same value as for the companies undertaking "biotechnology" as defined in by the OECD. Thus it is an important aspect of the contribution of biotechnology to the Australian economy.

This IDP proposes the use of a **dedicated biotechnology organisation** (defined by at least 50% of activity being biotechnology) to form a **biotechnology sector.** This leads to the development of economic measures comparable to those developed for any standard industry defined within a standard industrial classification. (The term "organisation" is used instead of "firm", so that it is clear that all types of statistical entities are included, not just business enterprises).

Users have also indicated the need to have data classified by the field in which the techniques are applied. The proposed Australian application field classification is:

- Agriculture – plant
- Agriculture - animals and animal health
- Biomedicine/ Human health
- Environment
- Natural resource extraction - mining, petroleum/energy extraction
- Industrial processing
- Other (please specify)…….

Section 3 – The Conceptual Model

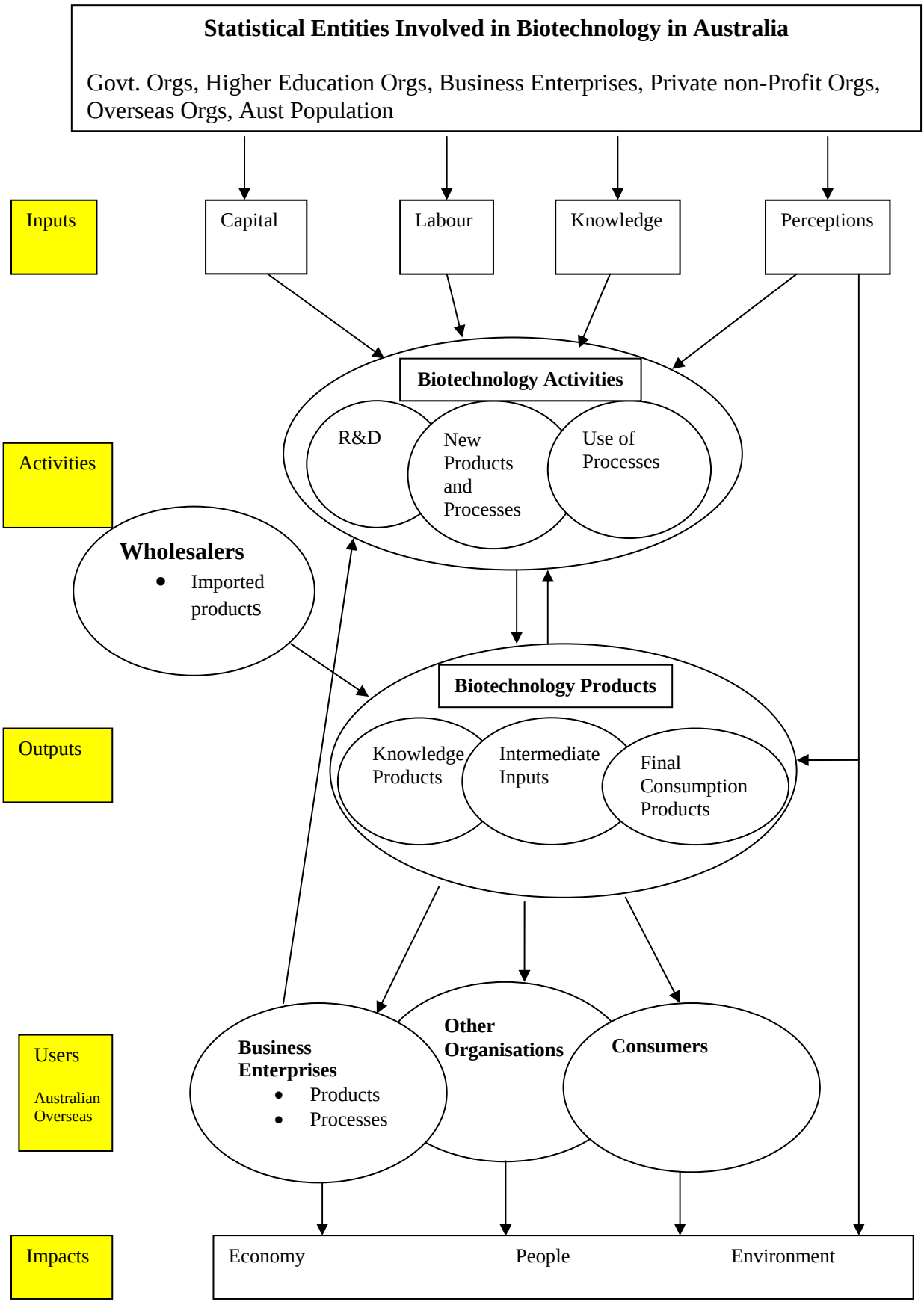
It is important to develop a Conceptual Model for the measurement of biotechnology statistical indicators to facilitate the derivation of statistical indicators that can best meet the needs of policy makers. The development of such a Model should help ensure that statistical developments undertaken are made in such a way as to better inform overall policy debate and to help users better understand how such indicators can be interpreted.

Biotechnology is an enabling technology and is therefore similar to information and communication technology. On the basis of being a technology, there are two broad

areas of interest – the supply of the technology and the use of the technology. In terms of these two broad areas, there is a requirement for information about the transactions involved in biotechnology and the transactors involved in making those transactions.

On the following page is a diagram showing the Conceptual Model for Biotechnology Statistical Indicators which shows both who the entities of interest are as well as the various transactions which take place. These are shown against input, activities, outputs, users and impacts of biotechnology. This conceptual model also applies to the collection of biotechnology related data.

FIGURE 3 - CONCEPTUAL MODEL FOR BIOTECHNOLOGY STATISTICAL INDICATORS



Section 4 – The Demand for Data

The following seven policy issues were agreed on by the BSUG as being the highest priority areas requiring data to support policy activities:

1. Encourage the development of innovative products and processes from biotechnology research.
2. Encourage the development of effective biotechnology enterprises.
3. Identify and understand the drivers and limiting factors for biotechnology activity. These include IP, regulation, capital etc.
4. Identify and understand the drivers and limiting factors for the adoption and use of biotechnology products and processes.
5. Provide the framework conditions for the commercialisation of biotechnology research and innovation.
6. Encourage the application of biotechnology processes and the use of biotechnology products to achieve improved social, health, environmental and economic outcomes for Australia.
7. Better understand the social, health, environmental and economic impacts of biotechnology in Australia including on individual industries, States and regions – especially rural areas.

The next four policy issues were also considered by the BSUG to be high priority areas requiring data to support policy activities:

8. Encourage biotechnology research including through the provision of public and private support and funding.
9. Encourage the diffusion of biotechnology research and innovation throughout the economy.
10. Understand public perceptions towards biotechnology and ensure there is informed debate on biotechnology issues.
11. Encourage Australia's competitiveness in the global biotechnology market.

The following priority policy issue was described as being a medium priority, noting that some jurisdictions have a strong interest in this area:

12. Encourage collaboration including through the development of networks and clusters.

Section 5 – Required Statistical Indicators

Having developed a set of priority policy issues requiring data, the BSUG then developed a list of indicators to address the policy issues. The indicators are set out in detail in Section 5 of this IDP but on the basis of the listing of indicators, it is possible to draw a number of summary conclusions:

- There is a requirement for a number of statistical indicators about biotechnology R&D, covering all sectors of the economy. The key requirements are similar to those collected in the ABS R&D surveys, namely expenditure, human resources expended on it, the number of organisations involved, the drivers of it, the barriers to its performance and some measures on the value of its outputs. Data should be classified by the field of application of the biotechnology product or process.

- There is a requirement for a number of indicators about biotechnology innovation. The requirement for statistical indicators is very similar to those expressed above for R&D – except that the scope is likely to be restricted to the private business enterprise sector. Data should be classified by the field of application of the biotechnology product or process.
- There is a requirement for indicators about the use of biotechnology in different groups of organisations (industry, size, region) and by type of biotechnology process. There is also a requirement of a measure of the outputs from biotechnology products. The scope of this requirement is in terms of the business enterprise sector.
- There is a requirement for measures of awareness, understanding and concerns with biotechnology amongst the population.
- There is a requirement for some measures of the economic significance of the biotechnology sector and its outputs.
- Users require some measures of the impact of biotechnology on the economy, which includes quantification of financial, social, health and environmental impacts.

Additionally, users of biotechnology data have indicated an over-riding need for data that can be broken down to the State and Territory level to assist in regional policy development.

Section 6 – The Supply of Data

The members of the BSUG provided information on their current data sources and collection activities. These have been set out in detail in Section 6 of this IDP. This comprehensive list of data sources enabled the BSUG to identify gaps between the available data and the data required to meet the policy issues set out in the IDP.

Section 7 – The Unmet Demand for Data and Strategies to Overcome that Demand

There is very little data available as part of an ongoing statistical program that provides biotechnology policy makers with the indicators they need for their work. The demand for indicators about biotechnology is already rated as high even at the present time. Thus, it is important that policy makers be given relevant indicators on which to base and monitor their policies in the very near future.

This IDP recommends a four stage development process to address the gaps in available biotechnology data. The later development stages are seen as being viable in the longer term and rely on building from work in the earlier stages.

Stage 1: develop a **biotechnology survey** and implement it on a regular basis. This survey would essentially be a list-based survey of organisations known to be:

a) dedicated biotechnology organisations;
b) biotechnology active organisations;
c) biotechnology-related organisation; and
d) users (list will expand over time).

Alternatively this survey could exclude users and be supplemented by a survey of organisations known to be users of biotechnology products, processes or biotechnology-related products.

Stage 2: enhance the biotechnology survey as identified in Stage 1 above by adding a few targeted questions to the IBCS or another of the economy-wide surveys, such as the EAS, or specific industry surveys, such as the Agriculture Survey. This would enable the estimation of statistical aggregates at a broader level than available in Stage 1 and may also provide supplementary lists of users for the biotechnology survey detailed in Stage 1.

Stage 3: supplement the Stage 2 approach by incorporating biotechnology questions into the ABS range of R&D and Innovation surveys.

Stage 4: implement a strategy which integrates the collection of biotechnology data as much as possible with other ABS collections but includes a separate biotechnology survey covering issues requiring greater depth of information. This would involve:

a) an economy-wide survey of biotechnology R&D performers and financiers similar to that carried out by the ABS in 2003-04, but across all sectors of the economy;
b) the incorporation of biotechnology innovation questions into a standard ABS Innovation survey spanning the whole of the business enterprise sector;
c) the conduct of a separate survey on the use of biotechnology products and processes across the business enterprise sector; and
d) the linking of dedicated biotechnology and biotechnology active businesses to ATO financial statistics to enable the compilation of aggregate statistics about the sector. When appropriate supplement these with biotechnology-related organisations.

On the premise that the spread of biotechnology will occur, a suggested timetable for the implementation of the staged approach outlined above is as follows:

Stage 1 – Implement initially from 2006–07
Stage 2 – Implement initially from 2007-08
Stage 3 – Implement initially from 2009-10
Stage 4 – Implement initially from 2013-14

Note that the Australian Government Department of Industry, Tourism and Resources has indicated that they plan to undertake an experimental survey, as described in Stage 1, in the 2006/07 timeframe. This includes, by the end of 2006, initial development of a list of:

i. dedicated biotechnology organisations;
ii. biotechnology active organisations;
iii. biotechnology-related organisation; and
iv. users of biotechnology products or biotechnology-related products.

This work is being undertaken in consultation with the BSUG and aims to contribute to the later development of an ongoing National Biotechnology Survey.

Users of biotechnology statistics in Australia have indicated the importance of having internationally comparable data on biotechnology. It is felt that the IDP for biotechnology statistics in Australia should be circulated widely to international agencies, especially the OECD as a model for implementing biotechnology statistics at a national level.