AN INFORMATION DEVELOPMENT PLAN

FOR

BIOTECHNOLOGY STATISTICS

Biotechnology Statistical Users Group
December 2006

Acknowledgements

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The Biotechnology Statistics Users Group consists of representatives from:

Biotechnology Australia
Australian Bureau of Statistics
Australian Government Department of Industry, Tourism and Resources
Australian Government Department of Education, Science and Training
Australian Government Department of the Environment and Heritage
Australian Government Department of Agriculture, Fisheries and Forestry
Australian Government Department of Health and Aging
Commonwealth, Scientific and Industrial Research Organisation
Queensland Office of Biotechnology
Office of the Chief Scientist, Queensland
Department of Business, Economic and Regional Development, Northern Territory
Department of Economic Development, Tasmania
Department of Industry, Innovation & Regional Development, Victoria
Bio Innovation South Australia
Department of Industry and Resources, Western Australia
Business ACT, Australian Capital Territory
AusBiotech

In addition to these organisations, the Biotechnology Statistical Users Group wishes to acknowledge the personal contributions made by a number of international experts in this field, namely:

Anthony Arundel – UNU-MERIT, the Netherlands
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George Slim - Ministry of Research, Science and Technology, NZ
John Jankowski – National Science Foundation, USA

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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

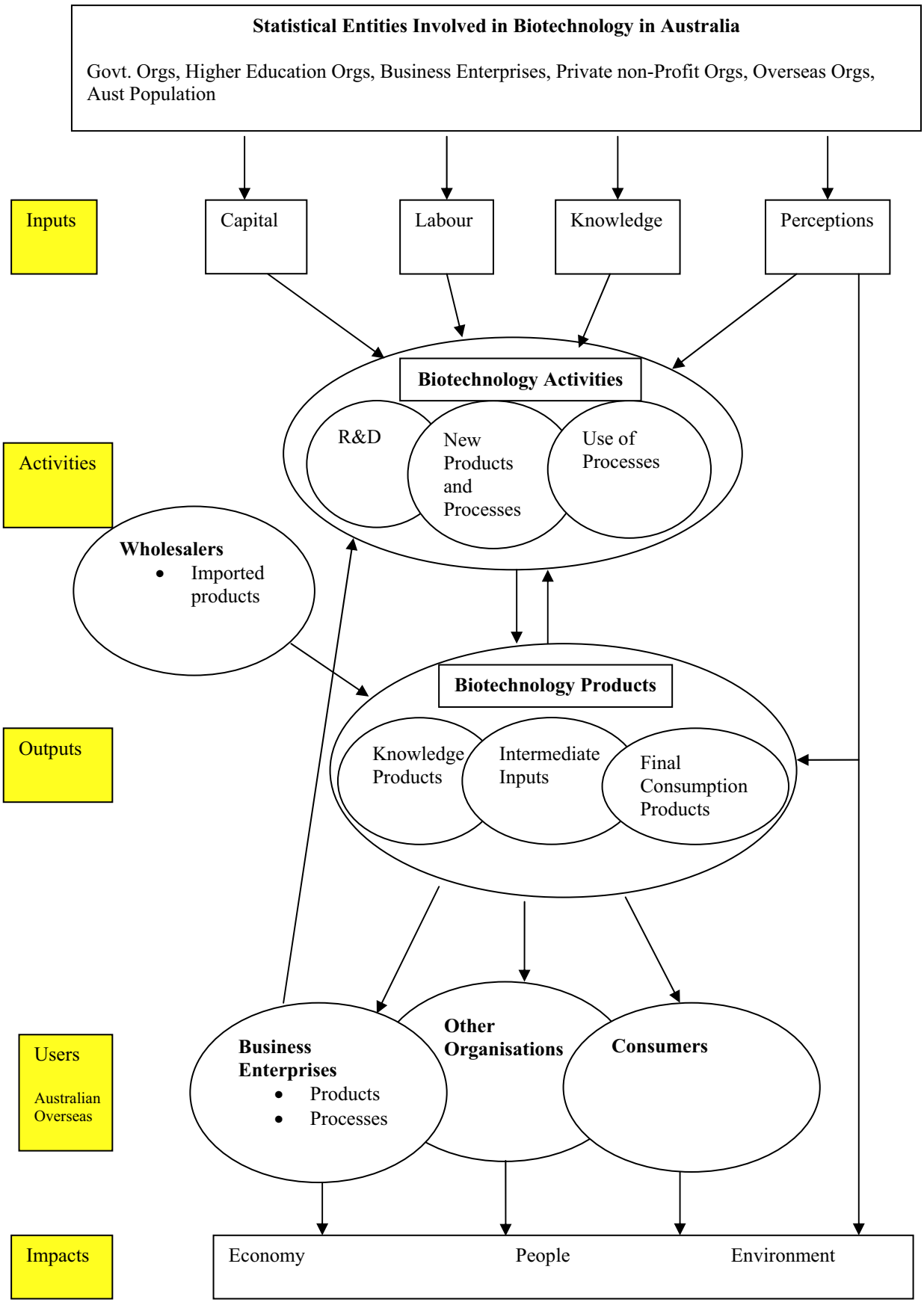
It is important to develop a Conceptual Model for the measurement of biotechnology statistical indicators to facilitate the derivation of statistical indicators that can best meet the needs of policy makers. The development of such a Model should help ensure that statistical developments undertaken are 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.

Section 1 - Introduction

1.1 - Background

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. For a particular field of statistics, the IDP aims to specify:

- the highest priority policy issues requiring statistical indicators;
- the main statistical indicators that would inform policy makers and other users of statistical information;
- the main statistical sources currently available, both inside the ABS and external to it; and
- a plan for matching the supply and demand for data.

This IDP aims to establish a basis for the future development of biotechnology statistics in Australia. As a key requirement for Australian statistics is to achieve international comparability, it is hoped that the document will provide impetus towards the development of internationally comparable indicators around the world.

The driving force behind the development of this IDP is the policy environment existing in Australia and the issues about which policy makers require statistical indicators. It is instructive to examine these briefly as part of this introduction. However, the main discussion of the policy issues and the corresponding statistical indicators is contained in Section 4.

1.2 - The Policy Environment in Australia

Biotechnology has received a large, and increasing, amount of policy attention in Australia in recent years. Central to this policy activity is the National Biotechnology Strategy (NBS)[2] released by the Australian Government in 2000. The Government's aim was encapsulated in the vision statement, which states as follows:

> *Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.*

The Australian Government's commitment to the NBS was reinforced by funding measures announced in the Australian Government's initiative *Backing Australia's Ability: Building Our Future through Science and Innovation* (BAA2) delivered by

[2] Australian Biotechnology: A National Strategy

the Prime Minister in 2004. The initiatives in this statement not only financed the NBS initiatives but also included a number of other initiatives related to biotechnology, including:

- The Commercial Ready Program which provides $1 billion over seven years to support early stage commercialisation activities and incorporates elements of the R&D Start and Biotechnology Innovation Fund programs.
- Biotechnology Centre of Excellence program which established the National Stem Cell Centre.
- Cooperative Research Centre (CRC) Program which provides seven years of funding for each successful centre. Many of the current CRCs are engaged in biotechnology research.
- National Collaborative Research Infrastructure Strategy (NCRIS) which sets out a list of priority areas for investment.
- Pre-Seed Fund which provides funding for universities and public sector research agencies to address the gap between promising scientific discoveries and commercialisation.
- Commercialising Emerging Technologies (COMET) is a competitive, merit based program that supports early-growth stage and spin off companies to successfully commercialise their innovations.
- CSIRO National Flagship Initiative which picks up biotechnology under flagships such as the Food Futures and Preventative Health Flagships.
- ARC National Competitive Grants Program.

In addition to the funding provided under BAA2, the Australian Government also provides support for biotechnology through funding programs in the National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC). National Research Priorities linked to these funding streams are: An Environmentally Sustainable Australia; Promoting and Maintaining Good Health; Frontier Technologies for Building and Transforming Australian Industries; and Safeguarding Australia. Biotechnology contributes to meeting the goals under each of these priorities. In 2004-05 Commonwealth Government organisations alone undertook $299.4 million in biotechnology research.[3] Given the high level of biotechnology research being undertaken, information on biotechnology will be important in sculpting future research policies; for example, the Research Quality Framework which is being developed by the Department of Education, Science and Training will form the basis for an improved assessment of the quality and impact of publicly funded research.

Policy interest in Biotechnology programs is not restricted to the Australian Government. State and Territory Governments have also developed their own specific biotechnology strategies:

- Biotechnology Strategic Plan for Victoria 2004;
- Queensland Biotechnology Strategic Plan 2005-2015: Biotechnology - Setting New Horizons;
- WA Biotechnology Industry Development Strategy, Strategic Directions 2006-2010;
- New South Wales BioFirst Strategy;

[3] 2004-04 Research and Experimental Development: Government and Private Non-Profit Organisations, Australian Bureau of Statistics 8109.0

- BioInnovation South Australia – Developing SA's Bioscience Sector; and
- ACT Biobusiness Strategy.

In addition, Tasmania is also in the process of developing a biotechnology strategy to be released in late 2006.

To ensure that these policies are effective and to improve future policy development for biotechnology, quality data is very important. This data should cover the activity coming from the Government policies, such as expenditure and outcomes in terms of products sales, exports, patents, licences, as well as broader flow-on effects in the economy such as retention of skilled workers or improved health outcomes. At a biotechnology Roundtable chaired by the Australian Government Minister for Industry, Tourism and Resources 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.

Biotechnology is an enabling technology that is important to many sectors of the economy and as such it is integral to many other Government policies and programs. Biotechnology R&D is a crucial part of the overall performance and funding of R&D in Australia and the development of new and innovative products is a key part of innovative activity in many industries, especially in the health sector. However, the application of new biotechnology processes also affects the structure and performance of many industries around Australia. For these reasons, a detailed understanding of the role of biotechnology in all these aspects is crucial to a better understanding of economic development in Australia and its science and technology base. Government polices that are not biotechnology specific are also affected by biotechnology developments. This includes agriculture, industry, sustainable development, energy and environmental policies.

As biotechnology is an enabling technology, it can be viewed in a similar way to that of information and communication technologies (ICT). In terms of ICT, there has always been a strong policy interest in the structure, growth and performance of ICT businesses and the ICT sector; but there also is a strong policy emphasis on the use of ICT goods and services in the various parts of the Australian community, the impact that ICT goods and services has on many businesses and industries and the change in many aspects of Australian life affected by ICT developments such as the Internet. The information needs about biotechnology are similar to those of ICT but with different emphases.

For biotechnology it will be important to understand aspects of:

- the structure, growth and performance of biotechnology organisations and the biotechnology sector;
- the use of biotechnology processes for the development of biotechnology products and in the reengineering of other business processes;
- the development of biotechnology products including those that are subsequently used as intermediate inputs in the production of other products; and
- the impact of biotechnology on the Australian economy, society and the environment.

It is this widespread set of policy interests that makes so important the development of a co-ordinated strategy for the development of biotechnology statistical indicators.

1.3 - International Experience

There has been considerable activity in the development of biotechnology indicators in the past few years. In 2005, the OECD released its first statistical framework for biotechnology statistics[4] which presents:

- concepts and definitions for the measurement of biotechnology;
- a Conceptual Model that provides the basis for the development of statistical indicators;
- a set of policy issues that need to be addressed and the indicators required to address them; and
- a set of collection guidelines for these indicators.

This Framework was intended to provide the basis for statistical compilation work within OECD Member Countries to facilitate international comparability for such indicators. It was seen as being an initial version of a statistical manual and largely reflected statistical activity that has been going on in a number of OECD countries over the previous decade. It is expected that this Framework would be revised as more experience was gained in this field of statistics.

Shortly after the release of the Framework, the OECD released a compendium publication of existing biotechnology statistical indicators[5]. This was released by the OECD early in 2006 and indicates the growing interest world-wide in these types of statistical indicators. The publication includes data from 25 countries, mostly OECD Member Countries, but points out that the comparability of the data for these countries is still limited although it has improved considerably since the first OECD compendium publication released in 2001.

Despite the improvement, there is still much work to do on a range of conceptual issues as shown below:

- Different definitions of biotechnology - some countries cover traditional biotechnology, such as that used in beer-making, as well as the more favoured concept of modern biotechnology.
- Different concepts of biotechnology firms – some countries use the concept of "core" biotechnology firms; some use the concept of biotechnology "active" firms. Canada, the leader in biotechnology statistics development uses the concept of innovative biotechnology firms.
- Different industrial scopes - most countries adopt definitions that limit the scope of the surveys to firms performing at least one of the defined biotechnology activities, but other countries include various service providers in the scope of their surveys.

[4] A Framework for Biotechnology Statistics, OECD, 2005
[5] OECD Biotechnology Statistics – 2006, OECD, 2006

- Different institutional scopes - sometimes the surveys are limited to the business enterprise sector. However, in a number of other cases, surveys also include Government bodies and higher education organisations.

These differences, of course, inhibit the ability of the policy maker to properly analyse differences between countries. In some countries, there are different treatments adopted between different surveying periods, obviously impacting on the ability of users to measure consistent trends over time.

All of these issues point to the need to reach international agreement on issues such as scope, coverage and definition in respect of biotechnology, biotechnology organisations and the biotechnology sector.

The biotechnology sector is not explicitly defined in the OECD Framework; in fact the OECD has often said that it does not support such a definition. However, the OECD Framework does define the concept of a biotechnology active firm – one that is engaged in at least one biotechnology activity – and of a dedicated biotechnology firm - a biotechnology active firm whose predominant activity involves the application of biotechnology techniques.

Either of these two concepts could be used to form a grouping of biotechnology firms that could be viewed as a biotechnology sector. In fact, this is how data is presented in *OECD Biotechnology Statistics - 2006* which draws comparisons between the following economic variables:

- number of firms;
- biotechnology employment;
- biotechnology sales; and
- biotechnology applications.

These variables relate to the group of firms meeting the definitions of biotechnology and biotechnology firms. It can therefore be viewed as a presentation of data about the biotechnology sector – without actually using that term. Thus the concept of a biotechnology sector is used implicitly, if not explicitly.

This practice is not restricted to the OECD. Many countries present data about the group of firms that meet their criteria for being called a biotechnology firm – but not always defined in the same way, as noted earlier.

The OECD has shown interest in this Information Development Plan as well as the project being undertaken by the Department of Industry, Tourism and Resources (DITR) on measuring biotechnology's contribution to the economy[6]. The definition of biotechnology related activities discussed in section 2.6 of this IDP as well as measuring the use of biotechnology may help guide future OECD work on biotechnology statistics.

[6] *A proposed methodology to identify biotechnology's contribution to the Australian economy*, Acil Tasman and Innovation Dynamics, December 2005

1.4 - Biotechnology in Australia

There have been two Australian surveys of the biotechnology sector funded by the Australian Government conducted in a similar way to that discussed above. The two surveys were both conducted by Ernst & Young in respect of 1999 and 2001. Both suffer from many of the definitional issues discussed earlier. In particular, the Australian surveys have had a different scope to most other countries in respect of the type of organisations being included. The Australian surveys have included medical devices companies, although they have been separately identified. These companies are often considered part of the biotechnology sector in Australia, although their activities do not always fall under the OECD definition of biotechnology. Medical devices companies are not included in the surveys of many other countries.

As well as these major surveys, most States and Territories have also carried out their own surveys. Post-graduate management research has also shown a great deal of interest in biotechnology and has undertaken various data collection exercises. The sheer number of data collection activities has placed a heavy response burden on the relatively small biotechnology community. By undertaking consistent national collections a large amount of this burden would be reduced and quality data would be available to the range of interested users.

1.5 - The Size of the Biotechnology Sector

The most recent data about the biotechnology sector for Australia comes from an international survey conducted by Ernst &Young[7]. This survey showed that the biotechnology sector in Australia:

- employed more than 8,000 people;
- earned revenues of more than A$3bn;
- had assets of more than A$5bn; and
- performed R&D of more than A$300m.

This shows that the sector is, in itself, a significant contributor to the total economic activity in Australia.

Taking an international perspective, the OECD Report shows that Australia had 304 biotechnology firms, making it the country with the 7th largest number of biotechnology firms in the OECD behind USA, Japan, France, Korea, Germany, Canada and the United Kingdom. If one uses expenditure on biotechnology R&D as a guide, Australia comes in at about 10th position.

These statistics show that Australia is a significant player world-wide in biotechnology development.

1.6 - The Importance of Biotechnology in Australia

[7] Beyond Borders, Global Biotechnology Report, 2006, Ernst &Young

Notwithstanding the statistics discussed above, the importance of biotechnology is significantly underplayed by such statistics. The importance of biotechnology to the Australian economy is likely to come less from the size of the sector, such as discussed above, and more from:

- the use of biotechnology in many other parts of the economy;
- the way in which production systems are being reworked to take advantage of newly developed biotechnology processes; and
- the outputs emanating from the economic units that are using biotechnology.

There are no current indicators available that provide any guidance to the significance of biotechnology in this regard.

Measuring the economic impact of biotechnology alone provides only one element of the impact that biotechnology has on Australia. For example, biotechnology has a significant impact on the national innovation system operating in this country, through its impact on the R&D systems operating in all sectors of the economy and through the flow-on effects of the use of that R&D to produce new and innovative products and processes.

Recent surveys by the ABS have shown that Australian businesses now spend about $400m on biotechnology R&D, a significant amount, approaching 10% of the total amount of R&D performed by Australian businesses. Based on the 2003 ABS survey[8], innovation in Australia is occurring in about one in three businesses. Much of this will emanate from the use of new technologies such as ICT and biotechnology. While biotechnology will have been the smaller of the contributors up till now, it can be confidently predicted that the impact of biotechnology on innovative activities will grow in importance in future years. Evidence of the growing importance of biotechnology can be seen through biotechnology businesses in the USA for the first time raising more venture capital funding than ICT businesses. Thus it will be important to measure this impact in the future.

In addition to the economic and science and technology effects, there will also be impacts on the social structure in Australia, especially through the way in which biotechnology is changing many aspects of health and welfare. There will also be many environmental impacts that also require consideration within an overall plan for the development of biotechnology statistical indicators. At this stage there is only very limited data available to assist policy makers develop and implement sound Government policies on these aspects at both a Federal and State level.

Biotechnology will be important for Australia in confronting a range of global issues including energy and fuel security, global warming, land degradation, an aging population and pollution. Broader government policies already address biotechnology where it can contribute to the policy aims. For example the Energy White Paper, *Securing Australia's Energy Future* which was released in 2004 covers biofuels and energy production from biomass which both involve biotechnology processes. In this respect information is required on the diffusion and use of biotechnology. This information will help policy makers to understand how biotechnology affects change and identify challenges to its uptake where better economic, environmental, health or

[8] Innovation in Australian Business, ABS Cat No. 8158.0

social outcomes could potentially be achieved. Many of these issues are not simply domestic issues, but quality data will be relied upon to support Australia's involvement in international forums around these issues.

It should also be noted that biotechnology does not fit within current code structures. As such there is very little data which can be extracted from current national collections. For example the current Research Field (RFCD) and Australian and New Zealand Standard Industry Classifications (ANZSIC) structures do not identify biotechnology. There is a great deal of existing information which can be extracted for other areas of the economy which is not available for biotechnology. Many of these areas receive much less policy interest or Government support than biotechnology.

Section 2 – Concepts, Definitions and Key Classifications

It is a crucial element of any statistical framework to develop a set of concepts, definitions and key classifications applicable to that framework. If the resulting statistics are required to be consistent with other countries, it will be important to develop these concepts, definitions and classifications in a way that can be linked directly to international guidelines. It should be noted that this does not mean that the definitions have to be identical; it is merely necessary for them be compatible and any data collection structured in such a way so as to ensure that the outputs can be derived in an internationally comparable manner. Because of the international comparability issue, this IDP starts from the base developed by the OECD in its statistical framework referenced earlier.

The OECD Framework introduces a range of concepts and definitions, the most significant of which relate to the actual definition of biotechnology. The OECD Framework does however also provide many other definitions that might be suitable for the compilation of biotechnology data. In this section we look at the OECD definitions and two which are not identified separately in that Framework – the concepts of a biotechnology sector and that of a biotechnology-related industry.

2.1 - The Definition of Biotechnology

The OECD definition of biotechnology is based on two definitions – a word based definition (called the "Single" definition) and a list-based definition (where the list is a list of exemplar biotechnology techniques). The OECD Framework recognises that the single definition **should always** be accompanied by the list-based definition. It is expected that this will help to clarify the type of activities to be included for measurement purposes.

2.2 - OECD Single definition

The OECD single definition is as follows[9]:

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.

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

biotechnology from the scope of any statistical collections. Thus any Australian definition should be accompanied by an instruction to that effect.

2.3 - OECD List-Based Definition

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.*
- *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".*

Since the initial list of techniques was drawn up, new techniques have been discovered. This has led to a recent proposal at OECD meetings to expand the above list of techniques to include the following techniques[10]:

- *Metabolomics/metabonomics: Identifying and analysing metabolites and their interactions.*
- *Systems biology: Modelling whole biological systems and sub-systems for purposes of research, predictive medicine and nutrition (nutrigenomics).*
- *Synthetic biology: Engineering whole cells.*
- *Others: biomimetics; biological control of pests; biocorrosion/biodegradation.*

Australian users have also indicated that they are keen to ensure that some of the key technologies used in environmental biotechnology are separately identified in the definition and are used in any statistical data collections. The key technologies are:

- bioremediation;

[10] Statistical Framework for Public Biotechnology R&D, Working Party of National Experts on Science and Technology Indicators, OECD, Paris 2006.

- biosensing;
- biological control; and
- biodiscovery.

The first three of these would normally be included in the category *process biotechnology techniques,* while the latter is likely to be included in a category titled *other*.

2.4 - Bringing Together the Two Definitions

The OECD Framework recognises that it is important to convey to suppliers of data that the surveys are aiming to measure "modern" biotechnology. To do this, the OECD recommends that the single definition should always be used in conjunction with the list-based definition. It believes that the combination of the two definitions will lead to correct interpretations of the scope of the survey by respondents. The rationale is that as the list-based definition includes only techniques found in "modern" biotechnology and this will help clarify to respondents that "traditional" biotechnology should be excluded despite being included within the single definition.

It is worthwhile noting that not all country surveys actually exclude "traditional" biotechnology. For example, the survey conducted in Japan explicitly includes "traditional" biotechnology but provides data separately for "traditional" biotechnology.

International experience suggests that the combination of the two definitions still leaves room for confusion. During the international collaboration undertaken as part of the development of this IDP, some concerns have been expressed by two international experts - Anthony Arundel[11] from UNU-MERIT in the Netherlands and George Slim[12] from MoRST in New Zealand. Arundel, who has worked with the OECD for a number of years on the development of biotechnology indicators has pointed out that many OECD countries have expressed concerns with the definition in recent times. Slim has also indicated that the definition of biotechnology has been a problem with the NZ surveys often leading to much confusion about which organisations should be included and which ones should not.

2.5 - The List-Based Definition as a Classification of Techniques

The list-based definition serves two purposes in the OECD Framework.

[11] Anthony is a leading academic in Europe in many issues surrounding biotechnology. He has been contracted by the OECD to write many of the papers leading to the publication of the OECD Framework.
[12] George Slim (Ministry of research, Science and Technology) is the officer in charge of the analysis of the biotechnology survey in New Zealand.

The first of these is to help clarify the single definition for respondents so that they only include modern biotechnology within the scope of the surveys - as discussed above.

The second is to establish the list of techniques about which diffusion indicators are required. These diffusion indicators measure the intensity at which these techniques have been employed in the business community, often further classified by type of biotechnology activity such as those discussed in Section 3 or by application field as discussed below.

When used for statistical collection purposes, the OECD Framework suggests that the list-based definition should be expanded to include an additional class:

Other (please specify) ……..

Arundel, in particular, cautions against creating too many new techniques about which indicators might be sought - primarily for respondent burden reasons. Despite this (legitimate) concern, it is felt that if the number of categories have to be expanded to meet policy needs, then it will be necessary to do so. Having said this, it must be remembered that it is all a matter of balance and compromise. In the final analysis it is important to limit any expansion to the minimum required to meet legitimate policy needs, consistent with respondent burden considerations.

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 additional 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
- Gene and RNA vectors
- Bioinformatics
- Nanobiotechnology
- Metabolomics/metabonomics
- Systems biology
- Synthetic biology
- Biodiscovery
- Other process biotechnology techniques
- Other

One issue that will have to be resolved as part of field testing for any statistical data collection will be the effect this increased classification list has on respondent burden and whether it is suitable for use in an economy wide survey. If the classification is too detailed for use in a general biotechnology survey, it may be better to reduce the

number of classes for a broadly based survey and potentially undertake a separate survey in respect of environmental biotechnology.

2.6 - Biotechnology-Related Activities

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
- 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 previous sections. Thus it is an important aspect of the contribution of biotechnology to the Australian economy.

Within the list of biotechnology-related activities will be activities which fall within the scope of the biotechnology definition. For example, production of a diagnostic kit (biotechnology-related) could involve synthesis of proteins (biotechnology). It is useful to retain this overlap as statistics users may wish to group the data for an activity with the biotechnology-related field (say, to consider all diagnostics activities), or with the biotechnology field (say, to consider all protein synthesis activities). When collecting information on biotechnology-related activities it will be important to be able to identify biotechnology activities within the list.

This IDP proposes that the definition of "biotechnology" be supplemented with the list-based definition for "biotechnology-related", as described above. Statistical data can then be collected for all activities of interest to Australian policy makers, with the ability to extract the data for those activities that align with the OECD definition of biotechnology, for the purpose of international comparisons.

2.6.1 - Medical Devices

A key issue for Australian policy makers has been the treatment of medical devices in the measurement of the biotechnology sector. It is interesting to note that medical

devices companies were excluded from the definition of "core" biotechnology companies by the Department of Industry, Science and Resources (DISR, now the Department of Industry, Tourism and Resources, DITR) and Ernst & Young in their 1998/99 Biotechnology Report[13] in Australia. However, in their 2001 report[14], a new category of "related biotechnology" companies was included in the survey. This category included a range of companies from the wider health and life-science sector, thus including medical device and diagnostic companies. In its most recent biotechnology report, Global Partners[15], DITR separately presented data about core biotechnology companies and medical device companies.

Given the interest in medical devices, it is important to understand those products and organisations if one is to put together a comprehensive view of biotechnology in Australia. In many cases the R&D phase, or manufacture of the medical device will fall under the OECD definition of biotechnology, but in other cases it will not. To ensure these activities are captured, this IDP has included medical devices under the definition of biotechnology-related.

2.7 - Definition of Biotechnology Products and Processes

The OECD Framework includes definitions for biotechnology products and processes, which are linked to the definition of biotechnology.

Biotechnology product *– defined as a good or service, the development of which requires the use of one or more biotechnology techniques per the list-based and single definitions above. It includes knowledge products (technical know-how) generated from biotechnology R&D.*

Biotechnology process *– defined as a production or other (e.g. environmental) process using one or more biotechnology techniques or products.*

This IDP accepts these definitions, to be used in connection with the single definition and the extended list-based definition for biotechnology, proposed above. Also, biotechnology-related products and processes can be defined in the same way, linked to the list-based definition of biotechnology-related.

2.8 - Classification by Application Field

Not only will users be interested in the diffusion of specific techniques across industry, they have also indicated that they need to have data classified by the field in which the techniques are being applied. There is no specific statistical classification used in Australia at this stage but it is clear that it will also be important to develop an application field classification suitable for that purpose.

[13] Australian Biotechnology Report, 1999, DISR and Ernst & Young
[14] Australian Biotechnology Report, 2001, DISR, Ernst & Young, Freehills
[15] Global Partners, Australian Biotechnology 2004, DITR, 2004

Classification of results by application field is seen as being very important internationally as well as in Australia. This has been made quite clear by Arundel, Slim and Jankowski[16] in their supplied comments on this project.

The two classifications that are most useful to consider in developing an official classification for biotechnology application fields in Australia are the scheme described by the OECD in its Framework and the scheme developed with Australian, State and Territory governments for mapping Australia's biotechnology capabilities[17]. These are shown below.

2.9 - OECD Classification

The OECD Framework contains a proposed classification for biotechnology applications. The classification has three levels - one broad, one intermediate and one detailed. The OECD Framework suggests that the intermediate level will be the most suitable level to apply in general biotechnology surveys, providing policy makers with the essential information for their work. The OECD recommends that the detailed level will probably be only practicable in a survey of a specific sector. The OECD intermediate classification of application fields is as follows:

- Human health – using rDNA technology
- Human health – other
- Veterinary health
- GM agricultural biotechnology
- Non-GM agricultural biotechnology
- Natural resource extraction
- Environment
- Industrial processing
- Non-specific applications
- Other (please specify)…….

2.10 - Classification in Australia's Biotechnology Capabilities

In Australia, policy makers have found it useful to adopt a similar classification for their work. This classification has four main classes, as shown below:

- Agribiotech
- Biomedical
- Environmental
- Industrial

This classification has many similarities to the OECD classification. With two minor modifications the two could be made to align reasonably consistently and provide the

[16] John Jankowski is the Director of the R&D Statistics program in the National Science Foundation in Washington, USA.
[17] Australia's Biotechnology Capabilities, Biotechnology Australia, 2005

mechanism for international comparability with those countries that adopt the OECD recommendations. The suggested modifications are to:

1) Dissect agribiotech into two components – plants and animals
2) Dissect industrial biotechnology into two components - natural resource extraction and industrial processing

2.11 - Proposed Australian Classification

If the modifications to the classification proposed above are adopted, the application field classification would be as shown below:

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

This classification is very similar to that proposed in the 2005 report on the Contribution to the Economy project[18].

2.12 - The Definition of Biotechnology Organisations and the Biotechnology Sector

The OECD Framework does not define a biotechnology sector. There are a number of reasons for this with the main one being that it is not possible to separately identify specific industrial classes within the International Standard Industrial Classification that could be viewed as biotechnology industries. This situation exists in Australia as well as in other countries.

Anthony Arundel (UNU-MERIT) has also expressed the view that the definition of a biotechnology sector is not appropriate for the reason mentioned above. However, he has suggested that a classification of many of the indicators by the field of application of the biotechnology process will provide more valid and useful information. The Australian view is that an application field classification is definitely needed; but this classification is viewed as being an addition to the range of classifications, not as an alternative to the concept of the biotechnology sector.

Despite these contrary views, it is noted that most countries actually adopt the concept of a biotechnology sector without actually adopting the terminology in their reports. As can be seen from the various statistical reports, data is generally shown about the range of organisations that have been defined as being biotechnology organisations on the basis of known information about them. In effect, this is equivalent to forming a biotechnology sector.

[18] A proposed methodology to identify biotechnology's contribution to the economy, Acil Tasman and Innovation Dynamics, Dec 2005

On the other hand, some countries do use the terminology of a biotechnology sector in their reports - with New Zealand being one specific example[19].

Most of the national surveys so far conducted in OECD Member Countries have been conducted using a population of known biotechnology firms. In this regard it should be noted that there may be differences between countries (and probably within countries over time) depending on how a list is actually compiled and how much effort goes into that compilation.

This IDP recommends a more formal definition of a biotechnology sector - one that is based on standard industrial classification **principles** and not on the specific classes included in the Australian and New Zealand Standard Industrial Classification (ANZSIC) or any other industrial classification.

These principles are that the statistical entities should be classified to the biotechnology sector if they are **predominately** involved in any of the defined biotechnology activities (that is, at least 50% of activity is biotechnology). These activities are the:

- performance of biotechnology R&D;
- the development of new biotechnology products and/or processes; or
- the application of biotechnology processes.

Expressed another way, a statistical entity would be considered to be in the biotechnology sector if its predominant outputs were biotechnology products, either knowledge products or other types of product or biotechnology processes.

The **predominance** criterion is consistent with the definition of a **dedicated biotechnology firm** as contained in the OECD Framework.

It is important to note that this definition is different from the concept of a **biotechnology active firm** as defined in the OECD Framework and used by a number of countries in their biotechnology surveys. In the OECD Framework, a **biotechnology active firm** is one that is engaged in a biotechnology activity as per the definition of biotechnology. The essential difference between that definition and that of a **dedicated biotechnology firm** is that the former includes all firms that use at least one biotechnology process, irrespective of the contribution of this biotechnology activity to the total activity of the firm. Thus dedicated biotechnology firms are a subset of biotechnology active firms.

This IDP proposes the use of a **dedicated biotechnology organisation** 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). Adopting the concept of a biotechnology active organisation to form a sector would lead to an overstatement of activity measures of biotechnology (such as employment

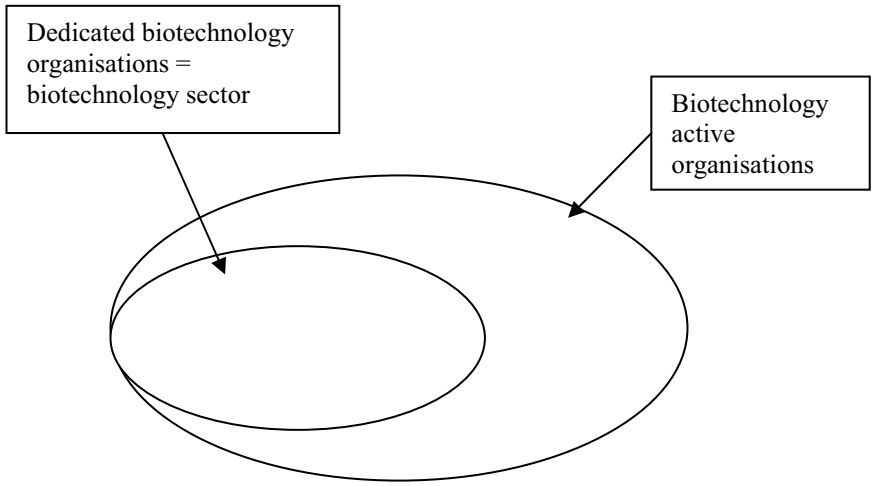
[19] Biotechnology in New Zealand, 2004, Statistics New Zealand

and value added) unless survey takers are able to collect a dissection of those variables into parts relevant to biotechnology and parts not related to biotechnology.

This IDP views the use of the biotechnology sector concept as being the relevant one for the measurement of most financial measures associated with biotechnology. It recognises, however, that it is important to have measures of the diffusion of biotechnology techniques across the economy, not only in the biotechnology sector.

The relationship between dedicated biotechnology organisations, the proposed biotechnology sector and the concept of a biotechnology active organisation is shown in the diagram below. In this diagram, the larger circle represents all biotechnology active organisations i.e. those that are using at least one biotechnology process. The inner circle represents the biotechnology sector, which is made up of only those organisations that are predominantly engaged in biotechnology i.e. dedicated biotechnology organisations, as defined by the OECD. All of these will also be biotechnology active organisations.

Figure 1 – A MAPPING OF BIOTECHNOLOGY ACTIVE ORGANISATIONS AND THE BIOTECHNOLOGY SECTOR



2.13 - The Measurement of Biotechnology Active Organisations

Although the concept of a biotechnology active organisation has not been chosen as the basis for the definition of a biotechnology sector, biotechnology active organisations still have an important role to play in the proposed Australian statistical system.

The most important role for the concept of biotechnology active organisations is in the measurement of the diffusion of biotechnology processes throughout industry. This is an essential requirement if one wishes to study the impact of biotechnology on the economy. As described earlier, the impact of biotechnology on the economy will

mainly come from the impact of the use of biotechnology products and processes, not merely from the size of the biotechnology sector.

The second use of the concept of biotechnology active organisations is in the measurement of total biotechnology activity and biotechnology products. To do this, it is important to note that the total activity is the sum of biotechnology activity by the biotechnology sector plus the biotechnology activity of other organisations that perform only secondary amounts of biotechnology activity. The relative size of biotechnology activity in the biotechnology sector compared to that conducted by biotechnology active organisations not in that sector will determine the priority that should be allocated to collecting data from the two components.

It is useful to compare biotechnology to ICT in the development of statistical indicators. In ICT statistics, measures of the size of the ICT sector are formed by summing the activities of all of the organisations coded to that sector (or a sample of them). However, total ICT activity can only be measured by surveying all (or a sample of) organisations that produce ICT products irrespective of whether the activity is performed by organisations in the ICT sector or whether it is performed by other organisations. The same is true for biotechnology.

The measurement of the diffusion of biotechnology also has similarities with the measurement of the diffusion of computers (and the Internet). In the latter case, statistics are compiled about the use of these technologies by organisations, governments and consumers. Similarly we could expect use of biotechnology or biotechnology products by the business enterprise sector, government organisations, other organisations and consumers.

2.14 - Biotechnology-related Organisations

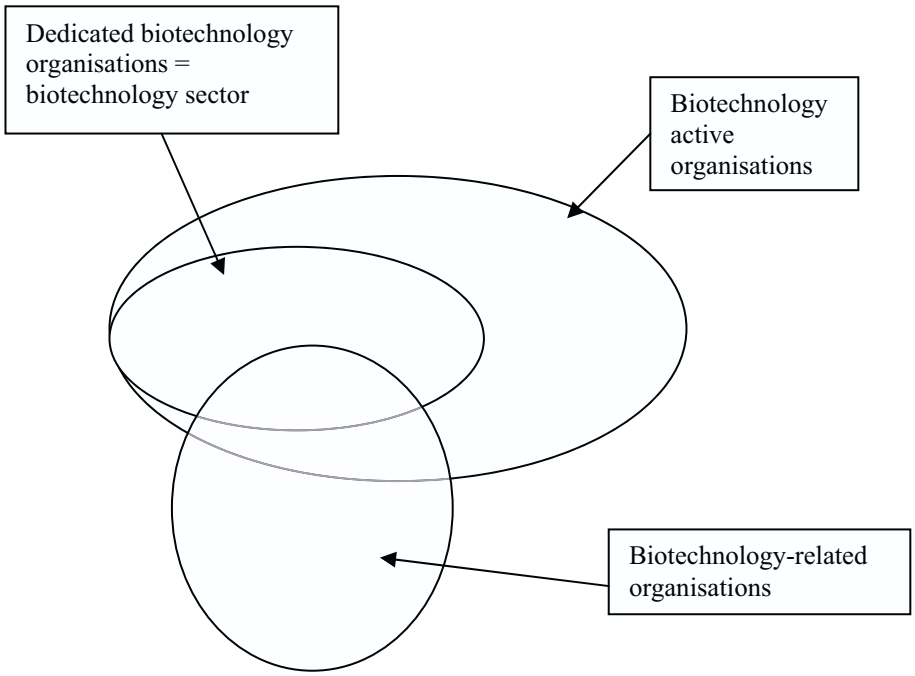
As discussed earlier, it is important that biotechnology-related activity is also measured. This IDP proposes the term **biotechnology-related organisation** to describe an organisation that engages in at least one biotechnology-related activity. This is comparable to the definition of a biotechnology active organisation.

Many of the organisations defined as biotechnology-related organisations will undertake biotechnology activities. So, there will be overlap between the sets of biotechnology-related organisations, biotechnology active organisations and dedicated biotechnology organisations. Consider a medical devices company. Where 50% of activity is biotechnology, the company will be a dedicated biotechnology organisation. Where the company is engaged in biotechnology activity, but it is less than 50% of activity, the company will be biotechnology active. Where none of the company's activities fall under "biotechnology" as defined earlier, the medical devices company will be a biotechnology-related organisation.

2.15 - The Biotechnology Landscape

Based on the discussion above, it is now possible to diagrammatically represent the concepts being proposed in this IDP. That representation is shown below.

Figure 2 – THE BIOTECHNOLOGY LANDSCAPE



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 policy debate overall and to help users better understand how such indicators can be interpreted.

The starting point for the Conceptual Model (shown diagrammatically at the end of this Section) is the depiction of how biotechnology activities occur within Australia and how these activities interact with other aspects of the Australian economy. For simplicity, discussion of this Conceptual Model refers to "biotechnology". This can be read as meaning "biotechnology and biotechnology-related", as this IDP proposes measurement of all these activities, as discussed earlier.

3.1 - Transactions and Transactors

The Conceptual Model has been prepared mainly to reflect the **transactions** that occur in the economy as they relate to biotechnology. The Model has not specifically been developed to indicate the relationship between the **transactors** involved in these transactions, although an understanding of the transactors is also an important aspect of any biotechnology statistical program. The main reason for taking the approach of concentrating on the transactions has been to keep the Model simple while consistent with its aims of informing statisticians and policy makers about the issues that require statistical measurement. However, it is important to remember that at all stages through the Model, there are policy interests about the **transactors** performing the transactions in addition to the interest in the **transactions** themselves.

As is the case with most economic transactions, there is a need to understand the inputs into the activity being measured and the outputs from that activity. In the case of biotechnology, there is no difference in this regard. It is crucial to understand both the inputs into biotechnology activity and the outputs from it. What is different in this case is that biotechnology is primarily an enabling technology – hence there is a lot more emphasis than normal in the use of the outputs. In this regard, biotechnology is fairly similar to ICT where there is much more emphasis placed on the use of the technology than in the production of it.

3.2 - Biotechnology Activities

This proposal starts from the same position as the OECD Framework – that there are three specific biotechnology activities of interest – namely research and development, innovation and the use of biotechnology processes. These activities are of interest both individually and combined. Thus the Model adopted needs to be able to inform Government policy about biotechnology R&D, biotechnology innovation and the use

of biotechnology processes to perform other activities. It also needs to be able to inform Government policy about biotechnology in total. There is also an important demand for statistical indicators about the performers of the transactions as well as the specific transactions themselves.

In the Model shown diagrammatically at the end of this Section, the three specific activities are shown to be overlapping, reflecting the overlap in the processes themselves. For example, as R&D is an essential component in Australian innovation, it is appropriate to show these two activities as overlapping activities. (The significance of R&D to innovation can be seen by the results of the ABS innovation surveys, which have shown that expenditure on R&D makes up nearly 50% of all Australian expenditure on innovation activities.) In addition, it will very often be important to use biotechnology processes as part of performing R&D and/or developing new biotechnology products and/or processes. Thus each of the transactions could occur within the same activity.

Not only do the activities overlap, it is also likely that the transactors will also overlap. Many organisations will have been established to perform biotechnology R&D, the successful outcome of which will be the development of new biotechnology products or processes. Often the organisation undertaking the R&D will also create new products and processes. Certainly, the organisations performing the R&D and/or developing new biotechnology products and processes will in general be using biotechnology processes.

3.3 - The Inputs to Biotechnology Activities

As described earlier, it is important to understand and measure the inputs into biotechnology activities. The Model depicts the key inputs into biotechnology activities as:

- capital, both in the form of the direct contribution of money into the system or through the provision of capital equipment;
- labour;
- knowledge, both in terms of the knowledge and skills of workers and that obtained from other assets including R&D, patents and the like. This knowledge can be sourced both domestically and from overseas; and
- perceptions, which will mainly emanate from members of the Australian population, but could also come from overseas.

As it will be important to understand where these inputs emanate from, and what types of organisations are providing them, the first box in the Model depicts the transactors that provide the necessary inputs into biotechnology. Importantly, the inputs can come from any sector of the Australian economy (business enterprise sector, government sector, higher education sector, private non-profit sector) from overseas organisations or from members of the Australian (or overseas) population. The sectors identified in this Model have been aligned to the sectors identified in the

OECD's Frascati Manual[20], reflecting the close links between biotechnology and other science and technology indicators. In addition, this Model recognises the important role that public perceptions of biotechnology play in developing Government policies and on the social acceptance of biotechnology products and techniques.

3.4 - The Outputs from Biotechnology Activities

The outputs of biotechnology activities are biotechnology products, which is consistent with the OECD Framework. These can take the form of:

- knowledge products – such as the conclusions from an R&D program, scientific articles and patents or other forms of security by which the intellectual property developed is protected (e.g. plant breeders rights);
- intermediate inputs – mainly products or processes that can be used in other activities or products; or
- products that are for final consumption by either other organisations or by Australian or overseas consumers.

Biotechnology products can be manufactured domestically or imported.

In a similar way that the biotechnology activities are shown to be overlapping, so to are the biotechnology products. In some cases outputs that are knowledge products may be subsequently used as inputs into other activities; in other cases there will be some products that can either be used as an intermediate input into the production of another biotechnology product (or even a non biotechnology product) or may be for final consumption.

3.5 - The Users of Biotechnology Products and Processes

The Conceptual Model recognises that the users of biotechnology products in Australia can either be business enterprises, other organisations or consumers. For Australian business enterprises, the outputs can either be products or processes. Biotechnology products may be sold/used either in Australia or exported to another country.

The final part of the Model depicts the impact of biotechnology on Australia. The transactions themselves will have impacts on the Australian economy through the creation of products and processes (some of which will be used elsewhere creating subsequent flow-on economic benefits). These transactions will impact on the economy through increased employment opportunities, increased gross domestic product and net effects on our international balance of trade.

The economic impacts do not stop there. Because of the social impacts of biotechnology, especially those relating to health and well-being, there will be subsequent impacts on the size of Australia's population and workforce, the age

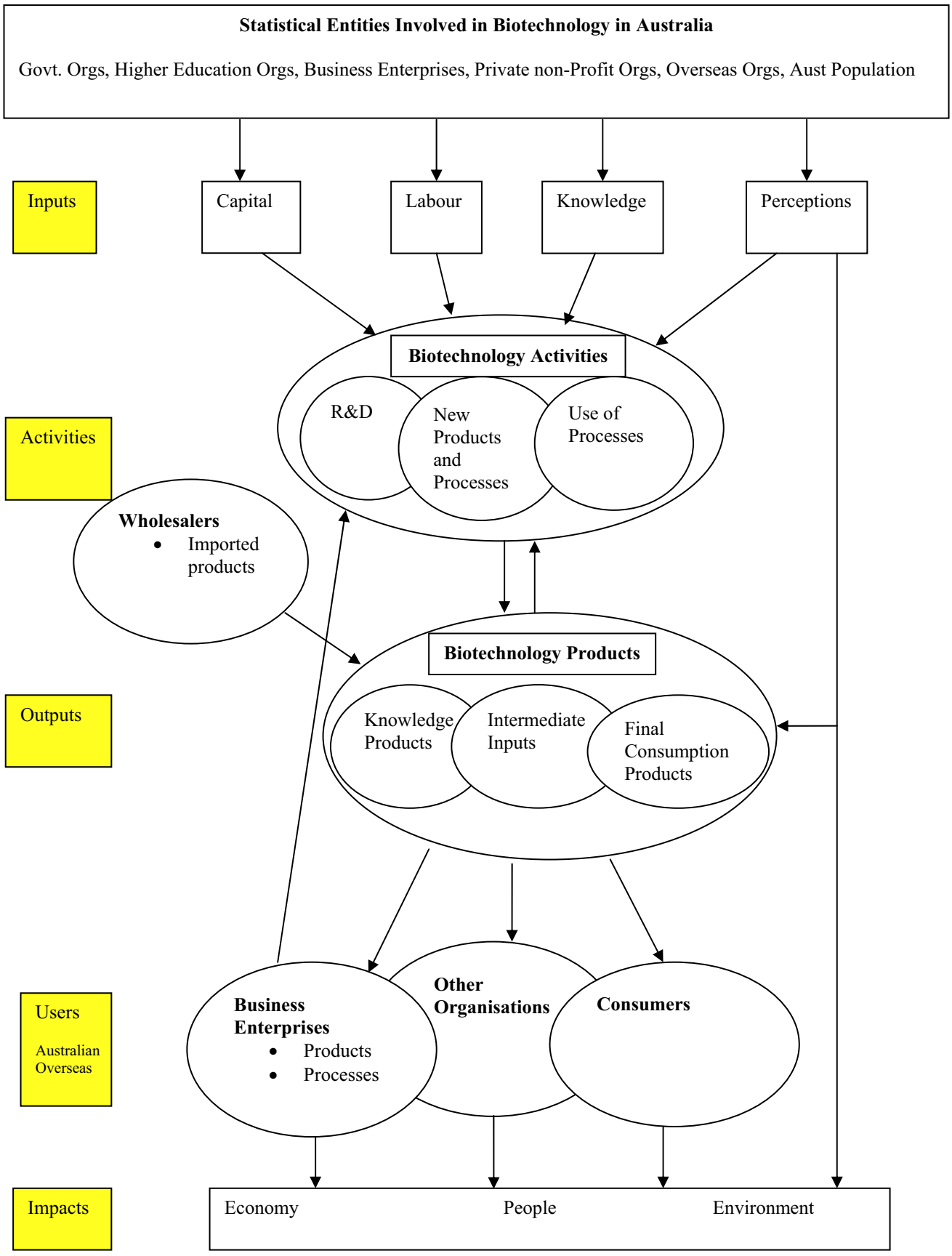
[20] Frascati Manual: Proposed Standard Practice for Surveys on Research and Experimental Development, sixth edition, OECD, 2002

distribution, health costs etc. Not only will these social impacts have an economic effect, they will also have a significant bearing on social structures and the demand for social services as the population age distribution varies.

Finally, the use of biotechnology products, and those from biotechnology-related industries, will also have effects on the environment in Australia ranging from changes in agricultural practices, energy production, waste management, chemicals and materials production, conservation measures and the like.

The Model also depicts the relationship between public perceptions and biotechnology issues, whether they are in terms of biotechnology activities, biotechnology products or the impacts of biotechnology.

FIGURE 3 - CONCEPTUAL MODEL FOR BIOTECHNOLOGY STATISTICAL INDICATORS



3.6 - Relationship between this Model and the OECD Framework

The Model proposed in this paper is broadly consistent with that depicted in the OECD Framework. This Model is compatible with the extended view of biotechnology as "biotechnology and biotechnology-related". This better fits the Australian situation, but does not change the structure of the Model. International comparisons can be made by considering only those activities that fall under "biotechnology", that is, only those that are consistent with the OECD definition of biotechnology. This is made possibly by collecting information in such a way that biotechnology and biotechnology related can be separately identified.

Compared to the model in the OECD Framework, the three groups of biotechnology activities are the same with similar inputs and outputs. However this Model extends the measurement framework to include information about the users of biotechnology products and the subsequent impacts of biotechnology on Australia's economy, society and the environment.

This Model further emphasises the need to also provide a measure of the source of the inputs into biotechnology activities and to ensure that these are viewed in an economy-wide perspective, rather than being mainly interested in the business enterprise sector.

As pointed out in the OECD Framework, it is important to recognise that biotechnology overlaps very significantly with the national innovation system, particularly those parts relating to the performance of R&D and innovation. The measurement concepts must therefore be closely aligned to the concepts and definitions contained within the OECD's Frascati and Oslo Manuals. The measurement concepts should also take into account specific conditions within Australia such as a high level of resource and service activities within regional economies.

Biotechnology is an enabling technology, in much the same way as ICT. The model therefore needs to consider the same issues that confronted the OECD in its development of a statistical framework for ICT and related statistics[21]. The key difference in that development is the greater emphasis on the use of ICT goods and services, particularly the internet. It is not clear yet as to whether there will be such a corresponding focal point for interest in respect of biotechnology.

[21] Guide to Measuring the Information Society, OECD, 2005.

Section 4 – The Demand for Data

This Section discusses the policy issues that require biotechnology data for their implementation and monitoring. It further ranks these in a priority order to assist statisticians in developing statistical indicators and programs in a manner consistent with these priorities. The indicators necessary for advising these policies are discussed in Section 5.

4.1 - Some General Comments

As discussed earlier, biotechnology is an enabling technology and is therefore similar to ICT. 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.

In terms of the supply of the technology, there are two main aspects – the R&D being performed on biotechnology and the development of new and innovative products from that R&D. These are shown in the Conceptual Map as two of the three biotechnology activities.

R&D and innovation are at the centre of the national innovation system in Australia. Thus R&D and innovation in biotechnology products and processes are of key interest not only as a part of biotechnology policies but also as part of science and technology policies more generally.

There is a need to develop indicators about the use of biotechnology within industry (including in further R&D and innovative activity). This is the third of the biotechnology activities shown in the Conceptual Map.

Irrespective of whether we are looking at the supply or use of biotechnology, it is important to understand that it is not only the activity that we wish to measure, but we also need to understand and measure the inputs to that activity and the outputs emanating from it. Of particular importance in the case of biotechnology is the intermediate use of biotechnology products in downstream activities which may occur outside the "biotechnology sector".

Governments at all levels are interested in the significance of biotechnology as a contributor to the Australian economy – particularly for their potential to create wealth and jobs for Australians well into the future. (This interest is not restricted to biotechnology – many other products or activities performed in Australia are also of importance for the same reason.) This interest is at the heart of the current DITR project to measure the economic significance of biotechnology to Australia and explains the widespread support being given to that project.

User requirements for indicators about the importance of biotechnology to Australia are not restricted to measures of economic significance – there are also many impacts

on social, health and environmental issues that are also of critical importance to Australian policy makers. These are also reflected in the Conceptual Map shown in Section 3.

The overlapping nature of many of the requirements discussed above is at the center of explaining the complexity of developing one overall set of requirements for biotechnology statistical indicators. This has led to difficulties both in Australia and elsewhere in creating a comprehensive strategy for measuring biotechnology.

4.2 - The Methodology Adopted for Establishing Priority Policy Issues

The methodology adopted for the enumeration of these policy issues and the allocation of priorities to them has been to undertake a consultation round with members of the Biotechnology Statistics Users Group (BSUG) established by the ABS and Biotechnology Australia (BA) in 2005. These consultations have led to the initial development of a set of policy issues about biotechnology and its impacts on the Australian economy. Through further consultation the BSUG then prioritised the priorities for the policy issues as set out below. It is noted that there may be some crossover in the policy issues such that similar indicators may address more than one policy issue. This will be addressed further in chapter 5.

4.3 - Highest Priority Policy Issues

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

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

4.4 - Other High Priority Policy Issues

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

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

4.5 - Medium Priority Policy Issue

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

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

Section 5 – Required Statistical Indicators

This Section aims to enumerate the statistical indicators that are of most relevance to policy makers as they perform their various roles and responsibilities. Having enumerated the range of indicators, a priority ranking is adopted as an aid to statisticians as they attempt to compile statistical programs to meet these needs.

5.1 - Some General Comments

Developing a priority set of statistical indicators is difficult because of the wide ranging nature of the user requirements as discussed in Section 5 above. Some of the indicators will relate to the individual biotechnology activities (and the statistical entities involved in those activities) identified in the Conceptual Map, viz:

- R&D;
- innovation; or
- use of processes.

Other indicators will relate to the group of biotechnology activities as a whole and so embrace the concepts of the biotechnology sector and biotechnology-related industries as developed in Section 2. When measuring the activities associated with the use of biotechnology processes and their outputs, it will be often more important to use the concept of biotechnology active organisations than the concepts of dedicated biotechnology organisations used to identify a biotechnology sector.

It should be noted that there are user demands for measuring the application of biotechnology products that are used as an input into other production processes, along with biotechnology products that are for final consumption and biotechnology processes that are applied to a range of other productive activities. These biotechnology products are an integral part of the contribution of biotechnology to the Australian economy and to the overall impact of biotechnology to the economy, the welfare of the Australian population and the environment. It is not clear at this stage as to the best way in which to measure the contribution of biotechnology to the economy or the impacts of biotechnology on the economy, society and the environment. It is quite likely that this type of requirement may have to be met by using more econometric or modelling strategies. This in turn may lead to the need for different data items to be included in any statistical surveys which would underpin future modelling activities.

Classification/coding structures will also be important in being able to break down indicators to provide information into areas of biotechnology activity including health, agriculture, environmental and industrial biotechnology. Classifications for biotechnology activities were discussed in chapter 2 of this IDP.

All of these issues will need to be borne in mind in developing appropriate statistical vehicles from which to derive relevant statistical indicators.

5.2 - The Methodology Adopted for Determining Priority Statistical Indicators

The methodology adopted for determining the priority statistical indicators is similar to that adopted for determining the priority policy issues. Members of the BSUG were asked to consider indicators required to address the policy issues and then prioritise those indicators.

Two categories of statistical indicators have been compiled. The first, called the highest priority statistical indicators and the second, called other priority indicators.

Merely because statistical indicators have been included in one or other of these lists does not necessarily mean that they will all be developed. What it does determine is the priority with which statistical indicators will be considered as part of the statistical developments. Whether such indicators are finally developed will depend on a range of statistical issues such as the ability of respondents to provide answers and the difficulties involved in the provision of such information.

It should be noted that other indicators may be added as statistical developments continue even though they may have had a lesser priority. This would be based on a relative cost basis – many indicators may be able to be derived for zero or very little cost as, for example, they may be a bi-product of the compilation of other statistical indicators. (For example, numbers of statistical entities performing a particular activity may not be a priority indicator, but can be generated at the same time as the revenues generated from that particular activity.)

5.3 - Highest Priority Statistical Indicators

Shown below are the highest priority statistical indicators for each of the policy issues discussed in Section 4 above. As all bar one of the policy issues were considered to be high priority (and the other was ranked as medium priority) all policy issues are shown below.

Policy Issue 1 - Encourage the development of innovative products and processes from biotechnology research.

- Number of organisations producing innovative products and processes
- Number of innovative new products or processes
- Sales of innovative products or processes
- Proportion of sales on innovative new products or processes

Policy Issue 2 - Encourage the development of effective biotechnology enterprises.

- Distribution of biotechnology activities across industry sectors
- Number and type of organisations performing biotechnology activities
- Number and type of organisations in the biotechnology sector
- Employment of biotechnology organisations performing biotechnology activities
- Biotechnology revenues and expenses of biotechnology organisations performing biotechnology activities.

Policy Issue 3 - Identify and understand the drivers and limiting factors for biotechnology activity. These include IP, regulation, capital etc.

- Identification of factors influencing biotechnology activity
- Relative importance of factors influencing biotechnology activity
- Effectiveness of Government sponsored initiatives to invest in biotechnology R&D and innovation

Policy Issue 4 - Identify and understand the drivers and limiting factors for the adoption and use of biotechnology products and processes.

- Importance/relative importance of specific barriers to biotechnology activity, including R&D and innovation

Policy Issue 5 - Provide the framework conditions for the commercialisation of biotechnology research and innovation.

- Number of organisations commercialising biotech R&D
- Time taken for commercialisation of biotech R&D
- Time taken for implementation of new biotechnology processes
- Returns accruing to businesses as a result of commercialisation of biotechnology R&D and innovation

Policy Issue 6 - Encourage the application of biotechnology processes and the use of biotechnology products to achieve improved social, health, environmental and economic outcomes for Australia.

- Number and proportion of organisations using biotechnology processes
- Proportion of organisations using specific types of biotechnology processes
- Share of outputs generated by biotechnology processes

Policy Issue 7 - Better understand the social, health, environmental and economic impacts of biotechnology in Australian including on individual industries, states and regions – especially rural areas.

- Type of biotechnology products being used as inputs to production processes
- Biotechnology revenue/expenses as a share of rural and regional revenue/expenses for biotechnology active organisations and dedicated biotechnology organisations
- Imports, exports and balance of trade in biotechnology products
- Area of crops using GM seeds

Policy Issue 8 - Encourage biotechnology research including through the provision of public and private support and funding.

- Number and type of organisations performing R&D
- Level and growth in biotechnology R&D (including by field of science)
- Public funding of biotechnology R&D
- Private funding of biotechnology R&D
- Human resources devoted to biotechnology R&D

Policy Issue 9 - Encourage the diffusion of biotechnology research and innovation throughout the economy.

- Number of organisations using biotechnology products or processes
- Industry classification of organisations using biotechnology products/processes

Policy Issue 10 - Understand public perceptions towards biotechnology and ensure there is informed debate on biotechnology issues.

- Proportion of people aware of specific biotechnology products/processes
- People's level of understanding of biotechnology products or processes
- Proportion of people concerned about specific biotechnology products/processes

Policy Issue 11 – Encourage Australia's competitiveness in the global biotechnology market.

- Relative costs of undertaking biotechnology activities.
- Relative returns from the conduct of biotechnology activities.
- Relative size of biotechnology activity.

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

- Number of collaborative arrangements for biotechnology R&D and innovation

5.4 - Other Priority Indicators

Set out below is a list of the policy indicators still considered important but not as high a priority by the BSUG. All of the statistical indicators sought have been included on the list as it is expected they will also be considered for inclusion/collection during the development phase.

- Sector of biotechnology R&D performance
- Level and growth of biotechnology R&D by field of science.
- Number of publications involving collaboration within Australia or internationally
- Value of sales of innovative new products or processes to for particular biotechnology activities (medical, agricultural etc)
- Financial performance of biotechnology enterprises
- Proportion of organisations affected by specific drivers
- Proportion of organisations affected by specific barriers
- Number of patents applied for and granted in biotechnology
- Importance of particular forms of security to biotechnology R&D and innovation
- Number and type of organisations using patents and other forms of security
- Relative importance of specific drivers for using biotechnology products or introducing biotechnology processes
- Number of papers, articles and citations of biotechnology R&D
- Increase/decrease in profits due to use of biotechnology process/product

- Number of organisations using collaborative arrangements
- Importance of collaborative arrangements with overseas partners
- Number of publications involving collaboration within Australia or internationally
- Number of organisations using biotechnology products as inputs to production processes
- Social/health/environmental/economic incentives or advantages to uptake of biotechnology
- Proportion of organisations using specific types of biotechnology products as inputs to production processes
- Share of outputs that are biotechnology products
- Value and type of products incorporating biotechnology products
- Number of people involved in medical trials for biotechnology produced health products
- Number of organisations generating biotechnology revenue in specific areas
- Biotechnology revenue/expenses as a share of total revenue/expenses for biotechnology active organisations and dedicated biotechnology organisations
- Biotechnology revenue/expenses as a share of industry revenue/expenses for biotechnology active organisations and dedicated biotechnology organisations
- Biotechnology revenue/expenses as a share of State revenue/expenses for biotechnology active organisations and dedicated biotechnology organisations
- Biotechnology employment as a share of total employment for industries, regions, States, Australia
- Environmental impact from uptake of biotechnology
- Relative costs of not undertaking biotechnology activities

5.6 - Some General Conclusions

On the basis of this listing of priority indicators, it is possible to draw a number of conclusions. These are:

- 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.

5.7 - Indicators Required for State Government Policy Purposes

In this report, no attempt has been made to differentiate between priority statistical indicators required for State and Australian Government purposes. The priority policy issues were decided by the BSUG which includes the States and the Australian Government departments, which shows the similarity in policy needs across governments. However, States have consistently indicated the overriding importance of availability of data at the State level. They recognise that this may require some aggregation of details within certain data items.

5.8 - The Frequency of the Indicators

It is important to develop an understanding of the frequency with which specific statistical indicators are required. This will be an important component of the overall statistical strategy formulated for biotechnology statistics.

Some general observations about the frequencies can be made as many of the indicators are similar to those already compiled by the ABS. It should be noted that the OECD's Oslo Manual recommends 3 year terms for some of these indicators. Thus it could be expected that the required frequencies for statistical indicators within existing collections would be as follows:

- For policy issues and statistical indicators surrounding biotechnology R&D at least two-yearly and, preferably, annually.
- For policies and statistical indicators about the creation of innovative products or processes at least two-yearly and, preferably, annually.
- For policies and statistical indicators about biotechnology activity associated with the use of biotechnology processes two-yearly.
- For policies and statistical indicators about biotechnology activity as a whole, two-yearly.
- For policies and statistical indicators about public awareness of biotechnology two-yearly.
- For policies and statistical indicators about the economic significance of the biotechnology sector two-yearly.

- For policies and statistical indicators about the impact of biotechnology on the economy, people and the environment two-yearly.

Note that measuring the impacts of biotechnology will involve derivation from indicators that are suitable measures of economic, social, health and environmental outcomes[22]. As these are already collected, or are included in the list above, this will not require additional collection vehicles. What is needed is the ability to link data on outcome measures to data on biotechnology activity. Where the indicators are leveraged off existing collections, the frequency of data will be based on the frequency of those collections.

[22] Impacts of Advances in Medical Technology in Australia, Productivity Commission, 2005.

Section 6 – The Supply of Data

In this Section, existing data sources are explored to ascertain which of the required data established in Section 5 is already available. This includes a series of ABS collections as well as other non ABS data sources.

6.1 - Biotechnology R&D

The publication *Research and Experimental Development Businesses, Australia 2003-04* (ABS cat. no. 8104.0) provides survey results of additional information collected specific to biotechnology-related R&D. Businesses that performed and/or paid others to perform biotechnology-related R&D (extramural), were asked additional questions.

The main biotechnology data outputs from this survey include:

- number of businesses who performed and/or paid another to perform biotechnology-related R&D;
- total biotechnology R&D expenditure;
- expenditure by R&D performed by the business as well as paid to another (split by type of domestic institutional type and overseas country);
- expenditure by ANZSIC;
- expenditure by bio-industry sector;
- human Resources by ANZSIC; and
- barriers to biotechnology R&D.

Specific information on biotechnology was also be collected in the 2004-05 survey of R&D by government and private non-profit organisations and included some comparable information to that collected in the 2003-04 Business survey of R&D. However both of these collections only provide limited comparability of data to overall R&D collected against ANSZIC codes.

Summary statistics of the *Research and Experimental Development, Government and Private Non-Profit Organisations, Australia 2004-05* (ABS cat. no. 8109.0) were released on 6 Oct 2006. The specific biotechnology collection included data on:

- government expenditure on biotechnology related R&D;
- private non-profit expenditure on biotechnology related R&D; and
- biotechnology related R&D expenditure by bio-industry.

There are no statistics available about biotechnology R&D performed by the higher education sector.

6.2 - Biotechnology Innovation

The ABS has conducted a number of Innovation surveys over the past decade – the most recent being in respect of 2003. These surveys collect information in respect of the creation of new products or processes. However, there has been no information collected that would enable the derivation of statistics about which of the innovations

was either biotechnology products or processes or were produced by the application of biotechnology products or processes.

6.3 - The Use of Biotechnology Processes

The ABS has not collected any information that would enable the derivation of economy wide statistics about the use of biotechnology processes in Australia. There are, however, some possibilities for future years. These are addressed in Section 7 of this IDP.

6.4 - Agriculture Statistics

Data used to monitor the agriculture industry is principally collected by the ABS and the Australian Bureau of Agricultural and Resource Economics (ABARE). There is no data available on biotechnology from the ABS' Agriculture Surveys Program. The Agriculture Census 2006 form does not contain any questions with biotechnology content. However, it may be possible to include biotechnology questions on future Agriculture Survey forms. The inclusion of biotechnology-related questions on the Agriculture Survey or Agriculture Census may be possible but would generally be conducted by the ABS on a user funded basis. It should be noted that there is limited physical space on the forms and user funded questions need to be proposed early on in the development of the census or survey forms.

ABARE conducts a National Farmer Survey, which includes a focus on production monitoring and biotechnology covering all industries in all states (the sample size for the next survey is still to be determined). The farm businesses comprising the survey frame for the National Farmer Survey are provided to ABARE by the ABS in an unidentifiable format under clause 6 of the Statistics Determination.

ABARE also conducts a collection on land care and resource management issues including a focus on disease management, biosecurity and vegetation management in all industries, nationally and in selected regions. The ABS also provides the framework for this survey.

One possible avenue to pursue in relation to the biotechnology-related outputs from the ABARE surveys is to consult with ABARE and determine the possibility of ABARE Main Unit Record Files being made available to the ABS for data linkage projects. The data linkage exercise would be supported by the fact that ABS business register lists are used as the frameworks for the ABARE surveys, facilitating comparability of collection units. Appropriate legislation would have to be reviewed before proceeding down this path.

The ABS has also committed to including agriculture in future R&D collections.

6.5 - Regular Industrial Financial Surveys

The ABS conducts a number of regular industry surveys aimed at measuring the structure and performance of units in those industries. These include the Economic Activity Survey (EAS), the Manufacturing Survey, the Mining and Utilities Survey, the Service Industries Survey and the Information and Communication Technology Industry Survey. The ABS is also developing the Annual Integrated Collection, which has as its objective to further integrate the collection of data across the EAS program through further consolidation of collection instruments and statistical infrastructure. As a result, the EAS Program will undertake a transition into the Annual Integrated Collection Program in the near future.

6.6 - Economic Activity Survey

The EAS is the core collection vehicle of the EAS family of collections. It is an economy wide survey collecting financial information that is despatched to approximately 12,000 business units and also collects data indirectly using Australian Taxation Office data. The EAS includes all active Australian businesses in its scope, except those classified to General Government (SISCA 03000) or Government Administration and Defence (ANZSIC Subdivisions 81 and 82), and Private Households Employing Staff (ANZSIC subdivision 97) and Finance and Insurance (ANZSIC subdivisions 73 and 74). This survey does not separately distinguish biotechnology companies at this stage and so no biotechnology data is available from it.

There is the **potential** to include a 'biotechnology flag' question on the EAS survey form, primarily as a means to identify core biotechnology organisations or those 'non core' organisations undertaking biotechnology activities. However, it is **probable** that only a relatively small number of organisations would be identified as core or non-core biotechnology organisations using the EAS vehicle and resources may be better utilised elsewhere in developing a biotechnology survey frame.

6.7 - EAS Manufacturing Survey

The EAS Manufacturing Survey is an annual collection which collects information about the operation and financial performance of all businesses which earn the majority of their income from trading in goods which they produce.

This survey does not separately identify biotechnology organisations and so does not produce any organisation level data about biotechnology. However, the EAS Manufacturing Survey does collect **commodity level** data, comprising some manufactured commodities which are biotechnology-related, eg vaccines, serums, antibiotics, antitoxins and ointments for human use; vitamins for human use; other pharmaceutical goods for human use and medical devices. Commodity data items are as per the Manufacturing Input-Output Commodity Classification, which is an aggregation of Australian and New Zealand Standard Commodity Classification items.

6.8 - EAS Mining and Utilities Survey

The EAS Mining and Utilities Survey is a standard income and expense financial collection which does not separately identify biotechnology organisations and so does not produce any organisation level data about biotechnology. There is potential to collect biotechnology-related income and expenditure data in the future, especially if it grows in importance for the businesses involved in the survey. This may be a possible avenue in the case of water and sewerage supply, where biotechnological products and processes are already used in water testing and are being developed for use in the supply and treatment of water and sewerage. Mineral processing and extraction is also an area of increasing interest for biotechnology. Income data is also collected from royalties obtained from copyright, IP and patents, which would be of interest if the royalties relate to any copyright, IP and patents of a biotechnological nature.

6.9 - Services Industries Survey

This program was introduced to meet users needs for detailed studies of selected service industries and activities, which concentrate on size and structure of the industry at a point in time. The service industries within the scope of Service Industries Survey are conducted on a rotating basis, depending on a range of factors put forward to the ABS for consideration and determination. It should be noted that not all service industries are currently included in the scope of the program and the ABS undertakes extensive user consultation in determining the service industries included within the scope of the Service Industries Survey program and when they will be surveyed within a particular Service Industries Survey reference period.

This range of surveys does not currently produce any biotechnology data. It is also unlikely that it will produce much biotechnology data in the future because of the intermittent and rotating nature of the surveys. It is unlikely that any survey of the biotechnology sector, as discussed earlier in Chapter 2, would fit within this program because of the component industries of that sector are not likely to be ANZSIC based and would not be confined to the services part of the economy. It is possible, however, that some questions could be added to a survey of a particular industry on an ad-hoc basis. One possible example might be in respect of the Health Services industry. This approach may be particularly useful in collecting information on users of biotechnology products or information on biotechnology-related activities.

Undertaking any collection for biotechnology around services may require compilation and dissemination of information on the use and interpretation of indicators for the service sector. This may require email conformation of conceptual issues, industries of the service sector and those of other sectors and analysing the impact of movements in indicators for services to the overall business cycle.

6.10 - Information and Communication Technology Survey

This survey collects information on the supply of Information and Communication Technology (ICT) goods and services by organisations within scope of the collection.

The industries included in the surveys come from different parts of the economy, including those mentioned above. This survey does not provide any data related to biotechnology – even though the use of ICT equipment is critical for biotechnology activity. It is unlikely to ever produce any data specific for biotechnology data as the range of industries that would need to be included in a biotechnology survey would be different from that for the ICT survey.

This particular survey does however provide practical guidance on the development and implementation of a survey that does not strictly fit the pattern of standard ABS industry surveys. Such experience will be of great value in developing a biotechnology survey.

6.11 - The Supply and Demand for Human Resources in Science and Technology

The ABS released a publication in 2003 titled *Human Resources in Science and Technology (HRST), 8149.0*. The publication presents data on human resources by selected qualifications and occupations. It follows definitions and guidelines in the OECD's manual, *The Measurement of Scientific and Technological Activities and the Manual on the Measurement of Human Resources Devoted to Science and Technology* ('Canberra Manual'), Paris 1995.

The ABS also published an earlier version of *Human Resources in Science and Technology (HRST), Australia, 8149.0* in 1996.

This analysis does not specifically identify biotechnology in either the measurement of the supply of or the demand for biotechnology personnel. This is because biotechnology is not separately identified in the classifications adopted in the survey, namely the qualifications classification (ASCED) or the occupation classification (ASCO).

It is possible that the ABS could look at compiling a HRST publication again in the next few years after the main outputs associated with 2006 Population Census have been released. However, it would first be necessary to develop an appropriate methodology to identify biotechnology occupations and qualifications before such an analysis would be able to separately identify these human resources.

6.12 - Venture Capital Survey

The ABS undertook the first survey for the period 1999-2000, and has since undertaken the survey annually with the partial financial support of DITR. The latest survey cycle was for the 2004-05 reference year, with results published in *Venture Capital, Australia* (ABS Cat. No. 5678.0).

This survey aims to cover all investments by resident venture capital vehicles in enterprises that meet the following definition of venture capital:

.... 'high risk private equity capital for typically new, innovative or fast growing unlisted companies. A venture capital investment is usually a short to medium-term investment with the potential of high capital gains on divestment (rather than long-term investment involving regular income streams)'.

Biotechnology is one of the activities separately identified in the survey. Thus it is possible to identify those investments into biotechnology organisations and provide data in respect of them. The data items about which data could be compiled include:

- Value of venture capital investment in investee companies
- Source of funds of investment vehicles
- Value of investment by venture capital investment vehicles in investee companies
- Value of investment in investee companies, by location of investee company head office
- Value of investment in investee companies, by industry of investee company
- Value of investment in investee companies, by stage of investee company

6.13 - Integrated Business Characteristics Strategy (IBCS)

This strategy has yet to be implemented but is included here as it represents the longer term strategy and direction proposed by the ABS.

The aim of the IBCS is to integrate the collection of a wide range of business characteristics data collected by the ABS. The IBCS will feature data on key business characteristics, including those related to business use of information technology and innovation (presently collected in separate surveys). The core (annual) characteristics data of the Business Characteristics Survey (BCS, the survey vehicle) will be part of Module One and this will facilitate longitudinal analysis as providers will remain in the BCS for up to 5 years in successive survey panels. Module Two will be biennial and either business use of information technology or innovation will be the alternating focus. The third Module of the IBCS will be a contestable, user funded option able to be responsive to policy priorities informed by user consultation. Module Three could therefore potentially include questions on biotechnology, depending on other priorities. Over time, including questions on Module Three would not only contribute to an understanding of the economy-wide penetration of biotechnology and its growth over time, if repeated, but it would also allow for the analysis of biotechnology using business characteristics such as innovation and performance.

An important allied component of the IBCS is the use of Australian Taxation Office financial data from either the Business Activity Survey or the Business Income Tax data. It is hoped that time series information at the individual business level from this source will further enrich the longitudinal analytical capabilities of the strategy, known as the Business Longitudinal Database.

The IBCS will come into effect with the release into the field of the BCS in February 2007 with the survey reference period of 2005-06. This iteration will have a Module Two focus on business use of Information Technology (IT). The BCS will be repeated annually using the IBCS approach.

6.14 - International Trade in Biotechnology Produced Goods

ABS produces regular statistics on the import and export of goods into and out of Australia. These statistics are based on Customs records and the results are published at a very detailed level of commodity. The classifications used for the Australian statistics are based on the international classifications – the so-called Harmonised System. Unfortunately these classifications do not differentiate between biotechnologically produced goods and those produced using other processes – thus they are not adequate for producing statistics separately identifying the range of biotechnologically produced goods.

For the purposes of measuring trade in "advanced technology" products, the US Census Bureau has developed an Advanced Technology Products list which represents leading technologies in the selected fields. For biotechnology, the list appears to be entirely based on biologics[23]. Although this list is not consistent with the definition of a 'biotechnology product' adopted in the OECD framework, it provides an example of the use of international trade data to provide statistical indicators about biotechnology. This approach does not account for products which can be produced using a chemical or biological process. Adding such products to the list would not give an accurate quantification of the export of biotechnology products. ATP import and export items used for this purpose for 2005 are shown below.

IMPORTS

Harmonized System Code	Description
2933294500	DRUGS (EXC AROM OR MOD AROM) CONT AN UNFUS IMI ETC
2937110000	SOMATOTROPIN, ITS DERIVS & STRUCT ANALOGUES
2937190000	POLYPEPTIDE, PROTEIN & GLYCOPROTEIN HORMONES,NESOI
2937231010	ESTROGENS OF ANIMAL OR VEGETABLE ORIGIN
2937231050	PROGESTINS OF ANIMAL OR VEGETABLE ORIGIN, NESOI
2937235010	ESTROGENS NOT DERIV FROM ANIMAL OR VEGETABLE MATER
2937235020	PROGESTERONE NOT DERIV FR ANIMAL OR VEGETBLE MATER
2937235050	PROGESTINS NOT OF ANIMAL OR VGTABLE ORIGIN, NESOI
2937399000	CATECHOLAMINE HORMONES, DERIVS & ANALOGUES NESOI
2937409000	HORMONE AMINO-ACID DERIVATIVES, NESOI
2937500000	PROSTAGLANDINS, THROMBOXANES & LEUKOTRIENES
2937900000	HORMONES, PROSTAGLANDINS, ETC NESOI
2940002000	D-ARABINOSE
2940006000	SUGARS, CHEM PURE (EXC SUCROSE,LACTOSE,ETC) NESOI

[23] Biologics as identified in *A Framework for Biotechnology Statistics* (OECD 2005) 'consists of therapeutic products derived directly from living organisms; these include vaccines, human blood and plasma, proteins and monoclonal antibodies. Major biotechnology drugs, such as humulin, interferon, epoetin, etc., fall under biologics'.

3002100190 BLOOD FRACTIONS NESOI
3002200000 VACCINES FOR HUMAN MEDICINE
3002300000 VACCINES FOR VETRINARY MEDICINE
3002905150 HUMAN BLOOD;ANIMAL BLOOD PREPARED FOR THERAP,NESOI

NESOI = not elsewhere specified or included

EXPORTS
Schedule B
Code Description

2937110000 SOMATOTROPIN, ITS DERIVS & STRUCT ANALOGUES
2937190000 POLYPEPTIDE, PROTEIN & GLYCOPROTEIN HORMONES,NESOI
2937230000 ESTROGENS AND PROGESTINS
2940002000 D-ARABINOSE
2940006000 SUGARS, CHEM PURE (EXC SUCROSE,LACTOSE,ETC) NESOI
3002100140 FETAL BOVINE SERUM (FBS)
3002100190 BLOOD FRACTIONS NESOI
3002200000 VACCINES FOR HUMAN MEDICINE
3002300000 VACCINES FOR VETRINARY MEDICINE
3002905120 ANTIALLERGENIC PREPERATIONS, NESOI
3002905150 HUMAN BLOOD;ANIMAL BLOOD PREPARED FOR THERAP,NESOI

NESOI = not elsewhere specified or included

Note: biotechnology in the Advanced Technology Products "Focuses on medical and industrial applications of advanced scientific discoveries in genetics to the creation of new drugs, hormones and other therapeutic items for both agricultural and human use"[24]

In Australia, imports are classified according to the Combined Australian Customs Tariff Nomenclature and Statistical Classification (10-digit classification) and exports according to the Australian Harmonised Export Commodity Classification (8-digit classification). These classifications are both based on 6-digit items of the Harmonised System (and are equivalent at that level) and have been extended for Customs purposes and statistical purposes. US trade classifications are also based on 6-digit items of the Harmonised System and with respect to the Advanced Technology Products codes listed above, align at the 6-digit level with the Australian classifications. However, care should be taken in using the Advanced Technology Products codes at the 6-digit level as the 10-digit codes may not represent a complete set of the US sub categories.

International trade data are produced by the ABS on a monthly basis. Detailed trade statistics are available from the ABS on request.

[24] See US Census Bureau website, http://www.census.gov/foreign-trade/reference/glossary/a/atp.html

The next 5 yearly revision of the Harmonised System is due for completion in January 2007.

6.15 - Non-ABS Sources of Data

Members of the BSUG were asked to identify the sources of biotechnology data used in their organisations. These sources are set out below. Note that many of these data sets are not available to the public, and in some cases may not be available outside the home agency, at this time. In addition, the Ernst & Young Survey is also discussed.

6.16 - Biotechnology Australia

Public Awareness Surveys which cover the public's awareness of and attitudes towards: biotechnology generally, biotechnology regulation, stem cells, cloning, GM food and gene technology in medicines and transplants.

6.17 - Department of Industry, Tourism and Resources (DITR)

- IP Australia: data available upon request about Australian biotechnology patents and patent applications.
- Company data from the Australian Stock Exchange on listed biotechnology companies.
- Invest Australia has monthly updates on biotechnology deals done with Australian organisations, the value of the deals, type of deal eg partnership, license etc, country deal is with.
- *Biotech Business Indicators* released quarterly by DITR including market capitalisation, new public listings, partnerships, mergers and acquisitions, capital raising, patents and grants, clinical trials.
- Data available on request from AusIndustry about grants under Commercial Ready given to biotechnology projects. Some information also available about applications.
- Historical data available on the Biotechnology Innovation Fund, now part of Commercial Ready.
- Data about biotechnology companies accessing other Australian Government programs including small business programs, the Commercialising Emerging Technologies Program (COMET) and the Pharmaceutical Partnerships Program (P3).
- Data available from AusIndustry on venture capital programs - Venture Capital Limited Partnerships, Innovation Investment Fund and Pre-Seed Fund.

6.18 - Department of Education Science Training (DEST)

The Australian Research Council (ARC), which is funded by the education portfolio, collects data from research grant recipients. The ARC receives final reports

including information about publications, patents, licenses and any other commercialisation activity from grant recipients, which are lodged online through a secure website. This information is **not** publicly accessible. Approximately one-fifth of data collected is biotechnology data.

The ARC also collects annual statistical information across six broad disciplines, one of which is biological sciences and biotechnology. Some statistics are publicly available on the ARC website. Some of these broad indicators include:

- status by discipline group;
- incidence of international collaboration;
- rural and regional application funding by discipline;
- number of industry partners and pledged contributions by industry type; and
- pledged industry partner contributions by institutions.

DEST also administers the Cooperative Research Centres (CRC) Program which funds a number of biotechnology specific centres including the Environmental Biotechnology CRC, CRC for Bioproducts, CRC for Sugar Industry Innovation through Biotechnology, Molecular Plant Breeding CRC and others. Information is collected by DEST on the CRC activities in a similar format to the ARC.

6.19 - Department of Agriculture Fisheries and Forestry (DAFF)

The Australian Bureau of Agriculture and Resource Economics (ABARE) and the Bureau of Rural Sciences (BRS) are both agencies under DAFF. ABARE undertakes a range of data collection across the agriculture and resources sectors but does not identify biotechnology in its regular information collections. Both ABARE and BRS have been commissioned to provide reports on specific aspects biotechnology in recent years.

6.21 - Queensland Office of Biotechnology

The Office of Biotechnology currently contracts external service providers to undertake a review of the Queensland biotechnology industry, with national and international comparisons, on a biennial basis, using a survey form direct to the industry and other secondary data such as the ABS. The most recent survey was undertaken in 2005 by Innovation Dynamics and contained the following indicators:

- Number and type of organisations in the biotechnology industry in Queensland (companies and research institutes)
- Sector distribution of organisations in Queensland (eg Human Therapeutics, Agbiotech, Food and/or Beverages, etc - companies and research institutes)
- Level of employment of Queensland biotechnology enterprises (companies and research institutes) and classifications (eg Admin, Marketing, R&D, Manufacturing, etc)
- Level of employment comparisons nationally and internationally (NB the data was inconsistent for the international comparisons)
- Average wage of bioscience workforce in Queensland with international

comparison (NB international data was inconsistent). No national data was available
- Market capitalisation of listed biotech companies in Queensland, Australia, and selected overseas countries
- Bioscience-related exports
- Revenues from Bioscience Activity - Queensland, Australia and international
- Innovation Dynamics tried to survey the application of biotechnology in other sectors but the question was not answered clearly
- Patents granted - Queensland, Australia, and selected overseas countries
- Angel / Venture Capital Investment Secured - Queensland, Australia, the US and Canada
- Spin-off companies formed - Queensland, Australia, the US and Canada
- Clinical Trials - Queensland, Australia, international
- Alliances established - Queensland, Australia, selected overseas countries (New Zealand)
- Licences issued - Queensland, Australia, the US and Canada
- Citations / publications - Queensland, Australia, selected overseas countries
- R&D expenditure, government - Queensland, Australia, Internationally
- R&D expenditure, bioscience firms - Queensland, Australia, Internationally
- Science graduates - Queensland, Australia, selected overseas countries
- Bioscience graduates - Queensland, Australia (no data was available for international comparison)

The Queensland Office of Biotechnology has indicated they currently conduct twice-yearly surveys and will be collecting data again in late 2007 for the 2006/07 financial year.

6.20 – BioInnovation SA

BioInnovation SA, in collaboration with Ernst & Young, conducts a bi-annual survey of the South Australian bioscience industry sector collecting data including: the current size of the sector in terms of company numbers, number of employees, skill sets of employees, areas of focus, future needs and the current challenges being faced by companies as well as a range of other data sets.

6.21 – Department of Industry, Innovation and Regional Development Victoria

The Victorian Government commissioned Blake Industry and Market Analysis Pty Ltd to produce *Victorian Life Science Industry Analysis*, which was released in March 2006. This report included data on listed Victorian biotechnology and pharmaceutical companies, capital raised by Victorian biotechnology companies, numbers of employees in the life science sector, numbers of clinical trials completed and underway and R&D expenditure. It should be noted that as it looked at the life science Industry, this includes biotechnology but is broader than the sector defined in this IDP.

6.22 - Ernst & Young Survey

Ernst & Young conduct a regular survey of biotechnology companies in Australia, as part of their overall international program. The data is mainly obtained from the Australian Stock Exchange and other freely available reports.

It is unclear precisely what definition of a biotechnology company is being applied by Ernst & Young in its work – almost certainly it will be somewhat loose in definition and is likely to relate to some of the large medical devices companies as well as those included in the biotechnology sector definition adopted in Section 2.

The data items published by Ernst & Young are: revenues; R&D expenditure; net income; number of employees; market capitalisation; assets; and number of companies.

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

In this Section, the gap between the data that is required for statistical purposes and that which is available from existing sources is examined. Some alternative strategies to meet this unmet demand are then considered.

It should be noted that the aim is not to replace all data collection activities but to address the gaps in information that are required. However, in the process of addressing information gaps, opportunities to reduce duplication and respondent burden should also be addressed.

7.1 - Highest Priority Requirements

The summary conclusions from Section 5 of the highest priority data requirements for the measurement of biotechnology were as follows:

- 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 survey, 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, the people and the environment.

This list can then be matched to the list of available information, providing the methodology to assess the gaps in the currently available data for biotechnology.

7.2 - Unmet Demand

As can be seen from below, 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.

7.3 - Biotechnology R&D data

A supplementary survey on biotechnology R&D data was conducted by ABS as part of its regular business enterprise sector R&D surveys in 2003-04. However, this survey was conducted on a "one-off" basis. To meet the stated need for biotechnology R&D data for the business enterprise sector it would be necessary to institute a similar survey into the regular survey schedule or to collect it independently as part of a special biotechnology survey.

A truncated survey for the Government and Private Non-Profit Organisations sector was conducted for 2004-05 and the results were released in October 2006. However, as the range of requirements for biotechnology R&D data is the same between the business enterprise and government sectors, the current survey requires enhancement to meet the user needs specified in this IDP. To meet the stated need for biotechnology R&D data for the government sector, a regular survey along the lines of the business enterprise survey will need to be fully incorporated into the ABS survey cycle or collected independently as part of a special biotechnology survey.

There has been no data collected from the Higher Education Sector R&D survey about biotechnology. It could be expected that it will be necessary to institute a similar data collection for this sector as is proposed for the business enterprise and general government sectors - either as part of the regular R&D survey program or as part of a special biotechnology survey.

In collecting data on the higher education sector it is important to distinguish between research and other higher education activities. A characteristic problem in the higher education sector is delineation between teaching and research. Some institutions counted most university professors as researchers in full time employment resulting in reporting all their earnings as R&D expenditure. This will obviously inflate the number of researchers in full time equivalent and R&D expenditure in the higher education sector.

7.4 - Biotechnology Innovation Data

There has been no collection of innovation activities utilising biotechnology products or practices in Australia. While the ABS Innovation survey last conducted in respect of 2003 could be used to provide the type of information required if a biotechnology identification question was added, it is not clear that such surveys will be conducted by the ABS in the future. It is more likely that the Innovation Survey will be replaced by the introduction of the Integrated Business Characteristics Survey. That particular

survey would appear, at face value, to provide the opportunity to collect the necessary data. However, it is too early yet to say if the sample size and structure would be suitable to allow adequate measurement of innovation in biotechnology products and processes. It is also not clear whether all the required data items would be included in the survey. It is possible to include innovative biotechnology businesses in a special biotechnology survey if they can be identified as part of the preparation of the framework for that survey.

7.5 - The Use of Biotechnology Processes

There is currently no data available about the use of biotechnology processes by organisations in Australia. Hence it will be a requirement to institute some form of collection to measure this attribute and the outputs from the use of biotechnology products.

7.6 - Public Perceptions Data

As noted in section 6, BA regularly commissions public perceptions surveys measuring people's level of awareness of biotechnology issues, their understanding of these issues and their concerns for them. This data is available from BA and is sufficiently reliable for their policy purposes.

7.7 - Economic Significance of Biotechnology Sector

The only data available about the economic significance of the biotechnology sector is that obtained from the Ernst & Young surveys mentioned in Section 6 above. In that survey, Ernst & Young compile and publish statistical indicators of the revenues, R&D expenditure, (net) income, employees, market capitalisation, value of assets and number of companies. What is unclear is how closely the coverage of this survey aligns with the concept of the biotechnology sector and biotechnology-related industries as defined in Section 2. The data collected tends to be that which is freely available from standard accounting records and hence is unlikely to show dissection of revenues, expenses and the like, broken down into components relating to biotechnology products separately from other components.

The economic significance of biotechnology should preferably also be measured in ways other than just the value of certain performance characteristics relating to a particular organisation or group of organisations. Users also want to be able to measure the economic significance in other ways –such as their contribution to the national innovation system, to international trade and the like. There is no data available to undertake these other measures at this stage. It should be noted that there are some indicators that can be drawn about international trade data by using the classifications discussed earlier in Section 6. The enhanced ABS Business Enterprise R&D survey conducted in 2003-04 has provided some measures of the economic significance of biotechnology to the national innovation system, insofar as it provides some measures of biotechnology R&D which are compatible with general R&D performance.

7.8 - Impact of Biotechnology

One of the key requirements for biotechnology data is to be able to measure the economic impact of biotechnology, and its impact on the population and the environment. Currently there are no statistical indicators to measure impacts of biotechnology available in Australia. Many users regard this requirement as one that can only be met by using modelling techniques. While this may be correct, such indicators require a long time series before sufficient data is available for the modelling to be effective. In the interim, it is likely that some indicators will be required to give a partial measure of the impacts of biotechnology on the economy, society and the environment.

7.9 - Alternative Strategies to Meet Unmet Demand

There are broadly two different strategies that could be adopted to meet the unmet demand described above. These are:

Option 1: Conduct a specific biotechnology survey covering all the known organisations of interest measuring their biotechnology activity. This is the approach that has been adopted in many countries round the world. That survey would need to be able to identify biotechnology R&D performers, biotechnology innovators, users of biotechnology processes, intermediate users of biotechnology products, both as an input into subsequent productive activity (whether biotechnology activity or not) or consumers of biotechnology products as an end product. This approach was part of the methodology developed and discussed in the report prepared for DITR on the Contribution to the Economy project[25]. As proposed in that report, the use of a biotechnology "flag question" in a range of ABS surveys would facilitate development of the list of targets for a biotechnology survey.

Option 2: Conduct a set of compatible collections for each of the biotechnology activities being measured. This might involve separate collections measuring biotechnology R&D, biotechnology innovation, the use of biotechnology processes and one measuring users of biotechnology products.

While either of these Options would meet most high priority needs, they both need to be supplemented by other data sets for some specific requirements. Foremost in these are:

- the collection of perceptions data currently compiled on behalf of BA – this is rated as a high priority requirement for Policy Issue 11 **-** Understand public perceptions towards biotechnology and ensure there is informed debate on biotechnology issues.
- the compilation of imports and exports data using ABS and Customs data – this is rated as a high priority requirement for Policy Issue 10 - Better understand the social, health, environmental and economic impacts of biotechnology in Australia including on individual industries, States and regions – especially rural areas

[25] A proposed methodology to identify biotechnology's contribution to the economy, ACIL Tasman and Innovation Dynamics, Dec 2005

- the compilation of indicators on the number of patents applied for and granted in biotechnology, both in Australia and overseas. This data can be derived from the various Patent Offices in different countries. This was regarded as an "other high priority" requirement for indicators.
- the compilation of indicators on the number of papers, articles and citations of biotech R&D. This was regarded as an "other high priority" requirement for indicators.

The two options as set out are not mutually exclusive but may be used in combination such that a specific biotechnology survey as in Option 1 could be used to collect some data and other data being collected as per Option 2, leveraging off existing data collection activities.

7.10 - A Comparison of Options 1 and 2

Option 1 has been used by many countries fairly frequently over the past decade. It has been fairly effective at meeting many of the known user requirements as biotechnology activities have been carried on by only a relatively small number of organisations. However, this may not be true in the longer term. While the number of biotechnology R&D performers may remain relatively small and easy to identify, it is highly likely that biotechnology innovation and the use of biotechnology processes will become much more widespread. This will create difficulties in being able to consistently measure the level and change in biotechnology activity over time.

When one attempts to measure the users of biotechnology products – both intermediate and final consumption users – it is likely that there will be many more users that are "unknown" and hence cannot be measured using a list–based approach that is generally adopted in this instance. The way that has been proposed for overcoming this problem in Australia is to identify users with a "flag question" in a range of ABS surveys.

An advantage of the approach outlined in Option 2 is that the outputs will be less reliant on having to develop a reliable list on which to base the collections. The drawback to Option 2 is that it will be more costly; there are a number of surveys to develop and conduct, rather than just one. Thus the actual cost of the survey program is likely to be much greater under Option 2. There will also be a cost involved in aggregating the data from the range of surveys.

Option 2 could be expected to provide biotechnology data that is much more compatible with other economic data series. In terms of the data about biotechnology R&D, that data will be fully compatible with the data for other types of R&D and hence provide far greater analytical value to it. The same situation would occur in respect of biotechnology innovation data if ABS was to add some biotechnology identification questions to a standard innovation survey.

The ABS has proposed a new methodology for the collection of information about specific business characteristics of interest, such as innovation. This is to collect business characteristics data as part of the Integrated Business Characteristics Survey (IBCS). Prima facie, it appears that the new strategy should be able to provide the

necessary infrastructure to develop reliable indicators of both biotechnology innovation and the diffusion of biotechnology processes through industry. The ABS is proposing to have three modules in their IBCS - the second of these is available to cover innovation while the third is available to cover other areas of interest. It could therefore be used to measure the diffusion of biotechnology processes through industry. Of course, much will depend on the size and scope of the IBCS.

An alternative to conducting a separate biotechnology diffusion survey might be to add some additional questions to some of the ABS Economic Activity Surveys (EAS), such as those relating to the Agriculture, Mining and Manufacturing Surveys. The problem with this approach is that it does not take an economy wide view, rather a view that provides data only about selected industries. However, it could arguably provide a useful tool for more detailed studies of industries of interest, such as agriculture.

Biotechnology statistics users have indicated a high degree of importance should be attributed to the measurement of the significance of the biotechnology sector. Currently most users around the world tend to use statistics about the size of the biotechnology sector for this purpose - as evidenced in the statistics published by the OECD in their 2006 Compendium publication referred to in Section 1. This IDP contends that such an approach is an important first step, but the economic significance of biotechnology can only be measured by a whole range of indicators such as the contribution of biotechnology organisations to international trade and the national innovation system rather than just a small number of indicators about the size of the biotechnology sector (perhaps including biotechnology-related organisations). Option 1 offers depth of data on biotechnology activity, whereas Option 2 offers breadth in coverage of biotechnology activity/use across the economy. Option 1 and Option 2 can therefore be seen as complementary approaches. Because of its breadth, some may argue that Option 2 above is a preferred option to Option 1 in respect to the measurement of the significance of the biotechnology sector and the impacts of biotechnology on the economy, the population and the environment. However, policy agencies do not believe that Option 2, on its own, will provide sufficiently detailed data to make a valuable contribution to national and state policies. Instead a combination of the two options is desirable, with a specific survey being conducted to gain in depth data across a range of priority areas which would be supplemented by an Option 2 approach to provide a greater breadth of data in less detail according to the policy needs of the users of the data.

7.11 - Implementation Strategy

As indicated above in Section 4, 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 which incorporates activities from both **Option 1** and **Option 2**. 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 (**as in Option 1 above) and implement it on a regular basis. Thus 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 to 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 an Option 2 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:

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

7 12 - The Timetable for Implementation

It is important to recognise that this staged implementation is a relatively long-term strategy. There is much work that needs to be done before all the proposed collections could be implemented. If the uptake of biotechnology products and processes throughout the economy does not grow, it would be unlikely that Stage 4 would be viable.

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 DITR 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:

v. dedicated biotechnology organisations;
vi. biotechnology active organisations;
vii. biotechnology-related organisation; and
viii. 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.

The BSUG is strongly in favour of commencing data collection through an experimental survey in 2006/07.

7.13 - International Collaboration

The OECD and many other countries are becoming increasingly active in the compilation of biotechnology statistical indicators. Users of biotechnology statistics in Australia have indicated the importance of having internationally comparable data on biotechnology. As such, international comment was sought in the development of this IDP. 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. It is therefore proposed that ABS and BA should look to opportunities to raise the development of a new international standard for biotechnology statistics through the relevant OECD committees, namely the Working Party on Biotechnology and the National Experts on Science and Technology Indicators. As such the IDP will be made available to OECD members at a Workshop on Biotechnology Outputs and Impacts being held in Paris in December 2006.

In seeking to produce internationally comparable data the timeliness of indicators may have an impact as statistical indicators must be comparable over time as well as between countries. Methodologies to improve the timeliness of statistics and accuracy may be a pre-requisite for effective international collaboration.

Glossary

ABARE	Australian Bureau of Agricultural and Resource Economics
ABS	Australian Bureau of Statistics
ANZSIC	Australian and New Zealand Standard Industrial Classification
ARC	Australian Research Council
BA	Biotechnology Australia
BCS	Business Characteristics Survey
BRS	Bureau of Rural Sciences
BSUG	Biotechnology Statistical Users Group
DAFF	Department of Agriculture, Fisheries and Forestry
DEH	Department of the Environment and Heritage
DEST	Department of Education, Science and Training
DITR	Department of Industry, Tourism and Resources
DoHA	Department of Health and Aging
EAS	Economic Activity Survey
IBCS	Integrated Business Characteristics Survey
ICT	Information and Communication Technology
IDP	Information Development Plan
NBS	National Biotechnology Strategy
OECD	Organisation for Economic Coordination and Development
R&D	Research and Development