

**Response to the Tasmanian
"Bioprospecting: Sharing the benefits for
Tasmania" Position Paper**

AusBiotech
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AusBiotech Ltd
ABN 87 006 509 726
Level 1, 322 Glenferrie Road
Malvern Vic 3144 Australia
Telephone: (03) 9828 1400
Fax: (03) 9824 5188

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Introduction

AusBiotech is the national industry organisation that represents one of the key industries of the future: biotechnology.

It is through a properly supported biotechnology industry that we will see solutions emerge to confronting global issues – whether they are in health, climate change, food or fuel. Biotechnology will be the 'enabler' to assist achievement of breakthroughs and drive wealth creation in Australia.

AusBiotech represents an industry that is the sixth largest of its kind in the world. The organisation is the third largest biotechnology industry organisation in the world and runs the most successful international annual conference in the Asia-Pacific region.

AusBiotech represents 3000 members covering the human health, agricultural, medical device, environmental and industrial sectors in biotechnology. AusBiotech is dedicated to the development, expansion and prosperity of the Australian biotechnology industry by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

We agree with Minister Llewellyn's forward in the Position Paper wherein he states that Tasmania's biodiversity has the potential for significant environmental, economic and social benefits. Tasmania does have unique flora and fauna with the potential to supply new bioactives for a number of industries from health to agriculture.

This submission from AusBiotech has addressed areas pertaining to Bioprospecting, an area of interest to members both in Tasmania and across Australia.

To compile this submission, AusBiotech sought a range of views from its members, including senior executives from large and small companies; as well as its advisory Board and staff.

The response from AusBiotech to the position paper

AusBiotech has responded to questions in the Position Paper that are of interest to members. Those questions are as follows:

Question 1: Do you agree with these key policy objectives? What other objectives should the policy aim to meet?

AusBiotech agrees with the key policy objectives of:

1. Realising the benefits to the State's economy and environment that come from managed access to, and benefit sharing from, those resources;

The biodiversity in Tasmania has yet to be explored in detail. As such, many potential bioactives have yet to be found. Companies such as Marinova and Botanical Resources have either developed products or are investing in bioactives sourced from Tasmanian biota. Both of these companies are based in Tasmania and sell on the global scale. These are examples of maximising the benefits to Tasmania.

It is probable that further bioprospecting will identify bioactives for other markets. Should the bioactives be in the health field, it is likely that the discovering organisation will be based outside of Tasmania. In these cases, the benefits to Tasmania will not be as great in the first instance, however, this situation should not be discouraged as secondary benefits to Tasmanians such as new medicines or agricultural crops and compounds may flow out of the discovery.

2. Simplifying access and benefit sharing arrangements as much as possible;

Clear processes allow effective discovery of biological resources while minimising regulatory burden and oversight. AusBiotech strongly supports the development of clear and simple processes that minimise costs to both the discovering organisation as well as the Government. In addition to a clear and simple process, defined timelines allow for certainty in the process.

Recommendation 1:

A single Government agency should be responsible for the preparation of Collection Permits and such permits should cover all relevant legislation allowing bioprospecting to take place.

As bioprospecting activities have a high probability of not producing a commercial outcome, any costs for Collection Permit should be minimal and reflect the time required to prepare the permit. As it is likely that research institutes would undertake the majority of the work, if costs were associated with Permits, they should be equal for all parties so that companies do not subsidise research organisations.

Recommendation 2:

Costs for Collection Permits should be minimal, reflect the time required to prepare the permit and be equal for all parties. Cost recovery should not be an objective of the Permit fee.

To provide clarity of process, a statutory timeframe for processing permits is required. Defined timeframes allow activities to be planned to occur at a time that suits the biological stage (for example the maturity or reproduction age) of resources and allow for project planning or research activities.

Recommendation 3:

A statutory timeframe for processing permits is required.

Permits should be for a defined period of time and renewal of permits should be allowable if the conditions of the original permit have not been breached. Such a system allows for the checking of validity of permits from an enforcement perspective while allowing a streamlined process for extending collection periods.

Recommendation 4:

Collection Permits should be for a defined period of time and renewal of permits should be allowable if the conditions of the original Collection Permit have not been breached.

3. Encourage investment in bioprospecting research in Tasmania

The most effective way to encourage investment in bioprospecting in Tasmania is to build local capabilities (for example Taxonomists to identify local flora and fauna) as well as scientific knowledge. Grants that allow Tasmanian researchers to access infrastructure elsewhere in Australia would assist in building local capability without purchasing expensive infrastructure or duplicating capabilities that already exist. Funding to encourage bioprospecting activities conducted in Tasmania would increase the interest of local and international organisations.

Recommendation 5:

Tasmania should consider funding bioprospecting activities conducted in the State on a competitive basis.

4. Ensure that activities are conducted in a manner that does not negatively impact on the sustainability of Tasmania's diverse biological resources.

Neither the industry nor the State has an interest in impacting negatively upon the sustainability of biological resources.

It may be that collection of species that are listed as protected or endangered in Tasmanian habitats, or sampling in sensitive areas may be requested. In sensitive areas or with endangered species, collection activities may be undertaken by a Government Agent in the presence of the Permit Holder, or by the Permit Holder under supervision of a Government Agent at no additional cost to the Permit Holder. Such a system would allow prospecting in areas that are considered to be sensitive under guidance of managers of those resources. The lack of Government resources to supervise collection activities should not be used as a mechanism to slow or prevent bioprospecting.

Recommendation 6:

In sensitive areas or with endangered species, collection activities may be undertaken by a Government Agent in the presence of the Permit Holder, or by the Permit Holder under supervision of a Government Agent at no additional cost to the Permit Holder.

Recommendation 7:

Permit Holders should report the number of samples collected and approximate weight/number of organisms, the location and the time and date of sampling. For confidentiality reasons, this information should not be made public in the context of Bioprospecting.

What other objectives should the policy aim to meet?

The objective of the policy is consistent and wherever possible harmonised with other States and Territories.

Question 2: Do you agree with these key outcomes? Are there any other outcomes that the policy should aim to achieve?

The outcomes described are a positive step forward for the development of a bioprospecting industry in Tasmania. These outcomes are consistent with the first four recommendations made by AusBiotech in response to key objectives.

Question 3: Do you agree with these guiding principles? Are there any other principles that should guide the policy approach to bioprospecting in Tasmania?

The Guiding principles are consistent with other jurisdictions. AusBiotech has developed some recommendations to articulate this further:

Recommendation 8:

As with other jurisdictions with legislation in place, the Tasmanian Government should not be party to benefit sharing agreements for access to biodiversity on private land or traditional Indigenous knowledge.

There is a concern that without Government intervention, such access agreements could favour the party desiring to access a particular biological resource as they have more knowledge about its potential worth than any one landowner or Indigenous community. This concern does not include the developmental cost of products derived from biological resources or the high likelihood of failure of biologically-derived therapeutic drugs. One mechanism for the Government to assist with this process would be to consult with industry and develop template benefit sharing agreements which could be drafted by the Government and placed on a website for public access and use by the company and the land holder.

Recommendation 9:

In consultation with Industry, The Tasmanian Government should develop template benefit sharing agreements which could be placed on a website for public access and use by the company and the land holders.

Bioprospecting activities have the potential to provide valuable data on the organisms that have been sampled including population numbers, distribution and genetic variability that may prove too costly for Government Departments to generate. However, research institutions and companies may consider some information aspects to be intellectual property, to be proprietary information or business secrets. This need should be considered in the context of the data that may be advantageous for the protection of Tasmanian biota. To balance these conflicting positions, bioprospecting entities should report the number of samples collected and approximate weight/number of organisms, the location and the time and date of sampling. For confidentiality reasons, this information should not be made public in the context of bioprospecting.

Recommendation 10:

Permit Holders must notify the Government Agent when a Benefit Sharing Agreement with a landholder has been reached. There is no need to include in the notification the details of the Agreement as these details may be confidential.

The general consensus of policy positions in other states such as Victoria, is that micro-organisms cultured from individuals are the property of that individual. An example of this is gut flora that is used to develop probiotics for food cultures. This positions is reasonable and logical, therefore should be outside the scope of this policy.

There is additional difficulty in demonstrating if a micro-organism is endemic to an individual, locality or State. Due to the difficulties in dealing with micro-organisms and the likely low impact of sampling, an exempt status would be most appropriate for both a permit system. Should there be an interest in demonstrating the origin of a micro-organism, the onus of proof as to whether a micro-organism is endemic or not should lie with the State

Recommendation 11:

Organisms cultured from individuals are considered to be the property of that individual.

Recommendation 12:

The onus of proof as to whether a micro-organism is endemic or not should lie with the State rather than the organization working with that material.

As Tasmania has a patchwork of land and water that is held by various Government jurisdictions in addition to freehold land, an instrument that provides clarity would be welcomed. To facilitate identification of parties that would be involved in negotiations on a parcel of land, a Geographic Information System should be made available where researchers and companies can examine ownership of areas of interest. This system should also identify waterways and identify

marine parks and jurisdiction ownership out to the boundary of Australian waters.

Recommendation 13:

To facilitate identification of parties that would be involved in negotiations on a parcel of land, a Geographic Information System should be made available where researchers and companies can examine ownership of areas of interest.

Recommendation 14:

Further consideration regarding the role of micro-organisms and their application in bioremediation is required. In this situation, a service is provided rather than a product.

Question 4: Do you agree that benefit-sharing agreements should be required by law? If not, why?

It is the understanding of AusBiotech that there is an obligation under the Convention on Biological Diversity to have a benefit-sharing agreement. Such an arrangement is consistent with other jurisdictions in Australia.

Recommendation 15:

The Tasmanian Government should have clear guidelines for benefit sharing agreements for access to biodiversity on State Managed Public land.

There is a concern that without Government intervention, such access agreements could favour the party desiring to access a particular biological resource as they have more knowledge about its potential worth than any one landowner or Indigenous community. This concern does not include the developmental cost of products derived from biological resources or the high likelihood of failure of biologically-derived therapeutic drugs. One mechanism for the Government to assist with this process would be to consult with industry and develop template benefit sharing agreements which could

be drafted by the Government and placed on a website for public access and use by the company and the land holder.

In Tasmania, several Departments have an interest in bioprospecting. Additionally, future Governments may restructure Departmental portfolios to reflect their policy objectives. Government Departments administrate and operate under various Acts that apply to biological resources. AusBiotech advocates that a single Government agency should be responsible for the administration of bioprospecting covering all relevant legislation allowing bioprospecting to take place. Such a system would ensure that appropriate legislative requirements were met while providing a clear avenue for obtaining permits.

Recommendation 16:

That bioprospecting is covered by a specific Act and administrated at a single location.

Recommendation 17:

Government Benefit-Sharing Agreements, should they be required, should be processed by the same Government Agent as the Collection Permit.

Question 6: Do you have any other comments to make about this Position Paper?

Bioprospecting is an important part of biotechnology, possibly leading to new therapeutic agents for the treatment of various diseases. The ease of bioprospecting must be tempered with the desire to protect biodiversity and our natural resources. By minimizing costs to research institutions and companies, the likelihood of compliance with any Permit system is higher without requiring significant resources from the Government to ensure enforcement or imposing significant costs that prevent or minimize bioprospecting. One effective mechanism for minimizing costs is for the Government to not be party to benefit sharing agreements on Private Land and in situations concerning indigenous knowledge, a position that is consistent across other jurisdictions. The advantage of this position is reduced costs to research institutes and companies while effectively charging private

landholders to become custodians of biodiversity on their properties and in their culture.