Bioprospecting Submission

AgResearch

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1) NZ's Biological Resources

Do you think we need to have good information about bioprospecting activities in New Zealand, including the type and nature of such activities?

From a CRI's perspective, it could be very useful to have a central register of the bioprospecting that is being carried out in New Zealand. However, any register would necessarily need to recognise confidentiality around biological material that was commercially sensitive. As there are so many upfront costs involved with developing products, that investment must be protected and not be publicly available without the permission of the organisation providing the information. We would suggest a public and confidential partitioning of any central register if organisations are to be encouraged to provide information.

Additionally, a register of the main groups in NZ working in the bioprospecting field, and their fields of endeavour, would be useful for locating groups with capabilities that could be accessed. It should be noted that any register or database is only useful if it is kept current and up to date.

As a traditional knowledge holder, bioprospector and/or access provider, what are your experiences of bioprospecting in New Zealand? Can you provide any information that would be useful to develop a bioprospecting framework in New Zealand, for example, provide information about bioprospecting costs, benefits, outcomes and current benefit sharing agreements? If so, please describe them.

AgResearch undertakes a considerable amount of bioprospecting including plants (forages); endophytes (fungi within plants); bacteria from a range of areas including soil, grubs (e.g. grass grub) and the rumen; proteins derived from various organisms including insects, rumen and plants; and genes from both plants and animals.

Most of the biological material is used in research with some of it ending up in commercial applications – notably forage plants and endophytes. These have been in R&D programmes for so long that we are now working almost solely with our own material.

Bioprospecting is expensive and rarely leads to a commercial outcome. As noted in the discussion document, the chance of finding a "valuable commercial application" via bioprospecting has been rated to be between 1 in 5,000 and 1 in 250,000. If bioprospecting does lead to a commercial outcome, then there will have been significant investment to get it there. For example, AgResearch worked with endophytes for over a decade before the first commercial product was achieved and total investment was in the millions. Taking a protein or gene from discovery to a commercial product will take up to 10 years and is likely to require >$5 million investment. It should be noted that developing a commercial product has been significantly more costly that the initial discovery science.

In the development of any co-ordinated policy related to bioprospecting, it will be important to minimise costs to organisations such as CRIs or our ability to undertake research will be compromised. Research is already hugely expensive and there is fierce competition for research funding. The same costs for research apply to most NZ companies (with a number of exceptions). If administrative costs are loaded upfront against very early stage research activities, that are likely to yield no commercial results, then bioprospecting will cease.

2) On New Zealand's current frameworks to access biological resources:

Do you think the existing access frameworks would benefit from operating within a more co-ordinated and comprehensive bioprospecting framework? If so, why? If not, why not?

A more comprehensive bioprospecting framework will ultimately be useful, primarily because it provides certainty as to where an organisation stands. We are constantly hampered by WAI 262, not because it exists or may impact our work, but because we don't know how it will impact our work. This means that potential collaborators aren't interested in working with some projects because they don't know what NZ's position is on freedom to operate for NZ native organisms. In the end, certainty over freedom to operate is more critical than costs to define freedom to operate (within reasonable limits). The only caveat I would put on this is that any framework must not be over bureaucratic because it won't work if it is.

By way of example – the ERMA legislation around GM field trials is extremely bureaucratic and as a result is avoided rather than utilised as it should be. Many organisations choose to do field trials overseas rather than work through the ERMA process which is endless – this is unfortunate and NZ ultimately loses out because the work goes offshore.

If the processes around a bioprospecting framework are bureaucratic – e.g. paperwork involved in lodging a deposit, lack of confidentiality for commercially orientated work; consultation required to make use of the organism (this is the primary problem with the ERMA legislation) – who owns the organism, the landowner, Maori (which iwi), do we consult with local government or central government or both, etc – number of agencies we have to work through and so on, then either organisms will be taken offshore illegally or bioprospecting work in NZ will simply stop because it will be too hard.

Therefore, whilst a more comprehensive framework could help organisations by providing clear FTO with respect to indigenous organisms, we do not wish to see an overly bureaucratic system emerge. A likely outcome of going down the regulatory track could be the world's best policy framework, while others just get on with discovering bioactives and developing applications.

New Zealand should take advantage of our indigenous resources by supporting scientific and commercial programmes to exploit local knowledge and proximity to resources, not rely on legal thickets designed to discourage others. A more regulated, controlling environment is not guaranteed to lead to any significant measurable benefits to NZ and could in fact stifle work that is currently being undertaken by diverting resources away from science. One view held at AgResearch is that what is required is:

(a) a number of strong, well funded fundamental discovery research programmes covering plants and animals based on science excellence;
(b) a process to identify promising bioactives around which product development projects can be developed; and
(c) access to commercial funding and appropriate PD mentoring once potential is confirmed.

3) On a comprehensive bioprospecting framework for New Zealand:

Do you think that New Zealand should have a comprehensive policy framework to manage bioprospecting activity in this country? Please give reasons for your answer

Answered above. We support the idea of a framework so that we are able to identify whether we have freedom to operate in certain research areas in a straight forward manner. Currently, we find

it difficult to clearly identify who we need to consult with to ensure FTO, therefore research projects stall.

If the framework involves issuing permits, these must ensure clear FTO, or they will be worthless to us. For example, if we are granted a permit to work on a particular organism, this must ensure that we are able to patent any discoveries, and will not be caught out by the citation of tradition knowledge at the patenting stage. Additionally, any framework must be policed as efficiently as possible. There is no point in AgResearch diligently following the policies, only to find out that an overseas organisation has illegally taken the same organism and already patented the same discovery in another country.

What are your views on the proposed vision and policy principles to guide New Zealand's bioprospecting policy?

We agree with the notion of differential cost loadings against domestic and international prospectors. Most international prospectors will have a solely commercial focus. Given that, they are likely to have significant budgets and prospecting costs will be factored in accordingly. It is to NZ's benefit to have certain phases of R&D undertaken here and would align with CRI activities to partner internationally. We already put in place collaborations internationally whereby we not only wish to receive royalties or licence fees (for whatever the activity is) but also wish to have the R&D undertaken by our own research teams here in NZ – that's common practise.

4) On mātauranga Māori:

How do you think use of mātauranga Māori for bioprospecting can be most appropriately managed and protected?

Use of Maori traditional knowledge should be encouraged through providing incentives for iwi to become involved in bioprospecting. For example, by training more Maori scientists and establishing joint ventures within NZ between Maori and research providers and companies with relevant scientific and commercial skills.

What do you think of the suggestions made in this document as options to protect mātauranga Māori (a voluntary register, ensuring legally and fully mandated governance entities, a code of best practice for bioprospectors, or an advisory council to a Competent National Authority)?

As mentioned previously, we believe that a co-ordinated policy could aid AgResearch's bioprospecting activities by providing a clear route for us to ensure FTO at an early stage of research. A voluntary register is a good idea, as long as it is taken up and Maori are aware that if mātauranga Māori of relevance is not registered, then it cannot be cited at a later date in a challenge to a patent application.

Additionally, the code of best practice must not be too difficult. As mentioned earlier, the Maori consultation section of gaining ERMA approval for field trials is far too onerous. Applicants have to consult with approximately 70 individual iwi groups before they can progress their application. At least, when seriously considering a field trial, a research organisation has evidence that makes them believe that their product could be commercially viable. They will have carried out numerous experiments in controlled environments. On the other hand, bioprospecting activities are research activities. At the time of the bioprospecting, research organisations have little idea of the commercial value of their experiments. Therefore, if the system is too complicated, time consuming or expensive, organisations will simply look for alternative compounds to investigate from overseas.

5) On international bioprospecting frameworks:

The Bonn guidelines provide a number of good aspects that should be considered when developing a domestic framework. In particular, the need to clarify roles and responsibilities of users and providers and the need to have a "National Focal Point" and one or more "Competent National Authority(ies)",

Non-commercial bioprospecting activities, if regulated, must be covered by a straight forward process. Hampering fundamental exploratory research with extra bureaucracy, removing funds and time from science in order to deal with the process, will not benefit New Zealand in any way.