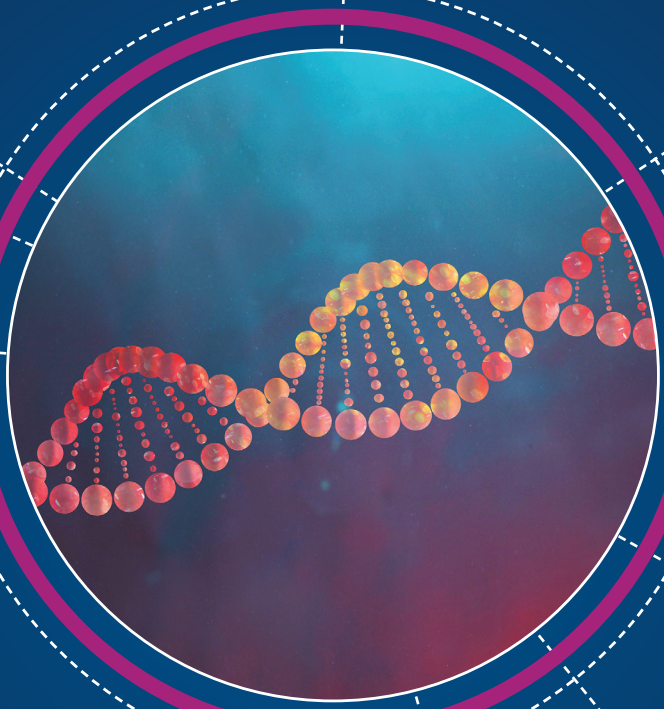
Australian Government
Department of Industry, Science, Energy and Resources

AusIndustry
R&D Tax Incentive

# Biotechnology and the R&D Tax Incentive

JANUARY 2017 (REBRANDED 2021)



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# Contents

# How to use this Guide

The R&D Tax Incentive programme provides an incentive for companies performing eligible research and development (R&D). The programme is legislated and the rules appear in the legislation[1].

### What does this guide do?

Biotechnology is a key enabling technology that is central to services, processes and products across many sectors of the economy. It drives growth and innovation across a broad range of industries, including agriculture, healthcare and the industrial sector.

This guide helps clarify how to self-assess the eligibility of biotechnology R&D activities.

A series of examples show how to identify what eligible R&D might be and how to register eligible R&D activities.

No single example (or set examples) can represent the multiple combinations of company structures, operations, management, record keeping systems and expenditure. However, the business scenarios chosen attempt to broadly examine some highlighted issues identified as facing the biotechnology industry and at various points in a business R&D cycle. These issues were identified during consultation with business, industry representatives and tax agents.

While they follow the same format, the focus of each example is different. Through this mix, the Department of Industry, Innovation and Science (the department) has aimed to illuminate the range of issues that arose during close consultation with the biotechnology sector.

In addition, the department provides information on the R&D Tax Incentive that highlights issues relevant to the biotechnology sector through business.gov.au and the *R&D Tax Incentive Information eBulletin*. This edition of the guide replaces the [2013] edition.

If your company is spending money to experimentally solve technical problems or experimentally develop new products or services, you may be undertaking some activities that qualify as R&D under the Incentive. The examples in the Guide [2] address key eligibility requirements such as:

- new knowledge,
- experimental process,

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1 See, division 355 of the *Income Tax Assessment Act 1997*. The definitions of eligible R&D activities are contained in sections 355-20, 25 and 30 of that Act.

[2] The examples used in this guidance are fictional examples created to illustrate application of the R&D Tax Incentive to hypothetical commercial enterprises. The examples reflect the department's experience with jointly administering the programme with the Australian Taxation Office. No similarity of the examples to existing enterprises or projects is intended.

- core and supporting R&D activities,
- records management and compliance assurance,
- excluded activities, and
- activities likely to be ineligible.[3]

These concepts are incorporated throughout the guide with clear examples to highlight the issues. Commentary is also provided at the end of each example to direct companies to the important linkages to other guidance that has already been published to assist companies to de-risk their participation in the programme and evaluate their own 'compliance readiness'.

This guidance should be used in conjunction with the *R&D Tax Incentive*: *A Guide to Interpretation* which is available on the business.gov.au website.

### Why is it important to use this guide?

This guide will assist companies and tax advisors to understand the eligibility requirements that apply to activities that are supported under the R&D Tax Incentive. Following this guide will:

- enable companies to self-assess and register eligible R&D, and
- help companies avoid:
  - compliance reviews, which may involve additional legal fees and tax agent fees, and
  - potential repayment of the tax benefit.

### What is eligible R&D?

Eligible R&D is defined in the legislation. Companies self-assess whether their activities are eligible R&D activities before registering under the programme.

### R&D Activities

Under the R&D Tax Incentive, R&D activities must either be:

- **Core R&D activities.** These are systematic, hypothesis-driven experimental activities with an unknown outcome and based on the principles of established science, undertaken to generate new knowledge (including new knowledge in the form of new or improved materials, products, devices, processes or services), or
- **Supporting R&D activities.** These are activities that are not part of the experimental activities, but directly support them.

### Registration

The programme is accessed by registering self-assessed R&D activities with the department (this must be done within 10 months of the end of the company's income

[3] See page 8 for summaries of the examples that show these concepts.

year) and claiming for eligible expenses relating to the registered activities in the company's tax return.[4]

Companies applying to register for the R&D Tax Incentive must self-assess their activities against the legislated eligibility criteria. When a registration is accepted this does not mean that the registered activities have been determined to be eligible. The department routinely examines registrations in detail for compliance and may contact companies for further information.

The department applies the programme's legislative requirements during its registration and compliance processes and will do so as set out in its guidance. Registering companies must maintain adequate records that can allow self-assessment by substantiating the eligibility of R&D activities. Companies must ensure expenditure claimed for R&D activities is based on genuine financial records, as is the case for any element of their tax return.

Companies may choose to use an R&D tax advisor to help prepare applications and registrations. However, the use of an R&D tax advisor is not a requirement of entry into any departmental programme and using the services of an R&D tax advisor to assist with the preparation of a registration application and offset claim does not guarantee eligibility. Companies wishing to get an assurance whether particular activities they are currently conducting, or are intending to conduct, are eligible R&D activities may apply to the department for an Advance Finding.

Eligibility must be self-assessed for activities, not for whole projects.

Companies and advisors also need to be aware of expenditure that is ineligible under the R&D Tax Incentive. This includes:

- interest expenditure (within the meaning of interest in the withholding tax rules),
- expenditure that is not at risk,
- core technology expenditure, and
- expenditure included in the cost of a depreciating asset (decline in value notional deductions may apply however).

**Note:** Readers with questions about the eligibility of expenditure items on R&D activities registered under the R&D Tax Incentive should consult the ATO through its website at ato.gov.au/business/research-and-development-tax-incentive/, by phone on 13 28 66 (for businesses) or 13 72 86 (for tax agents).

**Other relevant publications**

R&D Tax Incentive: A Guide to Interpretation – this document provides companies with the government's interpretation of the legislative requirements of the programme, including a detailed overview of core and supporting R&D activities. In addition, there are checklists and examples of activities unlikely to meet the programme requirements.

[4] Information on the benefits of the program and the registration application form are available at business.gov.au/rdti.

# Compliance Readiness

The department has released guidance to help companies that intend to register for the R&D Tax Incentive to ensure that they are 'compliance ready'[5]. Compliance readiness means having in place the systems and processes to identify, evaluate and record eligible R&D activities and expenditure on those activities. First-time participants in the programme should seek assistance from the department to make sure they understand the programme's requirements.

The following set of principles is suggested to assist companies in developing appropriate systems and processes to document their R&D activities and associated expenditure. It is important to note that the first step to ensuring compliance is reviewing and understanding the R&D Tax Incentive guidelines and requirements.

These principles have been informed by the department's experience in conducting compliance assurance activities. The principles also take into account key Administrative Appeals Tribunal decisions, where failures in a company's or tax agent's assessment of eligible R&D activities resulted in tax claims for R&D being overturned.

Maintaining contemporaneous documentation that demonstrates eligibility under the programme is essential. Companies cannot establish eligibility without maintaining detailed documentation that records the process of each activity as it develops.

**Principle 1**

Ensure that internal processes and systems allow for documentation of how activities meet eligibility requirements as part of the overall project planning and management process.

**Principle 2**

Identify and document eligible R&D activities at the time they are conducted – this improves the potential to capture associated costs in real time.

**Principle 3**

Document methods for identifying eligible R&D activities and recording expenditure associated with eligible activities. This ensures that there is a clear understanding of how information has been derived and enables the process to be repeated in future years.

**Principle 4**

Forge strong connections between those responsible for preparing and maintaining R&D Tax Incentive records and staff who understand the technical aspects of activities to enable a shared understanding of programme requirements.

**Principle 5**

Ensure that strong links have been established between activity and expenditure records.

[5] Information about *Compliance Readiness can be found at business.gov.au/rdti*.

# The Examples

Projects to develop new products or services undertaken by companies are generally comprised of activities. Eligibility under the R&D Tax Incentive cannot be self-assessed at the project level. The legislation governing the programme requires eligibility to be assessed at the level of the activities within the project.

The examples in this document illustrate the eligibility requirements of the programme in the context of activities being conducted in hypothetical business scenarios.

Table 1 provides the reader with an idea of the level of detail contained in the examples on particular concepts.

**Example 1 - BioMine** (page 11)

*Scenario*

Development of biomining bacteria capable of surviving within highly saline environments.

*R&D Tax Incentive Principles*

This example illustrates the separation **of core and supporting R&D activities** and explores the **dominant purpose** requirement of supporting R&D activities. It also highlights the importance of **record keeping**.

**Example 2 - Biofnatics** (page 17)

*Scenario*

Development of biodegradable coronary stents for use in heart surgery.

*R&D Tax Incentive Principles*

This example explores how companies register activities that need to be **conducted overseas** and looks at the eligibility of clinical trials.

**Example 3 - Encapsulate** (page 22)

*Scenario*

Development of metal protein attenuating compounds as therapies for Parkinson's disease.

*R&D Tax Incentive Principles*

This example follows an **in-licencing agreement** of **core technology** and eventual sale of **newly generated IP**, as well as some commentary on the implications of **company structure** and **who the activities are conducted for** on a company's **eligibility** to claim.

**Example 4 - TimbaFuels** (page 28)

*Scenario*

Development of technology in improving the extraction yield of ethanol from lignocellulose feedstock for generation of biofuels.

*R&D Tax Incentive Principles*

This example explores **R&D in a production environment**, and provides commentary on **dominant purpose**, **apportioning costs**, **feedstock** and **clawback** relating to grants.

**Example 5 - New Natural** (page 33)

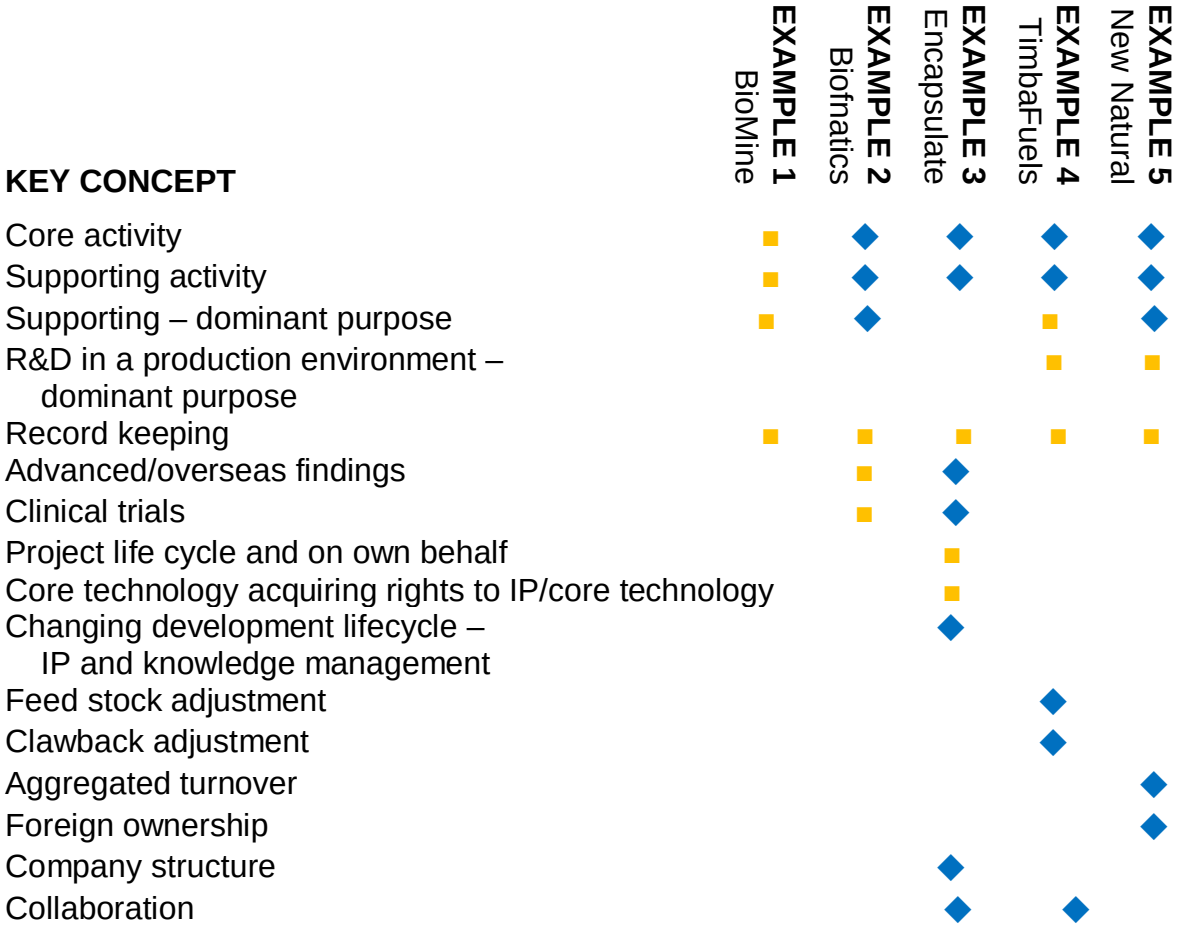
*Scenario*

Development of fungicide for protection of agricultural crops.

*R&D Tax Incentive Principles*

This example highlights the **separation of core and supporting R&D activities** in a **commercial environment** and provides commentary on **aggregated turnover**.

**TABLE 1 ·** This table demonstrates a range of relevant issues for companies and their treatment in each of the examples




- ■ Concept explored in the example and an expanded explanation given in the commentary
- ◆ Concept explored in the example
- ● Concept explored in the commentary section

Note that the following issues are administered by the ATO:

- Feedstock adjustment
- Clawback adjustment

# Example 1: BioMine

*This example explores key definitions of the R&D Tax Incentive in a practical biotechnology business scenario.*

In this context, the example presents a business scenario and commentary that applies the key definitions of **core R&D activities**, **supporting R&D activities**, **dominant purpose** and **records management**.

This example also shows how by keeping good documentation throughout the project, the company:

- is better placed to provide clear and accurate descriptions of its activities in its R&D Tax Incentive registration application,
- reduces its compliance costs and risks if it were to be selected for a review in the future, and
- helps to ensure that its project is well managed, efficiently carried out and knowledge is captured.

## Business scenario

**BioMine is a small company that develops innovative industrial solutions ranging from bioremediation to biomining, using bacteria to variously break down or extract particular chemicals. BioMine identified a need to produce new biomining bacteria suited to highly saline environments.**

After conducting extensive research, BioMine could not find an existing solution to conduct biomining in highly saline environments. It was also unable to find any existing knowledge about isolated saline resistant gene sequences that it could use to develop a solution.

BioMine embarked on an experimental project to develop a new GMO bacteria by identifying and testing bacterial strains that were able to survive in harsh saline environments; to potentially transfer this property into a biomining bacteria, while maintaining its efficiency in extracting ores.

BioMine clearly set out its initial hypotheses:

*'The addition of a saline resistant gene to an existing biomining bacteria will enable the bacteria to survive high saline environments without reducing its ability to leach ores.'*

The company also set out the approach that would be used to test the hypotheses.

In order to consider whether it could register under the R&D Tax Incentive BioMine needed to self-assess whether its activities could be eligible as either core or supporting R&D activities, and which were not eligible. In the course of its self-assessment the company decided that it could register two core R&D activities and two supporting R&D activities.

**Stage one:** *Engineering of biomining bacteria able to survive harsh saline environments*

**Core R&D Activity:** *Identification and transfer of saline resistant gene*

The company hypothesised that inserting a gene that coded for saline resistance into biomining bacteria would result in the expression of stable resistance to saline environments. BioMine considered the department's guidance material on eligible R&D activities and self-assessed that developing the new bacteria and testing it could be registered as an eligible core R&D activity because it was a new, experimental activity.

BioMine investigated bacterial strains that were known to exhibit a degree of saline resistance. The company identified Bacteria T as the most promising candidate. Through experimental inhibition of genes BioMine identified that Gene X in Bacteria T coded for saline resistance.

BioMine then isolated Gene X from the Bacteria T genome.

Once Gene X was successfully isolated it was transferred into a commonly used biomining bacteria, using a series of different gene transfer vectors. The biomining bacteria were monitored for the expression of the transferred gene and strains that expressed the gene most effectively were selected for further testing. Tests were undertaken in a laboratory environment to monitor the engineered Bacteria T for its saline sensitivity and its extraction efficiency. The new bacteria's extraction efficiency was assessed against the extraction rate of the control biomining bacteria operating in a non-saline environment. BioMine recorded the methodology and results of these tests.

**Supporting R&D Activities:** *Literature and knowledge review*

The company undertook extensive consultation and research to determine whether a biomining bacteria had been engineered with saline resistance previously.

The company then consulted with industry experts and were advised that the introduction of saline resistant genes into the biomining bacteria could not be achieved without conducting systematic hypothesis-driven experiments.

Once it was identified that the company would need to generate new knowledge to achieve its aims these activities turned to the search for bacteria that were known to be saline resistant, and to identify gene isolation and transfer methods.

Not all of these activities were eligible to register under the R&D Tax Incentive, however the research and consultation activities into saline resistant bacteria and gene technology that directly informed the experiments were self-assessed as directly related to the core R&D activity. Consequently, BioMine self-assessed these activities as an eligible supporting R&D activity.

**Stage two:** *Testing the engineered biomining bacteria in a mine*

**Core R&D Activities:** *Testing the viability of the engineered bacteria in a mining environment*

Although the engineered bacteria was effective under controlled laboratory conditions, it was not known to the company whether the results would be replicated in an uncontrolled mining environment. BioMine conducted its own research and consulted industry experts where it confirmed its view that the outcome of trialling the

engineered bacteria could not be known or determined without conducting the trial. The company self-assessed that the activity of experimentally testing the engineered bacteria in a mining environment would generate new knowledge and have the requisite purpose to be eligible as a core R&D activity. BioMine also recognised that the activity would cease to be a core R&D activity once that new knowledge had been generated and business as usual biomining had commenced. Under the R&D Tax Incentive, a core R&D activity may occur in a commercial environment where it meets the legislative conditions and is not excluded from being a core R&D activity[6].

The company undertook an experiment to monitor the new bacteria in different locations around the mine site. These trials were conducted to test the bacterium's efficiency to leach ores and its level of saline resistance. The results were recorded on a weekly basis through different times of the day. On the conclusion of the project new datasets were generated. With this data BioMine was able to evaluate the success of the project.

Before the commencement of the core R&D activity, BioMine ensured that the activity was carefully scoped with a clear hypothesis, methodology and a documented end date to ensure the activity did not rollover to commercial activities. These details were to ensure compliance with the legislative requirements.

BioMine recognised that once the new knowledge had been generated it was unlikely to be able to register an additional core R&D activity to trial the engineered bacteria at another mine unless it could identify a clear technical knowledge gap that would be bridged by that activity. On its own conducting the activity at a new site with different geology would not be enough to comprise a knowledge gap. To comprise an additional core R&D activity, the company would have to identify and articulate the presence of a specific technical knowledge gap that could not be known or determined in advance by a competent professional in the field.

For BioMine to successfully develop new bacteria that could survive and function in a highly saline environment, it was necessary to cultivate sufficient quantities of bacteria for experimentation. This activity involved cultivating both the engineered bacteria containing the salinity tolerance gene and the company's regular biomining bacteria for testing and gene transfer. Although the company realised that this work followed known procedures and was not experimental, it self-assessed that the cultivation was both directly related to the experiment and could not practicably be split from the core R&D activity.

It should be noted that this activity could also have been assessed as a supporting R&D activity (rather than part of the core R&D activity). BioMine's decision to include the cultivation of the bacteria as part of the core R&D activity was based on its expectation that it would be impractical to accurately record and separate the cultivation from the rest of the activity. If BioMine were to be selected by for a compliance review by the department, the company would need to ensure that it had

[6] The list of excluded core R&D activities and commentary on their meaning may be found on page 18 – 27 of the *R&D Tax Incentive: A Guide to Interpretation* which is available at business.gov.au/rdti.

records to both demonstrate the work undertaken and show why the decision was made.

In this case a departmental compliance review would likely have concluded that while the activity was eligible for support from the R&D Tax Incentive it would have been better assessed as a supporting R&D activity. This is because the cultivation of bacteria is generally not experimental, however, in the context of this example it directly supports an experimental activity and reclassifying the activity would not make any practical difference.

It should be noted that as a supporting R&D activity it would also have been subject to the dominant purpose test. In this case, as the company knew that the activity produced goods, BioMine ensured that all of the cultivated bacteria that would be claimed were used in R&D activities. This meant that although BioMine registered the culturing as part of the core R&D activity it was also compliant with the requirement that supporting R&D activities that produce, or are directly related to the production of goods or services were conducted for the dominant purpose of supporting a core R&D activity.

## What documentation did BioMine keep?

BioMine's R&D activities were closely monitored by its management executives as part of good business management practice. Evidence of relevant documentation that was kept included strategic plans, business cases, annual reports and investment proposals.

For each research project it planned to undertake, BioMine compiled a detailed project plan that included the project objectives, research hypotheses, experimental plan and milestones. Background research documents included literature reviews and patent searches. As the R&D progressed, the company's record keeping included records of experiments, data observations, analysis and conclusions, agreements, contracts, contractor invoices and minutes of project meetings. Scientific publications and patent applications were kept as supporting documentation.

BioMine retained all invoices and documents relating to the work performed by the contractor. It ensured its records were sufficiently documented for example:

- the date the R&D activities were undertaken,
- the amount of expenditure on the R&D activities and sufficient detail to explain any apportionment, and
- a description of the activities performed by the contractor to link the costs with a particular R&D activity.

The company also clearly defined the background intellectual property, the resulting intellectual property and who held the rights to each.

BioMine's record management system proved to be of great benefit to the company by:

- providing due diligence for regulatory bodies and venture capital raising,
- enabling them to quickly review their prior learning and corporate knowledge,
- providing the documents to secure new intellectual property,

- being able to refer to these documents as part of its annual registration of the R&D activities under the R&D Tax Incentive programme, and
- enabling the company to be compliance ready. That is, being able to substantiate its R&D Tax Incentive registration and claim if it were to be selected by the department or the Australian Tax Office for a compliance review or audit.

## Commentary

### Identifying Core R&D Activities

*Eligibility of core R&D activities is assessed at the activity level, not at the project level*

The R&D Tax Incentive requires core R&D activities to follow a systematic progression of work based on principles of established science. Core R&D activities must proceed from hypothesis through to experimentation, observation and evaluation and lead to logical conclusions. These activities must also be conducted for the purpose of generating new knowledge. The outcomes of core R&D activities must not be able to be known or determined in advance by a competent professional in the field.

### Clarifying the technical scope and number of registered R&D activities

In determining the number and type of activities to be registered the company made some practical judgements about the classification of the activities it registered. The scope of registered R&D activities is something which will always require a degree of subjective judgement.

Companies need to decide whether an activity that is closely connected to an experiment forms part of the core R&D activity or whether it would be more correctly classed as a supporting R&D activity. When making these judgements, companies should consider how close the activity is to the experiment, its significance to the experiment and the records that can substantiate their decisions.

In this example, the first core R&D activity was completed when the gene was successfully transferred into the bacteria and then lab tested to determine if it worked as effectively as the control bacteria. The second core R&D activity was completed when enough data had been gathered to draw conclusions about the hypothesis that the engineered bacteria operated successfully in a highly saline mining environment as it had in the laboratory.

### Supporting R&D Activities

Activities which do not form part of the experimental activities may be eligible as supporting R&D activities. As in the BioMine example, companies may register supporting R&D activities that are directly related to a core R&D activity. ‘Directly related’ requires an activity to have a direct, close and relatively immediate link, association, connection or relationship with one or more core R&D activities.

There is, however, an additional consideration where the activities:

- produce, or are directly related to producing, goods or services, or
- are referred to in the core R&D activities exclusion list.

In both these situations, the activities must also be undertaken for the dominant purpose of supporting one or more core R&D activities.

Companies should weigh up the various purposes for conducting the activity and then determine the dominant purpose (i.e. the ruling, prevailing or most influential purpose) for undertaking that particular activity.

**Dominant Purpose**

When self-assessing prospective supporting R&D activities which may also have a commercial nature it is important to assess whether the 'dominant purpose' is to support the core R&D activity. To self-assess the dominant purpose of an activity, consideration must be given to the overall circumstances in which the activities are conducted. It is possible that similar activities may be eligible in one context, but not in another. Companies need to consider:

- the extent to which the supporting R&D activities also achieve commercial or production outcomes in addition to assisting the conduct of the core R&D activities, and
- the importance of those non-R&D outcomes to the decision to undertake the activity.

This legislative requirement will be more commonly applicable in industrial biotechnology, where products are often manufactured in commercial environments. At times companies may use their own production line to produce the supporting materials for the core R&D activity. This introduces the importance of maintaining records of the production in order to be compliance ready. It is important to note that new records are not necessarily needed; normal records kept by companies may be sufficient.

In the cultivation of the bacteria for their experiments, BioMine needed to be able to demonstrate that it met the requirements for a supporting R&D activity that was undertaken for the dominant purpose of supporting a core R&D activity. This was done to ensure that BioMine was in a position to demonstrate its eligibility if the cultivation component was reclassified as a supporting R&D activity by the department in a compliance review. The company did this by maintaining production line run records, quality assurance documentation and batch numbers of cultivated bacteria.

# Example 2: Biofnatics

*This example explores the lodging of an overseas finding application, ensuring compliance readiness and clinical trials.*

This example also shows how by **keeping good documentation** throughout the project, the company:

- was better placed to provide a clear and accurate description of its activities for **lodging its overseas finding application,**
- reduced its compliance costs and risks if its R&D activities were reviewed in the future, and
- helped ensure its project was well managed, efficiently carried out and knowledge and intellectual property development was captured.

## Business Scenario

**Biofnatics is an Australian company engaged in the development of medical devices for surgical applications.**

In this scenario the company has recently created an improved biodegradable coronary stent device and is now proceeding to clinical trials.

To test the performance of the new stent in the clinical trials, Biofnatics required a number of prototypes to be manufactured for implantation in patients. Biofnatics investigated potential manufacturers and concluded that the necessary facilities and expertise for the manufacture of the new stent were not available in Australia. The company lodged an overseas finding application for this activity.

### Clinical trials of a new design

**Core R&D Activity:** *Phase II clinical trials of new stent design*

Prior to this activity, Biofnatics laboratory tested the new stent design in Australia. As initial trials were successful the company moved on to animal trials and then to Phase I clinical trials which were also conducted wholly in Australia. The clinical trials were successful and Biofnatics then moved on to Phase II clinical trials.

The Phase II clinical trials would be conducted both in Australia and overseas. The overseas trial was required to reach a larger and more diverse sample population size than was available in Australia.

This required Biofnatics to submit another overseas finding application for the Phase II clinical trials to be conducted overseas. As part of the overseas application the company was careful to document the reason the trials needed to be conducted overseas and that the Australian trials met all of the eligibility requirements for a core R&D activity. Biofnatics was also aware that under the R&D Tax Incentive legislation the project's expenditure on the overseas components could not exceed the expenditure on the related Australian components. As the company had already received an overseas finding for the manufacture of the new stent (which had a significant scientific link to the clinical trials conducted in Australia), it was careful to include those overseas expenditures in the calculations.

As part of the finding application process Biofnatics provided documents that substantiated its claim that the activities are not able to be conducted in Australia.

The company also provided documentation explaining how the overseas clinical trials of the stent had a significant scientific link to the development activities conducted in Australia and the proposed human clinical trials that were also conducted in Australia. In the legislation, 'a significant scientific link' means that the Australian core R&D activity cannot be completed without the overseas activity being conducted.

**Supporting R&D Activity:** *Overseas manufacturing of the new stents*

In self-assessing its eligibility for *the R&D Tax Incentive, Biofnatics* used the department's *Identification of Core R&D Activities*[7] decision tree. The company concluded that the manufacture of the new stent did not meet the requirements of an eligible core R&D activity as the manufacturing process was well known. However, the manufacture of the new stent was directly related to the clinical trial core R&D activity because it had a direct, close and relatively immediate link, association, connection or relationship to that activity.

During its review of the department's guidance material, Biofnatics paid particular attention to the information about overseas findings[8]. Biofnatics noted that companies must apply to Innovation and Science Australia for a finding for overseas activities occurring in the first income year that the activities are to be claimed.

Biofnatics used the department's R&D Tax Incentive Advance/Overseas Finding Application form[9] to apply for a finding on whether the overseas activities were eligible. Biofnatics received a positive finding from Innovation and Science Australia on their overseas finding.

## What documentation did Biofnatics keep?

The everyday business documents that Biofnatics kept enabled the company to demonstrate the eligibility of its activities and substantiate its claim for the R&D Tax Incentive.

In relation to the individual R&D activities, the company kept a register of all of the relevant technical scoping and business planning documents. For example the company:

- kept records of the planning for the clinical trials, including the identification of potential clinics and surgeons, ethics and regulatory approval processes,
- planned their R&D using a project plan that set out the business aims and technical hypotheses, explained the design of the experiments to test the hypotheses, described the observations and analysis that resulted from each of the experimental processes in which they engaged,
- ensured related licenses and commercial agreements clearly defined background intellectual property and the rights that are attached as well as resulting intellectual property and attendant rights, and

[7] Further information on core activities is available at business.gov.au/rdti.
[8] Information on Overseas Findings is available at business.gov.au/rdti.
[9] The application for an Advance/Overseas Finding is available at business.gov.au/rdti.

- used bound laboratory notebooks and observed the usual conventions for recording experimental procedures, results and information to establish dates of conception and reduction to practice of a technology as well as the inventorship of a patent application claiming the technology.

Biofnatics were aware that the detailed records they were keeping could provide valuable information for future projects forming part of the company's intellectual property portfolio. Biofnatics' Directors decided that records of the tests and experiments that were not successful, whilst not conclusive in themselves, could be supporting evidence that the outcome of the experimental activities was not known in advance. While the company kept these records for other reasons, it made sure copies could be easily located should the department conduct a compliance review.

## Commentary

This example concentrated on the clinical trials of the new stent design. The R&D project to design, manufacture and test the new stent involved a number of activities conducted both in Australia and overseas.

### Advance/overseas finding

Advance and overseas findings are designed to provide certainty to companies about the eligibility of activities under the R&D Tax Incentive. They provide a binding determination issued by Innovation and Science Australia[10] as to whether certain activities are eligible to be claimed under the programme.

R&D activities must satisfy four requirements in order to be eligible as an overseas activity:

1. the overseas activity must be an eligible R&D activity,
2. the overseas activity must have a significant scientific link to an Australian core R&D activity,
3. the overseas activity must be unable to be solely conducted in Australia or its external Territories, and
4. the expenditure on the overseas activities and activities not undertaken wholly in Australia cannot exceed the expenditure on the related activities undertaken solely in Australia.

The requirements are outlined in more detail below.

### The overseas activity must be an eligible R&D activity

If a company seeks an overseas finding on either a core or a supporting R&D activity, it is required to demonstrate that the activity satisfies the definition of either a core or supporting R&D activity.

[10] Industry Innovation and Science Australia (IISA) is the statutory authority ultimately responsible for administering the activity and eligibility components of the R&D Tax Incentive.

**The overseas activity must have a scientific link to an Australian core R&D activity**

In its advance/overseas finding application, Biofnatics clearly showed the linkage between the planned overseas activity and the Australian core R&D activity. To assess this, Innovation and Science Australia will examine the claimed Australian core R&D activity to ensure it is eligible. This will occur even where the company states that it doesn't require the Australian core R&D activity to be assessed.

The company explained that the manufacture of the polymer stent was required for the clinical trials and that its hypotheses could only be tested through conducting clinical trials overseas because the company was not able to recruit a sufficient population of patients with the relevant health conditions.

**The overseas activity must be unable to be conducted in Australia**

To be eligible for the R&D Tax Incentive, R&D activities proposed to be conducted overseas must not be able to be conducted solely in Australia (or its external Territories) for one of four reasons:

1. conducting the R&D activities requires access to a facility, expertise or equipment not available in Australia or its external Territories[11],
2. conducting the R&D activities in Australia or its external Territories would contravene a law relating to quarantine,
3. conducting the R&D activities requires access to a population (of living things) not available in Australia or its external Territories, or
4. conducting the R&D activities requires access to a geographical or geological feature not available in Australia or its external Territories.

Financial reasons alone are not sufficient[12].

**Total expenditure on eligible overseas activities of the project must be less than the expenditure on the related Australian R&D activities**

Condition four states that: *the total actual and reasonably anticipated expenditure of any entity in all income years on:*

- *the overseas activities; and*
- *each other activity (if any) conducted wholly or partly outside Australia and the external Territories that has a significant scientific link to the Australian core activities;*

*is less than the total actual and reasonably anticipated expenditure of any entity in all income years on:*

- *the Australian core activities; and*
- *activities conducted solely within Australia and the external Territories that are supporting R&D activities in relation to the Australian core activities.*

If the expenditure on overseas activities (both stated in the application and reasonably anticipated in all income years) is greater than the expenditure on

[11] Guidance on *What does 'not available in Australia' mean?* is available at business.gov.au/rdti.

[12] Information on Overseas Findings is available at business.gov.au/rdti.

activities conducted in Australia, a company will not be eligible for an overseas finding for the overseas activities. However, R&D activities conducted solely in Australia could still be eligible for the R&D Tax Incentive.

In its advance/overseas finding application, Biofnatics included the total actual and reasonably anticipated expenditure that would be incurred for each of the clinical trials. The detail in Biofnatics' application allowed Innovation and Science Australia to clearly see that the expenditure on core and supporting R&D activities undertaken wholly in Australia was anticipated to be greater than the expenditure on the related overseas activities and activities not undertaken solely in Australia. As the expenditure on the proposed overseas component by any entity in all income years was less than the Australian-based expenditure, the overseas component met this requirement.

# Example 3: Encapsulate

*This example shows how the identification and management of eligible R&D activities link to different points in the project life cycle.*

The example specifically looks at the agile and collaborative environment of the biotech industry. It shows how to determine which of the collaborative partners **'owns' the R&D** and are therefore **entitled to claim** the R&D Tax Incentive, as well as providing commentary on **company structure** and **eligibility**. The example also illustrates the importance of documentation and knowledge management to demonstrate ownership.

This example also shows how the identification and management of eligible R&D activities could link to different points in a company's business cycle, including:

- the decision between 'blue sky' research or acquiring a core technology,
- developing a new product or solution,
- manufacturing and trials, and
- the decision between commercialisation or capitalisation.

## Business Scenario

Encapsulate is an ASX listed company that identifies and develops metal protein attenuating compounds (MPACs) for use as therapies in the treatment of age related degenerative disorders. Encapsulate's key focus is on the development of therapeutic targets for Parkinson's Disease.

The University of Good Fortune (UGF) is a mature blue sky research organisation that identified a Zinc MPAC candidate, ZnV5, that it believes has the potential to be used in therapeutic treatments. UGF takes the business decision to offer ZnV5 under licence to Encapsulate.

Encapsulate is well known in the industry for its expertise in developing and testing its own MPAC's. This would be the first time the company has in-licenced a compound. Encapsulate uses the corporate knowledge contained within the company to assess the likelihood of success and potential markets for a new product containing ZnV5.

Encapsulate embarked on a R&D project to identify ZnV5's binding and transportation characteristics and develop a delivery system for the agent to treat age related degenerative disorders.

**Stage one:** *Developing a new product*

**Core R&D Activities:** *In vitro investigation of ZnV5*

The company conducted hypothesis-driven experiments on the ZnV5 compound and discovered that it could reversibly bind and transport zinc in neurons and across synapses.

ZnV5 had not previously been tested for its indications on neurons and synapses. As a result the outcome of these investigations could not be known or determined in advance. Accordingly, the process followed a scientific and systematic progression of work and was self-assessed by the company as a core R&D activity.

Encapsulate investigated the department's guidance material further to find out if expenditure incurred in acquiring core technology (the licenced compound developed by UGF) was eligible expenditure under the R&D Tax Incentive. The company discovered that it was not, but that it may qualify as a deduction under other provisions of income tax law.

**Supporting R&D Activities:** *Literature and knowledge review*

Prior to conducting the experimental activities, Encapsulate conducted a literature review to determine the state of knowledge on ZnV5 and related compounds. This research alerted the company to the potential of the ZnV5 compound and eliminated similar compounds from further consideration. The company recognised that ZnV5 was a strong candidate as an MPAC in the treatment of Parkinson's Disease; however, there were significant unknowns that could only be resolved through systematic progressions of work. The company assessed the aspects of the literature review that directly contributed to the design of the experiment as a supporting R&D activity.

## Commentary

As part of its record keeping process, Encapsulate developed project documentation including an R&D plan[13] prior to conducting its experimental investigation of ZnV5. The company set out its hypotheses and the processes of experimentation, observation and evaluation it would perform to investigate ZnV5.

For new entrants to the programme, particularly SMEs, adopting a systematic R&D planning framework means that a firm becomes 'compliance ready' and is better able to register for and claim the R&D Tax Incentive. Compliance readiness is about having in place the appropriate systems and processes to effectively identify, evaluate and record eligible R&D activities and their associated expenditure.

**Company structure**

Organisations that are establishing a company for the purpose of conducting R&D should consider the eligible entities requirement under the R&D Tax Incentive. For example, if an entity had decided to establish a spin-off company and seek venture capital funding, the structure of the company and funding agreement could affect the company's eligibility to claim.

*It is recommended that organisations seek advice from the ATO or a taxation professional before finalising a company structure or funding agreement.*

[13] Maintaining formal R&D plans is not compulsory under the R&D Tax Incentive; however evidence of good planning and governance processes form strong supporting evidence for compliance purposes. Information on record keeping is available at business.gov.au/rdti.

### Core Technology

Certain expenditure is excluded under the R&D Tax Incentive. In particular, expenditure incurred in acquiring technology, or acquiring the rights to use technology, that is 'core technology' cannot be claimed.

Technology is considered to be 'Core Technology' if it is for one or more R&D activities in the following circumstances:

- Where the purpose of the R&D activities is to obtain new knowledge based on that technology,
- Where the purpose of the R&D activities is to create new or improved materials, products, devices, processes, techniques or services to be based on that technology, or
- Where the R&D activities were or are an extension, continuation, development, or completion of the activities that produced the technology.

Expenditure on core technology[14] or the rights to use core technology cannot be considered in calculating entitlements under the R&D Tax Incentive. An example of a 'Core Technology' related to biotechnology is the acquiring of IP, or the right to use IP, related to the registered R&D activity.

While expenditure on core technology is excluded under the programme, it may qualify for deductions under other provisions of income tax law.

Companies may request a Finding from Innovation and Science Australia as to whether a technology is considered to be core technology.

### Who are the R&D Activities conducted for?

In most cases a company is only entitled to a tax offset for R&D activities conducted 'for' itself – when they are the major benefactor of expenditure on R&D activities[15]. This is determined by examining enabling agreements such as the in-licence of the background intellectual property and any funding agreements which, in turn, control the extent to which R&D activities are conducted for the R&D entity compared to the extent to which they are conducted for any other entity – in the case of Encapsulate, this may be UGF or a funding partner.

The major benefactor of expenditure on R&D activities is determined by examining the extent to which activities are conducted for the R&D entity compared to the extent to which they are conducted for any other entity. This is tested by weighing up three key criteria concerning who:

1. 'effectively owns' the newly developed know-how, resulting intellectual property or other results arising from the R&D entity's expenditure on the R&D activities,
2. has appropriate control over the conduct of the R&D activities, and
3. bears the financial burden of carrying out the R&D activities.

[14] More information on expenditure relating to core technology is available on the ATO website: ato.gov.au.

[15] More information on 'who the R&D Activities are conducted for' is available on the ATO website: ato.gov.au.

In this example, Encapsulate started to conduct activities (researching potential applications) for itself prior to entering into the licence agreement with UGF. These pre-licence activities were funded by and conducted for Encapsulate's benefit.

After entering into the in-licence, Encapsulate continues to fund and benefit from the R&D activities conducted and would again be considered entitled to claim the expenditure incurred on the eligible activities.

**Stage two:** *Manufacturing and clinical trials*

**Core R&D Activities:** *Clinical trials*

Encapsulate conducted successful clinical trials and commenced Phase I clinical trials to investigate the safety of ZnV5 MPAC. The trial provided important new knowledge regarding the effects of the compound and the dosing regime on patients. R&D activities were also conducted on stability testing and estimated shelf-life of the MPAC. The company self-assessed this work to be an eligible core R&D activity.

During the Phase I clinical trials, Encapsulate conducted a review of the company's finances and product pipeline. The ZnV5 project was identified as having the largest and most immediate potential income stream. The Company's Board of Directors decided to progress the development of ZnV5 with the view to out-licensing or divesting the new IP generated by the project to finance less mature projects.

**Supporting R&D Activities:** *Manufacture of ZnV5 for clinical trials*

Encapsulate investigated the technology and expertise required to manufacture the drug and they came to the conclusion that the required expertise was not available in Australia. The specialist company Parthenex Inc (Canada) was identified as the only company with sufficient experience to enable the stable encapsulation and consistent formulation required for clinical trials. Encapsulate self-assessed that this activity is directly related to the Australian core R&D activity of the Phase I clinical trials. Encapsulate applied for and were granted an overseas finding certificate[16] by Innovation and Science Australia.

## Commentary

As companies become acquainted with the R&D Tax Incentive programme and utilise their internal record management systems to capture the work they have done on projects, they will discover that, in most cases, their business as usual record keeping will provide a basis for clear and accurate description of R&D activities and the reasons for eligibility. This will enable them to easily and effectively prepare their annual application for registration.

**For whom are the R&D Activities conducted?**

As a further example of how to assess 'for whom' the activities are conducted, in this example, Encapsulate contracted DTIA (an Australian company) to undertake the scale-up of manufacturing of the active compound. DTIA are an eligible entity under the R&D Tax Incentive and have previously registered eligible R&D activities under

[16] Information on Overseas Findings is available at business.gov.au/rdti.

the programme. However, this body of work, the scale-up of manufacturing activities, were conducted 'for' Encapsulate as Encapsulate:

- 'effectively own' the know-how and resulting intellectual property arising from the activities,
- has appropriate control over the conduct of the R&D activities, and
- bears the financial burden of the R&D activities.

Encapsulate self-assessed that under the financial arrangement with DTIA, it (Encapsulate) was the major benefactor and as such is entitled to claim the related activities. DTIA are not eligible to register for the R&D Tax Incentive for this body of work.

**Stage three:** *Early termination of an R&D project*

Encapsulate plan a Phase IIa clinical trial to evaluate ZnV5 in patients with early to mid-stage Parkinson's Disease. The trial is to provide important new knowledge regarding the efficacy and safety of ZnV5 in patients with Parkinson's Disease.

Before the commencement of the Phase IIa clinical trial, Encapsulate already possessed substantial documentary evidence that ZnV5 has the potential to become a safe, effective and widely used treatment for Parkinson's Disease.

Encapsulate take the business decision to sell all its new IP relating to ZnV5's manufacture, encapsulation and therapeutic use to an Indian company, New Delhi Bio. As part of the sale agreement New Delhi Bio contracts Encapsulate to manage the Phase IIa clinical trials.

## Commentary

**For whom are the R&D Activities conducted?**

Encapsulate do not have an eligible R&D Tax Incentive claim for expenditure incurred during the Phase IIa clinical trials, as they no longer effectively own the IP associated with, or carry the financial burden of, carrying out the R&D activities. In other words, the R&D is not being conducted 'for' Encapsulate; the R&D is now for the benefit of New Delhi Bio.

The question of 'for whom' are the R&D activities conducted is an important question for all companies to take into consideration. The structure of a corporate deal involving intellectual property and the structure of the acquiring company may critically affect a company's eligibility to access the R&D Tax Incentive programme.

## What documentation did Encapsulate keep?

Encapsulate maintained comprehensive records and documentation for the duration of the research project.

This included laboratory notebooks, experimental protocols, experimental results, reports of statistical analysis, trial reports, manufacturing reports, contractor reports, progress reports and case report forms in clinical trials.

In addition to ensuring they were compliance ready, Encapsulate were aware that the detailed records they are keeping could provide valuable information for future projects forming part of the company’s intellectual property portfolio.

# Example 4: TimbaFuels

*This example shows how the identification and management of eligible R&D activities occurring in a production environment help to satisfy the dominant purpose requirement of the legislation.*

This example looks at a mature industry that is applying new technologies to existing processes. It illustrates the importance of documentation and knowledge management in demonstrating why the experimental activities were necessary, as well as identifying the point where the R&D activities end and the application of new knowledge commences, and **apportioning costs** appropriately.

This example shows how the identification and management of eligible R&D activities can link to different points in a company's product production cycle:

- Accessing a government grant to develop a new enzyme,
- Testing of a fermentation process in a pilot scale environment,
- Scaling up to larger production runs and **feedstock** requirements,
- Eligible spending on assessments of third party intellectual property that might affect freedom to operate, and in turn, product development, creation of intellectual property and exploitation.

## Business Scenario

**TimbaFuels is an Australian company that is well established within the industry as a producer of ethanol from lignocellulose feedstock. TimbaFuel's primary source of feedstock is wood waste.**

TimbaFuels believed that it had reached the limit of current pre-treatment technology as further development of the pre-treatment process resulted in a degradation of carbohydrates and lower ethanol yield. The company embarked on a new R&D project to develop an enzyme that would be more efficient at breaking down the rigid structures present in lignocellulose waste material. If the project was successful the company expected to be able to dispense with its expensive pre-treatment processes.

TimbaFuels had the goal of developing a new enzyme to remove the necessity for pre-treating the lignocellulose material while maintaining current ethanol yields.

**Stage one:** *Development and testing of new enzyme*

**Core R&D Activity:** *Development of new enzyme*

TimbaFuels applied for and received a Greening Up Technology co-investment grant[17] for the development of an enzyme and proof of concept pilot scale fermentation process. As TimbaFuels had no prior experience in developing enzymes they identified a suitable Research Service Provider (RSP) from the business.gov.au[18] website to develop the enzyme. From their own market research and knowledge of existing technology and solutions, TimbaFuels and the RSP concluded that this technology did not exist and, as a result, the work was eligible as

[17] Note: this is a fictional grant created for the purpose of this example.

[18] Information on Research Service Providers, including the contact details of current RSPs is available at business.gov.au/rdti.

a core R&D activity. TimbaFuels kept copies of its research and its email communications with the RSP to be able to substantiate this.

During the development activities the enzyme was tested on both raw timber and timber that had been through the pre-treatment process. Initial results indicated that the pre-treatment process was still beneficial in maximising ethanol yield.

**Stage two:** *Testing the new enzyme on wood waste subjected to different levels of pre-treatment*

**Core R&D Activities:** *Determining the optimum level of pre-treatment*

Following the observations of the new enzyme on the wood waste in Stage one, TimbaFuels embarked on the next stage of the R&D project, to identify the minimum amount of pre-treatment needed.

A production line diversion was fitted to the existing process to remove the wood waste at different stages of the pre-treatment process and pass it on to the pilot fermentation process. The ethanol produced in the pilot process was evaluated and then blended into the main process output which was made commercially available.

**Supporting R&D Activities:** *Pre-treating the wood waste*

TimbaFuels' existing production line supplied and removed the wood waste for fermentation using the new enzyme. This activity had a direct, close and relatively immediate link, association, connection or relationship with the experimental activities. As such, running the production line was a supporting R&D activity. However, because it was also a production activity, the company was required to apply the dominant purpose test.

TimbaFuels self-assessed that, although running the production line as a whole might be necessary for the experiment, only running the pre-treatment part of the production line was eligible as a supporting R&D activity. In their registration, therefore, the expenditure associated with the experiment included a reasonable apportionment of the cost of running the production line.

**Stage three:** *New enzyme in a production environment*

**Core R&D Activities:** *Experimentation on the effectiveness of the new enzyme using different quality wood waste*

TimbaFuels had no control over the quality of the waste wood available for their process. The company decided to conduct a further set of R&D activities to analyse the enzyme's performance over a production run using existing machinery, with varying qualities of wood waste.

The company stopped one of its production lines to clean out the fermentation process components. It then introduced the new enzyme and re-calibrated the pre-treatment process to the optimal settings discovered in Stage two. Once the production line was prepared, TimbaFuels ran the production line at normal capacity and evaluated both the ethanol and waste lignin outputs for varying quality of wood waste.

TimbaFuels self-assessed that the activities were for the purpose of acquiring new knowledge about the enzyme's performance and the quantity and quality of the lignin by-product when using different quality wood waste. The outcome of the experiment

could not be known or determined from existing knowledge about the enzyme, and the application of the scientific method was required to address the knowledge gap. Further, the hypothesis could only be tested by replicating the process on a large scale in a production environment.

TimbaFuels acknowledged that, although running the full production line was necessary for the experiment it also served the commercial purpose of producing ethanol. The R&D activity required that the testing be conducted during the production run. However, the tests were not required to be conducted continuously, they were only required to be conducted periodically and at a frequency that would enable robust statistical analysis.

Due to the R&D project's requirement to test different quality wood waste, the fermentation process and the overall design of the production line, it was not possible to stop the production line in between the periods of testing. As a result, in its R&D Tax Incentive registration TimbaFuels only apportioned part of the cost of running the production line to the R&D activity.

**Supporting R&D Activities**

As mentioned above, the production run was considered a core R&D activity while the testing was being conducted. TimbaFuels self-assessed that activities related to the operation of the production run were supporting R&D activities as they were undertaken for the dominant purpose of supporting the core R&D activities.

However, these same activities were not eligible activities when conducted for the periods between the testing. The company applied the same 'cost of run per hour' formula it used on the core R&D activities to the supporting R&D activities when registering its R&D Tax Incentive claim.

## What documentation did TimbaFuels Keep?

TimbaFuels was concerned about the level of documentation it would need to substantiate its claim for Stage three, as it was conducted in a production environment.

After studying the department's guidance material, TimbaFuels decided that its normal production run sheets and quality control sheets would suffice with the addition of columns identifying the sheets as being part of the R&D activities and providing an area for the operators to note their observations and comments.

The company also used the accounting part of their financial management software to identify costs associated to each of the core and supporting R&D activities. The rights to use any background intellectual property were also clearly documented along with the rights around the resulting intellectual property.

## Commentary

### R&D in a production environment – dominant purpose

TimbaFuels considered that running the production line was necessary to supply pre-treated wood waste to the pilot fermentation plant. The company self-assessed this as supporting the experiment. However, the production run went beyond the needs of the experiment as it also continued to pre-treat the remaining wood waste then progressed it to the fermentation process (its normal business operations). The design of the production line made it impractical to isolate the R&D activity.

A further important consideration was that conducting the production run along with the experiment was profitable in its own right, so there was a commercial purpose. However, this commercial purpose was clearly not the sole purpose of the production run, which was conducted in a different manner to a normal production run.

In this instance, the determinative factor lay in the reason why the production line needed to be run and the related consequences. The requirements of the experiment could not be met simply by taking raw wood waste. Obtaining wood waste that had undergone known varying stages of the pre-treatment process was a part of the experiment itself, in order to test whether the enzyme was more or less effective due to the level of pre-treatment the wood waste had been exposed to.

These factors indicated that the dominant purpose for running the production line was to support the experiment, rather than to make commercial use of the resulting ethanol. Profitably disposing of the resulting ethanol was incidental to this dominant purpose. Accordingly, the directly related activities in relation to running the production line were for the dominant purpose of supporting the experiment, and were eligible supporting R&D activities.

### R&D in a production environment – apportioning costs

As part of its Stage three, TimbaFuels concluded that the testing process was unobtrusive and that interruptions caused by the testing process not working as desired would be negligible compared with interruptions experienced during a normal production run.

The company also decided it was not viable to attempt a full production run if serious delays were likely, due to the cost in down time required to clean the new enzyme and pre-treated wood waste out of the production line.

TimbaFuels, therefore, took the business opportunity to piggyback the experiment onto a production run. The cost of the experiment claimed as eligible activities included a reasonable apportionment of the cost of running the production line over a production run. The company apportioned the cost on a ‘cost of run per hour’ basis plus a loading for any line stopping required and applied the costing for the accumulated duration of testing conducted over a production run.

TimbaFuels concluded that the operation of the production run in between the periods of testing was not conducted for the purpose of *acquiring new knowledge*. As such, the company concluded that the operation of the production run in between the periods of testing was not an eligible R&D activity.

### Feedstock

Companies may make the business decision to sell or use the immediate product of their eligible R&D activities (such as the ethanol produced from Timbafuel's experimental trials). Companies that sell or use the product of their eligible R&D activities need to examine the feedstock rules (available on the ATO website[19]) and include the necessary feedstock adjustment amount in their income tax return.

### When does clawback apply?

A clawback adjustment[20] may apply where an R&D entity receives, or becomes entitled to receive, a recoupment (including a grant) from an Australian government agency or State/Territory body that relates to R&D activities, unless the recoupment is received or receivable under the Cooperative Research Centres (CRC) programme.

[19] Information on Feedstock Rules is available on the ATO website: ato.gov.au.
[20] Information on Clawback Adjustment is available on the ATO website: ato.gov.au.

# Example 5: New Natural

*This example explores the nature of R&D activities conducted in a commercial environment.*

The example presents an Australian registered company that is partly owned by a large Multi-National Enterprise conducting R&D in Australia. It provides commentary around:

- **foreign ownership,**
- **aggregated turnover,** and
- R&D in a **production environment**.

In addition to these factors it also delivers guidance around a company's eligibility for R&D activities surrounding field trials and the importance of record management of these trials.

## Business Scenario

**New Natural is an Australian company that is 40% owned by a large Multi-National Enterprise (MNE) which has developed a range of environmentally friendly microbial biological pest control agents. New Natural develops biofungicidal seed treatments.**

The MNE developed several fungicides using different active ingredients. These active ingredients have been patented by the MNE. New Natural has an exclusive licence to manufacture and develop the fungicide active ingredients in Australia.

As most microbial fungicides target particular species, New Natural planned to create a formulation that combined a number of fungicides into one product. The company conducted literature and market searches for current products or processes and determined that the product or technology did not exist. Companies that had conducted similar experiments have encountered problems relating to fungicidal effectiveness and seed growth inhibition.

With these findings New Natural planned a research project with the following objectives:

(1) identifying and removing the compounds in the fungicides that are involved in plant growth inhibition, and

(2) combining the resulting active ingredients into a multi-fungicide that will maintain fungicidal activity and won't inhibit plant growth'.

New Natural broke down its project into separate R&D activities, which it planned to conduct over three business years.

- Activity 1: Development of a new fungicide formulation through the combination of known active ingredients.
- Activity 2: Testing the fungicide formulation utilising the optimal method in field trials.

These individual activities allowed New Natural to carry out experiments to test hypotheses with the overall goal of developing a combination fungicide that would impart protection from fungal pathogens.

**Stage one:** *Development of a new combination fungicide*

**Core R&D Activity:** *Developing a new fungicide formulation*

The company developed hypotheses and an experimental methodology to evaluate interactions between the different active ingredients in the mixture. Through investigation and laboratory based tests New Natural was able to determine a specific active ingredient mixture that provided protection from several species of fungi, while not inhibiting plant growth.

**Supporting R&D Activity:** *Manufacturing the active ingredients for experimentation*

New Natural discovered and documented that international and domestic experts had not been able to develop a fungicide that provided plants with protection from a combination of fungi species. Through early stage evaluation New Natural was able self-assess its eligibility for the R&D Tax Incentive.

New Natural had been producing the individual active ingredients required for the development of the new formulation as commercial products in their own right. Therefore New Natural decided that the production of these active ingredients would not be likely to meet the legislative definitions required to be classified as a core R&D activity, even though these ingredients are required in order to undertake the planned experimental R&D activities.

New Natural decided to register the production of sufficient quantities of the active ingredients for the R&D project as a supporting R&D activity directly related to the core R&D activity.

The company's rationale for this decision was based on the knowledge that:

- the process to manufacture the active ingredients would not generate new knowledge, and
- without the active ingredients the experimental activities required to develop the new fungicide could not be conducted.

The process of producing the active ingredients produced commercial goods. This meant New Natural was required to meet the dominant purpose requirement that supporting R&D activities that produce, or are directly related to producing goods or services must be for the dominant purpose of supporting the core R&D activity.

As the active ingredients were already produced commercially by New Natural, it claimed only the production of the active ingredients that were used in the core R&D activity.

From reviewing the department's guidance, New Natural determined that its normal production run records and quality assurance sheets showed the expenditure claimed on active ingredients was used solely for the experimental purposes.

**Stage two:** *Testing the fungicide formulation in field trials*

**Core R&D Activity:** *Determining the viability of the new fungicide in an external environment*

New Natural self-assessed the activity of testing the fungicide in a natural environment as a core R&D activity.

The company's rationale for this decision was that:

- the outcome of the field trials could not be known or determined on the basis of current knowledge, information or experience,
- a systematic progression of work based on the principles of established science would be necessary to generate the new knowledge required, and
- the activity was not excluded from being a core R&D activity under the R&D Tax Incentive legislation.

The field trials ran throughout the year to investigate the response of the plants during different seasons. The justification for the length of the experiment was clearly detailed and recorded. At the conclusion of the field trials the data was analysed, confirming that the new fungicide mixture worked successfully.

**Supporting R&D Activity:** *Manufacturing the active ingredients for experimentation*

After successful laboratory testing, New Natural moved to field trials to validate the efficacy of the fungicide mixture in a natural environment.

As the fungicide mixture used for the field trials was blended from the company's commercial production lines, New Natural was careful to document the proportion of the production run that it would claim as a supporting R&D activity.

New Natural self-assessed that although the activity was closely related to its commercial activities, the dominant purpose of manufacturing the ingredients required for the mixture was for the testing of the fungicide formulation in field trials (a core R&D activity).

## What documentation did New Natural keep?

New Natural kept records that demonstrated systematic progressions of work based on the principles of established science that proceeded from hypothesis to experiment, observation and evaluation, and led to logical conclusions. New Natural also clearly set out its hypotheses.

New Natural kept a number of different records including:

- Literature research that New Natural undertook to determine the current state of knowledge and that R&D activities would be needed to generate the new knowledge that it needed,
- Methodology of the experiments undertaken, demonstrating that a systematic approach has been applied in the experiments,
- Batch numbers of manufactured active ingredients and fungicide formulations used in the experimental activities,
- The results and analyses of the experiments; The intellectual property acquisition agreement with the MNE showing New Natural's ownership of the background intellectual property and rights to the resulting intellectual property, and
- Bound laboratory journal records of experimentation. When the usual conventions are observed for recording information the journals can establish dates of conception and reduction to practice of a technology as well as the inventorship of a patent application claiming the technology.

## Commentary

### R&D Activities in a production environment

Although running the production line as a whole might be necessary for the experiment, it is important to appreciate that only the proportion of the expenses relating to the eligible R&D activities may be claimed.

In this example, New Natural required the production of a number of active ingredients to be used in the core R&D activities. As the company was already producing the different ingredients for their commercial products, the company would only be able to claim the expenses incurred during the time it was running the necessary equipment to produce the fungicides used in the experiments.

Companies conducting field trials need to consider how long they need to conduct their core R&D activity to arrive at the new knowledge they need. This is an important consideration since, if an activity is continued after the new knowledge has been generated, it is no longer eligible. In most scientific experiments this occurs when the hypothesis is confirmed or rejected. However, this line can be blurred in experiments involving test environments such as field trials, commercial scale trials and production trials. For these activities it is important to make an assessment of the amount of testing that is required to attain the new knowledge. When making these assessments, companies should consider how close the activity is to the experiment, its significance to the experiment and the records that can substantiate its decisions.

### Aggregated Turnover

An important dimension to note is the term ‘aggregated turnover’. This plays a major role in determining the level of tax offset a company can receive when claiming the R&D Tax Incentive.

Aggregated turnover is the sum of the annual turnovers of not only the R&D entity (your company) but also any entities connected or affiliated with your company for tax purposes[21].

[21] Information on aggregated turnover is available on the ATO website: ato.gov.au.