







Specific Issue Guidance



'Scaling-up' refers to increasing the scale of a product, device, process or technology that is known to operate at a smaller scale.

A key requirement of the legislation governing the *R&D Tax Incentive* is that the outcome of experiment/s conducted within a core R&D activity must not be able to be known or determined in advance of conducting the experiment/s. Because the product, device, process or technology¹ that is being scaled-up is already understood at a smaller scale, it is critical that before registering scale-up activities, companies consider why the outcomes of specific activities can only be determined by conducting further experiments. Companies will also need to consider which specific activities are experimental, and which are not.

This guidance helps companies understand the key issues to consider when they are self-assessing the eligibility of scale-up activities under the *R&D Tax Incentive*.

Guidance

The legislative eligibility criteria apply to specific activities

When conducting research and development, companies may think in terms of projects and project outcomes rather than the specific activities. However, eligibility under the *R&D Tax Incentive* is based on specific activities.² Scaling-up is likely to be a project comprising many different activities, and is unlikely to be a single specific activity.

Some of the activities may involve experiments, while other activities might support experimental activities. Other activities may not be eligible activities. The eligibility of all activities associated with a scale-up project can't be determined by considering only the whole project, but must be determined by considering specific activities.

Scale-up activities must meet the legislative eligibility criteria for R&D activities under the *R&D Tax Incentive* program. The eligibility criteria for R&D activities are set out in the *Income Tax Assessment Act 1997*. AusIndustry has published the *R&D Tax Incentive: A Guide to Interpretation* to help companies to understand the legislative requirements.³ Program participants should review these publications when self-assessing the eligibility of activities.

This guidance document does not explore all the eligibility requirements that must be met; rather it will focus on some criteria and issues that are particularly important to the eligibility of scale-up activities. Specifically;

- whether an outcome of an activity could be known or determined
- 2. using existing knowledge or expertise, and the relationship of claimed supporting activities undertaken in a production environment to core R&D activities.

¹ Here after "processes"

² Activities are specific rather than general and what has been done in the activity should be described in detail at registration. The R&D Tax Incentive is governed by Division 355 of the Income Tax Assessment Act 1997 and sections 26 to 32 of the Industry Research and Development Act 1986. The eligibility criteria for activities are set out in sections 355-20 to 355-30 of the Income Tax Assessment Act 1997.

³ The R&D Tax Incentive: A Guide to Interpretation is available at www.business.gov.au/rdti

Eligibility under the R&D Tax Incentive is activity based.

Companies must break down their research and development projects into specific activities to demonstrate eligibility under the program.

Core R&D activities

What are the specific technical outcomes that can't be known or determined in advance?

The *R&D Tax Incentive* requires that eligible core R&D activities involve experiments that are undertaken for the purpose of addressing technical knowledge gaps. Tests or experiments that confirm information that is already known or is deducible by a competent professional⁴ in the field on the basis of current knowledge, information or experience without an experiment are not eligible under the legislation.

Scale-up activities often draw on the technical knowledge of smaller scale processes that are already known to work (for example, through 'bench' scale testing, or through a pilot plant at a small scale, or at a smaller production scale). As the process is already understood at a smaller scale, it is critical to identify the specific technical knowledge gaps that must be experimentally resolved to successfully scale-up the process.

Relying on a proposition that such a scale-up hasn't been done before, or that the proposed scale is larger than those done before, is not in itself sufficient to establish that the activities involved are eligible under the *R&D Tax Incentive*. Many scale-up activities will be engineering tasks that use existing knowledge and a systematic problem solving approach to resolve knowledge gaps without the need to conduct experiments. However, some scale-up activities will not be able to rely on existing knowledge and will require an experiment, or set of experiments to generate the new knowledge needed to complete the activity. Identifying those activities is necessary to establish eligibility as specific core R&D activities.

Scaling-up a process is generally more involved than enlarging apparatus and volumes of materials. Scaling-up often involves the use of new and different componentry that takes the place of the laboratory equipment or smaller or less complex equipment used in the smaller scale process – that is, new equipment that essentially manages the same processes differently. However, this in itself will not form the basis of a claim that the scale-up process outcome cannot be known in advance. Specific experiments which are designed to overcome specific technical unknown/s will still need to be identified.

To form the basis of a claim, you must identify a knowledge gap or technical challenge that arises from scale-up activities which cannot be known or determined by a competent professional without carrying out an experiment. For example, a proposition that a particular piece of equipment must be larger than any used previously won't be enough on its own to substantiate the carrying out of R&D activities, there must be evidence of what specific technical challenge that represented, and what experiments were undertaken to resolve the technical challenge.

Another useful consideration is to think in terms of the new knowledge or information generated by undertaking smaller scale activities compared with the technical challenges or knowledge gaps that still remain and which can only be tested by undertaking experiments as part of scale-up activities.

Consider the hypothetical scale-up example at the end of this guidance as an illustration. It is not intended to define specific eligible activities but rather to illustrate the relevant considerations.

⁴ A competent professional is understood by AusIndustry to be a professional in the relevant field that has access to journals and trade knowledge on a world-wide and reasonably accessible basis.

Determining the best configurations or settings

It is important to appreciate that not all scale-up activities with an apparently uncertain outcome will be eligible. This would include technical issues such as those concerning the best configuration or settings which can be resolved using existing knowledge, information and experience.

By their nature, configuration or settings issues relate to selecting the option from a number of competing options. As such, where they do involve uncertainty they tend not to involve a hypothesis which is being tested by applying a systematic progression of work (including an experiment), but operate in a trial and error manner (i.e. without a guiding hypothesis) which will not meet the legislated requirements for a core R&D activity.

However, where a company self-assesses that it has configuration or setting issues where a solution is not knowable or able to be determined in advance of conducting a hypothesis driven experiment, it may be able to demonstrate eligibility for a core R&D activity. Under these circumstances, the company will need to carefully document its analysis of its research and its reasons for arriving at this conclusion.

When self-assessing, companies need to be aware that it will not be sufficient to rely solely on reasoning that the configurations or settings are not able to be known or determined because the scale-up being undertaken is a first of a kind. This is because competent professionals have relevant knowledge and resources to determine otherwise unknown outcomes through principles established under the respective discipline/s, established formulae and calculations with the known inputs. Companies wishing to claim configuration or settings type activities as core R&D activities must be able to explain and have supporting evidence as to why the outcome they were seeking could not have been calculated or otherwise determined without needing to do an experiment.

Companies seeking to claim configuration or settings activities in scale-up settings must be able to explain why the outcome of the activities cannot be known or determined in advance by a competent professional in the field using the existing knowledge, information and experience reasonably available. It is not sufficient to rely solely on reasoning that the scale-up hasn't been done before.

Unanticipated problems that emerge during scale-up can lead to eligible core R&D activities where they meet the eligibility requirements. This is highlighted in the hypothetical example at the end of this guidance.

Supporting R&D activities

Where activities associated with scale-up are not core R&D activities they may be eligible as supporting R&D activities. For a scale-up type activity to be a supporting R&D activity (as with non-scale-up activities) it must demonstrate:

- 1. that it is directly related to a core R&D activity, and
- 2. where it produces goods or services or is directly related to the production of goods or services, or is excluded from being a core activity, that it was undertaken for the dominant purpose of supporting a core R&D activity.

Directly related to a core R&D activity

To be directly related to a core R&D activity, an activity must have a direct, close and relatively immediate relationship to one or more components of the systematic progression of work in the core R&D activity.

Activities that make a direct contribution to the conduct or evaluation of the experiment are likely to meet this requirement. Activities that do not have this relationship with one or more of these components of a core R&D activity are not supporting R&D activities.

Supporting R&D activities must have a direct, close and relatively immediate relationship with one or more components of the systematic progression of work in a core R&D activity.

Dominant purpose for conducting the activity

Some types of activities will need to fulfil a second requirement. An activity that produces, or is directly related to the production of goods or services⁵, must also be undertaken for the dominant purpose of supporting the core R&D activity to which it is directly related. The purpose for undertaking an activity can change over time. However, in regard to the dominant purpose test, the company's purpose for undertaking the relevant activity is assessed at the time the activity is undertaken.

Activities that produce, or are directly related to the production of goods or services have commercial objectives as part of the motivation for undertaking them. The fact that an activity serves a commercial objective as well as being directly related to R&D does not preclude it from qualifying as a supporting R&D activity. However, the fact that certain activities are necessary in order for core R&D activities to occur is not sufficient in itself to show that those activities are undertaken for the dominant purpose of supporting that core R&D activity. Nor will the dominant purpose test be satisfied merely because the activities occur in close proximity (either time or location) to the experimental activities.

When assessing the dominant purpose for undertaking an activity, consideration must be given to the overall circumstances in which the activity is conducted. It is possible that activities that are similar in nature might qualify as supporting R&D activities in one context, but not in another.

A critical consideration will be the extent to which the activities in question have a purpose of achieving outcomes (particularly production or other commercial goals) different to assisting the conduct of the core R&D activities, and the importance of those outcomes.

An activity that produces, or is directly related to the production of goods or services, must also be undertaken for the dominant purpose of supporting the core R&D activity to which it is directly related.

Record keeping

When planning R&D activities companies should be planning how they will document the eligibility of their scale-up work. Companies need to maintain records that show what the specific technical challenges were that required experiments to resolve, what their experiments were, and the specific ways in which the R&D activities were carried out. This should include records that detail what was done to conduct any scale-up or production activities claimed as either core or supporting R&D activities.

This document is intended to provide useful information for companies considering accessing the *R&D Tax Incentive*. However it is not exhaustive and it is not legal or financial advice. It is your responsibility, with the assistance of any advice you wish to seek, to satisfy yourself about the eligibility of your activities for the *R&D Tax Incentive*. The Commonwealth disclaims all liability for any loss or damage arising from you or anyone else relying on this document or any statement contained in it.

Scale-up Example

While planning its scale-up of a bioreactor, a company worked to identify specific production scale equipment and to design the process flow. The company started by using available knowledge and expertise of its own staff, equipment suppliers, and some technical papers that addressed similar processes.

The company knew that its work to identify the required commercially available equipment was not experimental, or directly related to an experimental activity. Likewise, it knew that much of the design work required was routine engineering, even though it was complex.

The company recognised that it would not be undertaking eligible R&D in the scale-up project until it identified a specific technical problem that it could only resolve experimentally.

⁵ Or it falls within one of the core R&D activity exclusions listed in section 355-25(2) of the *Income Tax Assessment Act 1997*.

⁶ This will place companies in a better position to demonstrate the eligibility of their activities if they are selected for a compliance review – documents prepared at the time of undertaking the work provide better evidence than documents developed after the fact. For further information see Keeping Records as Evidence at www.business.gov.au/rdti.

The company was aware that the oxygenation line in its small scale laboratory process also performed a necessary function in circulating the water which prevented water stagnation and the accumulation of toxins. However, as the scale-up project progressed, the company's engineers discovered that the increased volume of water would not be circulated to the same extent by a simple scale-up of the laboratory process oxygenation line and as a result biological waste would accumulate away from the oxygenation line, threatening the growth and the eventual viability of the micro-organisms. The company's engineers conducted research on available nozzle designs and modelling circulation flows to find a solution to the problem. The engineer's analysis of this research failed to identify or determine a solution.

The available nozzle designs, including some the company machined itself using research papers on bioreactors as a guide, were subsequently tested by running experiments on the oxygenation line in the production scale bioreactor in carefully designed and documented tests. The company conducted these tests after formulating hypotheses about specific technical variables because it could not find any information during its research that it could use to know or determine whether the technical features of these designs would provide the intensity and coverage of the circulation it needed. Evaluations of the tests found that each of the nozzle designs provided water circulation in the production scale tank that was too vigorous. This would impair the organism's access to nutrients and disrupt its reproductive and growth cycles observed in the small-scale process.

This activity involves an experiment that tested a nozzle for its specific performance attributes in relation to a specific task. The activity included an evaluation and led to logical conclusions about the suitability of the nozzle for the company's specific task. The information presented shows the company conducted the activity because it couldn't find any existing information to know whether the nozzle would suit its specific purpose. On the face of it, this activity would be a core R&D activity. The company would need to maintain contemporaneous documentation to evidence its claims against the legislated eligibility criteria.

The company's engineers then identified a nozzle design that had been used in a production process for volatile chemicals, which they believed could be adapted to provide the necessary oxygenation and mixing. However, they could not find information to know whether their adapted design could provide a flow pattern of oxygenated water that would support their required bioprocess.

They used a well understood and validated flow modelling tool to try to predict flow outcomes. From the modelling work, the engineers were able to formulate hypotheses about relationships between the technical variables of the nozzle and the desired oxygenation and mixing patterns in the bioreactor. They were then able to design experiments to determine whether the adapted design would give them the precise flow conditions and micro-organism growth required.

The modelling activity as described would be a supporting R&D activity. The modelling work directly contributed to the design of experiments to test an adapted prototype nozzle concept against specific technical variables that would be conducted in a subsequent experimental activity.

The engineers developed a prototype nozzle based on their preliminary design and carried out experiments in the production scale tank that tested a range of production conditions while varying flows through the nozzle. Initial flow was observed to be as they hypothesised, but the growth of the micro-organism was not consistent across the required range of production conditions. The engineers analysed the results to determine the cause of the inconsistent micro-organism growth, and used this knowledge to iteratively develop and test several different nozzle design configurations until an effective design was proven.

The process of proving the effective design required the experiments to be conducted more than once to ensure statistical significance in the outcome. As soon as the company was confident with its conclusions about the truth or falsity of the hypotheses any further production tank activity would not be eligible as the core R&D activity had concluded.

In the paragraph above, the development and production of the prototype nozzle would meet the requirements for a supporting R&D activity. The development and production of the prototype is directly related to the experiments conducted in a subsequent core R&D activity.

On the facts presented, the experiments carried out in the production scale tank to test the prototype nozzle would be a core R&D activity. These activities would continue to be eligible until such time as the outcome of the experiments was reliably known, that is, until a competent professional in the field could look at the knowledge that had already been generated and determine the outcome of running the experiments again.

Once the final design was identified, the engineers used that knowledge to revise elements of the overall process design and re-specified several pieces of equipment to deliver the particular flow rates they now knew were required.

The company carefully documented each step of the activities it carried out to:

- ensure it had records to substantiate its R&D tax claim;
- · capture the knowledge it had generated; and
- use the knowledge to maintain and improve this, and future systems.

The company knew that its initial equipment investigation, specification and design activities conducted before it identified its specific technical problem were not core R&D activities⁷ and were not directly related to the specific experimental activities. Similarly, the company knew that the construction of the scaled-up tank did not meet the eligibility requirements for a core R&D activity. Nor did the construction of the tank meet the eligibility requirements for a supporting R&D activity. While the full scale tank was necessary to conduct the nozzle experiments (the directly related test), the dominant purpose for its construction was for commercial production purposes and not to support the generation of new knowledge through the conduct of the nozzle experiments.

The fact that the activities were all part of the same project is not sufficient for a direct relationship. However, the company did identify that its preliminary design work on the in-tank oxygenation flow was directly used to design the experimental rig and the variations in conditions in the experiments, and assessed that these activities were eligible supporting R&D activities. The company also assessed that the nozzle design research, and the modelling of flow for the adapted nozzle, were directly related to the experimental activities.

The company was confident that it could identify its eligible core R&D activities, which involved the two sets of experiments, the analysis and evaluation of the results.

The company recognised that once it had experimentally proven that the adapted design would produce the intended results, its R&D work did not extend to implementing that proven design through its further project design and construction activities.

For further information on the R&DTI, visit www.business.gov.au/RDTI or contact us at: RDTI.Engagement@industry.gov.au

⁷ Before identifying a specific technical challenge, activities cannot have been carried out for the purpose of resolving that challenge