



September 2023

# Changes to import permits and charging arrangements for laboratory goods.

## What is changing?

The Department of Agriculture, Fisheries and Forestry (the department) will be making changes to the biosecurity import permit validity periods and charging arrangements for laboratory goods.

### Changes to validity period

From 20 September, the department will begin to grant non-standard import permits with a four-year validity period for most laboratory commodities. Non-standard permits for genetic material, culture media, foetal bovine serum and waste will retain a two-year permit validity period.

### Fees and charges for import permit applications:

Importers may notice some changes to the way that fees are charged for non-standard permit applications. The department has worked to create many new [standard import permits](#) with 5 year validity for a range of commodities to provide importers with additional flexibility. The department also recently undertook a thorough review of the time taken to complete assessments of non-standard import permit applications. As a result, goods such as test kits that have previously been charged one assessment fee per five products, will now be charged one assessment fee per product, unless the importer can provide evidence of their similarity. This is consistent with the department's [Charging guideline](#).

For most importers, the cost of applying for a biosecurity import permit for laboratory goods will be lower following the changes. As, instead of paying an application fee and an assessment fee once every two years, **most importers will now only need to pay these fees once every four years.**

## Will the department vary my permit?

The changes to permit validity periods will apply only to biosecurity import permits issued on or after 20 September 2023. The department will **not** be varying active biosecurity import permits to extend their end date.

## What laboratory commodities will be eligible for a four-year non-standard permit?

The department will be extending the non-standard permit validity period from two to four years for the following commodity types:

- Animal fluids and tissues (excluding foetal bovine serum)
- Antibodies
- Antigens

- Cell lines
- Environmental samples (soil and water)
- Enzymes (laboratory end use only)
- Human fluids and tissues
- Microorganisms and infectious agents
- Proficiency testing samples and reference materials

Note that the department already issues four-year non-standard permits for test kits.

If a permit application contains a combination of commodities with different validity periods, the shortest validity period will be applied to the issued import permit.

### **Why has the department decided not to extend the non-standard permit validity period for some laboratory commodities?**

The department has decided not to extend the non-standard permit validity period beyond two years for the following laboratory commodities:

- Culture media
- Foetal bovine serum
- Genetic material and nucleic acids
- Waste

This decision has been based on a review of the biosecurity risks presented by these laboratory commodities:

- Culture media and foetal bovine serum undergo a manufacturing process with significant potential for change in ingredients, supply chains and treatment over a four-year period and present an unacceptably high risk of adulteration, substitution or contamination with high risk products.
- Genetic material must be assessed on a case-by-case basis with consideration given to species of origin, genetic sequence (i.e., whether it increases replication, resistance and pathogenicity), the vector and the application of new and rapidly developing synthetic biology techniques.
- Waste must be assessed with consideration given to composition or ingredients, country of origin, quantity, treatment protocols and onshore end use (e.g., disposal or recycling) which carry a significant potential for change over a four-year period.

### **Will the application and assessment process itself change?**

No. The BICON application and assessment process will not be impacted by the change in permit validity periods or charging.

### **How will the changes to charging impact the cost of applying for a biosecurity import permit?**

For most importers, the cost of applying for a new biosecurity import permit will be lower. Instead of paying an application fee and an assessment fee once every two years, most importers will now only need to pay these fees once every four years.

The department expects there will only be a small number of importers who will end up having to pay more to cover the cost of a non-standard permit as a result of the changes to charging arrangements. These are generally importers who submit applications for a large number of products.

How are fees currently charged?	What is changing?
<p>Currently the department allows, at its discretion, importers the option of grouping similar products of the same commodity type (e.g., five microorganisms or five test kits etc) under a single assessment fee.</p> <p>This means a two-year non-standard permit application incurs:</p> <ul style="list-style-type: none"> <li>• A \$122 application fee; and</li> <li>• A minimum \$148 assessment fee per non-standard permit case.</li> <li>• Additional time-based charges of \$37 per quarter hour or part of a quarter hour beyond the initial assessment period.</li> <li>• Similar products (i.e., with similar components, manufacturing, sourcing, end use and biosecurity risk) may be grouped together and charged one assessment fee.</li> </ul> <p>Test kits may be grouped together and charged one assessment fee for every five test kits.</p>	<p>From 20 September 2023 the applicants will be expected to pay a one-for-one assessment fee for each product on their application.</p> <p>This change means a non-standard permit application will incur a:</p> <ul style="list-style-type: none"> <li>• A \$122 application fee; and</li> <li>• A minimum \$148 assessment fee per non-standard permit case.</li> <li>• Additional time-based charges of \$37 per quarter hour or part of a quarter hour beyond the initial assessment period.</li> <li>• Similar products (i.e., with similar components, manufacturing, sourcing, end use and biosecurity risk) may be grouped together and <b>charged a single assessment fee for every five products.</b></li> </ul> <p>Test kits can only be grouped together and charged one assessment fee for every five kits if they can be demonstrated to be similar products.</p>

### Why is this change being made?

These changes reflect the time and effort the department expends determining that two or more products are similar and the administrative work of assessing and developing a permit for each product.

The changes to test kit application assessments are required to align practices with the department's [charging guidelines](#) noting that the department has already developed numerous standard permit cases covering a variety of test kits. Those products which do not meet standard conditions are complex, may present high biosecurity risks and require significant resources to assess.

### Permit applications scenarios

The scenarios below outline how permit applications will be charged as of 20 September 2023. Please note that these are only examples and the actual fees you are charged may vary depending on your application.

#### Scenario 1: A non-standard import permit application for five laboratory commodities

Currently, an importer who applied for a non-standard permit for five laboratory commodities will pay a minimum of \$840 (i.e., a \$122 application fee and a five separate \$148 assessment fees) for a two-year permit. This means that over the next four years, the importer would spend \$1,724 on two different permits under the current arrangements.

From 20 September 2023, an importer applying for the same non-standard permit will pay a minimum of \$840 for five laboratory commodities, but will instead be issued a four-year permit. This includes the \$122 application fee and five \$148 assessment fees (one assessment fee per commodity).

	Current arrangements (2-year validity)	From 20 September 2023 (4-year permit validity)
Required fees over 4 years	\$1,724	\$840

#### Scenario 2a: A non-standard import permit application for five different test kits

Currently, an importer who applied for a non-standard permit for five **different** test kits will pay a minimum of \$270 (i.e., a \$122 application fee and a minimum \$148 assessment fee) for a two-year permit. This means that over the next four years, the importer would spend \$540 on two different permits under the current arrangements.

From 20 September 2023, an importer applying for a four-year non-standard permit will pay \$862 for five laboratory commodities. This includes the \$122 application fee and five \$148 assessment fees (one assessment fee per test kit), as these different test kits require individual assessment, assessment fees will be charged accordingly.

	Current arrangements (2-year validity)	From 20 September 2023 (4-year permit validity)
Required fees over 4 years	\$540	\$862

#### Scenario 2b: A non-standard import permit application for five similar test kits

Currently, an importer who applied for a non-standard permit for five **similar** test kits will pay a minimum of \$270 (i.e., a \$122 application fee and a minimum \$148 assessment fee) for a two-year permit. This means that over the next four years, the importer would spend \$540 on two different permits under the current arrangements.

From 20 September 2023, an importer applying for a four-year non-standard permit will pay \$270 for five **similar** test kits. This includes the \$122 application fee and one \$148 assessment fee (one assessment fee for a group of similar test kits).

	Current arrangements (2-year validity)	From 20 September 2023 (4-year permit validity)
Required fees over 4 years	\$540	\$270

## More information

Email [imports@aff.gov.au](mailto:imports@aff.gov.au)

## Acknowledgement of Country

Department of Agriculture, Fisheries and Forestry

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

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