Details: Hello BICON team!

I am inquiring about the changes made to the import conditions of Nucleic Acid Amplification Test Kits over the past month. I was unaware that these goods required an import permit until last week, when I received correspondence from the Department of Agriculture Fisheries and Forestry informing me that my shipment had been stopped at the border pending an import permit.

I have since spoken to the manufacturer of the goods, and they informed me that their understanding was that the requirement of an import permit for the Test Kits I ordered only came into effect on May 5th, which is why they consented to ship them to Australia. They were confused as to why my shipment was detained given it entered Australia on April 28th.

Is this correct? Or has the import permit been required historically, also? I note on the import conditions page (https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fbicon.agriculture.gov.au%2FBiconWeb4.0%2FImportConditions%2FQuestions%2FEvaluateCase%3FelementID%3D0000123379%26elementVersionID%3D304&data=05%7C02%7CImports%40aff.gov.au%7C35454bfc468645a2565408dd910d1ae8%7C2be67eb7400c4b3fa5a11258c0da0696%7C0%7C0%7C638826207671096950%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=ig%2BCVlyPvK3sgzw%2B9Ppou0Mccv87HI%2BJIcaKWnSkQT0%3D&reserved=0) it states that the current version of the Test Kits import case has been live since May 5th, but I am unsure what the policy was prior to then. Has there been a change to the policy on May 5, or was my supplier just unaware of its necessity until now?

If you would be able to clear up this confusion for me such that I can communicate what went wrong with my supplier, and ensure future import conditions are met, that would be wonderful.

This is the product I was attempting to import, if this information is helpful:https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Faltruan.com%2Fproducts%2Fpluslife-sars-cov-2-pcr-test-kits-10-tests-pack-10-tests&data=05%7C02%7CImports%40aff.gov.au%7C35454bfc468645a2565408dd910d1ae8%7C2be67eb7400c4b3fa5a11258c0da0696%7C0%7C0%7C638826207671117143%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=SiYBOF2kMjjR5dRCpLyb6vJC%2FZGwoaxzbVQCkAMHQ%2Bk%3D&reserved=0

Thank you :)

Thank you for contacting the Department of Agriculture, Fisheries and Forestry.

Can I please confirm whether you have goods currently at the border? If so, to best assist you, could you please provide us with the following details:

- Entry number or biosecurity direction of the goods (or airway bill number if you do not have an entry number)
- Which state did your goods arrive in?
- How did your goods arrive into Australia? (e.g. air freight, passenger)

Australian Biosecurity Import Conditions (BICON) lists the conditions for all goods imported into Australia.

Historically, test kits do require permits unless otherwise stated in BICON (depending the type of test kit).

As per the test kits page you have provided, the latest version has been updated on the 5th of May 2025, however this only indicates the latest version as the department routinely updates administrative areas of the webpage. Under case details -> history, you can view previous renditions of import conditions for test kit cases dating back to 2015.

Additionally, if import conditions do change and have an impact, importers will be notified prior to changes going live and an alert will be published on BICON.

For future imports of these goods, I suggest you determine the most suitable case for your goods. It is ultimately the importer's responsibility to determine if their goods can meet the outlined BICON case.

If your goods are unable to meet any of the "No permit required" or the "Standard permit" options, please select "other" and our assessing officers will conduct a case-by-case assessment of your goods.

Please let me know if you have any questions or concerns,

Kind regards,

Thanks for getting back to me and for all this excellent information! I previously had goods at the border last week, entering in [redacted] Their reference number was [redacted]

However, after calling your department last week, I was informed that my lack of permit at the time that the goods entered the country meant that there was no way for me to get to them. As such, I emailed vicdgo@aff.gov.au and asked them to return the goods to sender.

I assume the goods are beyond my reach now, and in the mean time have secured an import permit for future shipments.

However the supplier was confused when I brought this to them (to ensure they provided an appropriate Manufacturer's Declaration, etc) as they apparently haven't had a request like mine for importing these test kits before. Thus, I wanted to determine whether or not these import conditions had applied before May 5, in case my shipment had been stopped a couple of days in advance of a policy change/similar.

It sounds like that's not the case though! Does that sound right to you?

Warm regards,

Thank you for your email,

It would like to clarify the goods had been held at the border as there was no permit alongside the consignment, **not** because of any changing import conditions.

For future consignments your supplier/manufacturer will need to provide a manufacturer's declaration attesting to import conditions. For example looking at Test kits not testing for disease agents (Standard), under condition b, the manufacturer will need to provide the following statements:

> b. The goods must meet biosecurity requirements.
>
> To demonstrate compliance with this requirement you must present the following on a Manufacturer's declaration:
>
> A statement that:
>
> 1. The goods are test kits (or individual components specifically designed for use with kits eligible for import under these conditions), which:
>   1.1. do not test for disease agents
>   1.2. do not contain disease agents (live, live attenuated, or inactivated) or their derivatives (e.g. antigens)
>   1.3. do not contain any components raised against disease agents (e.g. antibodies).
> 2. All animal derived material contained in these test kit(s) is in volumes of no greater than 20ml or 20g per individually packaged unit.
>   Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.
>
> Product name(s) of each kit and each reagent, control, calibrator etc. (if imported separately to the kit) must be included on the manufacturer's declaration.
>
> The manufacturer's declaration must be supplied by either a legal manufacturer, or the individual manufacturing site.
>
> Note: The manufacturing declaration does not need to be issued from within the country of manufacture.
>
> c. The goods must be commercially manufactured and packaged.

Please ensure all documents align with the Minimum documentary and import declaration requirements policy - DAFF.

Please let me know if you have any further questions or concerns,

Kind regards,