



**This is a direction issued to all officers of the APVMA by the Chief Executive Officer under s 11(3) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992 (Cth)* and s 13(5) of the *Public Service Act 1999 (Cth)***

#### **CEO expectations on use of international data, standards and assessments**

It is expected everyone involved in the assessment of applications for product registration and active approvals understands and applies the APVMA's policy for the [use of international data, standards and assessments](#).

While the APVMA must make decisions based on Australian legislative requirements, APVMA officers are expected to use as much of any international assessments provided as possible.

Where an application for pre-application assistance is received, APVMA officers are expected to provide guidance to the applicant about whether international assessments (or components of the assessments) would be acceptable to support an application. They are expected to rely on the international assessments supplied as much as possible.

APVMA officers are to carry forward advice provided at the pre-application stage about the useability of international assessments to the evaluation stages and should not impose additional requirements, above any noted in pre-application advice, except under exceptional circumstances.

While the APVMA is not required to automatically accept the outcome of an international assessment, it is expected officers will give consideration to the international assessment report and its conclusions. If the APVMA does not consider the international assessment is supportive of the proposed Australian registration, then the statement of reasons being provided to an applicant must include scientific reasons why the international assessment cannot be relied on.

APVMA officers are to consider if international assessments are fit-for-purpose by undertaking an appropriate level of peer review. They are not to commission or undertake detailed analysis of supporting data, unless there is a justifiable reason to do so and permission is obtained from the relevant manager, delegate or Executive Director prior to the analysis being undertaken.

APVMA officers are not to impose additional requirements on applicants unless there is a justifiable reason to do so. At evaluation, any notices requesting information in addition to the international assessment must be approved by the relevant Executive Director.

APVMA officers are expected to deliver shorter assessment reports outlining considerations against legislative requirements, drawing on or referring to the international assessment report as needed.

Ms Lisa Croft  
Chief Executive Officer

8 December 2020