

Bio-Gene's registration plans for Flavocide® on track following APVMA feedback

Highlights

- **Studies planned for the Flavocide® insect control active ingredient regulatory dossier are confirmed following feedback received from the Australian Pesticides and Veterinary Medicines Authority (APVMA)**
- **APVMA provides assistance on the regulatory requirements to facilitate registration of new active ingredients**
- **Flavocide is a novel insecticidal active ingredient derived from nature being developed by Bio-Gene for use in public health, agriculture and by consumers**

Bio-Gene Technology Limited (ASX:BGT, Bio-Gene or the Company), an Australian company developing the next generation of novel bio-insecticides, has received feedback from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on studies required to support the Company's planned submission for regulatory approval of Flavocide active ingredient, currently expected to be filed with the APVMA in December 2025.

APVMA is the Australian Government regulator of agricultural and veterinary chemical products, established to centralise the registration and approval for use of these products in Australia. The regulations allow potential registration applicants, such as Bio-Gene, the opportunity to proactively request assistance on the technical requirements to facilitate registration from the APVMA. This process helps to ensure the range of regulatory studies planned to support an application for registration are consistent with the regulator's expectations. This process is called Pre-Application Assistance (PAA).

Bio-Gene submitted a PAA application for Flavocide to confirm the studies required to support the registration of this new active ingredient based on the Flavocide data generated to date. The APVMA provided feedback on areas such as assessment of the chemistry and manufacturing data and on the data requirements for safety studies to be included in the Flavocide regulatory information dossier. This feedback will assist Bio-Gene to ensure studies are comprehensive, aligned with the proposed use of the product once approved, and will support the Company's planned submission of its registration application in December 2025.

Tim Grogan, Managing Director & Chief Executive Officer of Bio-Gene said:

"We have taken this opportunity to proactively engage with the APVMA to pressure test our study plans for Flavocide. Engaging with the regulator now assists us to confirm and streamline the work that we need to do as part of the registration process."

“Based on the feedback received, we are currently on track to submit the regulatory information dossier for Flavocide as an active ingredient by the end of 2025. The APVMA’s feedback has clarified the range of studies required and also assisted in fine-tuning our existing strategy for regulatory approval.

It is very reassuring to receive this feedback from the APVMA at this time. It ensures our Flavocide regulatory development path in Australia is optimised and will include the range of studies required, based on all of the data on Flavocide we have generated so far.”

Bio-Gene is developing Flavocide as a new insecticide derived from nature for use in public health, crop protection, grain storage and consumer applications. As a nature-identical compound that has a novel way of killing pest insects (i.e. a new mode of action), Flavocide has been shown to overcome insecticide resistance. The development of insect resistance to current insecticides is an increasing challenge worldwide.

Approved for release by the Board of Directors.

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About Bio-Gene Technology Limited

Bio-Gene is an Australian company developing novel bio-insecticides to address the global challenges of insecticide resistance. Its unique products are based on a naturally occurring class of compounds proven to overcome resistance to control pests with minimal impact on human health and the environment.

Bio-Gene’s products have multiple applications across public health, crop protection, grain storage, and consumer use. They provide new options derived from nature to meet market demand for effective and safe pest management solutions.

Flavocide® is a trademark of Bio-Gene Technology Limited.