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Progress in regulatory development of Flavocide® and first regulatory submission timeline

Highlights

- **Flavocide® development program and toxicology studies are progressing well**
- **Results from initial toxicology studies have supported progression into the major reproductive and neurotoxicity studies**
- **Bio-Gene is targeting submission of its first application for registration of Flavocide as a new active constituent with APVMA in March 2027[1]**
- **The first application will seek approval of Flavocide active constituent to initially support product registrations as an insecticide for professional and domestic use**
- **Studies are generating data to OECD standards and will support subsequent regulatory submissions in other target countries[2]**

Melbourne, Australia: Bio-Gene Technology Limited (ASX:BGT or 'Bio-Gene' or 'the Company'), an Australian company developing the next generation of novel insecticides derived from nature, provides this update on the overall regulatory development of Flavocide, Bio-Gene's insecticidal active constituent[3] with a new mode of action, and the studies required to support its first application for the registration of Flavocide as a new active constituent.

This update includes details of the estimated development timelines for registration of Flavocide active constituent in Australia, including data generation to evaluate the safety, stability and product chemistry of Flavocide in accordance with international regulatory requirements.

Bio-Gene is targeting submission of its first application for registration of Flavocide as a new active constituent with the Australian Pesticides & Veterinary Medicines Authority (**APVMA)** in March 2027[4]. This application will relate to active constituent approval, and formulated product registrations will be pursued separately with product-specific data packages (including environmental fate and ecotoxicology). Subsequent applications for registration in the USA and other major territories are planned.

[1] This estimate is subject to a range of factors, including continued availability of planned study slots scheduled with Contract Research Organisations (CROs) and achievement of planned study start dates, QA release, data review, study report finalization and availability of capital required for completion of these studies and other business operations.
[2] Note that regulators in other countries may request additional, country-specific studies beyond the data package to be filed in Australia.
[3] Active constituents are the substance(s) in an agricultural or veterinary chemical product that are primarily responsible for a product's biological or other effects.
[4] See note 1.

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

"Bio-Gene has been running a significant program of studies that are progressing very well, with excellent progress to date when compared with our plans. A core focus for Bio-Gene is to execute on our strategy for the regulatory development of Flavocide to support commercialisation of our technology.

"We have successfully deployed funding provided by our shareholders, including funds allocated from our May 2025 capital raising, towards the studies that are now either completed or underway. We are eagerly awaiting the outcome of the recently announced major neurotoxicity (OECD 424) and reproductive toxicology (OECD 443) studies, with results expected in May 2026 and September 2026 respectively.

"The remaining studies to complete the toxicity data package are of relatively short duration and we plan to run them concurrently, with overlapping timelines to support the expected first regulatory filing for Flavocide in March 2027. This filing will be a significant milestone for Bio-Gene and our development of Flavocide."

Summary of toxicology studies to date

Bio-Gene is generating data from a series of animal toxicology studies designed to support its first application for approval of Flavocide. This will initially support intended use as the active constituent in indoor and/or outdoor insecticides for professional and domestic use but not for use in food producing situations. Formulated product registrations are separate from active constituent approval. They will be pursued subsequently by Bio-Gene's commercial partners, including use patterns for mosquito control and potentially other selected flying insects that are vectors of disease.

The following table summarises the current status of all key toxicology studies required to support this first application for the registration of Flavocide active constituent in Australia.

Code[5]:	Study Description:	Status:	Total Duration[6]:	Results Due[7]:
OECD 417 (part 1)	Pilot in-vivo metabolism in rats and pharmacokinetics (**PK**) study	Completed	6 months	Received
OECD 407	28-day rat repeat dose oral toxicity	Completed	7 months	Received

[5] Each of the study protocols comply with the relevant guidelines from the OECD's Mutual Acceptance of Data (MAD) system for the testing of chemicals using a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories. These guidelines provide a common basis for co-operation between regulatory bodies across the 38 OECD member countries (and a further seven non-member countries) to assess the toxicity of new chemical substances.

[6] The total study durations are indicative only and based on current study scope and laboratory scheduling. Actual timing may change due to operational factors, including CRO scheduling, protocol finalisation, regulatory feedback, sample logistics, QA and data review requirements.

[7] Preliminary report of study results.

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OECD 443	Extended one generation reproductive toxicity study (rat), including (completed) dose range-finding arm	In progress	15 months	September 2026
OECD 424	Acute neurotoxicity study of flavesone in rats, including (completed) dose range-finding arm	In progress	8 months	May 2026
OECD 417 (part 2)	GLP[8] study - in-vivo metabolism (rats) and pharmacokinetics	Planned	9 months	February 2027 (est.)
OECD 408	Rat 90-day oral repeat dose study (sub-chronic)	Planned	8 Months	January 2027 (est.)
OECD 409	Dog 14-day oral repeat dose study	Planned	4 months	September 2026 (est.)
OECD 414	Rabbit prenatal GLP developmental toxicology, including dose range-finding arms	Planned	8 months	January 2027 (est.)

As at the date of this announcement, the 28-day rat repeat dose oral toxicity (OECD 407) and the pilot in-vivo metabolism in rats and pharmacokinetics study (OECD 417 part 1) are complete. Results from these two studies have supported progression to the longer-term rat 90-day oral repeat dose (OECD 408) and definitive metabolism (OECD 417 part 2) studies.

The extended one generation reproductive toxicity study in rats (OECD 443) and the acute neurotoxicity study of flavesone in rats (OECD 424) have also commenced. The dose range-finding arms of both studies are now completed and the main study arms are in progress, with results scheduled to be received in May 2026[9] and September 2026[10] respectively. These four major studies represent 55% of the total duration of each of the planned studies measured in months.

The remaining studies are planned to run in parallel, with overlapping timelines to support the earliest practicable regulatory filing window. Based on progress to date and the expected availability of remaining study outputs, Bio-Gene is targeting submission of its first application for registration of Flavocide as a new active constituent with the APVMA in March 2027[11].

[8] Good Laboratory Practice (GLP) is a set of principles for planning, performing, monitoring, recording, and reporting non-clinical health and environmental safety studies. It ensures the quality, integrity, and reliability of data used for regulatory, agricultural, or pharmaceutical product assessments. Key elements include, but are not limited to, trained personnel, validated equipment, Standard Operating Procedures (SOPs), and proper documentation.
[9] See Bio-Gene ASX announcement dated 13 February 2026
[10] See Bio-Gene ASX announcement dated 9 February 2026
[11] See note 1.

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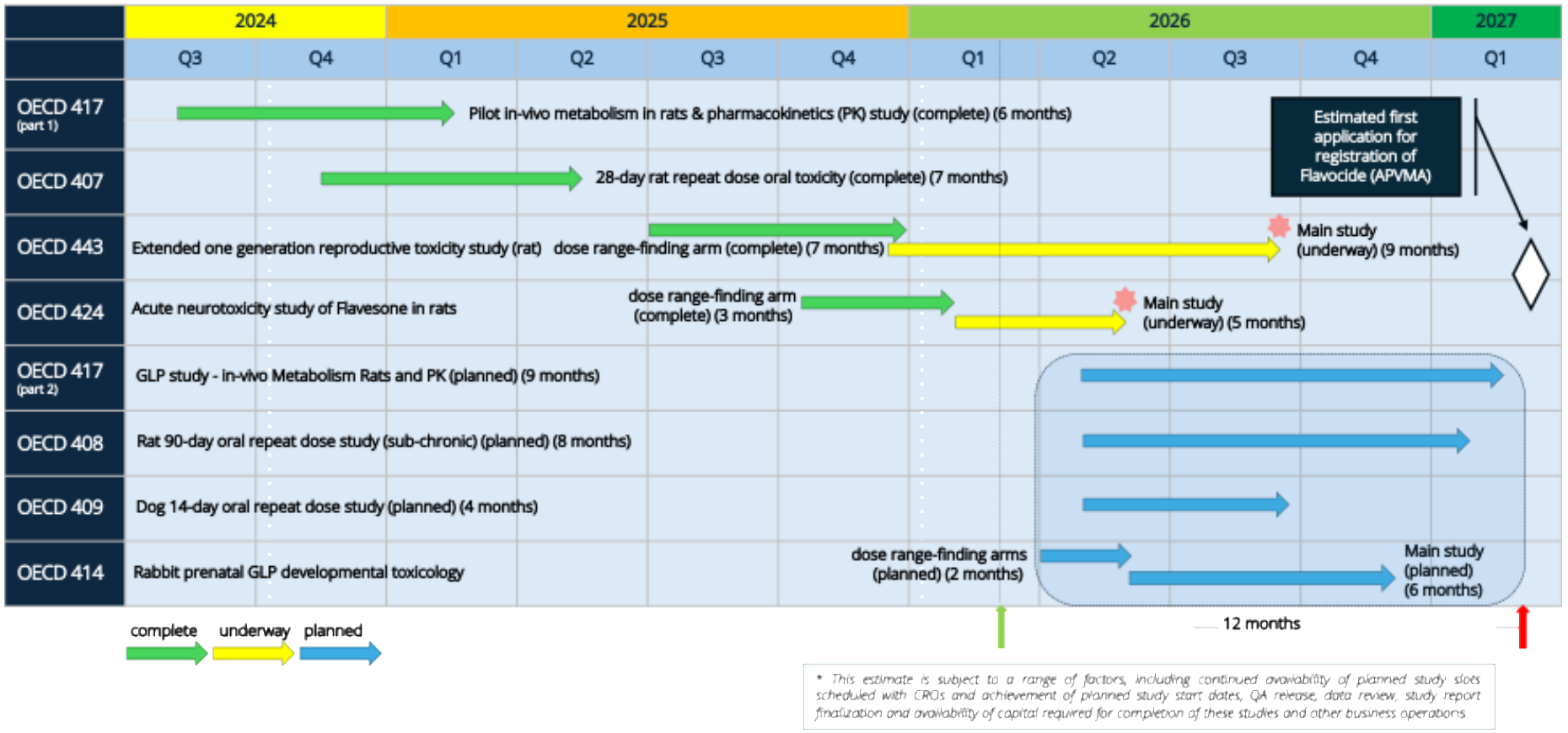
Figure 1: Flavocide development – study & first regulatory application timeline*



* This estimate is subject to a range of factors, including continued availability of planned study sites scheduled with CROs and achievement of planned study start dates, QA release, data review, study report finalization and availability of capital required for completion of these studies and other business operations.

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Figure 1 (above) summarises the current status of the complete, underway and planned studies for the development of Flavocide and the estimated timeline leading up to the first application for regulatory approval of Flavocide as an active constituent in March 2027[12].

Flavocide Stability & Product Chemistry

Following the completion of pilot-scale production of Flavocide by Rallis India Limited[13], Bio-Gene has undertaken a 5-batch analysis of the technical material to characterise the product composition and impurity profile and this work is in the final stages of completion.

A GLP 5-batch analysis is a standard component of the GLP chemistry and manufacturing data package used to support registration of technical active constituents across major international regulatory systems, including APVMA, U.S. Environmental Protection Agency (**US EPA**), and European Food Safety Authority (**EFSA**). It involves testing five representative production batches to quantify the active constituent and to identify impurities, and support the establishment of product specifications, chemical equivalence and manufacturing consistency.

A GLP accelerated storage stability study is planned and an ambient real-time storage stability study, which is a core element of the Flavocide product chemistry package, is planned to commence shortly. This study is designed to confirm the long-term stability of the technical material and track any changes in active constituent content and impurity profile under real-time conditions. This study will provide a fully traceable real-time stability dataset to support the APVMA dossier and future global registrations.

Q & A

Question 1:	*How did you decide on the range of toxicology studies required to be undertaken?*
Answer:	*The range of studies required is based on an assessment of the proposed use-pattern and the body of data on the safety profile of Flavocide. This assessment was undertaken with the assistance of external regulatory and toxicology experts and then confirmed with feedback received from the APVMA during the Pre-Application Assistance (**PAA**) stage.*[14]
Question 2:	*Which studies are the most important?*
Answer:	*All studies are equally important in that they are required for submission in the regulatory dossier. OECD 443 (extended one generation reproductive toxicity study in rats), OECD 424 (acute neurotoxicity study of Flavesone in rats), the OECD 408 (Rat 90-day oral repeat dose study – sub chronic) and OECD 417 (in-vivo metabolism in rats and pharmacokinetics) are the*

[12] See note 1.
[13] See BGT ASX announcement dated 2 September 2024.
[14] See BGT ASX release dated 8 August 2024.

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	longest studies and generate very detailed information about the toxicology profile of Flavocide.
Question 3:	*What are the typical stages or activities involved in running each of the studies?*
Answer:	*Although the stages vary depending on the individual study requirements, studies typically involve the following steps: audit of study site, study plan review, sample shipment, GLP analytical method development, liaison with study monitors, dose range-finding arm, preparation of animals, in-life phase, sample analysis and evaluation, preparation and review of preliminary and final study reports.*
Question 4:	*What are the key risks related to running the studies and what factors can have an impact on achievement of the estimated timelines?*
Answer:	*The selected CROs and their staff have significant prior experience with undertaking the various studies and are regularly audited to ensure their systems and compliance certifications are current. Sometimes the initial timeslots allocated for a study will need to be adjusted due to the CROs workload with other clients. All studies involve an element of technical risk and the possibility that any study may result in data showing an adverse safety profile.*
Question 5:	*How did Flavocide perform in the two completed studies (OECD 417 part 1 and OECD 407)?*
Answer:	*Results from the completed OECD 407 (28-day oral toxicity in rats) and the pilot OECD 417 ADME study were supportive of progressing the program. OECD 417 part 1 is informative because it tracks metabolism and distribution, i.e., how Flavocide is processed in the body, where it distributes, and how it is eliminated, which helps interpret toxicology findings across the broader dataset. These results supported initiation of the major reproductive toxicity and neurotoxicity studies now underway.*
Question 6:	*When will important data of key studies be reported?*
Answer:	*Bio-Gene currently anticipates that it will receive the preliminary study reports for OECD 424 (acute neurotoxicity study of Flavesone in rats) in May 2026 and for OECD 443 (extended one generation reproductive toxicity study in rats) in September 2026 respectively. OECD 417 (in-vivo metabolism in rats and pharmacokinetics) is anticipated in February 2027. ASX announcements will be released when those reports are received.*
Question 7:	*What type of use of Flavocide will Bio-Gene apply for first with the application to the APVMA? What other uses and applications are planned?*

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Answer:	*Bio-Gene's first planned APVMA submission is for approval of Flavocide as a new active constituent with intended use in insecticides for professional and domestic use, but not for use in food producing situations. This would include public health use patterns including mosquito control and potentially other selected flying insects. This first submission would be intended to support future formulated product registrations, noting that formulated product registrations are pursued via separate applications by Bio-Gene's commercial partners and require additional product-specific datasets, including environmental fate and ecotoxicology.* *Bio-Gene will evaluate additional uses and applications over time, including other indoor/outdoor settings and other end-use segments, subject to generation of further data and jurisdiction-specific regulatory requirements.*
Question 8:	*Why is the first regulatory submission and subsequent approval an important milestone for Bio-Gene?*
Answer:	*As Flavocide is a new insecticidal active constituent and it has an effect on insects through a new mode of action with relevance to global interest in Integrated Pest Management (**IPM**) to minimise the spread of insects resistant to some current products, the first regulatory approval will be an important precedent and provide a new option for the control of mosquitoes and certain other flying insects.*
Question 9:	*Once Bio-Gene's Flavocide application is submitted to the APVMA in March 2027, approximately how long will it take for the APVMA to review the dossier and approve the first registration of Flavocide active constituent?*
Answer:	*The APVMA is required by its legislation to review a new active constituent within 18 months. The actual APVMA review time for the Flavocide dossier may take less time, however it is not currently possible to provide an accurate estimate.*
Question 10:	*Are any other registrations or approvals required before Flavocide is approved for use by consumers in Australia?*
Answer:	*In addition to the Flavocide active constituent registrations, product formulations containing Flavocide will also be required to be registered. These are called product registrations and take significantly less data and time when compared with registration of the new active constituent. Bio-Gene's commercial partners will typically develop these formulations and apply for the individual product registrations.*
Question 11:	*What plans does Bio-Gene have to apply for registration of Flavocide active constituent outside Australia?*

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Answer:	*After applying in Australia, Bio-Gene intends to apply for registration for the same uses in the US and in other major markets in support of our commercial licensees.*
Question 12:	*What further data will be required to support future applications outside Australia and for additional types of uses of Flavocide?*
Answer:	*The data requirements may vary from country to country, depending on the proposed use pattern, however additional environmental toxicology and environmental fate (i.e. breakdown) data may be required, e.g. in the USA.*

Flavocide Background and Development Context

Flavocide is a novel insecticide containing flavesone, a naturally occurring plant compound present in some eucalypts. Bio-Gene has developed a proprietary process to synthesise this molecule and produce it in commercial quantities. Bio-Gene owns all intellectual property created by its contractors relating to this process to synthesise Flavocide.

Flavocide exhibits a new mode of action – that is, the way it controls or knocks down an insect – and is able to overcome insect resistance to many currently used insecticidal products. Bio-Gene is developing Flavocide to address the global problem of insecticide resistance in the areas of public health, crop protection, grain storage and consumer applications.

The Company's business model involves entering into licensing arrangements with commercial partners internationally to formulate and develop insecticidal products that contain Flavocide. Bio-Gene will then be entitled to receive up-front and milestone payments and then royalties from its commercial partners upon sale of these new products. Bio-Gene's business model also includes the supply of Flavocide to these partners in commercial quantities under a commercial supply agreement.

Approved for release on ASX by Bio-Gene Board of Directors.

- ENDS -

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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 insecticide resistance to control pests with minimal impact on human health and the environment.

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

www.bio-gene.com.au

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About this announcement

This announcement has been prepared in accordance with the AusBiotech *Code of Best Practice for Reporting by Life Sciences Companies* (2nd Edition), 2013. The objectives of this Code are to:

a. provide a reference tool to guide public Australian life science companies in effective and informative communication to the market according to a guidance framework;
b. incorporate international best practice in reporting, and thus maintain and enhance the reputation, integrity and credibility of the Australian life science sector; and
c. provide information to investors about the disclosure framework that identifies the key drivers of value for life science companies, supporting more informed investment decisions.