



December 23, 2025

NutraSteward, Inc.
Attention: Elizabeth Lewis, Ph.D.
Scientific and Regulatory Advisor
Frederick House
Johnston, Pembrokeshire SA62 3AQ
United Kingdom

Re: GRAS Notice AGRN 80 – Black Soldier Fly Larvae Oil

Dear Dr. Lewis:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) refers to a generally recognized as safe (GRAS) notice, dated May 8, 2025, submitted on behalf of your client Enviroflight LLC, (Enviroflight or the notifier). The subject of the notice is Black Soldier Fly Larvae Oil (hereafter referred to as the notified substance) to be used as a source of energy in the food for cats and dogs of all life stages in accordance with good feeding practices. On June 17, 2025, CVM received an amendment containing additional information. The submission informs us of your conclusion that the subject of the submission is GRAS through scientific procedures. You were notified in a letter, dated June 20, 2025, that the GRAS notice, as amended, was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 80. We have completed our evaluation of AGRN 80 and have no questions at this time regarding the conclusion of the use of the notified substance in the food for cats and dogs of all life stages in accordance with good feeding practices.

To address the identity, method of manufacture, and specifications of the notified substance, the notifier describes the black soldier fly (*Hermetia illucens*) taxonomy, breeding, growing, harvesting, downstream processing, composition and analytical methods. The notified substance is the oil fraction derived from mechanical extraction of the dried larvae of the black soldier fly. The larvae are raised on a feedstock composed exclusively of feed grade materials. The notifier provides specifications for the finished product which include: appearance (brown semi-solid), total fatty acids ($\geq 90\%$), free fatty acids ($\leq 10\%$), moisture ($\leq 2\%$), unsaponifiable matter ($\leq 2\%$), insoluble impurities ($\leq 1\%$), peroxide value (≤ 5 meq O₂/kg fat), arsenic (≤ 0.5 mg/kg), cadmium (≤ 0.05 mg/kg), lead (≤ 0.5 mg/kg) and mercury (≤ 0.05 mg/kg), *Salmonella* (absent/25g), and *E. coli* (absent/25g). The notifier has also provided stability and packaging information.

To address the utility of the intended use of the notified substance, the notifier provides data on the lipid composition and fatty acid profile of the notified substance. These data indicate the predominant fatty acids in the notified substance are also found in other fat sources commonly used in food for dogs and cats, and that the notified substance can make a significant

contribution to some of the dietary fatty acid requirements of dogs and cats under the conditions of intended use. In addition, the notifier provides data from feeding studies performed with adult dogs and adult and growing cats, which show that diets containing the notified substance, or its parent substance, Dried Black Soldier Fly Larvae, have good protein and fat digestibility.

To address the target animal safety of the intended use of the notified substance, the notifier notes that the identity of the notified substance is identical to that of the Black Soldier Fly Larvae Oil defined by the Association of American Feed Control Officials, which has been demonstrated to be safe for use in multiple animal species, including adult cats and dogs. The notifier states that the black soldier fly larvae are raised exclusively on feed grade materials in strictly controlled environments, which limits the potential for the accumulation of contaminants. The notifier substantiates this statement with analytical data from multiple batches of the notified substance that demonstrate the absence of heavy metals and pathogenic microorganisms. The notifier also provides data which show potential exposure by dogs and cats to the predominant fatty acids in the notified substance are equivalent to, or less than, the exposures that would occur from consumption of other fat sources commonly used in dog and cat foods. Furthermore, the notifier describes the absorption, distribution, metabolism, and excretion of fatty acids common to mammals, and states that based on these pathways, the fatty acids in the notified substance are expected to be fully metabolized by dogs and cats without excess accumulation in the tissues. Pivotal data to support the safety of the notified substance in cats come from two published feeding studies. One study demonstrated that adult cats fed a diet containing 1.5% of the notified substance for 70 days remained healthy with no adverse effects on feed intake, clinical parameters, and digestibility. The second study demonstrated that a diet containing Dried Black Soldier Fly Larvae, which contained the equivalent of 7.2% of the notified substance, maintained the health of queens during gestation and lactation, and the health of their kittens during growth up to approximately 16 weeks of age. There were no adverse effects on feed intake and clinical parameters in queens and kittens, nor on digestibility parameters in the kittens. Pivotal data to support the safety of the notified substance in dogs come from a 28-day study in adult dogs fed diets containing up to 5% of the notified substance, and a 65-day study in adult dogs fed 8% of a Black Soldier Fly Larvae Oil manufactured in a different manner than the notified substance. The dogs in both studies remained healthy and had good digestibility results. The notifier also provides supportive data from a 12-week study assessing the health of adult dogs fed 5% Dried Black Soldier Fly Larvae, and a 40-day study assessing the performance and health of piglets fed diets containing up to 6% of the notified substance.

Section 301(lI) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(lI) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(lI) (1)-(4) applies. In our evaluation of this notice, concluding that the notified substance is GRAS under its intended conditions of use, we did not consider whether section 301(lI) or any of its exemptions apply to foods containing the notified substance. Accordingly, our response should not be construed to be a statement that foods containing the notified substance, if introduced or delivered for introduction into interstate commerce, would not violate section 301(lI).

CONCLUSION

Based on the information contained in the notice, as amended, submitted on behalf of Enviroflight, and other information available to the FDA, we have no questions at this time regarding its conclusion that Black Soldier Fly Larvae Oil is GRAS as a source of energy in food for dogs and cats of all life stages at levels in accordance with good feeding practices. The Agency has not made its own determination regarding the GRAS status of the intended use of the notified substance in animal food under 21 CFR 570.35. Unless noted above, our evaluation did not address other provisions of the FD&C Act. As always, it is the continuing responsibility of Enviroflight, to ensure that animal food ingredients that it markets are safe and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 80 is accessible to the public on our website for the Current Animal Food GRAS Notices Inventory at <https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory>.

If you have any questions or comments, please contact Ms. Wasima Wahid at animalfood-premarket@fda.hhs.gov.

Sincerely,

/s/
Jeanette B. Murphy, M.S.
Acting Director
Office of Surveillance and Compliance
Center for Veterinary Medicine