Bovaer Feed Ingredient Protocol

Protocol ID	Version	Updated As Of
PRO-00000002	1.0	September 19, 2024

Athian

Acknowledgements

This protocol has been developed by Elanco Animal Health Incorporated.

Table of Contents

1 Introduction

Bovaer Quantification Methodology was developed by Elanco to provide a standardized methodology for the quantification of greenhouse gas (GHG) reductions associated with the use of 3-nitrooxypropanol (3-NOP) as a feed ingredient for U.S. lactating dairy cattle. The quantification of these reduction credits enables consumer packaged goods companies (CPG) to reduce their scope 3 emissions. In May of 2024, the Food and Drug Administration completed their review of safety and effectiveness data to determine that Bovaer may be marketed and sold for use in U.S. lactating dairy cattle.

Livestock supply chains are accountable for 14.5% of anthropogenic GHG emissions (Gerber et al., 2013). Enteric methane accounts for 43% of GHG emissions from U.S. dairy farms (Rotz et al., 2021) and has a global warming potential 27 times greater than CO_2 on a 100-year time-horizon (IPCC, 2021), therefore strategies to reduce enteric methane are paramount to achieving supply chain reduction goals. Feeding Bovaer prevents rumen methane formation through targeted inhibition of the final reaction of Archaeal methane production. A body of peer-reviewed literature shows Bovaer reduces enteric methane emissions approximately 30% or 1.2 metric ton (MT) CO_2e per lactating dairy cow per lactation, depending on dose and diet which can be modeled to provide a more accurate reduction estimate (Kebreab et al., 2023). If Bovaer were implemented in 50% of the 7.9 million lactating dairy cows in the U.S. (assuming 84% of the reported 9.36 million cows [dry and lactating] are lactating; USDA-NASS, 2024), between 3.1 and 6.3 MMT of CO_2e would be permanently avoided annually, depending on dose and diet which are modeled within the quantifications of this program to provide an accurate reduction estimate.

Elanco is a global leader in animal health dedicated to innovating and delivering products and services to prevent and treat disease in farm animals, creating value for farmers, stakeholders, and society as a whole. Elanco developed this intervention to provide guidance and quantification of GHG reductions associated with the use of Bovaer in lactating dairy cattle. Published peer-reviewed Bovaer data can be used to model dose- and diet-dependent effects, giving confidence in accurately quantifying GHG reductions from feeding Bovaer. To date, no negative impact on productivity from feeding Bovaer has been identified. Therefore, Bovaer implementation is reliant on accurate verification for carbon credits incentivizing use. The sale of these credits should incentivize GHG reductions from lactating dairy cattle. The intervention credits these reductions in a complete, consistent, transparent, and accurate manner.

2 Project Definition

Bovaer is a feed ingredient for lactating dairy cattle that reduces enteric methane. Bovaer must be fed according to label instructions. The Bovaer label dose was determined by the Food and Drug Administration in May of 2024 to be 60-80 mg/kg based on both effectiveness and safety data. Any FDA-reviewed and accepted changes made to the label dose will be immediately communicated to key stakeholders (including nutritionists, producers, Athian, verifiers, and UpLook personnel) and updated in UpLook, including updates to QAQC procedures in place to ensure adherence to label (i.e., IF/THEN statements where if the operation reports dose levels outside the label range, the calculated emissions reductions equal zero.) Any changes made to the label dose must be legally followed by the farm. Grazing lactating dairy cattle are ineligible for this program. The only activity associated with this intervention is the feeding of Bovaer daily to lactating dairy cows and all other business practices remain unchanged.

2.1 Impact on Yield

There is no impact of Bovaer on dry matter intake, digestibility, or energy corrected milk. This is evidenced by several meta-analyses which are summarized in Table 2.1

Table 2.1 *Impact of Bovaer on methane, dry matter intake, digestibility, and performance*

	Methane	Dry Matter Intake	Milk Yield	Adjusted Milk Yield[1]	Milk Fat	Milk Protein	Digestibility[2]
Jayanegara et al, 2018	-19%	=	=	=	Yield: NR %: ↑	Yield: NR %: =	=
Dijkstra et al., 2018	-39%	NR	NR	NR	NR	NR	NR
Kim et al., 2020	Linear ↓	=	=	=	Yield: NR %: =	Yield: NR %: =	=
Hristov et al., 2022	-28%	=	=	=	Yield: NR %: ↑	Yield: = %: =	NR
Kebreab et al., 2023	-32%	NR	NR	NR	NR	NR	NR

NR = not reported
[1]Adjusted for components as either energy-corrected milk, fat-corrected milk, or solids-corrected milk
[2]Includes dry matter, organic matter, and neutral detergent fiber (NDF) digestibility

2.2 Causality

Bovaer reduces enteric methane and thus absolute emissions in the production of a consumer good along the entire value chain. Each day Bovaer is not fed to lactating dairy cow, approximately 30% more enteric methane is released into the environment compared to what would be emitted if Bovaer were being fed (Jayanegara et al., 2018; Dijkstra et al., 2018; Kim et al., 2020; Hristov et al., 2022; Kebreab et al., 2023). Emissions reductions associated with feeding Bovaer are permanent and cannot be reversed. This creates a significant opportunity to make progress in GHG emissions reductions via a financial incentive from the supply chain. Currently, Bovaer is not fed in the U.S. (0% market penetration) and financial benefits do not exist for producers who feed Bovaer without their participation in a carbon market. Participating in a protocol and carbon market provides an incentive through financial support from inset or offset markets for the use of Bovaer. Eligibility and use of this program creates a data stream the supply chain will need for credibly delivering on greenhouse gas reduction commitments.

3 Eligibility

The only activity associated with this intervention is the feeding of Bovaer daily to lactating dairy cows and all other business practices remain unchanged. All projects participating in this intervention must meet the eligibility criteria outlined in Table 3.1.

Table 3.1 Summary of eligibility criteria for the generation of credits

Eligibility Criteria Summary	
Directions	Feed according to label instructions
Dose	60-80 mg 3-NOP per kg total ration DM (on-label dose as of May 2024)
Animal Types	Lactating dairy cattle
Location	U.S. or U.S. tribal lands
Reporting Period	No minimum reporting period. Maximum reporting period is 12 months. After 12 months a project may continue but it must use the most recent version of this protocol
Compliance	Attestation of voluntary compliance is required; Bovaer implementation must not be legally required.

3.1 Voluntary Compliance

All projects are subject to a legal requirement test to ensure that the GHG reductions achieved by this intervention are not required by federal, state, or local laws or regulations (e.g., air, water quality, water discharge, safety, labor, endangered species protection), or other legally binding mandates. The legal requirement test is applied to each project enrolled in the program. Therefore, if interventions at one project become legally required, it does not affect the other projects in the program.

To satisfy the legal requirement test, each producer whose dairy operation is a project within the program must sign an attestation of voluntary compliance. Attestations must be signed prior to the commencement of verification activities each time the intervention is verified. In addition, the Monitoring Plan must include procedures that the producer will follow to review existing legal requirements for the intervention location and ascertain and demonstrate that the project passes the legal requirement test.

3.2 Project Start Date

In May of 2024, the Food and Drug Administration completed their review of safety and effectiveness data to determine that Bovaer may be marketed and sold for use in U.S. lactating dairy cattle. Each project's reduction quantifications begin when Bovaer is incorporated into the lactating dairy cow ration and this incorporation is documented. Projects completing a successful verification within the first year after the publication of this protocol may generate credits on operations following program requirements and guidelines.

3.3 Reporting Period

The reporting period is the period of time during which the intervention was implemented. Impact units or reductions for each project can be quantified as frequently as monthly. The duration of this intervention is capped at a maximum of 5 years, or another determined at validation, when re-validation is required. Athian requires program review every 12 months and therefore re-validation may occur sooner than 5 years. Bovaer itself is intended for continuous use by program participants for the duration of their participation.

3.4 Location

Only projects located in the U.S., or on U.S. tribal lands, are eligible to generate credits under this protocol.

4 GHG Assessment Boundary

Bovaer acts by reducing enteric methane, thus the reductions in GHG emissions associated with feeding Bovaer are permanent emissions reductions that cannot be reversed. During the development of this protocol, the need to account for market-shifting leakage associated with changes in productivity, feed, and manure was evaluated. Bovaer does not negatively impact productivity or dry matter intake (feed requirements), as evidenced by the 5 meta-analyses conducted and highlighted in Table 2.1. Bovaer is metabolized by its own mode of action (Duin et al., 2016) and is not practically excreted in the environment (Bampidis et al., 2021). Studies between control and 3-NOP-fed animals have shown no differences in fecal characteristics (volatile solids, carbon, nitrogen or total solids) in forage- or grain-based diets (Nkemka et al., 2019), no differences in manure GHG and NH3 emissions or manure application to crop yield (Owens et al., 2020, 2021), and no impact on anaerobic digestion (Nkemka et al., 2019). Therefore, because Bovaer does not affect any GHG emission sources outside the identified GHG boundaries, leakage is not relevant to this project and no deductions will be applied to credits generated according to this protocol.

Table 4.1 *Sources and Sinks*

SSR	GHG	Included or Excluded	Justification
Direct Land Use	CO_2	Excluded	Emissions from land use do not change between the baseline and project scenario.
Enteric Fermentation	CH_4	Included	CH_4 emissions from enteric fermentation are the major source of emissions in the project scenario (Kebreab et al., 2023)
Fuel & Electricity Use	CO_2, CH_4, N_2O	Excluded	Fossil fuel emissions from electricity and stationary fuel use do not change between the baseline and project scenario
Ingredient Production & Transport	CO_2, N_2O	Included	Emissions from the manufacturing and transport of the feed ingredient intervention are included in this program.
Manure Management	CH_4, N_2O	Excluded	Emissions from the management of manure do not change between the baseline and project scenario.
Waste Processing	CO_2, CH_4, N_2O	Excluded	Emissions from the management of dead animals do not change between the baseline and project scenario.

5 GHG Quantification

Project GHG reduction is quantified for lactating dairy cattle according to the Dose + NDF model estimate published in Table 2 of the meta-analysis by Kebreab et al. (2023) which accounts for 3-NOP dose (mg/kg) and diet NDF (% DM). This reduction is applied to baseline emissions calculated from the 2019 Refinement to the 2006 IPCC Guidelines for National Greenhouse Gas Inventories according to Equation 5.3 to calculate the total project GHG emissions reduction due to implementation of the intervention during the reporting period.

5.1 Quantification Approach

Reductions from the intervention are calculated using a counterfactual approach based on each farm's individual data gathered through the UpLook carbon foot printing tool. Intervention GHG reduction is quantified according to the Dose + NDF model estimate published in Table 2 of the meta-analysis by Kebreab et al. (2023) which accounts for 3-NOP dose (mg/kg) and diet NDF (% DM). The production (g/d) equation was chosen over the yield (g/kg DM) and intensity (g/kg energy-corrected milk) equations in order to be consistent with VM0041 methodology (also quantifies on methane production per day basis) and for the intended purposes of quantifying absolute reductions in enteric GHG emissions. This reduction is applied to baseline emissions calculated from the 2019 Refinement to the 2006 IPCC Guidelines for National Greenhouse Gas Inventories according to Equation 5.3 to calculate the total intervention GHG emissions reduction due to implementation of the practices during the reporting period.

Per International Dairy Federation (IDF) guidelines, emissions factors are assessed against volume of fat and protein corrected milk according to the following equation (Equation 1 in 2022 IDF Guidelines):

FPCM (kg) = milk production (kg) × [0.1226 × fat% + 0.0776 × true protein% + 0.2534]

This program is not expected to have any impact on the volume of FPCM. It should be noted that this program addresses absolute emissions, not intensity emissions, and should have no effect on milk production.

5.2 Baseline GHG Emissions

Baseline GHG emissions from enteric fermentation follow the Intergovernmental Panel on Climate Change (IPCC, 2019) Tier 2 methodology. The baseline emissions are calculated according to the following equation:

$$BE_{Enteric} = \mathrm{CH4} \times \frac{GWP}{1000} \qquad \textit{(Equation 5.1)}$$

Where:

$BE_{Enteric}$	=	Baseline emissions from lactating dairy cattle during the reporting period (MT CO_2e)
$CH4$	=	Baseline methane emissions for lactating dairy cattle during the reporting period (kg CH_4)
GWP	=	Global warming potential of methane over a 100-year time frame; 27 is used per IPCC, 2021 (kg CO_2e per kg CH_4)
1000	=	kg CO_2e per MT CO_2e

Baseline methane emissions for lactating dairy cattle during the reporting period are calculated according to the following equation:

$$CH4 = \frac{(DMI \times GE) \times \left(\frac{Y_m}{100}\right) \times C \times t}{55.65} \qquad \text{(Equation 5.2)}$$

Where:

$CH4$	=	Baseline enteric methane emissions for lactating dairy cattle during the reporting period (kg CH_4)
DMI	=	Average daily dry matter intake for lactating dairy cattle during the reporting period (kg DM per head per day)
Y_m	=	Methane conversion factor for lactating dairy cattle during the reporting period (percentage of dietary gross energy lost as CH_4; obtained from Table 5.1 adapted from Table 10.12 of IPCC, 2019)
55.65	=	Energy content of methane (MJ per kg CH_4)
GE	=	Gross energy concentration of lactating dairy cattle diet (MJ per kg dry matter)
C	=	Average number of lactating dairy cattle during the reporting period (head)
t	=	Total number of days in the reporting period (days)

The appropriate Ym is selected from Table 5.1 based on diet nutrient composition documented in UpLook using feed ingredient composition weighted averages and feed values from the NASEM (2021) feed library.

Table 5.1 *Methane Conversion Factors (Ym) adapted from Table 10.12 of IPCC, 2019*

Lactating Dairy Cows	Ym
DE≥70 NDF≤35	5.7
DE≥70 NDF>35	6.0
DE 63-70 NDF>37	6.3
DE≤62 NDF>38	6.5

DE= Diet digestible energy (%)
NDF= Diet neutral detergent fiber (%)

Please note Table 10.12 from IPCC, 2019 does not allow for appropriate Ym selection guidance if DE <70% and NDF ≤ 37%. Therefore, if DE% and NDF% constraints do not allow for appropriate Ym selection guidance with Table 5.1 (e.g., a diet with 69% DE and 36% NDF), a value of 5.85 is used.

5.3 Project GHG Emissions Quantification

Emissions in the project scenario are estimated as the sum of emissions during the reporting period from enteric fermentation and the production and transport of Bovaer according to the following equation:

$$PE_{Enteric} = [CH4] \times \left[1 - \frac{|AF_H|}{100}\right] \times \left[\frac{GWP}{1000}\right] + GHG_{MT} \qquad \text{(Equation 5.3)}$$

Where:

$PE_{Enteric}$	=	Total project enteric CH_4 emissions from lactating dairy cattle during the reporting period (MT CO_2e)
$CH4$	=	Baseline enteric methane emissions for lactating dairy cattle during the reporting period (kg CH_4)
AF_H	=	Herd enteric methane adjustment factor due to project implementation (% reduction in methane due to feeding Bovaer; Equation 5.4)
GWP	=	Global warming potential of methane over a 100-year time frame (kg CO_2e per kg CH_4; IPCC, 2021)
1000	=	kg CO_2e per MT CO_2e
GHG_{MT}		Emissions associated with Bovaer manufacturing and transport during the reporting period (MT CO_2e)

5.4 Enteric Methane Adjustment Factor Quantification

The total lactating dairy cow herd enteric methane adjustment factor is determined by:

$$AF_H = AF \times PBCD \qquad \text{(Equation 5.4)}$$

Where:

AF_H	=	Herd enteric methane adjustment factor due to project implementation (% reduction in total lactating dairy cow herd methane due to feeding Bovaer)
AF	=	Enteric methane adjustment factor due to project implementation (% reduction in methane due to feeding Bovaer; Equation 5.6)
$PBCD$	=	Percent Bovaer-fed cow-days of total cow-days available (%; Equation 5.5)

Percent Bovaer-fed cow-days is calculated according to the following equation:

$$PBCD = \frac{\sum_i BC_i \times Bt_i}{C \times t} \qquad \text{(Equation 5.5)}$$

Where:

$PBCD$	=	Percent Bovaer-fed cow-days of total cow-days available (%)
BC_i	=	Average number of lactating dairy cattle in group i fed Bovaer during the reporting period (head)
Bt_i	=	Number of days in the reporting period Bovaer was fed to group i (days)
C	=	Average number of total lactating dairy cattle fed during the reporting period (head)
t	=	Total number of days in the reporting period (days)
i	=	Different groups of Bovaer-fed lactating dairy cattle where days and animal numbers differ between groups

A meta-analysis of 14 studies including 48 treatment means was utilized by Kebreab et al. (2023) to determine the effect of Bovaer on enteric methane in lactating dairy cattle. The effect of Bovaer on methane production is quantified in Equation 5.6 according to the Dose + NDF model in Table 2 of the meta-analysis which accounts for 3-NOP dose (mg/kg) and diet NDF (% DM). This equation was chosen in order to be consistent across baseline and intervention quantifications as the IPCC baseline equation does not account for dietary fat but does utilize diet NDF to determine the appropriate Ym tier.

Enteric methane adjustment factor due to intervention implementation is calculated according to the following equation:

$$AF = -32.8 - 0.285 \times (DOSE - 70.5) + 0.633 \times (NDF - 32.9) \qquad \text{(Equation 5.6)}$$

Where:

AF	=	Enteric methane adjustment factor due to intervention implementation (% reduction in methane due to feeding Bovaer)
-32.8	=	Overall mean estimate (intercept; % methane change) in Dose + NDF model in Table 2 of Kebreab et al. 2023
0.285	=	3-NOP dose factor in Dose + NDF model in Table 2 of Kebreab et al. 2023
$DOSE$	=	Dose of 3-NOP fed during the reporting period (mg 3-NOP per kg diet DM)
70.5	=	3-NOP dose constant (mean dose; mg/kg) from Table 1 of Kebreab et al., 2023
0.633	=	NDF content factor from Dose + NDF model in Table 2 of Kebreab et al., 2023
NDF	=	Average diet neutral detergent fiber during the reporting period (% diet DM)
32.9	=	NDF content constant (mean content; % DM) from Table 1 of Kebreab et al., 2023

5.5 Product Manufacturing and Transport GHG Quantification

Emissions from the feed ingredient are estimated by including all GHG sources from manufacturing and transport according to the following equation:

$$GHG_{MT} = GHG_M + GHG_T \quad \text{(Equation 5.7)}$$

Where:

GHG_{MT}	=	Emissions associated with Bovaer manufacturing and transport during the reporting period (MT CO_2e)
GHG_M	=	Emissions associated with Bovaer manufacturing during the reporting period (MT CO_2e)
GHG_T	=	Emissions associated with Bovaer transport during the reporting period (MT CO_2e)

The total amount of product used during the reporting period is calculated according to the following equation:

$$Bovaer10 = \frac{DMI \times DOSE}{0.1 \times 1000000} \times PBCD \times C \times t \quad \text{(Equation 5.8)}$$

Where:

$Bovaer10$	=	Amount of Bovaer10 used during the reporting period (kg)
DMI	=	Average daily dry matter intake during the reporting period (kg DM per head per day)
$DOSE$	=	Dose of 3-NOP fed during the reporting period (mg 3-NOP per kg diet DM)
$PBCD$	=	Percent Bovaer-fed cow-days of total cow-days available (%)
C	=	Average number of lactating dairy cattle fed Bovaer during the reporting period (head)
t	=	Number of days in the reporting period (days)
0.1	=	Active ingredient content of Bovaer10 (kg 3-NOP per kg Bovaer10)
1000000	=	mg 3-NOP per kg 3-NOP

Manufacturing-based GHGs associated with product (Bovaer) production are supplied by the manufacturer based on ISO standards 14040.44:2006 and ISO 14067:2018. The deduction to intervention GHG reductions (Equation 5.9) is calculated according to the following equation:

$$GHG_M = \frac{Bovaer10 \times PCF}{1000} \quad \text{(Equation 5.9)}$$

Where:

GHG_M	=	Manufacturing-based GHG emissions due to Bovaer use during the reporting period (MT CO_2e)
$Bovaer10$	=	Amount of Bovaer10 used during the reporting period according to Equation 5.8 (kg)
PCF	=	Product Carbon Footprint of Bovaer10 production (4.84 kg CO_2e per kg Bovaer10)
1000	=	kg CO_2e per MT CO_2e

Emissions from the transport of the feed ingredient to the project site are calculated as:

$$GHG_T = \frac{Bovaer10 \times (EFT_R + EFT_O)}{1000} \quad \text{(Equation 5.10)}$$

Where:

GHG_T	=	Emissions associated with Bovaer transport during the reporting period (MT CO_2e)
$Bovaer10$	=	Amount of Bovaer10 used during the reporting period according to Equation 5.8 (kg)
EFT_R	=	Emissions factor from road transportation of Bovaer10 during the reporting period (0.6097 kg CO_2e per kg Bovaer10)
EFT_O		Emissions factor from ocean transportation of Bovaer10 during the reporting period (0.2702 kg CO_2e per kg Bovaer10)
1000	=	kg CO_2e per MT CO_2e

Road transportation of Bovaer is estimated using Environmental Protection Agency 2024 GHG Emissions Factors Hub data (Scope 3 Category 4: Upstream Transportation and Distribution and Category 9: Downstream Transportation and Distribution) including CO_2, CH_4, and N_2O from medium- and heavy-duty truck emissions. Ocean transport is estimated using Department for Environment, Food and Rural Affairs, Annex 7 Freight Transport Conversion Tables and includes refrigerated cargo with the highest GHG emissions in order to be conservative.

Distances of travel are considered the same for all farms implementing Bovaer and are thus conservatively estimated as the distance for product to be delivered to Tulare, CA. This location was chosen because it contains the largest population of cows the furthest distance from the Elanco warehouse in Clinton, IN.

5.6 Leakage & Permanence

The need to account for market-shifting leakage associated with reductions in productivity was evaluated. Bovaer does not affect productivity (see **Table 2.1**) or any GHG emission sources outside the identified GHG boundaries, therefore leakage is not relevant to this project and no deductions will be applied to credits generated according to this program. Bovaer acts by reducing enteric methane, thus the reductions in GHG emissions associated with feeding Bovaer are permanent emissions reductions that cannot be reversed.

5.7 Uncertainty

The major risk that could substantially affect the intervention's GHG emission reductions is in the estimation of feed intake. Traditionally a large amount of uncertainty in dairy operation greenhouse gas calculations originates from estimations of feed intake and digestibility, which vary widely between and within cattle and geographies. A significant portion of this uncertainty is mitigated in this program through utilizing each operation's individual feed ingredient data to quantify dry matter intake and use contemporaneous estimates of gross and digestible energy for the quantification of both baseline and intervention emissions. The availability of these data facilitates a precise measure of gross energy intake from which enteric emissions reductions are calculated. Because feed intake is recorded and received directly from the dairy farm, the remaining uncertainty associated with the GHG reductions quantified in this program arise from the adjustments made around the intervention of Bovaer implementation. These adjustments are taken directly from a peer-reviewed meta-analysis. Bovaer has reliable and substantiated data regarding its mode of action and effect.

Because uncertainty associated with feed intake, a primary driver in GHG emissions, was mitigated through incorporating operation-specific feed data in a tier 2 approach to calculate GHG emissions and uncertainty associated with adjustment factors for Bovaer's effect were mitigated using a meta-analysis, no deductions for uncertainty will be taken. Outside of the product carbon footprint and transportation emissions (PCF, EFTR, and EFTO), which have minimal impact to the overall reductions, the adjustment factor is the major parameter Bovaer affects within emissions calculations. All other variables are the same for both Baseline and the Project. For additional detail regarding the uncertainty analysis, see **Appendix A**.

5.8 Deviations from Protocol Methodologies

Deviations from the methodologies in section 5 of this protocol are not allowed.

6 Monitoring

This program is 100% monitoring. All producers participating in the program will go through verification of their baseline data and verification of monitoring periods. A monitoring plan has been developed for all monitoring and reporting activities associated with the project.

Verifiers will use the monitoring plan and report to confirm that the requirements of this program have been met. This monitoring plan provides the processes, requirements, and sources of information necessary to assess the GHG reductions created by the practice of feeding Bovaer to U.S. lactating dairy cattle.

This includes:

1. The procedures for collecting data on intervention activities related to implementation.
2. The data points collected to verify emission reduction, project, and baseline calculations.
3. The QC/QA processes to ensure the accuracy and consistency of the data collected.

The monitoring reports described in the monitoring plan include the following elements:

1. General description of the project, including the location of the cattle operations
2. List of the practices implemented
3. Description of the process and frequency of data collection and the archiving procedures
4. Recordkeeping plan
5. Role of any individuals performing activities related to the practices implemented

6. Quality assurance/quality control (QA/QC) procedures to ensure the accurate collection and entry of data in quantification systems
7. Monitoring reports must include the monitoring time period.
8. Monitoring reports must include the list of parameters measured and monitored.
9. Monitoring reports must include the types of data and information reported, including units of measurement.
10. Monitoring reports must include the origin of the data.
11. The monitoring report must include an attestation as to regulatory compliance.
12. The monitoring report should be submitted no less frequently than annually and no more frequently than 30 days.
13. The monitoring period can be as short as 30 days. The maximum monitoring period is 12 months.
14. The monitoring report must be submitted and shared with Athian, as the program administrator.

6.1 Data Quality Assurance

Site specific data will be collected via UpLook, a digital tool enabling dairy owners, herd managers, and their advisors to calculate the carbon footprint of their operations, evaluate mitigation strategies, and document subsequent results in a verifiable manner. Reductions from implementation of Bovaer are calculated using a counterfactual approach based on each farm's individual data gathered through UpLook and integrated into Athian's platform. While UpLook calculates a carbon footprint for dairies operations, the only part of the tool that is relevant for this intervention is the enteric methane emissions of the lactating dairy cows. The main two factors contributing to enteric methane emissions are the number of cows and the total feed they consume. The next important factor is the type of diet the cows are consuming (i.e., diet composition and characteristics of feed ingredients).

Data sources utilized in UpLook ™ Dairy as it relates to Bovaer intervention include both manually entered primary data entered by the user inputs correlated to the dairy operation along with digital data transferred from herd records (e.g., average number of lactating dairy cows in the period, percent of cows receiving Bovaer, Bovaer dose, and total feed intake by ingredient) and secondary table values that are internal to UpLook (e.g., NASEM feed ingredient characteristics, Ym values, PCF of Bovaer).

Elanco is responsible for the data quality in the UpLook tool. Athian requires Elanco (UpLook) to have the GHG emissions quantification tool validated by an accredited 3rd party. Elanco is responsible for any changes to the monitoring data and establishing and implementing quality control procedures.

Athian directly ingests data without alteration from the UpLook API endpoint on a daily basis. This process is confirmed via Athian's software Quality Assurance process involving both automated and manual testing to confirm expected functionality. Additionally, data is verified via the monitoring and verification processes detailed in Sections 6-8.

6.2 Product Quality Assurance

Bovaer is formulated into the lactating cow total mixed ration by a professional dairy nutritionist who is legally required to follow any directions listed on the Bovaer label. Dairy nutritionists often use ration balancing software (e.g., Nutritional Dynamic Systems or Agricultural Modeling and Training Systems) as a tool to formulate and evaluate total mixed ration and premix recipes for the correct amounts of macronutrients (carbohydrates, protein, fat), micronutrients (vitamins and minerals), and feed ingredients. Nutritionists normally use ration software to ensure the correct amount of Bovaer is in the formulation. Within these ration balancing programs there is a library of feed ingredients, each with chemical composition documented. As an aid, Elanco has created a Bovaer feed ingredient specifications file for common ration balancing software to provide an easy-to-use ingredient profile for their recipe. Once these recipes are formulated by the dairy nutritionist, the recipe for the mix goes to a mill for manufacturing. For quality control measures, mills storing and handling Bovaer must follow Code of Federal Regulations 21 CFR Part 507 (entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Food for Animals”; https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-507), which includes following the guidelines of the Food Safety Modernization Act (FSMA). After the mix is delivered from the mill to the farm, the dairy producer is responsible for following the total mixed ration recipe formulated by the professional dairy nutritionist when loading and feeding their cattle. Please note that every farm’s situation is unique and there may be instances where Bovaer may be mixed into a premix on farm or delivered into the ration via a micro ingredient machine. Ultimately, the selection and implementation of the Bovaer dose incorporated into the ration is the responsibility of both the producer and the professional dairy nutritionist.

Table 6.1 *Monitoring parameters*

Data Parameter	Description	Data Unit	Data Source	Measurement Frequency	Values Applied	Measurement Methods and Procedures, QA/QC	Roles & Responsible	Data Management
C	Average number of lactating dairy cows during the monitoring period	Number of animals (head)	Primary data obtained from farm operating records	Every reporting period	Farm inventory is calculated as the average number of lactating dairy cows during the monitoring period (month)	Input data for herd population numbers can be obtained from dairy farm records or herd management software. Quality checks occur when data are entered in UpLook and values are audited at verification.	Producer/Farm Operator: Responsible for feeding Bovaer, recording total number of lactating dairy cows and percentage of cows receiving Bovaer during the reporting period, and data entry in UpLook Elanco: Responsible for reporting to user total number of lactating dairy cows from previous three months, initial data quality check, calculating the number of cows receiving Bovaer, storing farm data via UpLook, and reporting data to Athian	Data stored in UpLook
t	Number of days in the reporting period (month)	Days	UpLook / Calendar	Every reporting period	Number of days in month	Not applicable	Elanco: Responsible for UpLook that establishes the number of days for the month being analyzed	Data stored in UpLook

PBCD	Percent Bovaer-fed cow-days	Cow-days	Primary data obtained from farm operating records	Every reporting period	Calculated as total Bovaer-fed cow-days divided by total cow-days available in reporting period (month). Total Bovaer-fed cow days accounts for the number of cows fed Bovaer and the number of days they were fed Bovaer during the reporting period.	Values are audited at verification	Producer/Farm Operator: Responsible for feeding Bovaer and recording the number of cows and days it is fed during the reporting period and calculating PBCD and entering it in UpLook. Elanco: Responsible for storing farm data via UpLook, calculating total Bovaer use during reporting period and reporting data to Athian	Data stored in UpLook
DMI	Dry matter intake; Average dry mass of feed consumed by an animal on a given day during the reporting period	kg DM per head per day	Primary farm data obtained from operating records	Every reporting period	A weighted average of feed ingredients delivered to lactating dairy cows during the reporting period is used to calculate dry matter intake of lactating dairy cows	Values are audited at verification	Producer/Farm Operator: Responsible for data recording and entry in UpLook for feed ingredients fed to lactating dairy cows as either pounds per head per day or total pounds for the reporting period (month) Elanco: Responsible for reporting to user total dry matter intake for lactating dairy cows from previous three months, initial data quality check, converting all values to kg DM per head per day for calculations, storing farm data via UpLook, and reporting data to Athian	Data stored in UpLook

DE	Digestible energy; Diet digestible energy as a % of diet gross energy in the lactating cattle diet	% of gross energy	Calculated value using primary data from farm records & secondary data on chemical composition of feedstuffs	Every reporting period	Diet digestible energy composition is documented in UpLook using feed ingredient composition weighted averages and digestible energy values from the NASEM (2021) feed library	Calculated value in UpLook that is compared to an expected range (i.e., min and max acceptable values). Because the NASEM values used are standardized, the only way an alert should be triggered is if the user entered an unrealistic ingredient mix.	Elanco: Responsible for calculating DE value of diet, verifying that it is an acceptable value, and storing farm data via UpLook	Data stored in UpLook
NDF	Neutral detergent fiber; a measure of the fiber concentration of the lactating dairy cattle diet	% of diet dry matter	Calculated value using primary data from farm records & secondary data on chemical composition of feedstuffs	Every reporting period	Diet neutral detergent composition is documented in UpLook using feed ingredient composition weighted averages and neutral detergent fiber values from the NASEM (2021) feed library	Calculated value in UpLook that is compared to an expected range (i.e., min and max acceptable values). Because the NASEM values used are standardized, the only way an alert should be triggered is if the user entered an unrealistic ingredient mix.	Elanco: Responsible for calculating NDF value of diet, verifying that it is an acceptable value, and storing farm data via UpLook	Data stored in UpLook
GE	Gross energy concentration of the lactating dairy cattle diet	MJ per kg diet dry matter	Calculated value using primary data from farm records, secondary data on chemical composition of feedstuffs, and NASEM Equations	Every reporting period	Diet gross energy composition is documented in UpLook using feed ingredient composition weighted averages, feed chemical compositions from the NASEM (2021) feed library, and Equations 3-1 and 3-2 from NASEM (2021)	Calculated value in UpLook that is compared to an expected range (i.e., min and max acceptable values). Because the NASEM values used are standardized, the only way an alert should be triggered is if the user entered an unrealistic ingredient mix.	Elanco: Responsible for calculating GE value of diet, verifying that it is an acceptable value, and storing farm data via UpLook	Data stored in UpLook

Ym	Percentage of gross energy converted to methane	Methane conversion factor	Secondary data from IPCC, 2019 and adapted to Table 5.1	Every reporting period	The appropriate Ym is selected from Table 5.1 based on diet digestible energy (DE) and neutral detergent fiber (NDF) of the diet	Values are audited at verification	Elanco: Responsible for selecting correct Ym based on calculated DE and NDF values and storing farm data via UpLook.	Data stored in UpLook
GWP	Global warming potential of methane over 100-year time horizon	kg CO_2e per kg CH_4	Secondary data from Sixth Assessment Report from IPCC, 2021 (AR6)	Annually	27	Values are audited at verification	Elanco: Responsible for updating value in UpLook when deemed necessary	Data stored in UpLook
AF	Enteric methane adjustment factor due to Bovaer implementation	% reduction in methane due to feeding Bovaer	Calculated value using dose (primary farm data) and NDF (calculated parameter)	Every reporting period	Calculated value using Dose + NDF model in Table 2 from the Kebreab et al., 2023 meta-analysis of 3-NOP effects on enteric methane in lactating dairy cows and incorporating dose (primary farm data) and NDF (calculated value) for each reporting period	Values are audited at verification	Producer/Farm Operator: Responsible for feeding of Bovaer according to the label, data recording and entry in UpLook Elanco: Responsible for calculating value and storing farm data via UpLook	Data stored in UpLook

DOSE	Dose of 3-nitrooxypropanol (3-NOP) fed; Bovaer10 is 10% 3-NOP	mg 3-NOP per kg diet dry matter	Primary data obtained from farm records	Every reporting period	Any value allowed, but if value is not on-label (60-80 mg/kg DM), then AF is set equal to zero.	Values are audited at verification	Producer/Farm Operator: Responsible for feeding of Bovaer according to the label, providing records of proof of the dose fed, and data recording and entry in UpLook Elanco: Responsible for calculating the impact of Bovaer fed, storing farm data via UpLook, and producing and distributing Bovaer	Data stored in UpLook
PCF	Carbon footprint associated with manufacturing Bovaer10	kg CO_2e per kg Bovaer10	Secondary data originating from manufacturer	Annually	4.84	Values are audited at verification	Elanco: responsible for reviewing/updating product carbon footprint at annual protocol review	Data stored in UpLook
EFT_R	Carbon footprint associated with land transportation of Bovaer10	kg CO_2e per metric-ton mile for Bovaer10	Calculated data originating from secondary sources	Annually	0.18668	Values are audited at verification	Elanco: responsible for reviewing/updating product transportation carbon footprint at annual protocol review.	Data stored in UpLook
EFT_O	Carbon footprint associated with ocean transportation of Bovaer10	kg CO_2e per metric-ton mile for Bovaer10	Calculated data originating from secondary sources	Annually	0.06994	Values are audited at verification	Elanco: responsible for reviewing/updating product transportation carbon footprint at annual protocol review.	Data stored in UpLook

7 Reporting

Project developers must provide the following documentation each reporting period to generate credits from this protocol:

1. Name and address of the project developer
2. List of all of the operations included in the project including the owner/operator contact information and address of the operation
3. Regulatory compliance documentation and attestation
4. Monitoring plan
5. Monitoring report with all the data used in the calculations for Section 5 of the protocol
6. Monitoring report must include the intended use and user of the monitoring report.

7.1 Record Keeping

For purposes of third-party verification and historical documentation, project developers must keep all information listed in this protocol for a period of 10 years after the information is generated or 7 years after the last verification. The information the project developer should retain includes:

1. All data inputs for the calculation of the project emission reductions as well as the results of emission reduction calculations
2. Copies of all permits, Notices of Violations (NOVs), and any relevant administrative or legal orders dating back at least 3 years prior to the project start date
3. All verification records and results
4. All maintenance records relevant to the monitoring equipment

8 Verification

Verification bodies will contract directly with Athian for all validation and verification engagements.

Projects verified under this protocol will meet, at minimum, the auditing standard of limited assurance and adhere to 14064-3. The verification body must provide a factual statement expressing the outcome of the verification.

Issues identified during verification must be classified by verification bodies as either material (significant) or immaterial (insignificant). To be verified successfully, all reported emissions reductions must be free of material misstatements.

All projects developed under this protocol must achieve >95 percent level of accuracy. This means that the project's calculated emission reductions must be less than 5 percent different than those calculated by the verifier.

8.1 Verification Body Requirements

To conduct verification under this protocol, all Validation and Verification Bodies (VVB) must meet the following criteria:

1. Has obtained or is working towards ISO 14065 for Greenhouse Gas activities accreditation offered under the ANSI-GS Accreditation Program
2. Subject matter expertise in the on-farm operations related to an approved protocol (ex: Dairy Operations; Feedlot Operations)
3. Experience in a particular region or state where the verification will occur
4. Complete onboarding in the Athian Platform
5. Conduct monitoring in accordance with the requirements of the relevant protocol

8.2 Conflict of Interest

When conducting verification under this protocol VVBs must be seen as credible, independent, and transparent. To meet this requirement, a conflict of interest (COI) determination must be made prior to starting any verification activities. A COI occurs in any situation that compromises the VVB's ability to perform an independent verification. Every VVB must provide information about its organizational relationships, internal structures, and management systems for identifying potential COIs. VVBs must evaluate any potential conflicting services it has provided to the project developer, including any advice or consulting provided outside of the verification process.

8.3 Verification Process

To verify the project, the VVB must develop a risk-based verification plan that considers the size and complexity of the project and the relevant sector, technology, and processes. The VVB must follow the following process:

1. Complete a COI evaluation. If there is a potential COI, the VVB is not allowed to conduct the verification.
2. Prepare a verification plan that includes, at a minimum:
    a. A list of people from the VVB involved in the verification,
    b. A list of the location and dates of any on-site visits that will be conducted,
    c. The types of data and documents that will be reviewed by the VVB,
    d. A list of the people who are expected to be interviewed as a part of the verification.
3. Conduct a kick-off meeting with all parties to lay out the timeline and process of the verification.
4. Undertake a desk review of the data from the project.
5. Completion of a verification report stating any issues identified during the verification and their classification as either material (significant) or immaterial (insignificant).

9 References

Dijkstra, J., Bannink, A., France, J., Kebreab, E., & van Gastelen, S. (2018). Short communication: Antimethanogenic effects of 3-nitrooxypropanol depend on supplementation dose, dietary fiber content, and cattle type. Journal of Dairy Science, 101(10), 9041–9047. https://doi.org/10.3168/jds.2018-14456

Duin, E. C., Wagner, T., Shima, S., Prakash, D., Cronin, B., Yáñez-Ruiz, D. R., Duval, S., Rümbeli, R., Stemmler, R. T., Thauer, R. K., & Kindermann, M. (2016). Mode of action uncovered for the specific reduction of methane emissions from ruminants by the small molecule 3-nitrooxypropanol. Proceedings of the National Academy of Sciences of the United States of America, 113(22), 6172–6177. https://doi.org/10.1073/pnas.1600298113

Gerber, P. J., Steinfeld, H., Henderson, B., Mottet, A., Opio, C., Dijkman, J., Falcucci, A., & Tempio, G. (2013). Tackling Climate Change Through Livestock: A Global Assessment of Emissions and Mitigation Opportunities. In Food and Agriculture Organization of the United Nations.

Hristov, A. N., Oh, J., Giallongo, F., Frederick, T. W., Harper, M. T., Weeks, H. L., Branco, A. F., Moate, P. J., Deighton, M. H., Williams, S. R. O., Kindermann, M., & Duval, S. (2015). An inhibitor persistently decreased enteric methane emission from dairy cows with no negative effect on milk production. Proceedings of the National Academy of Sciences of the United States of America, 112(34), 10663–10668. https://doi.org/10.1073/pnas.1504124112

Hristov, A. N., Melgar, A., Wasson, D., & Arndt, C. (2022). Symposium review: Effective nutritional strategies to mitigate enteric methane in dairy cattle. Journal of Dairy Science, 105(10), 8543–8557. https://doi.org/10.3168/jds.2021-21398

IPCC, 2019. "Chapter 10: Emissions from Livestock and Manure Management." In 2019 Refinement to the 2006 IPCC Guidelines for National Greenhouse Gas Inventories: Volume 4. Agriculture, Forestry and Other Land Use. IPCC. 2019. Buendia, E. et al., Eds. https://www.ipcc-nggip.iges.or.jp/public/2019rf/vol4.html

IPCC, 2021. Climate Change 2021: The Physical Science Basis. Contribution of Working Group I to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change [Masson-Delmotte, V., P. Zhai, A. Pirani, S.L. Connors, C. Péan, S. Berger, N. Caud, Y. Chen, L. Goldfarb, M.I. Gomis, M. Huang, K. Leitzell, E. Lonnoy, J.B.R. Matthews, T.K. Maycock, T. Waterfield, O. Yelekçi, R. Yu, and B. Zhou (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA, 2391 pp. https://doi.org/10.1017/9781009157896

Jayanegara, A., Sarwono, K. A., Kondo, M., Matsui, H., Ridla, M., Laconi, E. B., & Nahrowi. (2018). Use of 3-nitrooxypropanol as feed ingredient for mitigating enteric methane emissions from ruminants: a meta-analysis. Italian Journal of Animal Science, 17(3), 650–656. https://doi.org/10.1080/1828051X.2017.1404945

Kebreab, E., Bannink, A., Pressman, E. M., Walker, N., Karagiannis, A., van Gastelen, S., & Dijkstra, J. (2023). A meta-analysis of effects of 3-nitrooxypropanol on methane production, yield, and intensity in dairy cattle. Journal of Dairy Science, 106(2), 927–936. https://doi.org/10.3168/jds.2022-22211

Kim, H., Lee, H. G., Baek, Y. C., Lee, S., & Seo, J. (2020). The effects of dietary supplementation with 3-nitrooxypropanol on enteric methane emissions, rumen fermentation, and production performance in ruminants: A meta-analysis. Journal of Animal Science and Technology, 62(1), 31–42. https://doi.org/10.5187/JAST.2020.62.1.31

Melgar, A., Welter, K. C., Nedelkov, K., Martins, C. M. M. R., Harper, M. T., Oh, J., Räisänen, S. E., Chen, X., Cueva, S. F., Duval, S., & Hristov, A. N. (2020). Dose-response effect of 3-nitrooxypropanol on enteric methane emissions in dairy cows. Journal of Dairy Science, 103(7), 6145–6156. https://doi.org/10.3168/jds.2019-17840

National Academies of Sciences, Engineering, and Medicine (NASEM). 2023. Nutrient Requirements of Dairy Cattle: Eight Revised Edition. Washington, DC: The National Academies Press. https://doi.org/10.17226/25806

Rotz, A. et al. (2021) Environmental assessment of United States dairy farms. Journal of Cleaner Production. 315:128153. https://doi.org/10.1016/j.jclepro.2021.128153

United States Department of Agriculture. National Agriculture Statistics Service. Accessed October 19th, 2023. Available at: https://quickstats.nass.usda.gov/

Appendix A. Table of Variable References

A quantitative uncertainty assessment for both the adjustment factor and across farm-level parameters was conducted. Table B reports uncertainty sources of all parameters used for Bovaer-related emissions quantifications. A description of the parameters with unknown certainty and their importance was assessed during validation. In accordance with GHG Protocol Scope 3 Quantitative Inventory Uncertainty guidance, a pedigree matrix approach was used to quantify uncertainty where a parameter uncertainty was unknown.

A Monte Carlo simulation was conducted to propagate parameter uncertainty to determine the overall uncertainty on the adjustment factor (AF) due to implementation of Bovaer and the parameters listed. This includes the SEM reported as ±1.6 for the intercept, ± 0.074 for Dose, ± 0.252 for NDF parameters from Kebreab et al. (2023) and the values from the pedigree matrix described above. The Monte Carlo simulation for the adjustment factor yielded an expected methane percent change of -31.60%, accompanied by a 90% confidence interval ranging from -34.90% (upper bound) to -28.39% (lower bound) and an uncertainty of 10.3% (calculated as (upper bound – lower bound) / (2 x expected))The Monte Carlo simulation for propagating uncertainty across all farm-level variables (and including the adjustment factor) equates to a mean CO2e change (project minus baseline) of - 1.46 MT CO2e with a 90% confidence interval ranging from -1.29 (lower bound) to -1.63 (upper bound) MT CO2e annually and an uncertainty of 11.6%. Both are represented in Figure A below.

Figure A *Impact assessment results of Bovaer implementation on methane reduction*