Anticoagulant Rodenticides Scientific Review Final Phase 1 Report

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1.0 Introduction

In 2024, the Harvard Law School Animal Law and Policy Clinic petitioned the Massachusetts Pesticide Board Subcommittee, requesting the immediate suspension of all anticoagulant rodenticide registrations in the Commonwealth. The petition claimed these rodenticides pose an unreasonable risk to non-target wildlife species, including raptors and other predators that suffer secondary poisoning from consuming affected rodents. The petition also raised concern about potential risks to domestic animals and human health, arguing that existing mitigation measures have not sufficiently prevented exposure.

In response to this petition, the Pesticide Board Subcommittee reviewed the available evidence and determined that additional scientific evaluation was necessary to inform any registration decisions. To support this effort, the Massachusetts Department of Agricultural Resources (MDAR) issued a Request for Quotes (RFQ) to commission an independent scientific review of the human health and ecological effects of anticoagulant rodenticides and their potential alternatives (both chemical and non-chemical). MDAR awarded a contract to Eastern Research Group, Inc. (ERG) to conduct this scientific review.

MDAR structured the anticoagulant rodenticide scientific review into three phases. In Phase One, ERG is tasked with identifying key scientific resources and scientific assessments relevant to evaluating the risks and benefits of anticoagulant rodenticides. This phase also includes compiling rodenticide usage data in Massachusetts, identifying common alternatives, and identifying stakeholders who may provide additional insight into rodenticide management, restrictions, and alternatives. In short, this Phase One report presents the research methodology that will be implemented in Phase Two, during which ERG will evaluate the identified resources and synthesize findings into a comprehensive scientific review. Phase Two will result in a draft report submitted to MDAR. During Phase Three, ERG will address MDAR's comments, finalize the scientific review report, and present results to the Pesticide Board Subcommittee. This final report will be released to the public for comment.

This Phase One report presents ERG's approach to gathering and evaluating relevant resources. It is organized into the following sections, which align with the original scope of work outlined in MDAR's RFQ.

- <u>Section 2.0</u> presents "a summary of available information on the use of anticoagulant rodenticides in the Commonwealth and key rodenticide agent alternatives," including available information on "use restrictions and requirements to minimize impacts."
- Section 3.0 lists "key assessments, including but not limited to, recent assessments by recognized authorities including, for example: the U.S. Environmental Protection Agency (EPA); peer reviewed publications; precedential judicial decisions, of the potential public health and environmental impacts of anticoagulant rodenticides and its alternatives." This section presents the requested information separately for anticoagulant rodenticides' public health impacts (Section 3.1) and environmental impacts (Section 3.2) and impacts of anticoagulant rodenticide alternatives (Section 3.3).
- <u>Section 4.0</u> lists "key stakeholders to be consulted" by ERG as part of the broader scientific review.
- <u>Section 5.0</u> lists the references cited throughout this report.
- <u>Section 6.0</u> provides a list of abbreviations.

On April 4, 2025, ERG submitted a draft of this Phase One report to MDAR. The draft report was posted on the Pesticide Board Subcommittee website and stakeholders were invited to comment. After reviewing the public comments, ERG corrected factual errors in the report that were identified in the public comments and submitted a revised Phase One report to MDAR. This revised report includes a summary of the revisions to this report in an appendix. The public comments will also be incorporated into the Phase Two report as appropriate.

ERG has proceeded with Phase Two by compiling, researching, and synthesizing information from the resources identified in this Phase One report. That work will culminate with ERG submitting the draft Phase Two report, which will include a scientific review of human health and environmental impacts of anticoagulant rodenticides and selected alternatives. As described later in this report, stakeholders will have the opportunity to provide input during Phase Two and to comment on the final Phase Two report.

2.0 Summary of Available Information on Uses of Anticoagulant Rodenticides and Alternatives

This section presents background information on anticoagulant rodenticides (<u>Section 2.1</u>); summarizes categories of anticoagulant rodenticides uses in the Commonwealth and the quantities of anticoagulant rodenticides used (<u>Section 2.2</u>); and identifies anticoagulant rodenticide alternatives that have been reported in the literature and the subset of anticoagulant rodenticides alternatives that will be evaluated in Phase Two (<u>Section 2.3</u>). The content presented below might be revised during Phase Two, based on stakeholder input.

2.1 Background Information on Anticoagulant Rodenticides

Anticoagulant rodenticides are a class of chemicals used to control rodent populations by disrupting normal blood clotting mechanisms. Specifically, these compounds interfere with the vitamin K cycle, which plays a crucial role in blood clotting in mammals and birds. Following exposure, animals internally bleed and die over a period of days to weeks. The delay in death is by design, allowing rodents to continue consuming bait and exposing others in their population. The timing of death depends on a combination of chemical-specific factors, such as the potency and bioaccumulation potential of the specific rodenticide used, as well as the dosage, metabolism, and susceptibility of the animal. In some instances, animals have become resistant to certain anticoagulant rodenticides.

The delayed time to death caused by these rodenticides also increases the risk of secondary poisoning in non-target species. Because poisoned rodents can live for days or weeks following exposure, they can be caught and consumed by predators and scavengers, such as hawks, owls, foxes, bobcats, and domestic pets. These secondary consumers can accumulate anticoagulant rodenticides in their systems leading to unintended poisoning. The bioaccumulation and biological persistence of the rodenticide chemicals can also lead to toxic effects in tertiary consumers (animals that eat secondary consumers). In addition, non-target species may be exposed to anticoagulant rodenticides directly if they consume bait intended for rodent control.

Anticoagulant rodenticides were first discovered in the 1940s, leading to the development of what are commonly known as first-generation anticoagulant rodenticides (FGARs). Warfarin was the first of these compounds to be widely used for rodent control, followed by others, such as chlorophacinone and diphacinone. FGARs typically require multiple feedings over several days to accumulate a lethal dose, making them effective but also allowing some rodents to develop resistance over time.

By the 1970s, as rodents had gained resistance to FGARs, manufacturers developed what are commonly known as second-generation anticoagulant rodenticides (SGARs). These are more potent, requiring only a single feeding to deliver a lethal dose—days later. These newer compounds, which include brodifacoum, bromadiolone, difenacoum, and difethialone, also have longer biological half-lives, meaning they persist in tissues of poisoned rodents for longer periods of time. While this increased

potency makes SGARs more effective for rodent control, it also heightens the risk of bioaccumulation in non-target species, leading to secondary poisoning in predators and scavengers that consume exposed rodents and raising concerns about their long-term ecological impacts. Like with FGARs, resistance to some SGARs has also been documented in certain animals.

2.2 Anticoagulant Rodenticide Use in Massachusetts

The seven anticoagulant rodenticides registered by the U.S. Environmental Protection Agency (EPA) are listed below (EPA, 2022):

- <u>EPA-registered FGARs</u>: Chlorophacinone, diphacinone (and its sodium salt), and warfarin (and its sodium salt)
- <u>EPA-registered SGARs:</u> Brodifacoum, bromadiolone, difenacoum, and difethialone

FGARs and SGARs can be found in products that have been approved by EPA and the Massachusetts Pesticide Board Subcommittee for "general use" and "restricted use." Restricted use pesticides (RUPs) can only be purchased, applied, or supervised by individuals who are certified applicators. Because of the toxicity of anticoagulant rodenticides, EPA has separate requirements for products that are intended to be used by general consumers and those that are marketed for agricultural users and professional applicators. For example, products marketed to consumers need to be sold with tamper-resistant baitstations and to be sold in smaller quantities.

Due to their greater toxicity and greater risks to non-target species, SGARs "no longer are registered for use in products geared toward consumers and are registered only for the commercial pest control and structural pest control markets" (EPA 2024c). While, SGARs are currently not categorically labeled as "restricted use," EPA's 2008 risk mitigation decision amended the registration of all SGAR products to "specify that registrants will control distribution of the products so that they shall only be distributed to or sold in agricultural, farm, and tractor stores or directly to pest control operators and other professional applicators, and that registrants will not sell or distribute SGAR products in channels of trade likely to result in retail sale in hardware and home improvement stores, grocery stores, convenience stores, drug stores, club stores, big box stores, and other general retailers. (EPA 2008; 2022e)" Even so, while they are not intended for use by the general public, because SGAR's are not classified as restricted use, they are available to individuals without a pesticide license. Because of ongoing concerns, in a 2022 "Proposed Interim Registration Review Decision," EPA proposes that all remaining SGARs be classified as restricted use (EPA 2022e). This proposed interim decision is not a binding regulation, and EPA is expected to make a final interim decision or a final registration review decision in 2025 (EPA 2025).

ERG searched the Massachusetts Pesticide Product Registration Information website (Kelly Solutions, 2025) for details on rodenticides containing the EPA-registered active ingredients above. As of March 5, 2025, the database includes records for 96 unique EPA registration numbers for the EPA-registered active ingredients shown in Table 1. Like other rodenticides, manufacturers formulate a mixture of the active ingredient and other ingredients, such as food-based materials, binding agents, and other materials, for maximum effectiveness. While manufacturers must disclose the identities and concentrations of active ingredients on product labels, no such requirement applies for other ingredients. The active ingredient(s) and other ingredients are typically mixed into small, solid blocks or paste to be placed in bait stations for rodents to consume. The bait stations are intended to protect bait from moisture and spillage and to prevent access by children, pets, and non-target species.

Generation	Active Ingredient	Range of % Active Ingredient in Products Registered for Use in Massachusetts in 2025	Number of Unique Products* Registered for Use in Massachusetts in 2025
FGAR	Chlorophacinone	0.005%	5
FGAR	Diphacinone (and its sodium salt)	0.005-0.2%	31
FGAR	Warfarin (and its sodium salt)**	0.025%	5
SGAR	Brodifacoum	0.0025-0.005%	16
SGAR	Bromadiolone	0.005%	31
SGAR	Difenacoum	0.005%	2
SGAR	Difethialone	0.0025%	6

Table 1. Counts of EPA-Registered FGAR and SGAR Products Registered for Use in Massachusetts

Source of data: Massachusetts Pesticide Product Registration Information website (Kelly Solutions, 2025).

* Determined by unique EPA Registration IDs; a single product can be sold under multiple brand names.

** Certain formulations have multiple active ingredients.

The Kelly Solutions database also includes:

- Information on the pests controlled by the various products
- Sites where the pesticides may be used
- Links to the EPA stamped labels for the products

The specific pests controlled by the anticoagulant rodenticides vary, but most control species of mice, rats, and voles. The sites to which the products can be applied also vary. Most registrations list more than a dozen types of sites where products may be applied. These include domestic dwellings, commercial/institutional/industrial areas and buildings, and transportation vehicles.

The EPA-accepted product labels include extensive information about the rodenticides, and most labels reviewed were at least five pages long. These labels have information on allowed application methods and rates, formulation details, precautionary statements, and other topics.

. Application is generally recommended in areas where rodents frequently feed (e.g., along walls, in corners, beside burrow openings). The amount of bait to apply can vary based on target species. The EPA-accepted labels provide further details on application methods for individual products. In most cases, labels warn users that the products are extremely toxic to mammals and birds, and to avoid contaminating water when disposing of equipment rinsate.

Anticoagulant pesticide bait products are required to be applied in tamper-resistant bait stations whenever bait is applied outdoors, above ground, or in any indoor or outdoor location where children under six years of age, pets or nontarget wildlife have access (EPA 2024c). The term tamper-resistant is defined by EPA as among other things, capable of being locked or sealed and as "strong enough to prohibit entry or destruction by dogs and by children under six years of age using their hands, their feet, or objects commonly found in the use environment (EPA 1994)." The term tamper-resistant was adopted to replace a previous description of bait-stations as "tamper-proof" to clarify that these bait-stations are not indestructible. EPA also notes that "label requirements for using tamper-resistant bait stations apply to those who place bait, not to bait station manufacturers. EPA has no direct regulatory authority over the production and sale of bait stations unless they are sold with rodenticide baits."

Additionally, Massachusetts regulations (333 CMR 13.08) require that rodenticide bait that is applied indoors and placed in generally accessible areas indoors must be placed in a tamper resistant bait station and be secured to prevent lifting and/or removal of the bait stations.

The Phase Two report will summarize use restrictions and requirements to minimize impact, as listed on the stamped labels.

Massachusetts regulation (333 CMR 10.14) requires licensed applicators to annually report the amount of certain pesticides, including rodenticides, that they use within the Commonwealth. Annual usage data for 2022 and 2023 is publicly available on the Commonwealth of Massachusetts' Annual Pesticide Use Information website (Commonwealth of Massachusetts, 2025). These data include fields for "Product Name," "EPA Reg. No.," "Active Ingredients," "Total Amount," and "Crop or Site Treated." This report summarizes only the 2023 usage data. The Phase Two report will summarize both the 2022 and 2023 usage data.

The 2023 database indicates that licensed applicators used the following anticoagulant rodenticides: chlorophacinone, diphacinone and its sodium salt, warfarin and its sodium salt, brodifacoum, bromadiolone, difenacoum, and difethialone. There was no reported use of sodium salt of warfarin in Massachusetts in 2023. According to the database, anticoagulant rodenticides were used in 2023 to treat ten different types of crops or sites. Table 2 lists those crops and sites and the numbers of unique products applied to them.

Table 2. Number of Unique Anticoagulant Rodenticide Products Applied in Massachusetts in 2023 by
Crop or Use Site

Crop or Site Treated	Number of Unique Products*
Structural Pest	50
Turf and Landscape	20
Tree Fruit	5
Greenhouse	4
Right-of-Way	3
Tree and Shrub	3
Non-Soil Fumigation	2
Agricultural Crops	1
Pastures, Hay, and Forage	1
Vegetable	1

Source of data: Annual Pesticide Use Information website (Commonwealth of Massachusetts, 2025).

* Determined by unique EPA Registration IDs; a single product can be sold under multiple brand names.

Most products were applied at sites labeled as "Structural pests," accounting for 56% of all applied products with a documented "crop or site treated." "Turf and landscape" was the next most common application site, accounting for 22%. All other "crop or site treated" fields had five or fewer documented products applied. Not shown in the table is the fact that some database records did not have any information entered in the field for "crop or site treated"; the reason for this is not known.

ERG also compiled data on the quantities of anticoagulant rodenticides used in Massachusetts in 2023. Most database records specified usage quantities in units of weight. When summarizing usage data in the Phase Two report, ERG will convert all database entries to a common unit of measurement and sum quantities by active ingredients. The usage statistics available in the state database are based only on what licensed applicators use. This does not include quantities that consumers buy from retail establishments. In the Phase Two report, ERG will attempt to identify data on consumer use of anticoagulant rodenticides from other sources (e.g., peer-reviewed literature) and summarize these data if available.

2.3 Anticoagulant Rodenticide Alternatives

The scope of work calls for ERG to compile and summarize available information on alternatives to anticoagulant rodenticides. In its research, ERG identified both chemical alternatives to anticoagulant rodenticides and a broader range of non-chemical options. We identified rodenticide alternatives based on review of the following resources:

- Key EPA assessments as documented in (see Section 3.0)
- Massachusetts Pesticide Product Registration Information website (Kelly Solutions, 2025)
- Commonwealth of Massachusetts' Annual Pesticide Use Information website (Commonwealth of Massachusetts, 2025)
- National Pesticide Information Center website on rodenticides (<u>https://npic.orst.edu/factsheets/rodenticides.html</u>)
- EPA website on rodent control pesticide safety review (<u>https://www.epa.gov/rodenticides/rodent-control-pesticide-safety-review</u>)
- Research showing efficacy of rodent traps in handling infestations (e.g., Motro et al., 2019)

These sources generally categorize alternatives to anticoagulant rodenticide into four groups. The list below describes the range of alternatives that are currently available, without considering their viability in the Commonwealth. The feasibility of alternatives will depend on the application setting and other factors, such as desired effectiveness, environmental impact, and cost. Preferred alternatives may vary between commercial applicators and homeowners.

Phase Two will consider the following four categories of alternatives. ERG will seek stakeholder input (see <u>Section 4.0</u>) on experiences with these—and potentially other—alternatives in Massachusetts.

- <u>Chemical methods</u> involve the use of rodenticides that do not contain anticoagulants. These
 alternatives target rodents through different mechanisms, such as neurotoxins, disruption of
 calcium absorption, asphyxiation, contraceptives (e.g., ContraPest), and impairment of cellular
 function.
- <u>Mechanical methods</u> use physical devices to trap rodents without relying on chemical agents. Examples include snap traps, glue traps, snare traps, cage traps, and drawstring bags.
- <u>Physical methods</u> focus on altering the environment to remove the rodents' sources of food, water, and shelter. This can include sealing possible entry points to buildings and practicing good sanitation methods, like not placing trash bags directly on the ground.
- <u>Biological methods</u> can include pathogens (e.g., Salmonella) and predatory animals (e.g., cats) to control rodent populations.

Table 3 lists examples of chemical alternatives that ERG will consider during the Phase Two research. EPA, 2022). All the chemicals in the table, except for alphachloralose and strychnine have been registered by EPA and/or used as active ingredients in Massachusetts-registered pesticide products.

Table 3 lists the number of unique rodenticide products registered for use in Massachusetts in 2025 and the number of unique rodenticide products used in 2023.

Active Ingredient	Range of % Active Ingredient in Products Registered for Use in Massachusetts in 2025	Number of Unique Rodenticide Products* Registered for Use in Massachusetts in 2025	Number of Unique Rodenticide Products* Used in Massachusetts in 2023
4-Vinylcyclohexene	0.096%	1	1
diepoxide			
Alphachloralose	- **	0	0
Aluminum phosphide	55-77.5%	11	0
Bromethalin	0.01-0.025%	59	14
Carbon dioxide	99.9-100%	3	2
Cholecalciferol	0.075%	8	5
Strychnine	- **	0	0
Triptolide	0.0011%	1	1
Zinc phosphide	2-63.2%	16	3

Data Sources: Massachusetts Pesticide Product Registration Information website (Kelly Solutions, 2025) and the Annual Pesticide Use Information website (Commonwealth of Massachusetts, 2025).

* Determined by unique EPA Registration IDs; a single product can be sold under multiple brand names.

**Not registered for use in Massachusetts.

In Phase Two, the ERG Team will refine the list of alternative chemical options shown in Table 3 based on input from stakeholders (see <u>Section 4.0</u>) and our own research. The ERG Team will ask stakeholders about:

- current and prospective uses of chemical anticoagulant rodenticide alternatives, including input on any viable alternatives not listed in Table 3 or elsewhere in this report,
- whether alternatives are better suited for specific applications,
- use patterns,
- insights on resistance, and
- information on alternatives' effectiveness.

There may be other chemical alternatives to anticoagulant rodenticide products that are not registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that meet the criteria for "minimum risk pesticides." To be eligible for this designation, the products must contain active ingredients and inert ingredients from lists of substances developed by EPA and meet additional criteria for labeling, health claims, and other factors. In Phase Two, ERG will investigate whether any "minimum risk pesticides" are viable anticoagulant rodenticide alternatives.

2.4 Use and Restrictions in Other States

In Phase 2, ERG will review anticoagulant rodenticide regulations and statutes in selected other states, focusing on those with established restrictions or regulatory actions. The review will identify policies, regulations, and laws that govern rodenticide use, including bans, mitigation measures, and licensing

requirements. ERG will limit the search to states with known regulatory activity and to states that are identified during stakeholder engagement.

3.0 Key Assessments to Review

This section presents a list of "key assessments" that the ERG team proposes reviewing during Phase Two. Consistent with the contract scope of work, we consider "key assessments" to include (1) recent assessments published by selected government agencies and international bodies and (2) peer-reviewed publications in scientific journals. The ERG team compiled the list of assessments and relevant publications from a diverse set of resources, including state and federal government agencies, agencies from selected foreign countries, international bodies, non-governmental organizations, and the peerreviewed literature.

This section identifies "key assessments" that the ERG team will review on anticoagulant rodenticides' human health impacts (see <u>Section 3.1</u>) and anticoagulant rodenticides' environmental impacts (see <u>Section 3.2</u>) and assessments of the most common alternative rodenticides (see <u>Section 3.3</u>). The ERG team will review the identified assessments and relevant supporting documents, which may include interim assessments, final determinations, and responses to comments. In many instances the key assessments that present impacts on human health also present impacts on ecological impacts. If that is the case, the assessment is listed in both subsections.

It is important to note that the state of the science of anticoagulant rodenticides' human health and environmental impacts continues to evolve. That is why ERG will consider information included in the completed assessments and findings in the more recent peer-reviewed literature.

3.1 Assessments of Anticoagulant Rodenticides' Human Health Impacts

This section identifies the "key assessments" that the ERG team will consider on anticoagulant rodenticides' human health impacts and the approach to reviewing peer-reviewed literature.

3.1.1 Recent and Ongoing Assessments Published by Recognized Authorities

The ERG team proposes reviewing and summarizing the following publications in Phase Two, considering a range of human health impacts. The Phase Two review will consider the fact that the various assessments have different scopes, reviewed different sets of literature (i.e., the assessments were completed in different years), and followed different methodologies. These differences will factor into the ERG Team's synthesis of information on human health impacts.

The list is organized into three categories of authors. For purposes of this project, an assessment was considered either a publication that comprehensively reviews the literature on anticoagulant rodenticide toxicity and reaches conclusions on human toxicity and risk or an ongoing significant research study of anticoagulant rodenticide toxicity in humans.

Assessments Issued by EPA

ERG will consider the most recent registration reviews for the first generation anticoagulant rodenticides, which include the <u>Warfarin Registration Review</u> docket (EPA, 2022i), the <u>Chlorophacinone Registration Review</u> docket (EPA, 2022c), and the <u>Diphacinone and</u> <u>Diphacinone Sodium Salt Registration Review</u> docket (EPA, 2022f). All three of these dockets include a shared <u>Pesticide Registration Review</u>: <u>Draft Human Health and/or Ecological Risk</u> <u>Assessments for Several Rodenticides</u> (EPA, 2020d), as well as pesticide-specific human health assessment scoping documents: <u>warfarin</u> (EPA, 2016h), <u>chlorophacinone</u> (EPA, 2016c), and <u>diphacinone</u> (EPA, 2016f).

- ERG will consider similar assessments for the second-generation anticoagulant rodenticides (brodifacoum, bromadiolone, difenacoum, and difethialone). The most recent registration reviews for these pesticides include the <u>Brodifacoum Registration Review</u> docket (EPA, 2022a), the <u>Bromadiolone Registration Review</u> (EPA, 2022b), the <u>Difenacoum Registration Review</u> docket (EPA, 2022d), and the <u>Difethialone Registration Review</u> dockets (EPA, 2022e). All four dockets were last updated in 2022 as described in the <u>Pesticide Registration Review</u>: Proposed <u>Interim Decisions for the Rodenticides</u>, which addresses the registration review decisions for both first- and second-generation anticoagulant rodenticides together (EPA, 2022g). Pesticidespecific human health assessment scoping documents are available for <u>brodifacoum</u> (EPA, 2016a), <u>bromadiolone</u> (EPA, 2016b), <u>difenacoum</u> (EPA, 2016d), and <u>difethialone</u> (EPA, 2016e). ERG will also review human exposure incidents to second-generation anticoagulant rodenticides, which are documented in <u>Rodenticide: Tier I (Scoping) Review of Human Incidents</u> and Epidemiology Assessment (EPA, 2016g) and <u>Rodenticides: Tier I Update Review of Human</u> <u>Incidents</u> (EPA, 2020c).
- As part of EPA's registration reviews, all first- and second-generation anticoagulant rodenticides, except for warfarin, were addressed in the <u>Draft Human Health Risk Assessment for Registration</u> <u>Review of Anticoagulant Rodenticides</u> (EPA, 2020a). Warfarin and its sodium salt were not included in this document because the <u>draft human health risk assessment for warfarin and its</u> <u>sodium salt</u> was previously finalized in 2015 (EPA, 2016h).
- In response to concerns about accidental poisoning, especially among children and non-target aquatic and terrestrial species, EPA conducted a <u>rodenticides risk mitigation investigation</u> which culminated in a <u>Proposed Risk Mitigation Decision</u> (EPA, 2007) and a <u>Revised Risk Mitigation</u> <u>Decision for Ten Rodenticides</u> (EPA, 2008). The final risk mitigation decision required all rodenticide bait products be sold in bait station form and restricted the sale and distribution of second-generation anticoagulant rodenticides. This decision also led to the <u>voluntary</u> <u>cancellation of certain pesticide registrations</u> (EPA, 2013).

Assessments Issued by State Authorities in the United States

California has undertaken a series of regulatory actions to address the environmental impact of anticoagulant rodenticides. Most recently, in addition to various laws passed by the legislature, California Department of Pesticide Regulation (DPR) published the <u>Notice of Final Decision to Begin Reevaluation of Second-Generation Anticoagulant Rodenticides</u> initiating formal reevaluation of products containing brodifacoum, bromadiolone, difenacoum, and difethialone (CDPR, 2019). And in 2023, DPR issued the <u>Notice of Final Decision to Begin Reevaluation of Diphacinone</u> due to similar concerns over potential ecological effects (CDPR, 2023). In September 2024, California legislature expanded upon existing restrictions on SGARs and diphacinone by prohibiting uses of all SGARs and FGARs throughout the state with some limited exceptions. ERG will summarize the regulatory landscape and review DPR's investigative reports produced throughout this process.

Assessments Issued by International Bodies and Agencies of Selected Foreign Countries

 Canada's Pest Management Regulatory Agency (PMRA) re-evaluated six rodenticides (brodifacoum, bromadiolone, chlorophacinone, diphacinone, warfarin, and zinc phosphide) and published <u>Re-evaluation Decision Documents RRD2006-11 and RVD2007-01</u> in 2006 and 2007, respectively (PMRA 2006).

- The World Health Organization (WHO) published a report on <u>anticoagulant rodenticides</u> in 1995. This report, while three decades old, is the most recent WHO assessment on anticoagulant rodenticides and reviews their effects on humans, animals, and the environment (WHO, 1995).
- In 2023, the European Chemicals Agency (ECHA) Standing Committee on Biocidal Products published their opinion in <u>Questions relating to the comparative assessment of anticoagulant rodenticides</u> (ECHA, 2023). This document details the comparative assessment completed for anticoagulant rodenticides, an evaluation of alternative chemical and non-chemical control measures, and potential risks to human and animal health. The European Union Standing Committee on Biocidal Products is housed within ECHA, consists of representatives of European Union countries, and delivers opinions on draft legislative measures that the European Commission intends to adopt. The European Union Standing Committee on Biocidal Products recently published its <u>Second comparative assessment of anticoagulant rodenticides</u> and alternative rodent control measures and resulted in greater restrictions on the type, sale, and distribution of rodenticides within the European Union (ECHA, 2024).

3.1.2 Peer-reviewed Publications

The major assessments described in the previous section were published at different times and are based on research available up to a specific literature cutoff date, meaning they do not include findings from studies published after those dates. This presents a gap in our review, as ongoing research continues to investigate the human health impacts associated with anticoagulant rodenticide exposures.

To ensure this project's scientific review is current, ERG will perform a literature search for recent peerreviewed studies on the human health impacts of anticoagulant rodenticides. The search will initially focus on publications related to human toxicity and risks from the past five years (2020-2025) using PubMed. Keywords will include terms related to the class of rodenticides (e.g., "anticoagulant rodenticide") and the active ingredients. Preliminary searches indicated that just these two search terms will yield a manageable number of articles to review. ERG will supplement this search with additional targeted searches on specific topic areas such as child poisonings, zoonotic diseases, bioaccumulation, and food safety; these targeted searches will not be date limited.

Upon executing the search, ERG will compile potentially relevant publications in a reference management system (either EndNote or RefWorks), remove duplicate entries, and exclude non-English publications. Next, ERG will review the titles and abstracts for relevance, creating a final list of studies related to the human health impacts of anticoagulant rodenticides. ERG will then obtain the full text of the selected publications, reviewing them again for relevance. ERG intends to review every publication that passes through the different screening stages. The Phase Two report will document the literature search and results.

3.2 Assessments of Anticoagulant Rodenticides Environmental Impacts

This section identifies the "key assessments" that the ERG team will consider on environmental impacts of anticoagulant rodenticides. The content is organized into the three types of "key assessments" included in this contract's scope of work. Assessments that report on both human health impacts and environmental impacts are listed both below and in <u>Section 3.1</u>.

The ERG Team will consider a range of environmental impacts when reviewing publications listed in this section. These impacts include direct toxicity effects on both target and non-target species due to

contact with anticoagulant rodenticides, including for rare, threatened, and endangered species in Massachusetts; sublethal effects on aquatic and terrestrial biota, such as behavioral effects that may have ecological significance on species populations; and biodiversity loss. The ERG Team will consider the various anticoagulant rodenticide environmental impacts that have been studied and the uncertainties associated with the assessments.

As with the key assessments of human health impacts, the key assessments presented below were originally prepared to address different issues, employed different methodologies, and drew from different subsets of the peer-reviewed literature. The ERG Team will account for and explain these differences when preparing the Phase Two report.

3.2.1 Recent and Ongoing Assessments Published by Recognized Authorities

During Phase Two of the project, the ERG team proposes reviewing and summarizing the following ecological assessments conducted by recognized authorities. The list is organized into four categories of authors.

Assessments Issued by EPA

- All the most recent registration reviews for first-generation and second-generation anticoagulant rodenticides, as noted above in Section 3.1.1, will be summarized.
- Additionally, all first- and second-generation anticoagulant rodenticides, except for warfarin, were addressed in the <u>Seven Anticoagulant Rodenticides Draft Ecological Risk Assessment for</u> <u>Registration Review</u> (EPA, 2020d) and the <u>Response to Public Comments on Draft Ecological Risk</u> <u>Assessment for 7 Anticoagulant Rodenticides</u> (EPA, 2022h).
- As noted above in Section 3.1.1, concerns about accidental poisoning, including for non-target aquatic and terrestrial species, led EPA to conduct a <u>rodenticides risk mitigation investigation</u> which culminated in a <u>Proposed Risk Mitigation Decision</u> (EPA, 2007), and a <u>Revised Risk Mitigation Decision for Ten Rodenticides</u> (EPA, 2008). The final risk mitigation decision required all rodenticide bait products be sold in bait station form and restricted the sale and distribution of second-generation anticoagulant rodenticides. This decision also led to the <u>voluntary</u> <u>cancellation of certain pesticide registrations</u> (EPA, 2013).
- Most recently, as part of its Endangered Species Act assessment, EPA is required to determine whether use of rodenticides will have any effect on a species or critical habitat. EPA has documented its effects determinations in the <u>National Level Threatened and Endangered</u> <u>Species Biological Evaluation for 11 Rodenticides</u> docket (EPA, 2024a). All seven anticoagulant rodenticides are included in this docket, which includes a major assessment (<u>Rodenticides: Final Biological Evaluation, Effects Determinations, and Mitigation Strategy for Federally Listed and Proposed Endangered and Threatened Species and Designated and Proposed Critical Habitats [EPA, 2024b]) and EPA's responses to comments.</u>

Assessments Issued by State Authorities in the United States

- In 2013, the State of California Department of Pesticide Regulation published the <u>Second</u> <u>Generation Anticoagulant Rodenticide Assessment</u> which reviews the risk of these rodenticides to nontarget wildlife (CDPR, 2013). As described in 3.1.1, ERG will also evaluate the documents produced as a part of California's decision to reevaluate use and restrictions to anticoagulant rodenticides.
- The ERG Team will consult with MDAR for publicly available assessments or summaries that other Massachusetts agencies have developed on anticoagulant rodenticide's environmental

impacts, beyond the <u>Wildlife and Rodenticide</u> webpage published by the Massachusetts Division of Fisheries and Wildlife (Massachusetts Division of Fisheries and Wildlife, n.d.).

Assessments Issued by International Bodies and Agencies of Selected Foreign Countries

- In 2021 the Ministry of Environment and Climate Change Strategy of British Columbia published <u>A Review of Second Generation Anticoagulant Rodenticides and Risks to Non-target Wildlife in</u> <u>British Columbia</u> (British Columbia Ministry of Environment and Climate Change Strategy, 2021).
- The assessments produced by international bodies that are listed in Section 3.1.1.

Assessments Issued by Selected Non-Governmental Organizations (NGOs)

 In 2024, the Harvard Law School Animal Law and Policy Clinic submitted a petition to MDAR to <u>Suspend the Registration of Anticoagulant Rodenticide Products in Massachusetts</u> (Harvard Law School Animal Law and Policy Clinic, 2024). This petition collected evidence of severe and widespread adverse effects of anticoagulant rodenticides on Massachusetts wildlife.

3.2.2 Peer-reviewed Publications

In recent decades, many peer-reviewed journal articles have reported on the effects of anticoagulant rodenticides on the environment and wildlife, exposures to this contamination, and specific biological effects. Conducting a systematic review of the entire history of anticoagulant rodenticide-related journal articles is outside the scope of this work. However, to ensure the Phase Two research is current, ERG will conduct a supplemental literature search focused on studies measuring ecotoxicological effects of anticoagulant rodenticides published after the literature cutoff dates in the most recent assessments identified in Section 3.2.1 (i.e., after 2020). This literature search will be conducted using EPA's ECOTOX database, and search terms will include the active ingredients in anticoagulant rodenticides.

The above search will be supplemented with additional targeted searches using scholarly search engine tools (e.g., Google Scholar, Science.gov, Elsevier/Science Direct) on specific topics of interest to address data gaps identified in ERG's review of recent and ongoing assessments (see Section 3.2.1). These topics might include sublethal effects, resistance development, and bioaccumulation.

Table 4 lists the active ingredients and CAS numbers that will be included in these searches.

Generation	Active Ingredient	CAS No.
FGAR	Chlorophacinone	3691-35-8
FGAR	Diphacinone	82-66-6
FGAR	Warfarin	81-81-2
SGAR	Brodifacoum	56073-10-0
SGAR	Bromadiolone	28772-56-7
SGAR	Difenacoum	56073-07-5
SGAR	Difethialone	104653-34-1

Table 4. FGAR and SGAR Active Ingredient Identifying Information

ERG will screen studies identified as potentially relevant for the following characteristics:

 Lab or field studies conducted on *in vivo* organisms (i.e., on whole live organisms) examining the toxicological effects of a single anticoagulant rodenticide active ingredient (i.e., not mixtures of potential toxicants) and using experimental controls.

- Studies on organisms with plausible exposure pathways to anticoagulant rodenticides (e.g., through primary or secondary dietary exposure, transport to surface waters, etc.). This will include studies on species endemic to Massachusetts including ones that are listed as Threatened or Endangered under the Massachusetts Endangered Species Act (MESA).
- Studies that measure toxicological effects related to survival, growth, reproduction, and development.
- Studies must be available in English.

3.3 Assessments of Anticoagulant Rodenticide Alternatives

For selected anticoagulant rodenticide alternatives, the Phase Two report will provide information on uses, effectiveness, and impacts on human health and the environment. The report will address the four categories of options listed in <u>Section 2.3</u>.

For the chemical anticoagulant rodenticide alternatives reviewed in Phase Two, the ERG Team will consider the following two information sources for human health and environmental assessments:

- The ERG Team will conduct substance-specific searches on EPA's Pesticide Chemical Search website (<u>https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1</u>). For most substances listed in Table 1 of this report, this website provides links to documents with some combination of the following information: regulatory status, Reregistration Eligibility Decision (RED) documents, draft and final human health and ecological risk assessments, Endangered Species Act litigation, environmental fate and transport information, and regulatory dockets (which can include links to additional references).
- The ERG Team will also conduct substance-specific searches for human health and ecological risk assessments from other authoritative agencies for the chemical alternatives of greatest interest as identified through the stakeholder engagement process.
- Project resources do not allow for comprehensive searches of assessments and peer-reviewed literature for every alternative. ERG is also not charged with conducting cost-benefit analyses of the various rodenticide alternatives.

4.0 Key Stakeholders to Consult

This project's scope of work calls for ERG to "consult with stakeholder groups on data and information collection." In Phase One, ERG was only required to identify the stakeholder groups who will be contacted; those groups will not be contacted until Phase Two. The ERG Team intends to contact stakeholders in Phase Two for the following reasons:

- To identify any relevant scientific assessments on the human health and environmental impacts of anticoagulant rodenticides, beyond those already identified in Sections 3.1 and 3.2.
- To seek input on relevant research in progress and pending assessments.
- To seek information on anticoagulant uses in Massachusetts, the amounts of different formulations used, and experiences with using anticoagulant alternatives.
- To understand anticoagulant related issues of greatest interest.
- To identify whether other jurisdictions have restricted the use of anticoagulant rodenticides and to better understand the decision-making process for those restrictions.

The identified stakeholders will be invited to provide technical input at the beginning of Phase Two, and they will be invited to review the draft Phase Two report. All stakeholder outreach will be conducted with consideration for project scope and available resources.

ERG's approach to stakeholder engagement will include the following:

- Phone Interviews with Government Stakeholders. ERG will offer phone interviews to all identified government-affiliated stakeholders.
- Survey Distribution to All Stakeholders. ERG will send all stakeholders listed below an invitation to complete a short online survey about anticoagulant rodenticides. The survey will be sent to representatives of non-governmental organizations, academic experts, industry representatives, and advocacy groups.
- Follow-Up Interviews with Selected Non-Government Stakeholders. Based on survey
 responses and in consultation with MDAR, ERG may identify a subset of non-government
 stakeholders to invite for follow-up phone interviews. Project resources will limit the number of
 interviews that can be conducted.

The draft Phase 1 report identified stakeholders to contact for additional input. The list of stakeholders to contact was expanded, based on input from the Pesticide Board Subcommittee and suggestions made in public comments. In some instances, the individuals listed below were referred to ERG by other members or designees of their respective organizations. ERG will contact the following stakeholders as described above.

Massachusetts Pesticide Board Subcommittee Members and Designees

- Michael Moore, Chairperson, Director, DPH
- Brian Arrigo, Commissioner, Massachusetts Department of Conservation and Recreation (DCR)
- Nicole Keleher, DCR Designee
- Robert Goldstein, Commissioner of the Massachusetts Department of Public Health, (DPH)
- Meg Blanchet, DPH Designee
- Ashley E. Randle, Commissioner of the Massachusetts Department of Agricultural Resources (MDAR)
- Taryn LaScola, Director, MDAR Designee
- Richard Berman, public member (Appointed by Governor)

Selected Contacts from Government Agencies

- Bret Allen, Nevada Department of Agriculture
- Howard Cook, Rhode Island Department of Environmental Management, Division of Agriculture and Foresty
- Diane Jorsey, Connecticut Department of Energy and Environmental Protection

- Derrick Lastinger, Georgia Department of Agriculture
- Victor Lennon, North Carolina Department of Agriculture and Consumer Services, Structural Pest Control and Pesticides Division
- Joshua Ogawa, Department of Pesticide Regulation, California
- Theodore Puetz, Ak-Chin Indian Community, Tribal
- David J Rousseau, New Hampshire Division of Pesticide Control
- Eve Schlüter, Assistant Director, Massachusetts Natural Heritage and Endangered Species Program, MassWildlife
- Tim Stein, Washington State Department of Agriculture, State Pesticide Compliance Program

Selected Non-Government Organizations (Alphabetical Order by first Name of Contact)

- Alan Buckle, Immediate Past Chairman, Campaign for Responsible Rodenticide
- Allison Cuellar, President, Association of Structural Pest Control Regulatory Officials
- Andrea Coron, Executive Director, United Producers, Formulators & Distributors Association
- Aquinnah Wampanoag
- Billy Olesen, Pest Stop (Operations Manager), Washington State Pest Management Association (VP)
- Carlene Pavlos, Executive Director, Massachusetts Public Health Association
- Charles Clarkson, Director of Avian Research, Audubon Society of Rhode Island
- Chaubuagungamaug Band of Nipmuc
- Claire O'Neill, President and Founder of Earthwise Aware Inc, Co-founder EwA Rat Poison (AR) Brigade
- Clint Richmond, MDAR Conservationist Pesticide Advisory Council, Sierra Club
- Dave Shepard, Massachusetts Association of Dairy Farmers
- David Needle, University of New Hampshire, New Hampshire Veterinary Diagnostic Laboratory, Clinical Associate Professor
- Dillon Gabbert, RISE, Director of State Regulatory Affairs
- Dorothy (Dot) McGlincy, Massachusetts Association of Conservation Commissions, Executive Director
- E. Hardy Kern III, Director of Government Relations, Pesticides and Birds Campaign, American Bird Conservancy
- Earthjustice
- Emily Norton, Charles River Watershed Association

- Food Production Solutions Association
- Hassanamisco Nipmuc
- Heidi Ricci, Mass Audubon
- Herring Pond Wampanoag
- J.D. Darr, Director, Legislative and Regulatory Affairs, National Pest Management Association
- Jacqueline Frair, Department of Environmental Forest Biology from the State University of New York College of Environmental Science and Forestry
- Jake Fowler, Fowler and Sons Pest Control
- Jane Kelly, On The Wing
- Jane Newhouse, Newhouse Wildlife
- Janet Domenitz, Executive Director, MASSPIRG
- Jennifer Hauge, Legislative Affairs Manager, Animal Legal Defense Fund
- Jim Joyce, Operation Woburn Wildlife
- Jodi Swenson, Cape Ann Wildlife, Inc
- Jody Gangloff-Kaufman, Coordinator of NYS Integrated Pest Management Program; Associated with Cornell University
- John Mangiaratti, President, Massachusetts Municipal Association President
- Jonathan Evans, Environmental Health Legal Director, The Center for Biological Diversity
- Josh Morse, Commissioner of Public Buildings, City of Newton
- Kallie Robertson, Northeast Organic Farming Association, Massachusetts chapter (NOFA-MA)
- Kansas State University, Veterinary Diagnostic Laboratory
- Katie Swift, Chair, Rodenticide Task Force
- Kristie Sullivan, Director, Regulatory Testing Issues, Physicians Committee for Responsible Medicine
- Laura Kiesel, Save Arlington Wildlife
- Lisa Owens-Vianni, Raptors Are The Solution, Executive Director
- Manojit Basu, Vice President, Science Policy, CropLife America
- Marci Cemenska, Save Lexington Wildlife
- Margaret O'Gorman, President, Wildlife Habitat Council
- Mary Hollingsworth, Director, Animal Law & Policy Clinic, Harvard Law School, one of the lead authors of the Petition to Suspend the Registrations of Anticoagulant Rodenticide Products in Massachusetts (Harvard Law School Animal Law and Policy Clinic, 2024)

- Mashpee Wampanoag
- Massachusetts Food Association
- Massachusetts Restaurant Association (MRA)
- Matt Frye, Cornell University
- Matt Lopez, Rodenticide Committee Chair, Association of Structural Pest Control Regulatory Officials
- Maureen Murray, Tufts University Cummings School of Veterinary Medicine
- Massachusett Tribe
- McGregor, Legere, & Stevens PC
- Megan J. Provost, President, Responsible Industry for a Sound Environment
- Megan Striegel, NPMA's Director of Legislative and Regulatory Affairs
- Kara Holmquist, MSPCA-Angell
- Melissa Hoffer, Climate Chief of Massachusetts
- Mike Bourdeau, President, (Adam Corace, State Liaison) New England Pest Management Association
- Dr. Monica Mansfield, President, Massachusetts Veterinary Medical Association
- Natasha Waden, Director of Recreation & Community Services, Arlington, MA
- New England Convenience Store and Energy Marketers Association
- New England Wildlife Center
- Niamh Quinn, University of California Agriculture and Natural Resources, Human-Wildlife Interactions Advisor
- Parker River National Wildlife Refuge
- Patrick Herron, Mystic River Watershed Association
- Patty Reilly, President, Wildlife Rehabilitators' Association of Massachusetts
- Pennsylvania Animal Diagnostic Laboratory System
- Rebeckah Freeman Adcock, Vice President, U.S. Government Relations, International Fresh Produce Association
- Regen Milani, Massachusetts Society of Municipal Conservation Professionals, Canton PresidentMACC
- Retailers Association of Massachusetts
- Richard J. Pollack, PhD, Senior Environmental Public Health Office, Environmental Health and Safety (EH&S), Harvard Campus Services

- Richard Kelly, Banner Pest Control
- Richard Ostfeld, Distinguished Senior Scientist at the Cary Institute of Ecosystem Studies, member of the National Academy of Sciences
- Robert (Bobby) Corrigan, Urban Rodentologist (Author of the Boston Rat Action Plan, 2024)
- Robert Linscott, NorthShore Wildlife, PAC Agent
- Robin Charlton, Chair, Administrative Committee, FIFRA Endangered Species Task Force (FESTF)
- Ryan Okey, Clemson University Department Pesticide Regulation, South Carolina
- Save Mass Wildlife
- Sheida Soleimani, Congress of the Birds
- Stephanie Ellis, WildCare of Cape Cod, Executive Director and Wildlife Rehabilitator
- Steve Hensley, Chair, Pesticide Policy Coalition
- Stockbridge-Munsee
- The Peregrine Fund
- Theodore Puetz, Ak-Chin Indian Community, Tribal (SURVEY?)
- Timothy Muir McDonald, President, Massachusetts Health Officers Association
- Tufts Wildlife Clinic
- US Poultry & Egg Association
- USDA Animal and Plant Health Inspection Service
- Warren Shaw, President, Massachusetts Farm Bureau Federation
- Wildlife Rehabilitators' Association of Massachusetts (WRAM)
- Zachery Mertz, New England Wildlife Centers, Executive Director

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6.0 Abbreviations Used in the Report

APVMA	Australian Pesticides and Veterinary Medicines Authority
CDC	Centers for Disease Control and Prevention
DCR	(Massachusetts) Department of Conservation and Recreation
DPH	(Massachusetts) Department of Public Health
DPR	(State of California) Department of Pesticide Regulation
DVM	Doctor of Veterinary Medicine
ECHA	European Chemicals Agency
EPA	U.S. Environmental Protection Agency
ERG	Eastern Research Group, Inc.
FESTF	FIFRA Endangered Species Task Force (see below for FIFRA)

FGAR	First Generation Anticoagulant Rodenticides
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
MDAR	Massachusetts Department of Agricultural Resources
NGO	non-governmental organization
NPIC	National Pesticide Information Center
PMRA	(Canada's) Pest Management Regulatory Agency
RED	Reregistration Eligibility Decision
RFQ	Request for Quotes
SGAR	Second Generation Anticoagulant Rodenticides
USDA	U.S. Department of Agriculture
WHO	World Health Organization

Appendix A: Summary of Public Comments on Phase 1 Report

MDAR sought public feedback on the Phase One report during a public comment period that closed on April 30, 2025. In total, 233 comments were received. MDAR and ERG reviewed these public comments and found that approximately 85% primarily expressed opinions in favor of restricting or banning anticoagulant rodenticides. The remaining 15% provided substantial input to the Phase One report and/or the forthcoming Phase Two report. These included the identification of errors, suggestions for additional data sources or publications, and recommendations for additional stakeholders to contact. ERG incorporated relevant substantive comments into this revised Phase One report and will also consider them when developing the Phase Two report.

The bullets below summarize key themes raised in public comments and how ERG addressed them. In particular, multiple commenters:

- Identified errors in the description of California's regulatory history on anticoagulant rodenticides. Edits were made to correct these inaccuracies in this report, and more detailed descriptions will be included in the Phase 2 report.
- Suggested clarifications to the background section regarding EPA labels and use restrictions. ERG
 made minor text edits to improve clarity and address inaccuracies. However, not every point
 raised in the public comments was expanded upon, as the background section of this Phase One
 report is not intended to be an exhaustive accounting of all issues related to anticoagulant
 rodenticides.
- Submitted specific publications, datasets, and peer-reviewed studies for consideration. ERG will
 review these materials and incorporate relevant information into the Phase 2 report.
- Recommended expanding the discussion of alternatives to anticoagulant rodenticides, including biological apex predators, traps, sanitation, contraceptives, and Integrated Pest Management (IPM) frameworks. ERG added contraceptives to the list of chemical alternatives and will expand upon the other alternatives mentioned in the Phase Two report.
- Recommended noting that rodents are developing resistance to second-generation anticoagulant rodenticides (SGARs), similar to first-generation compounds. ERG noted this in the revised text to this report.
- Recommended explaining that SGARs can still be purchased online. ERG clarified in the revised text of this report that SGARS are can still be obtained by the general public.

In addition to the above changes, the list of non-government stakeholders that ERG contacted was expanded to 92 stakeholders based on suggestions in the public comments. These stakeholders were all contacted by ERG and asked to complete a survey. Feedback from these surveys will be incorporated in the Phase Two report. The full list of stakeholders is included in the main body of this revised report.