# Anticoagulant Rodenticides Scientific Review Draft Phase 1 Report

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April 2025

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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 request 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 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. 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, the Phase One report will present 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... 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). While the original scope of work in the RFQ included a review of precedential judicial decisions, MDAR has since determined that this component is not necessary.
- <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.

This Phase One report will be presented to the Pesticide Board Subcommittee for review. Following the Subcommittee's review, the report will be made available for public comment. ERG will address any

factual errors identified through the Subcommittee's review or public comments, and submit a revised Phase One report to MDAR. The revised report will include all original comments as an appendix. Upon final approval, the Subcommittee will instruct ERG to proceed with Phase Two.

ERG will then proceed 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.

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

This section presents background information on anticoagulant rodenticides (Section 2.1); summarizes categories of anticoagulant rodenticides uses in the Commonwealth and the quantities of anticoagulant rodenticides used (Section 2.2); 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 (Section 2.3). 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 allows rodents to continue consuming bait and exposing others in their population, increasing overall effectiveness. 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.

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. 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.

#### 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)
- EPA-registered SGARs: Brodifacoum, bromadiolone, difenacoum, and difethialone

FGARs and SGARs can be found in products that have been registered 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, 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)." In 2022 EPA issued a proposed interim decision that all SGARs be classified as restricted use (EPA 2022e). The agency is expected to make a final decision on this matter in 2025 (EPA 2024d).

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 protect bait from moisture and spillage, and they 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. Anticoagulant pesticide bait products are typically required to be applied in tamper-resistant bait stations that placed out of reach of children, pets, livestock, and non-target wildlife. 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. The Phase Two report will summarize use restrictions and requirements to minimize impact, as listed on the EPA-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 indicate 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 (https://www.epa.gov/rodenticides/rodent-control-pesticide-safety-review)
- 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, 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/Cultural 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> are less common; and they rely on 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
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
Zinc phosphide	2-63.2%	16	3

Table 3. 0	Chemical Anticoagu	lant Rodenticide	e Alternatives to	Be Considere	d in Phase Two
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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 cancer and non-cancer 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 carcinogenicity, non-cancer toxicity, or both 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>: Draft Human Health and/or Ecological Risk <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> docket (EPA, 2022e). All four dockets were last updated in 2022 as described in the <u>Pesticide Registration Review</u>: <u>Proposed</u> <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> <u>and Epidemiology Assessment</u> (EPA, 2016g) and <u>Rodenticides: Tier I Update Review of Human Incidents (EPA, 2020c).</u>

- 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 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 published the <u>Notice of Proposed Decision to Begin Reevaluation of Second-Generation Anticoagulant Rodenticides and Public Report</u> (CDPR, 2018), the <u>Notice of Final Decision to Begin Reevaluation of Second-Generation Anticoagulant Rodenticides</u> (CDPR, 2019), and <u>Second Generation Anticoagulant Rodenticides – Revised Law and Updates to Allowed Uses</u> (CDPR, 2021). In September 2024, California expanded the <u>existing moratorium</u> on first-generation anticoagulant rodenticides to include second-generation anticoagulant rodenticides. ERG will review any of the State of California Department of Pesticide Regulation's reports that led to the expansion of anticoagulant rodenticide restrictions.

#### 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</u> <u>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 rodenticide biocidal</u> <u>products (2024)</u>. This report analyzes the human health impact of anticoagulant rodenticides 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. ERG will first prepare a literature search methodology memorandum for MDAR's review. The search will focus on publications 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. No further restrictions on the search will be used because preliminary searches indicated that just these two search terms will yield a manageable number of articles to review.

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 in sufficient detail such that interested third parties can replicate the findings. The report will also describe the process ERG applied for evaluating the quality and reliability of individual publications.

## 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, concerns have been raised about the impact of rodenticides on threatened and endangered species, leading the EPA to open 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</u> <u>Biological Evaluation, Effects Determinations, and Mitigation Strategy for Federally Listed and</u> <u>Proposed Endangered and Threatened Species and Designated and Proposed Critical Habitats</u> [EPA, 2024b]) and EPA's responses to comments.

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 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.

## **3.2.2** Other Evaluations and Information Sources Issued by Selected Non-Governmental Organizations (NGOs)

While not formal risk assessments, several non-governmental organizations have developed informational resources or submitted materials relevant to the use and impacts of anti-coagulant rodenticides. For example,

- 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.
- The National Pesticide Information Center has developed information resources for <u>rodenticides</u> generally (NPIC, 2016), and more specifically for <u>bromadiolone</u> (NPIC, 2013). The National Pesticide Information Center is a cooperative agreement between Oregon State University and EPA to provide objective, science-based information about pesticides and pesticide-related topics to enable people to make informed decisions about pesticides and their use.

#### 3.2.3 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).

The literature search will be conducted using EPA's ECOTOX database, and search terms will include the active ingredients in anticoagulant rodenticides. The search will be supplemented using scholarly search engine tools (e.g., Google Scholar, Science.gov, Elsevier/Science Direct) using search terms related to the toxicants of concern and relevant biological effects. Additional search terms may be included to identify studies that address data gaps identified in ERG's review of recent and ongoing assessments (see Section 3.2.1).

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 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, including federal, state, and municipal representatives.
- 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 will 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 ERG Team identified five categories of stakeholder groups to contact. Within each category, the stakeholders are listed in alphabetical order, by the last names of the points of contact. The list of stakeholders to contact might change, based on input from the Pesticide Board Subcommittee and suggestions made in public comments. The individuals listed below may refer ERG to other members or designees of their respective organizations. ERG will contact stakeholders as described above, and the Phase Two report will list all stakeholders contacted.

#### Scientific Leads of Selected Key Assessments

- Laura Bacon, Biologist, EPA, Risk Assessor and listed contact for the Draft Human Health Risk Assessment for Registration Review of Anticoagulant Rodenticides (EPA, 2020)
- Deborah Daniels, DVM, Senior Environmental Scientist, Lead for the State of California Department of Pesticide Regulation Second Generation Anticoagulant Rodenticide Assessment (California DPR, 2013)
- William P. Eckel, Ph.D., EPA, Senior Science Advisor for the Final Biological Evaluation, Effects Determinations, and Mitigation Strategy for Federally Listed and Proposed Endangered and Threatened Species and Designated and Proposed Critical Habitats (EPA, 2024)
- Kent Fothergill, Pesticide Re-Evaluation Division, EPA, Chemical Review Manager for Anticoagulant Rodenticide Registration Review Cases (EPA, 2022)
- Ann M. Prichard, Chief of the State of California Pesticide Registration Branch, Author of the Notice of Final Decision to Begin Reevaluation of Second-Generation Anticoagulant Rodenticides (California DPR, 2018)

#### Massachusetts Pesticide Board Subcommittee Members and Designees

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

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

- Manojit Basu, Vice President, Science Policy, CropLife America
- Mike Bourdeau, President, (Adam Corace, State Liaison) New England Pest Management Association
- Robin Charlton, Chair, Administrative Committee, FIFRA Endangered Species Task Force (FESTF)
- Andrea Coron, Executive Director, United Producers, Formulators & Distributors Association
- Allison Cuellar, President, Association of Structural Pest Control Regulatory Officials
- J.D. Darr, Director, Legislative and Regulatory Affairs, National Pest Management Association
- Janet Domenitz, Executive Director, MASSPIRG
- Jonathan Evans, Environmental Health Legal Director, The Center for Biological Diversity
- Rebeckah Freeman Adcock, Vice President, U.S. Government Relations, International Fresh Produce Association
- Jennifer Hauge, Legislative Affairs Manager, Animal Legal Defense Fund
- Steve Hensley, Chair, Pesticide Policy Coalition
- E. Hardy Kern III, Director of Government Relations, Pesticides and Birds Campaign, American Bird Conservancy
- Matt Lopez, Rodenticide Committee Chair, Association of Structural Pest Control Regulatory Officials
- John Mangiaratti, President, Massachusetts Municipal Association President
- Monica Mansfield, President, Massachusetts Veterinary Medical Association
- Timothy Muir McDonald, President, Massachusetts Health Officers Association
- David O'Neill, President, Massachusetts Audubon Society

- Margaret O'Gorman, President, Wildlife Habitat Council
- Carlene Pavlos, Executive Director, Massachusetts Public Health Association
- Megan J. Provost, President, Responsible Industry for a Sound Environment
- Patty Reilly, President, Wildlife Rehabilitators' Association of Massachusetts
- Warren Shaw, President, Massachusetts Farm Bureau Federation
- Kristie Sullivan, Director, Regulatory Testing Issues, Physicians Committee for Responsible Medicine
- Katie Swift, Chair, Rodenticide Task Force

#### Selected Contacts from Federal Government Agencies

- Elizabeth Nelson, Chief, Environmental and Risk Analysis Services, Policy and Program Development, Animal and Plant Health Inspection Servies, United States Department of Agriculture
- Kimberly Nesci, Director, Office of Pest Management Policy, United States Department of Agriculture
- Eric Svendsen, Director, Division of Environmental Health Science and Practice, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC)

#### Selected Contacts from Massachusetts Government Agencies and Universities

- Brian Hawthorne, Habitat Program Manager, MassWildlife
- 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)
- Richard J. Pollack, PhD, Senior Environmental Public Health Office, Environmental Health and Safety (EH&S), Harvard Campus Services
- Eve Schlüter, Assistant Director, Massachusetts Natural Heritage and Endangered Species Program, MassWildlife

#### Selected Contacts from Other State Government Agencies and Universities

- Bret Allen, Nevada Department of Agriculture
- Howard Cook, Rhode Island Department of Environmental Management, Division of Agriculture and Forestry
- David Huber, Vermont Agency of Agriculture, Food, and Markets
- Diane Jorsey, Connecticut Department of Energy and Environmental Protection
- Anthony Lamanno, New York State Department of Environmental Conservation, Bureau of Pesticides Management

- Derrick Lastinger, Georgia Department of Agriculture
- Victor Lennon, North Carolina Department of Agriculture and Consumer Services, Structural Pest Control and Pesticides Division
- Ryan Okey, Clemson University Department Pesticide Regulation, South Carolina
- Megan Patterson, Maine Department of Agriculture, Conservation, and Forestry, Division of Animal and Plant Health
- Theodore Puetz, Ak-Chin Indian Community, Tribal
- David J Rousseau, New Hampshire Division of Pesticide Control
- Tim Stein, Washington State Department of Agriculture, State Pesticide Compliance Program
- Leslie Talpasanu, Department of Pesticide Regulation, California

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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