Glyphosate Scientific Review
Final Phase 1 Report

Prepared for:

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1.0 Introduction

In 2021, the Massachusetts legislature enacted the Acts of 2021. Chapter 24 of this legislation established budgets for many state government activities, including the formation of a commission charged with conducting "a scientific review of the potential impacts of glyphosate and its most common alternative herbicides on the environment and public health" (Commonwealth of Massachusetts, 2021).

The legislation further states that: "…the pesticide subcommittee established under section 3A of chapter 132B of the General Laws shall use said scientific review as part of an individual review conducted under 333 C.M.R. 8.03 to determine whether current uses of glyphosate pose unreasonable adverse effects to the environment, and whether current registered uses of glyphosate should be altered or suspended" (Commonwealth of Massachusetts, 2021).

Pursuant to the Acts, the Glyphosate Commission was formed, and the Commission opted to use contractor support to conduct the glyphosate scientific review. The Massachusetts Department of Agricultural Resources (MDAR), on behalf of the Glyphosate Commission, issued a Request for Quotes to seek contractor support for this project. After an open bidding process, MDAR issued a contract to Eastern Research Group, Inc. (ERG) to conduct the scientific review of glyphosate and its alternatives. The review is to consider uses, restrictions, public health impacts, and environmental impacts of glyphosate. The results of the review will be presented to the Glyphosate Commission and then submitted to the joint Committee of Environment, Natural Resources and Agriculture.

MDAR split the glyphosate scientific review project into two phases. In Phase One, MDAR tasked ERG with identifying all resources to consider for the scientific review, and ERG will then review those resources in Phase Two. ERG, with assistance from its subcontractor Tetra Tech, Inc., prepared this Phase One report, which is organized into the following sections. The list quotes text from the scope of work from this project's original Request for Quotes.

- Section 2.0 presents "a summary of available information on the use of glyphosate in the Commonwealth and key herbicide agent alternatives," including available information on "use restrictions and requirements to minimize impacts."
- Section 3.0 lists "key assessments (e.g., recent assessments by recognized authorities including, for example, the U.S. Environmental Protection Agency; peer reviewed publications; precedential judicial decisions), of the potential public health and environmental impacts of glyphosate and its alternatives." This section presents the requested information separately for glyphosate's public health impacts (Section 3.1) and environmental impacts (Section 3.2) and impacts of glyphosate alternatives (Section 3.3).
- Section 4.0 lists "key stakeholders to be consulted" by ERG and Tetra Tech as part of the broader glyphosate scientific review.
- Section 5.0 lists the references cited throughout this report.
- Section 6.0 provides a list of abbreviations.

On June 6, 2022, ERG submitted a draft of this report. The Glyphosate Commission posted the draft to its website and invited stakeholders to comment. On July 6, 2022, all comments received were compiled into a file, which is posted to the Glyphosate Commission website. After reviewing the public comments, ERG issued a letter to the Glyphosate Commission on August 24, 2022. That letter listed issues identified in the public comments for which ERG sought the Glyphosate Commission's input before completing Phase One. During its meeting on September 15, 2022, the Glyphosate Commission discussed the issues raised in ERG's letter and resolved all matters needed for completing this report. ERG incorporated revisions, as necessary, and submitted this final Phase One report on January 3, 2023.

ERG and Tetra Tech will now 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 Phase Two report, which will include a scientific review of human health and environmental impacts of glyphosate 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 draft Phase Two report.

2.0 Summary of Available Information on Uses of Glyphosate and Alternatives

This section presents background information on glyphosate (Section 2.1); summarizes categories of glyphosate uses in the Commonwealth and, where data are available, the quantities of glyphosate used (Section 2.2); and identifies glyphosate alternatives that have been reported in the literature and the subset of herbicide alternatives that will be evaluated in Phase Two (Section 2.3).

During Phase Two of this project, the ERG Team will contact key stakeholders, as necessary, on glyphosate use in Massachusetts (see Section 4.0). Through those stakeholder contacts, ERG will seek additional Massachusetts-specific input on glyphosate uses, glyphosate usage quantities, and glyphosate alternatives.

2.1 Background Information on Glyphosate

Glyphosate is a synthetic, non-selective systemic herbicide that controls a wide variety of plants including grasses, annuals, perennials, and woody plants. Since it is non-selective and acts systemically, it has been frequently used in commercial farming, transportation right of ways (such as highway borders and railways), residential applications, and for habitat management. Both nationally and in Massachusetts, glyphosate usage has increased dramatically over the past 30 years (Benbrook, 2016 and references therein). The increase is due at least in part to the availability of commonly produced crops (e.g., corn, soybeans) genetically modified to be herbicide tolerant. As a result, at farms that grow glyphosate-tolerant crops, a wide variety of weeds can be controlled using glyphosate without harming crop production.

Glyphosate is the active ingredient in many herbicide formulations that have been registered by the U.S. Environmental Protection Agency (EPA) and approved by Massachusetts authorities for use in the Commonwealth. ERG searched the Massachusetts Pesticide Product Registration Information website (Kelly Solutions, 2022) for details on the herbicides that contain glyphosate or glyphosate salts (e.g., ammonium glyphosate, potassium glyphosate, the isopropylamine salt of glyphosate). As of May 1, 2022, the database includes records for ten active ingredients for glyphosate or glyphosate compounds, and these records pertain to 156 unique EPA registration numbers. The glyphosate concentrations across these 156 herbicides range from 0.14 percent to 95.2 percent, with a median active ingredient concentration of 41 percent. Like other herbicide active ingredients, manufacturers formulate a mixture of glyphosate and other ingredients, such as carriers, solvents, and surfactants, to maintain efficient application and maximum effectiveness. While manufacturers must disclose the identities and concentrations of active ingredients on product labels, no such requirement applies for other ingredients.

The Kelly Solutions database also includes information on weeds controlled by the various products, sites where the herbicides may be used, and links to the EPA stamped labels for the products. The specific weeds controlled by the registered glyphosate-containing herbicides vary. Many glyphosate-containing herbicides registered in Massachusetts include more than 100 weeds that the products control—and some registered herbicides list more than 300 weeds that are controlled. The sites to which the products can be applied also vary. Some registrations list only one site where products may be applied (e.g., some products are only used in corn fields) but others list more than 500 sites.

The EPA-accepted product labels include extensive information about the herbicides, and most labels reviewed were at least 50 pages long. These labels have information on application methods and rates, formulation details, precautionary statements, steps to prevent resistance, and other topics. Glyphosate products are applied to target areas using a variety of mechanical devices, including hand-held or backpack sprayers and other methods. The most appropriate application method depends on the size of the target area, the density of plant pests, concerns about impacts to surrounding areas, and other factors. The EPA-accepted labels provide further details on application methods for individual products. In most cases, labels warn users not to apply glyphosate-containing herbicides directly to water and outline steps users should take to prevent contamination of water resources; however, some glyphosate-containing herbicides can be used to control emergent aquatic weeds in certain circumstances.

2.2 Glyphosate Uses in Massachusetts

As noted previously, the Massachusetts Pesticide Product Registration Information website lists the approved uses of every glyphosate-containing herbicide registered in the Commonwealth, and these lists include hundreds of entries. Based on this information, most glyphosate uses in Massachusetts fall under the following categories:

- Weed control for row crops (e.g., corn, soybeans, alfalfa)
- Weed control in orchards (e.g., apples)
- Weed control at nurseries
- Control of problematic plants (e.g., dodder, dewberries) in cranberry farming (UMass, 2008)
- Control of nuisance plants in and along transportation rights of way (e.g., highways, railways)
- Residential and commercial landscape management to control weeds and unwanted plants
- Aquatic weed control as a restricted use herbicide in MassDEP-permitted applications
- Habitat management for wildlife and unique ecosystems to control invasive plant species

Additional glyphosate uses in the Commonwealth were identified in the public comments submitted on the draft of this report. The ERG Team will research information on those uses during Phase Two of this project.

The ERG Team also sought data on the amounts of glyphosate-containing herbicides used in Massachusetts for different purposes, but quantitative usage information was only available for row crop applications. Specifically, the most recent agricultural herbicide usage data reported by the United States Geological Survey (Wieben, 2021) indicates the following glyphosate usage quantities in 2019 for row crops in Massachusetts:

- 5,381 kg for corn
- 520 kg for fruits and vegetables
- 78 kg for soybeans
- 77 kg for orchards
- 51 kg for alfalfa

In the Phase Two report, ERG will convert these data to application rates for these commodities, to the extent sufficient underlying data are available.

The ERG Team searched for estimates of glyphosate usage quantities for the various non-agricultural uses noted above, but no reports were identified that include this information specific to Massachusetts. ERG is aware that licensed applicators must submit annual reports on pesticide applications to MDAR, and glyphosate usage quantities for certain applications can be derived from information in these reports. However, the applicators' annual reports are only available in paper form and must be reviewed individually to estimate statewide usages; and this project's budget cannot accommodate the estimated costs for manually reviewing the hard copy reports.

During its meeting on September 15, 2022, the Glyphosate Commission agreed that ERG should proceed with Phase Two work without manually reviewing the licensed applicators' annual reports. This decision was based on multiple factors, including the costs involved, the fact that licensed applicators' annual reports do not account for potentially large quantities of glyphosate applied by non-licensed users (e.g., homeowner use), and the fact that EPA published estimates of glyphosate usage for the northeastern United States in its 2021 *Biological Evaluation for Glyphosate*.

2.3 Glyphosate Alternatives

This contract's scope of work calls for the ERG Team to not only summarize available information on glyphosate uses in the Commonwealth, but also to summarize use of "key herbicide agent alternatives." ERG interprets this requirement as referring to chemical alternatives to glyphosate, but for completeness, ERG is considering a broader range of glyphosate alternatives (i.e., chemical and non-chemical methods).

ERG first identified resources that identify glyphosate alternatives. These include, but are not limited to: a University of Massachusetts (UMass) Extension Turf Program website on glyphosate alternatives (UMass CAFE, 2020); an herbicide alternatives research study that UMass researchers conducted for the Massachusetts Executive Office of Transportation (Barker and Prostak, 2008; 2009); the latest Massachusetts Department of Transportation (MassDOT) Vegetation Management Plan (MassDOT, 2021); a North Carolina State University Extension website on glyphosate alternatives for landscapers (Neal and Senesac, 2022); a technical committee report on glyphosate alternatives for vegetation management in the Los Angeles area (Chiotti et al., 2010); and multiple weed control manuals issued by various state agencies nationwide.

These resources group glyphosate alternatives into multiple categories. For purposes of this project, ERG will consider four categories of alternatives. The list below demonstrates the range of alternatives that are currently available, without consideration for what alternatives are most viable for specific uses in the Commonwealth. Whether a given alternative is feasible will depend on the use, and preferred alternatives might vary between farmers, organic farmers, orchard owners, roadside applicators, nursery owners, habitat managers, landscapers, and homeowners. The feasibility of alternatives and preferred application methods will depend on other factors, like target species, desired effectiveness, potential environmental impacts, area of application, site access, applicable regulations and restrictions, and cost.

Phase Two will consider the following four categories of alternatives. ERG will seek stakeholder input (see Section 4.0) on preferred alternatives in Massachusetts.

- Chemical methods are use of chemical herbicides. A wide range of chemical formulations is available, as discussed below.
- Mechanical methods include use of mechanical devices to control weeds. Examples include tilling soils, mowing weeds, burning weeds, or killing them with steam (with or without foam).
- Physical methods are options for controlling weeds manually, whether by removing weeds from the soil (e.g., hand-picking weeds, hoeing weeds) or by applying materials to suppress weed growth (e.g., mulch, weed mats).
- Biological methods include use of other organisms to remove weeds or inhibit their growth. These include use of herbivores (e.g., sheep, goats, cattle) to consume weeds and use of other plants (e.g., clover) to compete with weeds.

The ERG Team will consider multiple chemical methods in Phase Two. The chemical herbicide alternatives exhibit a range of properties relevant to weed control (e.g., systemic vs. contact herbicides; selective vs. non-selective herbicides; pre-emergent vs. post-emergent herbicides) and may require multiple applications to achieve the desired effectiveness. The Phase Two evaluation will consider two groups of chemical methods as alternatives:

- EPA-registered herbicides. The resources that the ERG Team reviewed (Barker and Prostak, 2008; 2009; Chiotti et al., 2010; MassDOT, 2021; Neal and Senesac, 2022; UMass CAFE, 2020) list EPA-registered herbicide products that researchers have proposed or investigated as glyphosate alternatives for certain uses. Table 1 lists the alternative active ingredients for selected products, considering those that are registered for use in Massachusetts. These alternatives contain various active ingredients, including both synthetic chemicals and substances derived from natural sources. Note: Just because Table 1 lists potential alternatives does not mean they have been demonstrated to serve as effective glyphosate substitutes in Massachusetts or elsewhere.

Table 1. Potential Chemical Herbicide Alternatives to Be Considered in Phase Two

Active Ingredient [a]	Number of Unique Pesticide Registrations Containing Active Ingredient in Massachusetts	Concentration Range of Active Ingredient in Products Registered in Massachusetts
2,4-D	47	0.146% – 38.87%
Aminopyralid compounds [b]	6	2.22% – 71.01%

Active Ingredient [a]	Number of Unique Pesticide Registrations Containing Active Ingredient in Massachusetts	Concentration Range of Active Ingredient in Products Registered in Massachusetts
Caprylic acid	14	0.099% – 47%
Chlorsulfuron	6	15% – 75%
Clethodim	19	12.6% – 26.4%
Clopyralid compounds [b]	21	0.071% – 60%
Diquat compounds [b]	44	0.04% – 37.3%
Dithiopyr	82	0.08% – 40%
Fluazifop-P-butyl	22	0.06% – 24.5%
Glufosinate compounds [b]	29	0.36% – 45.9%
Imazapyr compounds [b]	44	0.16% – 63.2%
Imazethapyr compounds [b]	12	1.38% – 50.2%
Indaziflam	13	0.0061% – 24.3%
Isoxaben	14	0.0008% – 93.5%
d-Limonene	9	1% – 70%
Metsulfuron compounds [b]	20	0.75% – 60%
Oryzalin	9	1% – 41%
Pelargonic acid	23	2% – 57%
Pendimethalin	37	0.81% – 39%
Prodiamine	69	0.2% – 65%
Sethoxydim	7	13% – 18%
Simazine	9	41.9% – 90%
Sulfometuron methyl	8	6.5% – 75%
Triclopyr compounds [b]	84	0.084% – 83.9%

Notes:
Data compiled from queries of the Massachusetts Pesticide Product Registration Information website (Kelly Solutions, 2022).
[a] Certain formulations have multiple active ingredients, which may include glyphosate.
[b] Where active ingredients are in multiple chemical forms, Table 1 collapses the various active ingredients into one entry labeled with "compounds." For example, Table 1 lists the multiple salts of aminopyralid as "aminopyralid compounds."

In Phase Two of the project, the ERG Team will narrow the list of alternative chemical options based on input from the Glyphosate Commission and from stakeholders (see Section 4.0). The ERG Team will ask stakeholders about current and prospective uses of chemical herbicide alternatives, including input on any viable alternatives not listed in Table 1 or elsewhere in this report; whether alternatives are better suited for specific uses (e.g., commercial agriculture, organic farming, roadside weed control, nurseries, residential landscaping); use patterns; insights on resistance; and information on alternatives' effectiveness.

- Minimum risk pesticides. The other chemical alternatives to glyphosate-containing products are those that meet the criteria for "minimum risk pesticides" and therefore EPA does not register them under the Federal Insecticide, Fungicide, and Rodenticide Act. To be eligible for this designation, the products must contain active ingredients and inert ingredients[1] from lists of substances developed by EPA (EPA, 2015a; 2016) and meet additional criteria for labeling, health claims, and other factors. Examples of active ingredients for "minimum risk pesticides" include citric acid, clove oil, coconut oil, corn gluten meal, garlic

[1] Multiple public comments recommended that the ERG Team investigate "inert" ingredients as part of the Glyphosate Scientific Review. This issue was discussed at the Glyphosate Commission meeting held on September 15, 2022. The Commission agreed that the current project is to focus on the human health and environmental impacts of glyphosate and that impacts from "inert ingredients" are outside the scope of this project.

oil, and lauryl sulfate (EPA, 2015a). Formulations containing acetic acid at concentrations up to 8 percent are also eligible to be "minimum risk pesticides," provide the other applicability criteria are met.

3.0 Key Assessments to Review

This section presents a list of "key assessments" that the ERG team proposes reviewing. Consistent with the contract scope of work, we consider "key assessments" to include (1) recent assessments published by selected government agencies and international bodies, (2) peer-reviewed publications in scientific journals, and (3) precedential judicial decisions. 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, databases of judicial decisions, and the peer-reviewed literature.

This section identifies "key assessments" that the ERG team will review on glyphosate's human health impacts (see Section 3.1) and glyphosate's environmental impacts (see Section 3.2) and assessments of the most common alternative herbicides (see Section 3.3). The ERG team will review the assessments listed throughout this section and relevant supporting documents, which may include interim assessments, final determinations, and responses to comments. In Phase Two, the ERG Team will acknowledge which findings pertain to technical grade glyphosate separately from findings that pertain to commercial formulations that contain glyphosate and other substances (adjuvants), to the extent this information is available.

It is important to note that the state of the science of glyphosate's human health and environmental impacts continues to evolve. The following sub-sections include provisions to account for recently completed studies and for key assessments expected to be issued later this year.

3.1 Assessments of Glyphosate's Human Health Impacts

This section identifies the "key assessments" that the ERG team will consider on glyphosate's human health impacts.

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. Importantly, 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 glyphosate toxicity and reaches conclusions on carcinogenicity, non-cancer toxicity, or both or an ongoing significant research study of glyphosate toxicity in humans.

Assessments Issued by Federal and State Authorities in the United States

- EPA first registered glyphosate as a pesticide in 1974 and has periodically reassessed health risks since. The ERG team will review multiple documents posted to the EPA Glyphosate Registration Review docket. These documents include the most recent Interim Registration Review Decision to continue to list glyphosate (EPA, 2020a) and the accompanying Draft Human Health Risk Assessment (EPA, 2018a); EPA's responses to comments (EPA, 2019; 2020b; 2020c); and other relevant supporting documents (EPA 2018b; 2018c). Note that the ERG Team will not review every entry in the EPA docket, because the docket contains more than 14,000 entries. ERG is aware that EPA recently withdrew its Glyphosate Interim Registration Review Decision—an action that has no effect on ongoing uses of glyphosate according to instructions on product labels.
- Congress mandated the Agency for Toxic Substances and Disease Registry (ATSDR) to develop toxicological profiles for hazardous substances found at Superfund sites. ATSDR has prepared more than

180 toxicological profiles, including its Toxicological Profile for Glyphosate (ATSDR, 2020). The profile considered peer-reviewed literature published through September 2017.

- The National Toxicology Program (NTP) falls within the U.S. Department of Health and Human Services. NTP has previously issued cancer classifications for selected hazardous substances and the program's Report on Carcinogens is a widely cited resource for evidence of carcinogenicity. Although NTP has not yet classified glyphosate for carcinogenicity, the program is currently researching the toxicity of glyphosate and selected glyphosate formulations. NTP has released limited results from *in vitro* and genetic toxicity tests and may issue additional publications in 2022 (NTP, 2022). ERG will also review publicly available information from NTP on its research regarding oxidative stress induced by glyphosate.
- The U.S. Forest Service (USFS) within the U.S. Department of Agriculture (USDA) has a mission to "sustain the health, diversity, and productivity of the Nation's forests and grasslands." In support of that mission, USFS has evaluated the toxicity of various herbicides, including a 2011 contractor report that presented a human health and ecological risk assessment of glyphosate (USFS, 2011). A 2003 contractor report addressed the same topic (USFS, 2003).
- The Agricultural Health Study is an ongoing prospective epidemiological study that is examining adverse health effects among pesticide applicators and their spouses. The National Cancer Institute and the National Institute of Environmental Health Studies fund this study, which has included collaboration from EPA and the National Institute for Occupational Safety and Health. Westat, a government contractor, has been coordinating the study. Although the study is not specific to glyphosate, the investigators have published journal articles on relationships between cancer incidence and glyphosate use (Androtti et al., 2018; De Roos et al., 2005).
- California's Office of Environmental Health Hazard Assessment (OEHHA) sets "No Significant Risk Levels" (NSRLs) for toxic substances regulated under the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (i.e., Proposition 65). In July 2017, OEHHA issued an Initial Statement of Reasons for glyphosate that proposed an NSRL for glyphosate based on cancer outcomes observed in laboratory animals. (A previous OEHHA analysis derived an acceptable daily dose based on non-cancer effects.) The state has also proposed changes to the wording of warnings on glyphosate-containing products used in California. A final rulemaking on the updated warnings has not been issued, and the public comment period for that initiative ended earlier this month (CalEPA, 2022). The Phase Two report will synthesize OEHHA's most current carcinogenicity assessment expected to be available in early 2023.

Assessments Issued by International Bodies (e.g., European Union and World Health Organization)

- The International Agency for Research on Cancer (IARC) is the agency within the World Health Organization that, among other functions, issues monographs to classify toxic substances by human carcinogenic potential. In 2015, IARC completed an assessment evaluating carcinogenicity for five pesticides and herbicides, including glyphosate. IARC's monograph concludes that glyphosate is "probably carcinogenic to humans." IARC's work was completed in 2015, and the version of the monograph posted to IARC's website is dated 2017 (IARC, 2017).
- Other European Union agencies have completed assessments of glyphosate toxicity. In 2015, for example, the European Food Safety Authority (EFSA) completed an assessment that, among other findings, concluded that glyphosate is "unlikely to pose a carcinogenic hazard to humans" (EFSA, 2015). ERG will also consider classification decisions issued by the European Chemicals Agency. The European Union has approved the use of glyphosate, but that approval expires in December 2022. Another glyphosate assessment is currently being conducted by the Assessment Group on Glyphosate (AGG). In 2021, the AGG submitted both a draft Renewal Assessment Report (more than 10,000 pages) and an update to EFSA (AGG, 2021). The final Renewal Assessment Report, which will include final conclusions on human health impacts, is expected to be released in late 2022 or 2023.
- In May 2016, the Food and Agriculture Organization of the United Nations and the Core Assessment Group on Pesticide Residues of the World Health Organization (WHO) convened a panel to evaluate human health risks of consuming food products that contain pesticide residues; and a summary report was issued later in the year. This evaluation considered health risks for three pesticides, including

glyphosate. The panel found that long-term exposures to glyphosate residues in food are "unlikely to present a human health concern" and that short-term exposures are "unlikely to present a risk to consumers" (FAO/WHO, 2016).

Assessments Issued by Selected Foreign Governments (Outside the European Union)

- In Canada, the Pest Management Regulatory Agency (PMRA) of Health Canada authorizes uses of pesticides. In 2017, PMRA re-authorized use of glyphosate and published an assessment that considered cancer risk and potential health impacts associated with dietary exposures, occupational exposures, and household uses. An advocacy group sued the agency regarding the re-authorization decision; and in February 2022, a Federal Court of Appeal in Canada issued a ruling that directed the PMRA to reconsider certain procedural aspects of the re-authorization. The court decision did not change the glyphosate authorization, however. In Phase Two, ERG will investigate whether PMRA has issued new assessment documents on glyphosate human health impacts, given the implications of the recent court decision.
- In 2016, the Food Safety Commission of Japan completed a human health risk assessment of different commercial grades of glyphosate. The complete assessment report is only available in Japanese, but ERG will review the summary of conclusions, which is written in English (FSCJ, 2016). The human health risk assessment considered a range of cancer and non-cancer outcomes and derived an acceptable daily intake for glyphosate.
- The Australian Pesticide and Veterinary Medicines Authority (APVMA) has multiple mandates, including regulation of the use of pesticides in Australia. In 2016, APVMA issued a regulatory position paper that found no "scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration," based both on human health and ecological considerations (APVMA, 2016).

3.1.2 Peer-reviewed Publications

The major assessments reviewed in the previous section were completed in different years, and they considered peer-reviewed literature issued up through different cutoff dates (e.g., the ATSDR 2020 Toxicological Profile is based on a literature search completed in September 2017). These assessments therefore do not consider findings from research published after the corresponding literature search cutoff dates. This is an important disconnect because scientists worldwide continue to study human health impacts associated with glyphosate exposure, and highly relevant publications have become available in recent years on glyphosate genotoxicity (e.g., Benbrook et al., 2019), cancer (e.g., Leon et al., 2019; Zhang et al., 2019; Boffetta et al., 2021), reproductive effects (e.g., Mohammadi et al., 2021), and various other health outcomes.

To ensure this project's scientific review is complete and current, the ERG Team will perform a literature search to identify recent peer-reviewed publications on glyphosate's human health impacts. ERG will prepare a literature search methodology memorandum for review by the Glyphosate Commission before executing the search. We anticipate conducting this task using the PubMed search engine and focusing on the most recent 5 years of publications (2018-2022). Key words for the search will include terms related to the herbicide (e.g., glyphosate, Roundup), the various health outcomes under consideration (e.g., cancer, genotoxicity, reproductive toxicity, developmental toxicity, endocrine disruption), and others (e.g., epidemiology). ERG will select the key words in an iterative fashion, using approaches ERG has previously applied in literature review projects and considering key words that EPA used in a recent glyphosate literature search (EPA, 2018d).

Upon executing the search, ERG will compile potentially relevant publications in a reference management system (either EndNote or RefWorks), remove duplicate entries, and remove entries for publications not written in English. The next step will be reviewing the references' titles and abstracts for relevance, after which ERG will have a final list of the recent literature of relevance to glyphosate human health impacts. ERG will then obtain the publications that passed the initial title and abstract screening and again review publications for relevance. ERG then intends to review every publication that passed the different tiers of screening. However, should this search identify an unexpectedly substantial number of potentially relevant publications, ERG will discuss with the Glyphosate Commission options for synthesizing the literature within the bounds of the project budget (e.g., focusing on review articles and meta-analyses, focusing on health endpoints of greatest interest). 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.

3.1.3 Precedential Judicial Decisions

To identify precedential judicial decisions, an attorney with ERG executed a search of a case law database using the Casetext Research software platform. The Casetext database includes cases for which a judicial order has been issued. This includes federal and state case law, with all 50 states considered. A judicial order could mean that a court or judicial officer issued a decision or that an order was issued after two parties reached agreement. Not all filed claims result in judicial orders. Selected details of the initial Casetext searches follow:

- Searching on "glyphosate" without a date range yielded 255 cases filed in state and federal courts, but no case law from Massachusetts state court. Of the cases identified, 108 were filed in the last 5 years. EPA was a party in five of the cases.
- Over the last 5 years, 49 glyphosate tort law cases were identified, most of which focused on cancer outcomes (particularly lymphoma); and 39 glyphosate regulatory law cases were identified. The two most litigated issues in the tort law cases include the causes of action on product liability and negligence. Upon initial review, the product liability cases are rooted in what information should be included in product labels and whether plaintiffs were properly warned about carcinogens, ecological concerns, and other issues. The negligence claims are centered around plaintiffs' ability to show that the products containing glyphosate are the actual cause of their health effects.
- 19 cases were identified that addressed ecological issues but did not address lymphoma. These cases related to product liability, the Endangered Species Act, and the Plant Protection Act.
- Ongoing legal proceedings pertain to EPA's January 2020 interim registration review decision to continue to register various forms of glyphosate as a pesticide. Multiple parties, including the Natural Resources Defense Council, the Rural Coalition, the National Family Farm Coalition, the Center for Biological Diversity, and the Pesticide Action Network, sued EPA over its interim decision. In May 2021, EPA submitted a filing to the U.S. Court of Appeals that sought permission to revise previously issued glyphosate assessment documents—but did not propose changing the glyphosate registration status. ERG is also aware of ongoing developments this year, which recently resulted in EPA withdrawing its Glyphosate Interim Registration Review Decision.

During its meeting on September 15, 2022, the Glyphosate Commission confirmed that ERG's review of judicial cases should focus on identifying publicly available and peer-reviewed scientific information on glyphosate's human health and environmental impacts that was not identified through ERG's other research for this project. ERG is not tasked with reviewing the status of every ongoing legal proceeding pertaining to glyphosate.

3.2 Assessments of Glyphosate's Environmental Impacts

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

The ERG Team will consider a range of environmental impacts when reviewing publications listed in this section. These impacts include direct toxicity effects on non-target aquatic and terrestrial species due to contact with glyphosate, especially for species that may be rare or endangered in Massachusetts; sublethal effects on aquatic and terrestrial biota such as behavioral effects that may have ecological significance on particular species populations; indirect effects on pollinators (e.g., honeybees, monarch butterflies) due to potential habitat impacts; biodiversity loss; and indirect effects on other aquatic and terrestrial biota due to potential impacts on their habitats. The ERG Team will consider the various glyphosate-related environmental impacts that have been studied as well as the uncertainties associated with the assessments.

As with the key assessments of human health impacts, the key assessments presented below were 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.

The public comments on the draft Phase One report included several observations and clarifications regarding the information that the ERG Team will review on glyphosate's environmental impacts. The project team will consider this input in Phase Two. The following text was revised only to address inaccuracies in the draft Phase One report that were identified in the public comments.

3.2.1 Recent and Ongoing Assessments Published by Recognized Authorities

The ERG team proposes reviewing and summarizing the following assessments conducted by recognized authorities in Phase Two of the contract. The list is organized into three categories of authors.

Assessments Issued by Federal and State Authorities in the United States

- As noted previously, EPA originally registered glyphosate as a pesticide and has since reassessed the use as part of the statutorily mandated 15-year review cycle. The ERG team will review documents that EPA and its contractors prepared (or reviewed) on glyphosate environmental risks, and most of these documents are posted to the EPA Glyphosate Registration Review docket. The documents authored by EPA and its contractors include but are not limited to the "Final National Level Listed Species Biological Evaluation for Glyphosate" (EPA, 2021); the "Interim Registration Review Decision: Case Number 0178" (EPA, 2020a); and the 2015 "Preliminary Ecological Risk Assessment in Support of the Registration Review of Glyphosate and Its Salts" (EPA, 2015b). The ERG team will also review materials posted to the "Browse Documents" section of EPA's docket, but as noted previously, a review of every docket entry is beyond the scope of this project.
- The ERG Team will review multiple publications issued by the USFS, including the 2003 and 2011 human health and ecological risk assessment cited in Section 3.1 (USGS, 2003; 2011), articles in the peer-reviewed literature authored or co-authored by USFS and USDA scientists (e.g., Busse et al., 2001; Linz et al., 1999), and selected earlier profiles of glyphosate environmental impacts (e.g., USFS, 1997).
- The ERG Team will consult with MDAR for publicly available assessments that Massachusetts agencies have issued on glyphosate's environmental impacts, beyond the updated summary fact sheet that MDAR has already issued (MDAR, 2022).

Assessments Issued by International Bodies and Agencies of Selected Foreign Countries

- In the European Union, glyphosate is currently being reevaluated for ecological effects and risk and this reevaluation is expected to be completed in late 2022 or 2023. EFSA and the European Chemical Agency are jointly reassessing glyphosate exposure and effects, and these parties have issued various public statements about their ongoing assessment efforts. Thus far, a working group has prepared a draft Renewal Assessment Report (dRAR), and that draft is currently being reviewed and will eventually be made public along with any modifications to the assessment. The ERG Team will review all available information on the ongoing EFSA work, including: the Authority's summary of the dRAR (AGG, 2021); the Authority's evaluation of glyphosate residues in animal feed and potential impacts to animal health (EFSA, 2018); and the Authority's evaluation of glyphosate's endocrine disruption potential (EFSA, 2017). The ERG Team will review the final Renewal Assessment Report, if it is issued within this project's period of performance.
- Recognizing that EFSA (and its AGG) has published more extensively on glyphosate's environmental impacts than other foreign government agencies, the ERG Team's review of assessments issued by international bodies will be limited to the EFSA publications. As the only exception, the ERG Team will also consider findings from the Australian regulatory position paper on glyphosate, as that specifically addressed ecological impacts (APVMA, 2016).

Assessments Issued by Selected Non-Governmental Organizations (NGOs)

- In 2020, the Forest Stewardship Council (FSC), an NGO that advocates for forest management, issued environmental and social risk assessment guidance. The guidance includes appendixes that present information on six specific pesticides. The ERG Team will consider the contents of Appendix 1, which addresses glyphosate (FSC, 2020).
- In 2017, two organizations in Europe—Générations Futures and the Pesticide Action Network—issued a joint publication that, among other things, critiqued the literature search conducted by authors of a previous EFSA Renewal Assessment Report (GF and PAN, 2017). The report argued that the literature search should have been more inclusive of publications that reported various glyphosate-related impacts.
- In 2019, the Natural Resources Defense Council (NRDC) published a report raising concern about 10 species in the United States that are imperiled by pesticide use, and some of the concern centered on reported glyphosate impacts (NRDC, 2019).
- Massachusetts-based NGOs have developed websites that raise additional environmental impact concerns about glyphosate, such as the potential to contribute to development of glyphosate-resistant strains of weeds ("super weeds") that may then be difficult to control (NOFA/Mass, 2018). This NGO publication will be reviewed in Phase Two, along with others that are identified during the Glyphosate Commission's review of this Phase One report.

3.2.2 Peer-reviewed Publications

In recent decades, hundreds of peer-reviewed journal articles have reported on glyphosate contamination in the environment, exposures to this contamination, and specific biological effects. Conducting a systematic review of the entire history of glyphosate-related journal articles is outside the scope of this work. However, as part of its ongoing support for EPA's glyphosate review, ERG's subcontractor (Tetra Tech) has conducted extensive literature reviews of the evidence of glyphosate's environmental impacts.

Through that effort, ERG's subcontractor is familiar with the literature that addresses glyphosate's environmental impacts broadly (e.g., Ghandi et al., 2021; Gill et al., 2018; Maggi et al., 2020; Meftaul et al., 2020) as well as literature on glyphosate's impacts to specific receptors and species, including water fleas (Marek et al., 2013), rice fish (Smith et al., 2019), earthworms (Stellin et al., 2018), and phytoplankton (Wang et al., 2016). The citations presented in the previous sentence are only intended to show examples of relevant peer-reviewed literature and not to suggest that this is the universe of relevant publications. The Phase Two work will be based on our understanding of the overall body of literature, which was considered in the development of EPA's recent "Final National Level Listed Species Biological Evaluation for Glyphosate" (EPA, 2021). This review will consider the various types of environmental impacts listed at the beginning of this section, as well as strengths, limitations, and uncertainties associated with characterizing the impacts.

To ensure the Phase Two research is complete and current, Tetra Tech will assess the need for conducting a supplemental literature search. Whether this is necessary will depend on multiple factors, most notably on whether EFSA issues its final Renewal Assessment Report during Phase Two—and what date range of scientific publications were considered. The ERG Team will inform the Glyphosate Commission if a supplemental literature search will be conducted in Phase Two on glyphosate environmental impacts. If one is to be performed, the ERG Team will share with the Glyphosate Commission the search parameters (e.g., the search engine, the time frame of publications, and the search keywords).

3.2.3 Precedential Judicial Decisions

Certain aspects of the EPA pesticide registration process have faced legal challenges. While some litigation is still pending, the ERG Team is aware of developments throughout 2022, which recently resulted in EPA withdrawing its Glyphosate Interim Registration Review Decision (EPA, 2022).

Additional precedential judicial decisions relevant to environmental impacts might be identified as ERG completes its review of case law at the beginning of Phase Two. However, as noted previously, ERG will focus on the extent to

which judicial decisions raise or cite publicly available and peer-reviewed scientific information. ERG is not tasked with documenting the outcome of all relevant judicial proceedings.

3.3 Assessments of Glyphosate Alternatives

For selected glyphosate 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 Section 2.3, and provide more detailed information on selected EPA-registered chemical herbicide alternatives. The Phase Two report will consider assessments published for "minimum risk pesticides" that may serve as glyphosate alternatives; however, these alternatives might have limited published information on health and environmental impacts due to their "minimum risk" designation from EPA.

For the chemical herbicide 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 (https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1). 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 conducted by the USFS. These will be identified via searching the USFS Pesticide-Use Risk Assessments and Worksheets website (https://www.fs.fed.us/foresthealth/protecting-forest/integrated-pest-management/pesticide-management/pesticide-risk-assessments.shtml).

Project resources do not allow for more comprehensive searches of assessments for every alternative.

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, but 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 glyphosate's human health and environmental impacts, beyond those identified in Sections 3.1 and 3.2.
- To seek input on relevant research in progress and pending assessments.
- To seek information on glyphosate uses in Massachusetts, the amounts of different glyphosate-containing formulations used, and experiences with using glyphosate alternatives.
- To understand glyphosate-related issues of greatest interest.

Based on these information needs, the ERG Team identified four categories of stakeholder groups to contact. Those categories are listed below, along with the stakeholders within each category whom ERG proposes contacting. ERG presented an initial list of proposed stakeholder contacts (and the rationale for selecting them) during the Glyphosate Commission meeting held on May 23, 2022. During ERG's presentation, Commission members and meeting participants recommended additional stakeholders to consider contacting. The ERG Team included those recommendations in an updated list that appeared in the draft Phase One report issued on June 6, 2022. Public comments on the draft Phase One report subsequently identified several additional stakeholders to consider. The following list includes the complete list of stakeholders identified to date.

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. As needed, the ERG Team will contact stakeholders to discuss input provided during Phase Two.

The following list includes initial points of contact for each stakeholder. The list is organized into four categories; within each category, the stakeholders are listed in alphabetical order, by the last names of the points of contact. The individuals listed below may refer ERG to other members or designees of their respective organizations. As noted above, these stakeholders will be invited to provide input on Phase Two and to comment on the draft report. ERG will directly contact stakeholders on a case-by-case basis, and the Phase Two report will list all stakeholders contacted. (Note: At a minimum, ERG will contact the scientific leads of selected glyphosate assessments listed below and the members of the Massachusetts Pesticide Board Subcommittee.)

Scientific Leads of Selected Glyphosate Assessments

- Dr. Aaron Blair, NCI, Chair for the 2017 IARC monograph
- Dr. Laura Beane Freeman, NCI, Principal Investigator for the Agricultural Health Study
- Dr. James Hetrick, EPA, Senior Advisor for the 2015 preliminary ecological risk assessment
- Dr. Hana Pohl, ATSDR, Lead for the 2020 Toxicological Profile for Glyphosate

Massachusetts Pesticide Board Subcommittee Members

- Michael Moore, chairperson, Massachusetts Department of Public Health
- Richard Berman, public member of the Pesticide Board Subcommittee
- Margret Cooke, Acting Commissioner, Massachusetts Department of Public Health
- John Lebeaux, Commissioner, MDAR
- Jim Montgomery, Commissioner, Massachusetts Department of Conservation and Recreation

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

- Jackie Applegate, President of North America Crop Science, Bayer
- Diane Butt, Board of Directors, Massachusetts Christmas Tree Association
- Leigh-Anne Cole, Acting Executive Director, Community Action Works
- Marcia Cooper, President, Green Newton
- Janet Domenitz, Executive Director, MASSPIRG
- Dr. David Eastmond, Professor Emeritus, University of California, Riverside
- Daniel Faber, Coordinator, New England Environmental Justice Research Network
- Jocelyn Forbush, Acting President and Chief Executive Office, The Trustees of Reservations
- Cathleen Haggerty, Executive Director, Massachusetts Chapter of the American Academy of Pediatrics
- Robb Johnson, Executive Director, Massachusetts Land Trust Coalition
- Karen Kerr, President, Massachusetts Association of Landscape Professionals
- Dr. Phil Landrigan, Director, Global Public Health Program and Global Pollution Observatory, Boston College
- Jocelyn Langer, Executive Director, Northeast Organic Farming Association, Massachusetts Chapter
- Brita Lundberg, Chair, Massachusetts Medical Society Committee on Environmental and Occupational Health
- Rie Macchiarolo, President, Ecological Landscape Alliance
- Doak Marasco, President, International Society of Arboriculture, New England Chapter
- Natalie Camacho Mendoza, Chair, Farmworker Justice
- Dr. Carmen Messerlian, Director of the Scientific Early Life Environmental Health and Development Program, Harvard School of Public Health
- Peter Mezitt, President, Massachusetts Nursery and Landscape Association
- Kristin O'Brien, Coordinator, Sudbury-Assabet-Concord Cooperative Invasive Species Management Area

- Margaret O'Gorman, President, Wildlife Habitat Council
- David O'Neill, President, Massachusetts Audubon Society
- Deb Pasternak, Chapter Director, Massachusetts Sierra Club
- Carlene Pavlos, Executive Director, Massachusetts Public Health Association
- Joe Szczechowizc, President, Massachusetts Association of Lawn Care Professionals
- Steve Seymour, Executive Director, GreenCAPE
- Warren Shaw, President, Massachusetts Farm Bureau Federation
- Mark Smith, President, Grow Native Massachusetts
- Ed Stockman, Co-Founder, Regeneration Massachusetts
- Dwaign Tyndal, Executive Director, Alternatives for Community and Environment
- Steve Ward, President, Cape Cod Cranberry Growers' Association
- Kate Wilson, President, North American Invasive Species Management Association

Selected Contacts from State Government Agencies and Universities in Massachusetts

- George Batchelor, Supervisor of Landscape Design, Massachusetts Department of Transportation
- Brian Hawthorne, Habitat Program Manager, MassWildlife
- Dr. Randall Prostak, Extension Weed Specialist, University of Massachusetts Extension
- Nancy Putnam, Director of Ecology, Massachusetts Department of Conservation and Recreation
- Eve Schlüter, Assistant Director, Massachusetts Natural Heritage and Endangered Species Program, and member of the Glyphosate Commission

The ERG Team will consider project resources before contacting stakeholders through individual consultations, because the current budget does not allow for contacting every stakeholder on this list. ERG will invite all identified stakeholders to provide technical input at the beginning of Phase Two, and they will be invited to review the draft Phase Two report. In addition, ERG may request clarification regarding materials the stakeholders submitted during the Phase 1 comment period and during Phase Two.

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6.0 Abbreviations Used in the Report

AGG Assessment Group on Glyphosate

APVMA Australian Pesticide and Veterinary Medicines Authority

ATSDR Agency for Toxic Substances and Disease Registry

dRAR draft Renewal Assessment Report

ECHA European Chemicals Agency

EFSA European Food Safety Authority

EPA U.S. Environmental Protection Agency

ERG Eastern Research Group, Inc.

FSC Forest Stewardship Council

IARC International Agency for Research on Cancer

MDAR Massachusetts Department of Agricultural Resources

NGO non-governmental organization

NRDC Natural Resources Defense Council

NSRL No Significant Risk Level

NTP National Toxicology Program

OEHHA (California's) Office of Environmental Health Hazard Assessment

PMRA (Canada's) Pest Management Regulatory Agency

RED Reregistration Eligibility Decision

UMass University of Massachusetts

USDA U.S. Department of Agriculture

WHO World Health Organization