

## **A. Cover Page**

### **1. Project Title.**

**Rodenticide Research for Mandatory Data Requirements**

### **2. Project Leader(s).**

Liphatech, Inc.

### **3. Cooperator(s).**

- CDFA
- Bell Laboratories, Inc.
- Liphatech, Inc.
- Neogen Corporation,
- Scimetrics Limited Corporation

### **4. CDFA Funding Request Amount/Other Funding.**

This proposal requests up to \$500,000 from CDFA.

Bell Laboratories, Inc. - up to \$500,000 of in-kind funding

Robert Schromm, J.D.  
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Windsor, WI. 53598  
(608) 906-8140  
[Rschromm@belllabs.com](mailto:Rschromm@belllabs.com)

Liphatech - up to \$500,000 of in-kind funding

Katie Swift  
Senior Manager of Governmental Affairs  
Liphatech, Inc.  
3600 West Elm Street  
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(808) 284-8322 cell  
[swiftk@liphatech.com](mailto:swiftk@liphatech.com)

Neogen Corporation. - up to \$500,000 of in-kind funding

Greg Hastings

Vice President & General Manager  
Animal Health  
944 Nandino Blvd  
Lexington KY 40511  
P: 859.246.6072 | C: 859.221.2246  
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Scimetrics Limited Corporation. - up to \$500,000 of in-kind funding

Richard Poché  
President & CEO  
Scimetrics Limited Corp.  
PO Box 1045  
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## **5. Agreement Managers.**

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Liphatech:

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Three Points Ecotox Consulting :

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## **B. Executive Summary**

### **1. Problem.**

U.S. Environmental Protection Agency (EPA) stated in the 2022 Proposed Interim Decision (PID) for the anticoagulant rodenticides:

*'Tolerances are not established for the anticoagulant rodenticides. Rodenticides have long been evaluated as non-food use pesticides, as previous risk assessments were based upon an understanding that registered uses were limited to those that would not result in potential uptake in food or feed crops. However, the Agency has identified registrations of chlorophacinone and diphacinone that allow application of loose meal bait formulations above ground via spot/scatter and broadcast treatments, as well as belowground treatments in burrows to agricultural cropped areas (e.g., orchards, groves, vineyards, alfalfa), and to rangeland, pastureland, and fallow land that could potentially result in plant uptake and therefore residues on food and feed crops.*

*EPA does not have sufficient residue data to support the establishment of tolerances for chlorophacinone and diphacinone, or to demonstrate there is no plant uptake in order to make a non-food use determination.'*

Therefore, EPA proposed in the 2022 PID that for aboveground applications other than in bait stations, and for belowground applications:

*'1) applications cannot be made directly to food or feed crops; 2) the application can only be made during the non-growth ("dormant") period of the target crop; and 3) application is made along fence lines, border areas, and buffer strips adjacent to target crops.*

*For applications made to non-bearing crops, EPA is proposing to add a restriction for harvesting food/feed from that crop within one year of application.*

*For below-ground or in-burrow use, EPA is proposing that: 1) applications must be made below ground into the main run of the burrow; and 2) the application can only be made during the non-growth ("dormant") period of the target crop.*

*For above ground applications to rangeland and pastureland, EPA is proposing to prohibit spot/scatter and broadcast applications. Above ground applications to rangeland, pastureland, and fallow land may only be made using a tamper-resistant bait station.*

*Chlorophacinone and diphacinone products that are applied belowground will still be permitted to be applied in rangeland, pastureland, and fallow land, since belowground use is less likely to result in potential residues in animal feed items.'*

This means that all currently labelled uses for all target species (rats, mice, voles, pocket gophers, ground squirrels) in crops, pasture, rangeland, and fallow land for aboveground applications via spot/scatter and broadcast treatments, and all belowground applications during the growing season, will be cancelled when EPA issues their Interim Decision. Although the deadline is currently October 1, 2026, this is likely to be extended substantially.

The only uses that will remain on labels will be:

- i. Bait stations in all use sites.
- ii. Broadcast and hand applications only during the non-growth ("dormant") period of the target crop, and only along fence lines, border areas, and buffer strips adjacent to target crops. No in-field applications allowed.
- iii. Belowground applications in pasture, rangeland, and fallow land; in crop applications allowed only during the dormant period.

## **2. Objectives, Approach, and Evaluation.**

In 2023 a number of grower groups supported project requests for a wide variety of crops; however, EPA has ultimate authority to deny IR-4 project requests. In August of 2023, EPA notified the IR-4 administrators at North Carolina State University that the requests for chlorophacinone and diphacinone failed to meet the requirements for the following two criteria:

- the active ingredient, for which the data are developed, must have been already registered for use on a food commodity; and
- the active ingredient/crop combination has been pre-screened by EPA prior to the Food Use Workshop, and EPA has discussed any risk concerns that might hinder registration or the establishment of tolerances with IR-4.

EPA noted significant concerns that even low residues could pose risks to humans due to the toxicity of the compounds.

With substantial ongoing assistance from USDA's Office of Pest Management Policy (OPMP), the registrants have negotiated a compromise with EPA.

In numerous subsequent discussions from 2023 to the present, EPA has maintained that registrants must submit data from studies 'showing no uptake of residues from treated areas into the aerial portion of the growing crop (both human and livestock consumption). The residue needs to be less than the limit of quantitation (LOQ) or minimum quantifiable limit (MQL) for all raw agricultural commodities (RACs) of concern for the crop as delineated in Table 1 of OCSP guideline 860.1000. Furthermore, the LOQ/MQL needs to be 5 ppb (0.005 ppm) or lower to establish no uptake of residues and thus have the use be considered nonfood. If residues occur in the food/feed portion of the plant, or if there are no data available to make this determination, the uses are considered to be food uses requiring tolerances.'

The registrants have retained a consultant with expertise in EPA's plant uptake data requirements, and registrants are proposing to EPA to provide a Weight of the Evidence document summarizing the chemical properties relevant to evaluating the risk of uptake, followed by confirmatory greenhouse studies. EPA and the registrants have agreed to this process, which has substantial costs for the registrants.

Registrants are joining together in a formal cost-sharing agreement which will give them the rights to own and cite the data submitted to EPA in support of their registrations. Registrants of associated registrations for Special Local Needs labels will need to participate in sharing the costs in order to use the data to support these labels.

### **3. Audience.**

CDFA maintains Special Local Needs (24(c)) labels for chlorophacinone and diphacinone. EPA has indicated additional data are needed to support certain uses and maintain non-food/non-crop classifications in areas adjacent to agriculture. Private registrants are pursuing a coordinated study effort led by Liphatech, with a shared funding structure and project management components.

### **C. Justification**

The four Special Local Needs (FIFRA Section 24c) labels for chlorophacinone and diphacinone that are registered to the California Department of Food and Agriculture are also subject to the proposed prohibitions; or CDFA must submit plant uptake data in order to maintain the nonfood use status for the application methods described in Section I. EPA has evaluated all of the residue studies that CDFA conducted, which all date from the late 1990s (on potatoes, alfalfa, and rangeland grasses), and concluded that they contained deficiencies and did not support the EPA's previous determination that they were nonfood uses.

#### **D. Objectives**

##### Development and Submission of the New Study and Associated Supporting Rationale

The Parties will develop the Data and associated supporting rationale (including a weight-of-evidence (WoE) document), and Liphatech will engage and supervise qualified contractors to conduct all of the study work and associated supporting rationale and communicate with the EPA.

The Parties shall exercise reasonable efforts to assure that the Data are performed in accordance with applicable protocols and consistent with any applicable EPA requirements and guidelines.

Liphatech will coordinate communications with EPA with respect to the Data. Liphatech shall organize all meetings with EPA related to the Data and accommodate any Parties who would like to attend in person or by Data and Liphatech shall discuss in advance and copy all Parties on all significant correspondence to or from the EPA relating to the Data. The Parties will use reasonable efforts to provide any information required for generating the Data as may be requested by EPA or Liphatech.

Bell, CDFA, Liphatech, Neogen, and Scimetrics shall meet at mutually agreeable times and locations, to discuss and review draft protocols, the associated supporting rationale document, study progress, and, prior to finalization and submission of the Data to EPA, the study report, along with the proposed results and conclusions of the Data.

Liphatech shall provide Bell, CDFA, Neogen, and Scimetrics with a draft of any and all proposed formal correspondence and proposed submissions to EPA regarding the Data and associated supporting rationale, and shall provide Bell, CDFA, Neogen, and Scimetrics a reasonable opportunity to provide input before any such materials are provided to EPA.

Liphatech shall provide Bell, CDFA, Neogen, and Scimetrics with a proposed final study report for the Data, and the associated supporting rationale, and Bell, CDFA, Neogen, and Scimetrics shall have at least ten(10) business days to review and comment before Liphatech submits the associated supporting rationale and the final study report to EPA.

Liphatech will, with reasonable consideration of any comments received from the Parties, determine the final form and content of the associated supporting rationale and the study report submitted to EPA.

Liphatech shall transmit the Data to EPA in support of chlorophacinone and diphacinone registrations held by Liphatech, Bell, CDFA, Neogen, and Scimetrics. On or after the date the Data are submitted to EPA, Bell, CDFA, Liphatech, Neogen, and Scimetrics are free to submit the Data to any pesticide regulatory authority in any or all States.

**E. Work Plans and Methods (for multi-year projects, include a work plan for each year)**

1. Work Plan.

- Compile existing data and use it to support a Weight of Evidence rationale for why the compounds would not be expected to be taken up by plant root cells; communicate with EPA the details of the confirmatory plant greenhouse studies
- Conduct the plant greenhouse studies
- Assist with administration of the overall project and the oversight of the studies
- Manage the project and final submission of the deliverables to EPA for addition to each registrants’ products’ data matrices.

**ESTIMATED TESTING SCHEDULE**

<b>Milestone Activity:</b>	<b>Completion No Later Than</b>
<b>Proposal Authorization</b>	<b>March 6, 2026</b>
Master Service Agreement (MSA) / Terms & Conditions (T&C) Signed	Complete
Test Substance Onsite	March 13, 2026*

\*Pertains to additional chlorophacinone technical and diphacinone technical as well as white winter wheat grains for preparation of test substance and dose confirmation verification, as diphacinone and chlorophacinone analytical standards have already been received.

<b>Item/Test</b>	<b>Signed Protocol Receipt</b>	<b>Start Date</b>	<b>In-Life Termination</b>	<b>Draft Report Date</b>	<b>Final Report Date</b>
Non-GLP Analytical Method Development	NA	March 2026	April 2026	NA	NA
Analytical Method Validation, Crops	April 2026	May 2026	June 2026	August 2026	September 2026

Test Substance Preparation and Dose Confirmation	NA	May 2026	May 2026	NA	NA
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## F. Project Management, Evaluation, and Outreach

### 1. Management.

1. Exponent: will compile existing data and use it to support a Weight of Evidence rationale for why the compounds would not be expected to be taken up by plant root cells; Exponent will assist us with negotiations with EPA on the details of the confirmatory plant greenhouse studies;
2. Smithers: will conduct the plant greenhouse studies
3. Three Points Ecotox Consulting: will assist with administration of the overall project and the oversight of the Smithers studies
4. Liphatech: managing entity for the entire project; responsible for final submission of the deliverables to EPA for addition to each registrants' products' data matrices.
5. CDFA: Share prior research, participate in review process.

### 2. Evaluation.

Project Leader will give regular status updates at Vertebrate Pest Control Research Advisory Committee meetings. Oversight and coordination of the proposed EPA research needs will be provided directly by the IPC Senior Environmental Scientist who is also the CDFA representative on the VPCRAC Committee. CDFA will join the cost share with the other registrants to maintain the rodenticide labels and their existing uses. The Environmental Program Manager I will track the progress of the creation of the Weight of the Evidence document and confirmatory greenhouse studies.

## G. Budget Narrative

### 1. Narrative.

Liphatech shall be responsible for managing the costs to conduct the Data. The Costs shall consist of the actual costs incurred for: (a) the associated supporting rationale and

the design and conduct of the Data; (b) required quality control and quality assurance, to be performed by Three Points Ecotox Consulting, LLC and Liphatech, including to ensure the study results are consistent with the stated objectives of the study; (c) preparing and submitting the final study report, and other regulatory work necessary to developing and submitting the Data; and (d) invoiced legal and administrative services relating solely to the Data; and (e) the Management Fee defined in Paragraph 12 below (collectively, the “Costs”), including those previously incurred by the Anticoagulant Rodenticide Task Force.

- A “Management Fee” will serve as partial compensation for all internal time spent by Liphatech to manage the conduct of the Data (separate from the quality control and assurance work which will be invoiced on an hourly basis) and to prepare them for submission to EPA, and to coordinate communications and organize meetings with EPA. The fee is calculated as 20% of the Costs incurred pursuant to (a) through (d) above on behalf of the Parties.
- Liphatech shall coordinate invoicing for Bell, CDFA, Liphatech, Neogen, and Scimetrics as often as needed to pay invoices from the contractors and the Management Fee, with an accompanying statement of the Costs expended. A statement of costs to date will be provided to each company at least once every three (3) months.
- Bell, CDFA, Liphatech, Neogen, and Scimetrics shall each be responsible for an equal one-fifth (1/5) share of the Costs of conducting the Data.
- The documentation of Costs shall be supported by invoices for work performed by each contractor. In the event that cost documentation is not available for any portion of the final Costs of the Data, a reasonable written estimate with a detailed explanation may be used.
- Liphatech will ensure a final invoice is issued to Bell, CDFA, Liphatech, Neogen, and Scimetrics within sixty (60) days after notification of acceptance of the Data by EPA stating each Party’s share of the total Costs as defined above. Notwithstanding the foregoing, Liphatech may issue additional invoices to Bell, CDFA, Liphatech, Neogen, and Scimetrics after this date if Liphatech has not yet received, as of the preceding date, all invoices or complete invoices for Costs incurred prior to notification of acceptance of the Data.
- Any other registrant of a chlorophacinone or diphacinone product subject to the EPA Plant Uptake Data requirement may join with the existing Parties in this Agreement prior to the submission of the final study report to EPA, subject to written approval from each Party; with the following conditions:
  - a. Payment of an equal share of all costs incurred by the Parties up to the date of joining;

b. Payment on such costs of a rate of interest that shall be equal to two percent (2%) above the average daily prime rate published in the Wall Street Journal (or, if such rate is higher than permitted by applicable law, such lower rate as may be permitted by applicable law) for the period between the first due date of the payment(s) by the existing Parties and the date such payment is actually made by the late-joining Party.

2. Other Funding Sources:

See Section A. 4 of this proposal. Funding will be distributed per the budget narrative.

## 2026 VPCRAC Project Proposal Budget Template

Complete the budget template below by filling in information. This template uses formulas to automatically calculate totals. **Do not** alter the formatting or formulas in cells. Rows may be added to accommodate additional personnel or funding sources, if necessary. Contact the CDFA staff at (916) 764-7759 or IPCinfo@cdfa.ca.gov for help filling out this template.

**Project Title:** Rodenticide Research for Mandatory Data Requirements  
**Project Leader(s):** Liphatech, Inc.

	2025-2026	2026-2027	2027-2028	Total
<b>A. PERSONNEL (name, role, % based on full time salary)</b>				
<b>Salary</b>				
<input style="width: 100%;" type="text"/>				\$0.00
<input style="width: 100%;" type="text"/>				\$0.00
<input style="width: 100%;" type="text"/>				\$0.00
<input style="width: 100%;" type="text"/>				\$0.00
<i>Salary Total</i>	\$0.00	\$0.00	\$0.00	\$0.00
<b>Benefits</b>				
<input style="width: 100%;" type="text"/>				\$0.00
<input style="width: 100%;" type="text"/>				\$0.00
<input style="width: 100%;" type="text"/>				\$0.00
<input style="width: 100%;" type="text"/>				\$0.00
<i>Benefits Total</i>	\$0.00	\$0.00	\$0.00	\$0.00
<b>Personnel Cost (A)</b>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>
<b>B. OPERATING EXPENSES</b>				
Supplies	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
Equipment	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
Travel	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
Professional/Consultant Services(Cannot exceed \$65/hour)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
Other	\$250,000.00	\$250,000.00	<input style="width: 100%;" type="text"/>	\$500,000.00
<b>Operating Cost (B)</b>	<u>\$250,000.00</u>	<u>\$250,000.00</u>	<u>\$0.00</u>	<u>\$500,000.00</u>
<b>TOTAL Costs (A+B)</b>	<u>\$250,000.00</u>	<u>\$250,000.00</u>	<u>\$0.00</u>	<u>\$500,000.00</u>
<b>C. Indirect Costs</b> (Cannot Exceed 10% of Total Costs (A+B))				\$0.00
<b>TOTAL CDFA FUNDING REQUESTED (A+B+C)</b>	<u>\$250,000.00</u>	<u>\$250,000.00</u>	<u>\$0.00</u>	<u>\$500,000.00</u>
<b>D. OTHER FUNDING SOURCES</b>				
*Bell Laboratories, Inc.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
*Liphatech, Inc.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
*Neogen Corporation	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
*Scimetrics Limited Corporation	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
*Each of these parties will provide an equal share of funding	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	\$0.00
<b>TOTAL OTHER FUNDING (C)</b>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>
<b>TOTAL PROJECT BUDGET (A+B+C+D)</b>	<u>\$250,000.00</u>	<u>\$250,000.00</u>	<u>\$0.00</u>	<u>\$500,000.00</u>