NEW YORK STATE OF OPPORTUNITY. | Lake George Park Commission

Bruce E. Young
Chairman

Dave Wick
Executive Director

To:	**Adirondack Park Agency**
From:	**Dave Wick, LGPC Executive Director**
Date:	**June 13, 2024**
Re:	**Response to Public Comments - ProcellaCOR**

Background

The NYS Lake George Park Commission (Commission) is appreciative of the opportunity to respond to the submitted comments regarding APA Projects 2023-0017 and 2023-0018 (ProcellaCOR aquatic herbicide project).

The Commission is the New York State agency charged with the long-term protection of Lake George and its users, including invasive species management and prevention. This agency has managed Eurasian watermilfoil for more than three decades, always seeking to identify and implement the best practices and technology available, working in partnership with the NYS DEC and NYS Adirondack Park Agency.

The Commission has determined that it is in the best interest of Lake George to utilize this new tool in the control of the invasive species Eurasian watermilfoil. This project in front of the Adirondack Park Agency represents a reasonable entry into the utilization of the low-impact, high-efficacy aquatic herbicide known as ProcellaCOR EC. Given the great successes of the Minerva Lake, Lake Luzerne, Glen Lake, Saratoga Lake and many others in the region, this herbicide shows great promise towards the Commission's three-decade battle against this invasive species.

The public comments received by the Agency show both support and opposition, which was expected for such a proposal. It has been the Commission's sincere interest and intent to be as transparent about this project as possible, including several public meetings and presentations to a large array of interested parties over the past three year since we began looking at this new tool. Substantial information is currently hosted on the Commission's website, right on the homepage, where the public can learn about the proposal, the product's regulatory reviews and its many levels of approvals.

It is noted that there are several comments expressing concern from a misunderstanding regarding the behavior, environmental fate and safety profile of ProcellaCOR. The behavior and safety of this product and its active ingredient are well understood, as state and federal approvals have long demonstrated.

The Commission has reviewed both the supportive and opposing comments submitted by members of the public, and has categorized the primary concerns into several categories as noted below:

1. No chemicals in Lake George (in general)
2. Concerns over long-term effects (more testing needed)
3. Drinking water and general water use (swimming/fishing)
4. 'Forever chemicals' or PFAS based on the Minnesota interim report
5. Negative ecological impacts
6. Milfoil is 'not a crisis', why use chemicals when traditional means are working
7. Perceived economic damage/tourism loss
8. Product labeling not being followed (circulation patterns of the lake are complex)

In addition, the Commission will seek to address the comments of the LGA/Waterkeeper, who has been the primary opposed party to this effort and has conducted considerable public outreach asking individuals to oppose this project. Many of the aforementioned points of opposition stem from specific outreach points from this organization.

Responses to the primary topics of concern are noted below:

1. **No chemicals in Lake George (in general):** The Commission understands the general idea that people might be concerned about an aquatic herbicide put into a waterbody like Lake George. It is natural to feel that such an action will have long-term consequences and could potentially harm the lake's ecology or even have potential impacts upon recreation, drinking water or fishing. However, none of these concerns are borne out by the considerable scientific or regulatory record regarding this particular herbicide, ProcellaCOR. The Commission has spent, at this point, thousands of staff hours researching this product, its regulatory approvals, and the scientific record as well as speaking with experienced top-tier lake managers from across the Northeast. To date, the Commission has identified no scientific or regulatory report that identifies or validates concerns regarding the EPA registered and DEC labeled use of this product in any waterbody. This document will highlight several of the key concerns noted by the public and provide responses based on the established public regulatory record.

2. **Concerns over long-term effects (more study needed):** This aquatic herbicide has been subject to dozens of peer-reviewed research studies, an Environmental Impact Statement, US Environmental Protection Agency review and registration, NYS DEC and Department of Health review and registration, review and approval by every state in the contiguous U.S. (49 out of 49) that has conducted their own independent analyses, approval by the Canadian Health Ministry, The European Union and many other countries. All of these

extensive reviews document zero public health impacts from its labeled use, and exceedingly limited impacts upon native plants and organisms. ProcellaCOR has been used in hundreds of waterbodies across the nation including 30 in New York State and 50+ in New Hampshire. There are many published papers available (and on the Commission's website) to outline the selectivity of ProcellaCOR treatments. There are also pre and post treatment plant surveys from many waterbodies that show increased native plant diversity following milfoil treatment with ProcellaCOR. The Commission, as an applicant, must rely on published science and approvals from the expert review authorities at US Environmental Protection Agency, NYS Department of Environmental Conservation, NYS Department of Health, and others for its guidance regarding product environmental fate and public health. Regarding 'additional science', the NYS DEC identifies that there are no 'data gaps' regarding the herbicide's potential impacts and registration in NYS. The record regarding ProcellaCOR's safe and effective use has not been contested by any regulatory entity that the Commission has identified.

3. **Drinking water and general water use (swimming/fishing)**: ProcellaCOR's EPA and DEC product registrations contain no restrictions on drinking water, contact recreation (swimming) or fishing following product application. In addition, the product is taken up by the target plant (Eurasian watermilfoil) and is also broken down by natural processes (photolysis and hydrolysis) in a very short amount of time (generally between 24-72 hours). The dosage of this aquatic herbicide in Lake George is 7.7 parts per billion, which equates to one or two drops in a large swimming pool. In their product assessment and registration, The European Food Safety Authority's "No Observable Adverse Effects Level" (NOAEL) notes that an average 150 lb adult would have to drink 232,690 gallons of ProcellaCOR treated water, per day, over a 90 day period to reach the NOAEL. Not only is it impossible to drink enough ProcellaCOR treated water to observe an adverse effect, but ProcellaCOR would never persist in the water for 90-days considering it has a half-life of about 1.5 days in general aquatic conditions. This finding is one among many regulatory agencies' findings that report similar evaluations.

4. **'Forever chemicals' or PFAS based on the Minnesota interim report**: ProcellaCOR aquatic herbicide is not a 'Forever Chemical' (PFAS). The US Environmental Protection Agency does not classify ProcellaCOR as PFAS based on its chemical structure, and the regulatory science and evaluations validates that it does not have the characteristics of long environmental persistence and toxicity risks common to long-chain PFAS.

   NYS DEC Statement Regarding ProcellaCOR:
   New York State is a national leader in emerging contaminant response and pesticide

regulation, and in particular DEC conducts extensive science-based reviews of aquatic pesticide products prior to approval for use in New York State to ensure these products are fully protective of public health and the environment. The product must first be registered with the U.S. Environmental Protection Agency (EPA) before being submitted to DEC and the New York State Department of Health (DOH) for a stringent review, as mandated by law. DEC experts' review of ProcellaCOR's active ingredient, florpyrauxifen-benzyl, with DOH, and EPA have not identified any concerns regarding the toxicity or persistence of florpyrauxifen-benzyl when used as labeled in the ProcellaCOR EC product. New York State approved its registration in 2019. EPA's review of current federally registered pesticides found "no pesticide active or inert ingredients with structures similar to prominent PFAS such as PFOS, PFOA, and GenX." DEC permitting decisions will continue to be guided by the State's stringent pesticide regulations and approved registrations.

Where does this concern originate from? Under a new Minnesota law, the Minnesota Department of Agriculture (MDA) was required to generate a report and issue a preliminary list of PFAS pesticides active ingredients. Florpyrauxifen-benzyl, the active ingredient in ProcellaCOR, is included on the MDA preliminary list simply because they are using the broadest interpretation of their definition of PFAS (much broader than any other regulatory definition, which classifies any active ingredient containing a fluorine molecule as PFAS, regardless of its environmental persistence or toxicity characteristics. From the MDA report (page 4): "The definition of PFAS in Minnesota Law (Minn. Stat. 18B.01 subd. 15(c)) is the broadest definition in regulatory use. It categorizes more chemicals as PFAS than the definitions used by EPA, the European Chemicals Agency, and the Organization for Economic Co-operation and Development. The MDA identified 95 pesticide active ingredients registered in Minnesota (as of June 2023) that would be considered PFAS under the Minnesota definition. By comparison, approximately six active ingredients registered in Minnesota would be PFAS under the EPA Office of Pollution Prevention and Toxics (OPPT) definition."

While Minnesota's new definition of PFAS classifies 95 pesticide active ingredients as PFAS, most of those pesticides do not have the characteristics of "forever chemicals". MDA acknowledges that it makes no distinction between long-chain PFAS such as PFOA and PFOS that have long persistence in the environment, and pesticide active ingredients that have been through many years of development and rigorous regulatory review by EPA to ensure safety for humans, wildlife, and the environment. As an example described in the MN report, under Minnesota's new definition, Prozac, one of the most widely used medicines on the market will be classified as a PFAS. The report acknowledges the challenges it has created in the state of Minnesota with this new definition.

For many chemicals more broadly in the PFAS class, the potential risks are simply unknown. However, by contrast, a substantial amount of information is available regarding pesticides and their risks to human health and the environment because of rigorous EPA registration requirements (also noted in the report). Further, florpyrauxifen-benzyl (ProcellaCOR EC), has been granted a tolerance exemption on all food commodities from US EPA because of its non-toxic safety profile for use on and around food and feed-use sites, including the use of irrigation water for food crops previously treated with ProcellaCOR aquatic herbicides. Finally, NYS has aggressively regulated certain long-chain PFAS compounds like PFOA and PFOS because we know they persist in the environment and in our bodies and can cause us harm. ProcellaCOR is chemically nothing like those compounds, it's been exhaustively studied, and the research makes clear it doesn't persist in the environment, doesn't bioaccumulate, and poses no risk to non-target organisms, including humans.

5. **Negative ecological impacts**: ProcellaCOR aquatic herbicide is registered by EPA and NYS DEC, and is shown to be highly selective in its aquatic plant impacts. In its review, the EPA found that florpyrauxifen-benzyl has no risk concerns for non-target wildlife, and does not bioaccumulate in fish or freshwater clams. This aquatic herbicide has been subject to dozens of peer-reviewed research studies, plus state and federal agency approvals, all of which document the exceptionally limited impacts upon native plants and organisms.

   There are few non-target plants impacted; these include water shield and native milfoil. Water shield plants have rebound in the same growing season following treatment, and are not present in the subject treatment areas. Native milfoil is common throughout the Lake, and from a whole-lake population perspective, the population will not be significantly impacted by treatments.

   The EPA set the maximum allowable application rate of ProcellaCOR at 48 ppb due to concern for non-target aquatic vascular plants. The proposed application rate for the demonstration sites in Lake George are significantly and safely below this threshold (~7.7ppb).

   ProcellaCOR has been used in hundreds of waterbodies in the Northeast alone, all with documented results showing high selectivity related to the target invasive species. There are many published papers available (and on the Commission's website) to outline the selectivity of ProcellaCOR treatments. There are also pre and post treatment plant surveys from many waterbodies that show increased native plant diversity following milfoil treatment with ProcellaCOR. The Commission relies on published science and approvals from the expert review authorities at EPA, New York DEC, New York DOH, and others for its guidance regarding these issues.

6. **<u>Milfoil is not a crisis in Lake George:</u>** Several commenters repeat the LGA talking point that milfoil is not a crisis in Lake George, and that this invasive species should only be managed through traditional physical means. The Commission has never called milfoil a crisis, and has managed the Eurasian watermilfoil program to the best of its ability for more than 30 years with the best available techniques and technology. It is the job of any lake management organization to understand, evaluate and apply the best management techniques possible to achieve the best and longest-term outcomes on any issue. This is true of Eurasian watermilfoil management as well.

   The Commission spends approximately $300,000 - $350,000 per year on milfoil control activities throughout the lake, supplemented by another $140,000 annually by the Lake George association, totaling upwards of $500,000 per year. This level of effort and expenditure has occurred for most of the past decade, especially in a few intervening years when an additional $200,000 was available from a NYS grant. With these funds, the Commission fully harvested almost all known dense beds of Eurasian milfoil in Lake George, totaling 40 dense and moderately dense sites (among more than 200 known sites throughout the lake).

   As can be evidenced by the Commission's annual reports on its website, even with this high expenditure, on an annual basis, the Commission's contracted dive crews continue to harvest the same sites, year after year, often to similar levels to the prior year. It can be very difficult for the divers to get all of the root mass and all plant matter and fragments during the dive operations. If any of these are left behind, the plant will simply grow back and will require harvest in a subsequent year. Such hand pulling of plants under water has its own challenges with creating turbid (cloudy) water, releasing phosphorus and nitrogen into the water column, that can be concerning to the lake's ecology and local residents.

   ProcellaCOR aquatic herbicide, by contrast, kills every part of the plant with no disturbance to the sediment, and the one-time treatment of 7 parts per billion will eliminate these milfoil beds completely with no impact to human health, ecology or water quality. This management technique also costs considerably less than other traditional means, especially long-term.

   As an example, the Town of Minerva traditionally spent $70,000 each year to harvest Eurasian watermilfoil, just trying to keep ahead of it. In 2020, following a lake manager's advice and the proper permits, they applied ProcellaCOR to the affected area for $27,000, which eliminated all invasive milfoil in the treated area. Over the period of three years, the final cost of treatment, $27k vs $210k, equates to just over 10% of the cost of their harvesting technique. And their results are still holding up four years later. This is a common theme among all ProcellaCOR treatments.

The Commission has a responsibility to utilize the best tools for the project, and as evidenced by hundreds of other treatments in NY and the Northeast, this small project on Lake George will allow the Commission to evaluate its future utility in difficult to manage areas of the lake.

7. **Perceived economic damage/tourism loss:** The Commission is unaware of any study that documents economic or tourism loss from the utilization of ProcellaCOR aquatic herbicide to eliminate invasive Eurasian watermilfoil. In speaking with professional lake managers in NYS and the Northeast, these professionals concur and note that traditionally, the opposite is true. When an invasive species affects a waterbody, particularly nearshore as is the case with aquatic invasive plants, these species tend to reduce property values if the uses of that lake are affected in the nearby area.

8. **Product labeling not being followed/Lake George has complex circulation:** ProcellaCOR is a hydrophobic herbicide that binds tightly to vegetation (only affecting dicots like Eurasian watermilfoil) and it is degraded by exposure to sunlight in a matter of hours. The Commission and its licensed agent SOLitude Lake Management have provided the DEC and APA with the state-approved modeling required for aquatic herbicide treatments. This modeling has been reviewed and accepted by the NYS DEC experts in this area. An Affidavit from the NYS Department of Environmental Conservation from the DEC Regional Pesticides Program Manager notes, in part, as follows: "In my professional opinion, the use of ProcellaCOR EC as proposed in the permit application and as specified in the permits does not conflict with the registered ProcellaCOR EC labeling. The proposed treatment sites are not near the outlet of Lake George as claimed by the petitioners. In fact, the treatment area in Blairs Bay is over four miles from the outlet of Lake George, and the treatment area in Sheep Meadow Bay is over twelve miles from the outlet. The proposed use of ProcellaCOR EC as permitted by DEC would not be in conflict with the registered ProcellaCOR EC labeling."

Response to Comments: Lake George Association/Waterkeeper

(Response to LGA Comments from March 16, 2023 submittal to APA)

Comment #1: Application error regarding wetlands
Response: As determined by the APA, Blairs Bay is categorized as a Class 1 wetland and Sheep Meadow Bay is categorized as a Class 3 wetland.

Comment #2: Wetlands reclassification needed
Response: The Commission is not responsible for wetlands classifications.

Comment #3: Hydrodynamics and dilution model
Response: See response #8, page 7. The Commission has utilized the NYS DEC required modeling, which has been accepted by the NYS DEC.

Comments #4 and #5: Plant surveys should not use rake toss method
Response: This specific methodology is required by APA for aquatic vegetation surveys and was conducted by Robert Bombard, noted plant expert with Warren County Soil and Water Conservation District. The surveys have been accepted by the APA as proper and complete.

Comment #6: Applications are incomplete due to lack of ecological information
Response: The Commission and its agent have provided all required information to the APA regarding these permit applications, and they have been deemed complete.

(Response to LGA Comments from May 30, 2024 submittal to APA)

Comment: #1: No demonstrated need for use of herbicides
Response: See response #6, page 6.

Comment #2: Freshwater wetlands act deviation
Response: The Commission is not the arbiter of APA wetlands jurisdiction.

Comment #3: NYS agencies have overstated the strength of science supporting ProcellaCOR
Response: The Commission (and all applicants) must adhere to NYS regulations, registrations and laws. ProcellaCOR is registered for use in NYS since 2019 following EPA registration in 2018. These product registrations are supported by the outcomes of hundreds of ProcellaCOR treatments in the Northeast, several within 30 miles of Lake George. The Commission has seen no evidence of treatments that don't show outcomes as intended and permitted.

Comment #4: Non-quiescent waters/hydrodynamics
Response: See response #8, page 7.

Comment #5: Hydrodynamics (a second time)
Response: See response #8, page 7.

Comment #6: Hydrodynamics (a third time)
Response: See response #8, page 7.

Comment #7: Hydrodynamics (a fourth time)
Response: See response #8, page 7.

Comment #8: Hydrodynamics (a fifth time) and product labeling
Response: See response #8, page 7.

Comment #9: Product degradation and metabolites

Response: The appropriateness, effectiveness, and safety of this product and its metabolites are supported by product review and registrations from EPA, New York State, and many other state regulatory and international review and approval agencies. In their reviews, the EPA and NYS DEC/DOH independently review all active and inactive ingredients. It is accepted science that the active ingredient will be absorbed by target vegetation or break down in a matter of hours to days by photolysis and hydrolysis.

With respect to the product's metabolites, the science and approvals show that the inert metabolites of the product are, as would commonly be expected, less effective than the product itself. The EPA's Environmental Fate and Ecological Risk Assessment for florpyrauxifen-benzyl looked at toxicity for the three different breakdown compounds to non-target vascular aquatic plants using EWM as one reference plant. Compared to ProcellaCOR (florpyrauxifen-benzyl), EPA concluded: ...the relative toxicity of the transformation products on SAVs:

- florpyrauxifen-acid was 30x less toxic
- benzyl-hydroxy was 1,700x less toxic
- hydroxy-acid was 11,400x less toxic

Comment #10: Risks to native vegetation and invertebrates
Response: See response #5, page 5.

Comment #11: Timing of herbicide application
Response: The timing of herbicide application is set by the Adirondack Park Agency, and is based on plant growth. The timeframe for application will be before June 30th, when all invasive milfoil is present but native milfoil has yet to emerge. No adverse impacts from ProcellaCOR have been shown for zooplankton, as suggested in the comment.

Comment #12: Impacts to native vegetation
Response: Timing of application is intended to minimize any impacts to native vegetation, which are not anticipated based on product registration and established science.

Comment #13: Potential plant product resistance following multiple applications
Response: The Commission has no intention of conducting a second ProcellaCOR application at either of the proposed project sites, let alone conduct 'repeated applications' year after year, which the EPA notes could possibly lead to plant resistance. Therefore, this concern is unfounded. Importantly, the Commission has identified no lake applications in New York State or the Northeast that have required even a second application of ProcellaCOR, given its effectiveness upon one treatment. Also, APA requires that all sites be surveyed annually and, if needed, hand harvested in the future if new milfoil plants emerge from the unaffected seeds or comes from outside the treatment area.

Comment #14: PFAS, or 'forever chemicals' based on MN interim report
Response: See response #4, page 3.

Response to Comments: Protect the Adirondacks

Comment #1: Adjudicatory hearing
Response: The NYS Appellate Court, Third Circuit, unanimously decided that the Adirondack Park Agency rightly decided that there was no need for an adjudicatory hearing on this project.

Comment #2: PFAS, or 'forever chemicals' based on MN interim report
Response: See response #4, page 3.

Comment #3: Non-quiescent waters/hydrodynamics
Response: See response #8, page 7.

Comment #4: No rationale for selected sites
Response: Rationale for selected sites is provided in the application materials

Comment #5: Potential for algae blooms or HAB's due to plant die-off
Response: ProcellaCOR treatment occurs early in the growing season when the plant is at 10-20% of its total potential biomass, greatly reducing annual nutrient release associated with natural EWM senescence by 80-90% in the treatment year. Not only is the plant biomass die off considerably less following a ProcellaCOR treatment, but this die-off only happens one time in the weeks following treatments. Conversely, these milfoil beds if not treated would grow to their maximum extent, and then die off, with a much larger nutrient release due to the larger biomass. Plus, following the ProcellaCOR treatment, there will be no biomass to die off in any subsequent years, as opposed to annual die offs without treatment. Since ProcellaCOR provides long-term milfoil control, the milfoil life-cycle in this area would be stopped and the nutrient release would decrease in the long-term, thereby reducing risk of harmful algal blooms.

Comment #6: Inadequate data on ecosystem impacts
Response: See response #5, page 5.

Comment #7: Product breakdown and sub-compounds not in application materials
Response: ProcellaCOR is a registered aquatic herbicide in NYS, and the product label including all pertinent product information was provided in the Commission's application to NYS DEC. The Adirondack Park Agency is not involved in NYS pesticide registration.

Comment #8: Mesocosms should be used first
Response: ProcellaCOR has undergone extensive regulatory review and scientific studies, including mesocosms, as noted in the EPA's product registration documents and associated noted scientific studies. It is registered for use via labeled use in NYS with appropriate permits and licensed application.

Comment #9: 'Enhanced' use of harvesting instead
Response: The Commission's Statement of Need in the APA application packet discusses the reasoning why other alternatives were selected for these sites.

*** END OF DOCUMENT ***