BUFFALO RIVER AREA OF CONCERN

Fish Tumors and Other Deformities Beneficial Use Impairment Removal Report

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Buffalo River Area of Concern

Fish Tumors and Other Deformities

Beneficial Use Impairment (BUI) Removal Report

Prepared by:

New York State Department of Environmental Conservation

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Contents

[Table 1 Descriptive statistics summary of brown bullhead data from Buffalo River \(2021\) and LPIB \(2019\)](#page-12-2) [..](#page-12-2) 13 [Table 2 Tumor data for Buffalo River and LPIB \(Neoplasm Notes: HA: Hepatocellular Adenoma, HC:](#page-12-3) [Hepatocellular Carcinoma, CO: Cholangiocarcinoma\)..](#page-12-3) 13

Appendices

- A. Statistical Analysis
- B. Brown Bullhead Data
- C. Public Comment Summary
- D. Letter of Support

List of Abbreviations

1. Introduction

This Beneficial Use Impairment (BUI) removal report identifies the background, criteria, supporting data, and rationale to remove the *Fish Tumors and Other Deformities* BUI from the Buffalo River Area of Concern (AOC). The status of this BUI is currently designated as "Impaired" presumably due primarily to polycyclic aromatic hydrocarbons (PAHs) in Buffalo River sediments. Potential sources of the contamination were determined to be the upland inactive hazardous waste sites and combined sewer overflows (CSOs). In recent years, significant remedial efforts have been completed to address this contamination, including sediment removal and capping, and upland source control at former and current industrial facilities along the river. In addition, the Buffalo Sewer Authority is implementing the [Long-Term Control Plan](https://buffalosewer.org/app/uploads/2017/08/LTCP-Exec-Summary.pdf) to reduce CSOs including the Buffalo River watershed. The New York State Department of Environmental Conservation (DEC), with support from the Buffalo River Remedial Advisory Committee (RAC), recommends the removal of the *Fish Tumors and Other Deformities* BUI from the Buffalo River AOC, based on the completion of remedial efforts, ongoing source control, and an evaluation of applicable postremediation data sets and other evidence gathered to address this impairment.

2. Background

Under Annex 1 of the Great Lakes Water Quality Agreement (GLWQA), the International Joint Commission (IJC) identified 43 AOCs in the Great Lakes Basin where pollution from past industrial production and waste disposal practices caused significant ecological degradation. Up to 14 BUIs, or indicators of environmental degradation, are used to evaluate the condition of an AOC.

The Buffalo River AOC is located in the City of Buffalo, Erie County, in western New York State. The Buffalo River flows from east to west and discharges into Lake Erie near the head of the Niagara River. The AOC extends along the historically industrialized portion of the river, beginning at the mouth of the river and continuing upstream to the Bailey Avenue Bridge. The extent of the Buffalo River AOC is depicted in Figure 1. The impact area is 6.2 miles (10 kilometers [km]) in length, and the AOC also includes the entire 1.4 mile (2.3 km) stretch of the City Ship Canal, located adjacent to the river. The drainage area of the Buffalo River is approximately 446 mi² (1155 km²). The primary tributaries which feed the Buffalo River are Buffalo Creek, Cazenovia Creek, and Cayuga Creek. A large extent of the Buffalo River and City Ship Canal within the AOC boundary is designated as a federal navigation channel, which is maintained by the United States Army Corps of Engineers (USACE) to a depth of 22 feet below low water datum.

Figure 1: AOC boundary and federal navigation channel boundary in the Buffalo River

Prior to anthropogenic activities, the river was originally a marshy creek that was less than four feet deep. As the City of Buffalo experienced population growth, the Buffalo River was modified to support commercial shipping activities. The river was dredged at the sides and in the center of the channel to accommodate cargo vessels transporting goods to industrial facilities located along its banks. Nearly the entire stretch of the river within the AOC boundary was surrounded by industrial facilities from the late 1800s to 1980s. Over the course of the last century, the Buffalo River became polluted with direct industrial discharges including PAHs, polychlorinated biphenyls, chlorinated organic pesticides, aniline dye byproducts, and metals. Contaminants settled into the sediments or bound with suspended organic matter and settled to the bed of the Buffalo River within the AOC area (Boyer 2010).

Chemical pollutants also found their way into the river indirectly, leaching from upland waste storage and disposal areas. Industries along the river managed and disposed of their solid waste by burning, burying, or storing in lagoons on-site. These disposal practices led to chemicals entering the river via surface water runoff of rain and snow as well as groundwater leaching (Rossi 1996). Today, many of these waste storage sites have become inactive hazardous waste sites, though some facilities remain and are currently in use. In all cases, efforts continue to eliminate or control future contaminant releases, either through remedial program site cleanups or other environmental regulations that did not exist for most of the industrialized history of the Buffalo River.

Under Annex 1 of the GLWQA, all AOCs are mandated to develop a Remedial Action Plan (RAP) in three stages:

- Stage I, which collectively identifies specific BUIs and their causes,
- Stage II, which outlines the restoration work needed to address the root problems and restore the identified BUIs, and
- Stage III, which documents the fulfillment of the commitments made in Stage II and recommends the delisting of the AOC.

In 1987, a group of concerned citizens, scientists, and stakeholders, along with DEC, formed the Buffalo River RAC, formerly known as the Buffalo River Citizens' Committee, to identify and address BUIs within the AOC. Collectively, the RAC developed and published the RAP for the Buffalo River AOC in 1989. The goal of the RAP is "to restore and maintain the chemical, physical, and biological integrity of the Buffalo River ecosystem in accordance with the Great Lakes Water Quality Agreement" (DEC 1989). In 2005, Buffalo Niagara Waterkeeper (BNW) published the Buffalo River RAP status report (Buffalo Niagara Waterkeeper 2005) which documented progress that had been made towards delisting, updated removal criteria and restoration targets for several BUIs and identified data gaps related to BUI assessment.

Through the combined 1989 Stage I and Stage II RAP, 2005 RAP status report, and subsequent 2011 RAP addenda, (BNW 2011) the Buffalo River RAC has designated nine out of the possible fourteen BUIs as being impaired for the Buffalo River AOC. The *Fish Tumors and Other Deformities* BUI was initially designated as impaired in the 1989 Stage I and Stage II RAP.

2.1Rationale for BUI Listing

The *Fish Tumors and Other Deformities* BUI was originally listed as impaired in the Buffalo River AOC due to probable linkages between PAH contamination in the sediments and fish tumor development. Studies conducted in the late 1970's and early 1980's revealed a high incidence of fish tumors and showed that extracts of river sediments caused skin and liver tumors in brown bullhead (Black 1983 and Baumann 2000). Scientists have linked the development of fish tumors to PAHs from the discovery of greater amounts of carcinogenic metabolites of these compounds (Eufemia et al. 1997). Additional research has indicated that other contaminants can't be ruled out as the causation of tumor incidence in fish (DEC 1989). High prevalence of fish tumors is both an indicator of contaminant stresses in the ecosystem, and an interference with human uses of the resource such as fishing and fish consumption. They may also constitute a health risk, if human carcinogens are present in the flesh of food fish (DEC 1989).

Tumor formation in fish is prevalent in the liver, the detoxifying organ therefore is susceptible to chemical metabolites (Pinkney et al. 2004 and Yang and Baumann 2006). According to the IJC, the association between hepatic neoplasms and sediment contamination suggests that tumors can be used as a proxy of environmental integrity (Baumann et al. 1996). Therefore, "fish tumors and other deformities" has been listed as one of the fourteen (14) BUIs established under the GLWQA (IJC 2003). Fish tumor assessment in AOCs has traditionally relied on survey data comparing exposed (impacted) and reference (unimpacted) sites for two tumor types in the livers of two inshore fish species: brown bullhead and white suckers. These two species are preferred indicators due to their life history traits, including their dietary habits (omnivores preying upon invertebrates buried in sediments), limited migration patterns, preferred habitats in muddy lake bottoms, as well as their resilience in low dissolved oxygen conditions (Visha et al. 2021).

2.2BUI Removal Criteria

In December 2001, the Restoring United States Area of Concern: Delisting Principles and Guidelines document developed by USEPA was adopted by the United States Policy Committee (USPC). This document was intended to "guide the restoration and maintenance of beneficial uses and the subsequent formal delisting in order to achieve a measure of consistency across the basin" (USPC 2001), and provided the following scenarios under which a BUI can be removed:

- A. A delisting target has been met through remedial actions which confirms that the beneficial use has been restored;
- B. It can be demonstrated that the BUI is due to natural rather than human causes;
- C. It can be demonstrated that the impairment is not limited to the local geographic extent but rather is typical of lake-wide, region-wide, or area-wide conditions (under this situation, the beneficial use may not have been originally needed to be recognized as impaired); or
- D. The impairment is caused by sources outside the AOC. The impairment is not restored but the impairment classification can be removed or changed to "impaired–not due to local sources." Responsibility for addressing "out of AOC" sources is given to another party.

The most comprehensive path to BUI removal is represented by option A, where specific targets or removal criteria are established and, after implementation of the necessary remedial actions, it can be demonstrated that the beneficial use has been restored.

The Fish Tumors and Other Deformities BUI removal criteria developed for the Buffalo River AOC as presented in the *Monitoring Plan for the Delisting of "Impaired" Beneficial Use Impairments* (BNW 2014) reads:

Analysis shows that the prevalence of neoplastic liver tumors found in Brown Bullheads, within the AOC, is not significantly higher than those found within a designated comparable control site.

3. Management Actions and Assessments Supporting BUI Removal

3.1 Inactive Hazardous Waste Site Remediation

Historic industrial waste disposal practices had a negative ecological impact on the Buffalo River AOC (Rossi 1996) and mitigating upland contaminant sources was necessary to reduce and prevent reintroduction of contaminants into the river. Historical locations of contaminant inputs along the shoreline of the Buffalo River AOC have been designated (where necessary) as inactive hazardous waste sites over the last 40 years. DEC issues different classifications for waste sites based on the nature and extent of the site-specific contamination, as well as the potential impacts to human health and the environment. To address contamination at inactive hazardous waste sites, there are numerous remedial programs in New York State which include the State Superfund Program, the Brownfields Cleanup Program, and the Voluntary Cleanup Program. Sites identified in the Buffalo River watershed were subsequently entered into appropriate state programs to facilitate remediation of site-specific contamination which included both off-site disposal and onsite containment. Only one remaining primary historical contributor (PVS Chemicals, Inc) is still an active industrial facility and is required to comply with all applicable regulatory requirements that may exist to control contaminant releases.

Remedial investigations and, where it was determined necessary, remedial actions at all designated inactive hazardous waste sites in the vicinity of the Buffalo River AOC have been completed as of 2021. Sites that required no action, as determined though the remedial investigations, documented no impacts to the Buffalo River and contamination was unlikely to transport off-site. Information about hazardous waste sites, including remedial investigation reports and monitoring plans, within the vicinity of the Buffalo River AOC can be found on DEC's [DECinfo Locator.](https://gisservices.dec.ny.gov/gis/dil/)

3.2Great Lakes Legacy Act

In 2002, the Great Lakes Legacy Act (GLLA) was passed by U.S. Congress for the purpose of accelerating cleanup of contaminated sediment within the Great Lakes AOCs. This boosted additional Buffalo River AOC studies to be conducted to determine the extent of contamination in the sediments and prompted remediation alternatives to be assessed. The Buffalo River Restoration Partnership Project Coordination Team (PCT), formed in 2007, led coordination and planning efforts to address the contaminated bottom sediments within the AOC. This group consisted of USEPA, DEC, BNW, USACE, the City of Buffalo, and Honeywell, Inc. Each organization was a key partner in progressing the restoration of the Buffalo River. Information collected over the years led to the development of the baseline and feasibility study which determined the best course of action to effectively manage potential ecological and human health risks associated with elevated sediment contaminant concentrations (ENVIRON 2011). The feasibility study identified site-specific remedial goals for four indicator chemicals, PAHs, PCBs, lead, and mercury, using

multiple lines of evidence based on sediment toxicity tests and comprehensive contaminant analyses. The *Restrictions on Dredging Activities Beneficial Use Impairment Removal Report* provides a comprehensive summary of the selected remedial alternative (DEC 2022).

Over one million cubic yards of sediment were removed from the river, through combined efforts of the PCT, funded by GLLA and USACE Operations and Maintenance funds. A major portion of the remedial work was completed in 2015, with additional dredging and placement of a cover in targeted areas completed in 2021. Post-remediation monitoring was performed in 2017 (Year 2) and 2020/2021 (Year 5) to assess the effectiveness of remedial actions in restoring beneficial uses after the completion of GLLA remedial dredging (DEC 2022). Studies document a reduction in contaminant concentrations within the surface sediments throughout the AOC over time confirming that sediment and water quality is improving (Ramboll and Anchor QEA 2021). Sampling plans to address AOC impairments post-remediation were originally developed and documented in the *Monitoring Plan for the Delisting of "Impaired" Beneficial Use Impairments,* including for the *Fish Tumors and Other Deformities* BUI (BNW 2014) which led Year 2 and Year 5 sampling activities.

3.2.1 Pre-Remedial Sampling

A key study, led by DEC and USEPA Great Lakes National Program Office (GLNPO), was conducted in 2008 to document the extent of chemical contamination and assess baseline ecological conditions for the Buffalo River AOC before sediment remedial actions were implemented. As part of this, brown bullheads were collected from the Buffalo River AOC in the fall of 2008 to evaluate the status of the *Fish Tumors and Other Deformities* BUI at that time. Fish were collected from three pre-determined zones within the AOC boundary as indicated in Figure 2. Thirteen bullheads were collected from Zone 1, 16 from Zone 2, and eight from Zone 3, totaling to 37. Tumors were found in three of the 37 brown bullhead livers, in one fish from each of the three reaches of the river (ENVIRON 2009 and Lauren et al. 2010). This baseline data was compared to historic samples collected in the 1980s and 1990s, and tumor prevalence were determined to be substantially reduced from tumors reported in the two earlier surveys (Baumann et al. 2000). Collection and analysis methods have changed over the decades so this was not an exact comparison but rather a general comparison to assess trends over time. The prevalence of tumors in brown bullhead had decreased over the course of several decades, likely explained due to natural attenuation, where uncontaminated upstream sediments deposited in the lower river (Lauren et al. 2010). Figure 3 represents the long-term trends of documented liver tumors found in brown bullhead (Baumann et al. 2000, Lauren et al. and Appendix B).

Figure 2 Collection sites for brown bullhead within three zones of the Buffalo River, New York, USA, October 2008. Fish were collected within 200 feet of the indicated locations (triangles).

Figure 3 Long-term trends of liver tumor prevalence in brown bullhead in the Buffalo River

3.2.2 Post-Remedial Sampling

As part of post-remedial monitoring in 2021, 50 brown bullheads were collected from the Buffalo River via DC boat electrofishing. Fish were collected from 4 zones within the Buffalo River and City Ship Canal, shown in Figure 4. Three fish had tumors, one was located in a liver and two were found in the biliary ducts. The three fish were aged to be nine years old. The Buffalo River data was compared to a control site: Long Point Inner Bay (LPIB) to evaluate this BUI, as described in Section 4 of this report. Fifty brown bullheads were collected from LPIB in 2019 where two fish were found to have tumors, both were aged 10 years old (Table 1). Three of the 50 fish were not able to be aged so 47 fish were used in the statistical analysis for both LPIB and Buffalo River fish. Methods of collection and processing were the same for the Buffalo River and LPIB. All fish captured were measured for total length to the nearest millimeter. For aging purposes, otoliths were extracted according to the methods of Rafferty and Grazio (2006). Otoliths were aged independently by two experienced readers, if agreement was not reached both readers reexamined the otoliths in question and reached a consensus. If an otolith was unreadable, an attempt was made to prepare and cut the second otolith if present. Several otoliths were unreadable (2 LPIB and 3 Buffalo River).

LPIB was selected as the control site because it was previously determined to be the least impacted control site amongst several that were considered, and it lacked point source discharges of pollutants or known sediment contamination and had a resident bullhead population (PADEP 2012). Tumor prevalence was compared for several control site candidates and LPIB had the second lowest estimated tumor prevalence but a narrow confidence interval, or less uncertainty, in the estimate (DEC 2015). LPIB drains a primarily agricultural watershed, and the bay is considered to be relatively pristine (Blazer 2009). LPIB is located on the Canadian north shore of Lake Erie. Sampling areas within the bay were not documented.

Table 1 Descriptive statistics summary of brown bullhead data from Buffalo River (2021) and LPIB (2019)

Table 2 indicates the type of tumors found in brown bullhead from the Buffalo River and control site, LPIB. Tumors were categorized into hepatocellular adenoma, hepatocellular carcinoma, and cholangiocarcinoma. Hepatocellular adenoma and hepatocellular carcinoma both occur in the liver whereas cholangiocarcinoma occurs in the bile ducts (located in the liver and connect the liver to the gallbladder). The full data set to the 2021 Buffalo River and 2019 LPIB sampling events can be found in Appendix B.

Table 2 Tumor data for Buffalo River and LPIB (Neoplasm Notes: HA: Hepatocellular Adenoma, HC: Hepatocellular Carcinoma, CO: Cholangiocarcinoma)

							Neoplasm
Sample Date	Location	Sex	Length (mm)	Weight (g)	Age (otolith)	Neoplasms	Type
5/6/2019	LPIB	M	325	456	10		HC
5/6/2019	LPIB	M	315	428	10		CO.
6/22/2021	Buffalo River		363	613	9		CO
6/22/2021	Buffalo River		335	522.5	9		CO.
6/22/2021	Buffalo River	M	355	679.5	9		HA

4. Analysis

4.1 Statistical Analysis

A statistical analysis of tumor prevalence in brown bullhead residing in the Buffalo River AOC and the control site LPIB was conducted by Dr. Michael A. Rutter to determine whether the BUI-removal criteria was met. The 2021 Buffalo River and 2019 LPIB data were used for this analysis. The methodology for the analysis is complex but a comparison of the liver tumor prevalence percentages between the AOC and LPIB (i.e. 6% vs 4%) is not appropriate for the following reasons:

- It would involve the assumption that every fish collected for analysis has an equal probability of having a tumor which is not the case. The probability will vary with characteristics such as age, length, weight and gender of fish.
- It would involve the assumption of having a "simple random sample" of fish from each site. Almost all statistical techniques assume a simple random sample. However, sampling occurred in multiple locations within the AOC and the control site so this assumption cannot be made. As a result, true

confidence intervals for estimates of tumor prevalence become larger than one would calculate under the simple random sample assumption.

To address the first concern, a logistic regression model is appropriate because the dependent variable has only two possible outcomes, the presence or absence of a tumor. Logistic regression can incorporate the effects of any number of demographic characteristics, or predictor variables, (age, length, gender, and weight) on the probability of a fish having a tumor. Using a hierarchical model approach addresses the second concern because it accounts for the correlation among fish samples in the same year and location (DEC 2015). This approach accounts for the (slight) correlation among fish sampled in the same location. The overall effect of a predictor variable (e.g. age) on the probability of a fish having a tumor for the Buffalo River is modelled as a combination of the effect of that variable specific to each sampling location (4 zones). Therefore, the hierarchy has an overall Buffalo River effect at the top, which depends on the site-specific effects at the next level.

When comparing liver tumor prevalence between two sites, ensuring that the amount of data is sufficient to detect meaningful differences is important; this is the "power" of the statistical procedure. Power is a measure of the ability of a method to find a statistical difference when a statistical difference actually exists (i.e., to avoid a false negative test). Greater statistical power is associated with larger sample sizes. Ensuring sufficient power is important in this analysis so that finding no statistical difference in tumor prevalence between AOC and control site will be due to an actual small difference in tumor prevalence and not due simply to small sample sizes. No available statistical software can perform a power analysis for a traditional mixed-model logistic regression. Use of a Bayesian framework essentially transforms the power measurement into the width of a confidence interval, with a smaller interval width indicating greater statistical power. Therefore, specifying a maximum acceptable width of a confidence interval is equivalent to requiring sufficient power.

The first phase of carrying out the analysis was to determine which combination of predictor variables best described the observed tumor prevalence. Hierarchical logistic regression models using all possible combinations of the four predictor variables (age, length, weight, and gender) were tested using the Bayesian framework. The best model of those examined included age as a predictor variable.

The tumor prevalence for the LPIB control site and Buffalo River were then estimated. All the sampling sites for the AOC were combined into a single estimate of tumor prevalence. Because the probability of having a tumor varies with the age of the fish, it was necessary to choose an age to calculate the estimates. The median age was 7 years and was used to calculate tumor prevalence.

While a traditional statistical method would generate a point estimate for the desired result, Bayesian analysis generates a probability distribution over the range of possible result values. For this analysis, each probability distribution was summarized by finding its median and the 95% highest probability density interval (HPDI), which is the smallest interval within the range of possible result values that is associated with a total probability of 95%. Figure 5 provides an illustration for an arbitrary probability distribution. The horizontal axis represents possible result values, and the vertical axis represents probability. The median is the result value for which the total probability associated with all lower values and the total probability associated with all higher values are both equal to 50%. The 95% HPDI is shaded (a, b). In this analysis, the median of the probability distribution is used as a point estimate of tumor prevalence while the 95% HPDI is a Bayesian analogue of a 95% confidence interval.

Figure 5 Example Probability Distribution

The final step of the analysis was to conduct a statistical test for equivalency between the tumor prevalence at the AOC and at LPIB using a Two One-Sided Tests (TOSTs) procedure, which is accepted by the U.S. Food and Drug Administration for evaluating the comparability between two groups. Hypothesis testing commonly involves a null hypothesis that no difference exists in some quantity measured for two groups and an alternative hypothesis that a difference does exist, at an accepted significance value (alpha, α). However, for the TOST procedure, the null hypothesis is that the measurements for two groups are not equivalent or, stated another way, that the difference in the measurements exceeds a pre-defined tolerance level. The first test determines if the difference in tumor incidence is less than or equal to θ and the second test determines if the difference in tumor incidence is greater than or equal to $-\theta$, where θ is a predetermined tolerance level.

The p-value for the TOST is the larger of those obtained for the two one sided tests. If the p-value is less than an acceptable significance value (chosen to be 0.05) then sufficient evidence exists to suggest the tumor prevalences are equivalent at the θ tolerance level.

An equivalent approach to the TOST procedure is to construct a (1−2α)% confidence interval for the difference in tumor prevalence between the AOC and control sites (Rutter 2010 which cites Berger and Hsu 1996, FDA Guidance 2001). The alpha (α) set at 0.05 for Buffalo River AOC resulting in a 90% confidence interval and analogous 90% HPDI. If this 90% interval (HPDI) is entirely between the tolerance limits $-\theta$ and θ , then the tumor prevalence can be considered to equivalent. If the interval is too large or does not contain zero, then the tumor prevalence is statistically significantly different.

The tolerance, θ , is determined by applying the TOST procedure to compare the AOC to itself. The bound of this interval can be viewed as the tolerance level required for two sites with sampling designs similar to the Buffalo River to exhibit equivalence if the true tumor incidence at the sites were identical. To allow sites with similar, but not exact, tumor incidences to demonstrate evidence of equivalence, a specified % is added to the initial tolerance interval (Rutter 2010). The reference interval must contain

zero because it is generated by comparing the AOC to itself. The size of the reference interval is dependent upon the parameters of the hierarchical model representing the sampling design which are estimated using the available AOC tumor data. If both intervals contain zero, that indicates equivalency.

Using the above methods, the TOST reference tolerance interval was created by comparing the Buffalo River site to itself for an age 7 fish. The comparison results in a 90% HPDI of (-9.5%,9.3%). The recommended difference in tumor prevalence for similar (and not identical) sites is 5% (Rutter, 2010), therefore 5% was added to the initial tolerance level estimate. Adding 5% to each bound and making it symmetric results in a TOST reference tolerance interval of (-14.5%,14.5%).

Using the confidence interval TOST procedure equivalent noted above, the difference in tumor incidence for age 7 fish between the Buffalo River and LPIB has a 90% HPDI of (-1.0%,13.1%), which is completely within the TOST reference interval (-14.5%, 14.5%) and does contain zero. Therefore, the Buffalo River and LPIB are considered to have statistically equivalent tumor incidences or put another way, the difference between sampling sites is smaller than what is considered meaningful. A full summary of the analysis can be found in Appendix A.

4.2 Age and Tumor Correlation

In fish, neoplasm development is strongly correlated with age, not only because older fish have potentially been exposed to environmental contaminants for longer periods, but because there is a latent period between exposure and tumor development (Baumann 2010). An important question in the Buffalo River AOC is whether the liver neoplasms found in recently collected bullhead developed from historic or current exposure to contaminates in local sediments. The bullhead with tumors were 9 years old when they were collected in 2021, therefore were young-of-year in 2012 during remedial activities and were exposed to sediments under both recent (post-remediation) and past (pre-remediation) periods. It would be more concerning if liver neoplasms were found in 3 to 5 year-old bullhead because neoplasms in young fish might indicate exposure to carcinogenic contaminants rather than natural tumor development sometimes observed in older individuals regardless of contaminant exposure. As previously mentioned, fish collected from LPIB that had liver tumors were 10 years old and supports this statement.

4.3 Polycyclic Aromatic Hydrocarbons and Tumor Correlation

Over the years, field and laboratory studies have linked liver neoplasms in fish to PAHs in some waterbodies of the Great Lakes. Extensive long-term sampling in the Black River AOC of Ohio provides some of the best field-based evidence of the strong relationship between PAHs and liver tumors in brown bullhead (Pinkney et al. 2004). Surveys conducted in the 1980's and 1990's revealed that liver tumor occurrence was positively correlated with PAH concentrations in sediments (Pinkney et al. 2004). Laboratory studies also supported a cause-and-effect relationship between PAH concentrations and liver tumors (Pinkney et al. 2004).

Sediment was sampled for PAH concentrations in the Buffalo River AOC during 2017 and 2020. The final post remedial monitoring reports show that PAH concentrations have decreased over time following remedial activities (Ramboll and Anchor QEA, 2021). The 9-year-old brown bullhead (collected in 2021 from the Buffalo River) that exhibited liver neoplasms were born in 2012. Remedial dredging was occurring in parts of the Buffalo River AOC during their early years. Consequently, these fish were likely exposed to high contaminant concentrations during dredging operations when buried contaminants were uncovered. Cornell University and DEC conducted laboratory experiments in the 1980s and 1990s that concluded that "the age of fish at the time of carcinogen exposure can strongly influence the prevalence of neoplasia in exposed fish, with embryonic fish generally being most susceptible to tumor induction" (Spitsbergen and Wolfe 1995). Thus, tumor occurrences in 9-year-old bullhead from the Buffalo River AOC do not necessarily indicate recent exposure to high concentrations of carcinogens.

Anthropogenic sources of PAHs include highway runoff, coke oven and wood burning/coal tar (Baumann 1990). CSOs provide a direct pathway for pollutants to enter the waterways during storm events, both from untreated waste and stormwater runoff. Urban runoff supplies a continual input of PAHs from roadways and asphalt driveways to the Buffalo River. There are 16 CSOs located along the Buffalo River and 11 located in the upstream tributary Cazenovia Creek. To address the many issues CSOs pose to human health and environment, the City of Buffalo developed the Long Term Control Plan (LTCP) in 2014 to reduce the volume of CSO discharges by 73% and incorporate stormwater capture.

4.4 Other Considerations

The occurrence of liver tumors in bullhead may be caused by several other factors besides contaminated sediments, although no specific studies are known to have been conducted in recent years to fully assess other potential causes. One factor to consider is the natural formation of carcinogens in waterways. In the 1980's to 1990's, pathologists at Cornell University, along with biologists at DEC conducted an intensive study to clarify why brown bullhead in relatively unpolluted waters were observed to have a high percentage of skin and liver tumors (Spitsbergen and Wolfe 1995). Fish were sampled from lakes and reservoirs that were defined as relatively pristine, not containing any PAHs at detectable limits. After studying hundreds of fish from several NY lakes, Cornell scientists observed a relatively high prevalence of many types of tumors, both external and internal (ex. 21-33%, Spitsbergen and Wolfe 1995). A possible explanation was the natural occurrence of carcinogens, N-nitroso compounds, which form spontaneously in areas of decomposing plant material where nitrite is abundant or where pH is less than 7.0. Cornell's Fish Pathology Laboratory has documented relatively high concentrations of N-nitroso carcinogens in sediments in Presque Isle Bay that potentially contribute to the high prevalence of skin and liver neoplasms in fish located within the bay. The study concluded that caution is needed when using fish from natural waters as indicators of anthropogenic carcinogens (Spitsbergen and Wolfe 1995).

Another factor to consider is that bile duct cell changes in brown bullhead have been linked to myxozoan parasites that inhabit bile ducts in fish, commonly found in wild populations (Blazer et al. 2009 and Lauren et al. 2010). These parasites cause scarring and promote cell proliferation, increasing risks for disease. However, there is uncertainty with the progression of brown bullhead bile duct cell proliferation and scarring to the development of tumors (Baumann et al. 2008 as cited in Baumann 2010 and PADEP 2012). In the 2008 study (Lauren et al. 2010), the brown bullheads collected seemed to have relatively healthy livers, with the exception of parasites in the bile ducts (Lauren et al. 2010). It is not known how many brown bullhead were found to have parasites in bile ducts. In the 2021 Buffalo River dataset, 42% of the 50 fish collected were found to have myxozoan parasites in their livers. Two of the three fish to have tumors in the 2021 fish collection, were found to have tumors in the bile ducts, and one of the two with bile duct tumors were discovered to have myxozoan parasites (EPL 2021a). A review of the 2019 LPIB data set revealed 76% of the 50 fish collected had myxozoan parasites in the bile ducts and both fish found to have myxozoan parasites in the bile ducts though only one fish has tumors in the bile ducts (refer to Table 2 for tumor types in each fish, EPL 2021b). According to the data, there is no direct correlation to parasites

and tumor formation, more research is needed to understand tumor development in connection to chemical exposure as well as parasite-induced responses (Blazer et al. 2014 and Blazer et al. 2017).

Additionally, emerging contaminants such as estrogenic compounds, cyanobacteria, hypoxia, low pH, and genetic and viral factors also seem to affect fish and the incidence of tumors that develop in fish livers (Baumann et al. 2000 and Blazer et al. 2014). It is not possible to determine whether age, contaminated sediments, or other environmental factors were the primary cause for liver tumors observed in brown bullhead recently collected from the Buffalo River AOC, hence the need for statistical comparison between fish from the AOC and from the LPIB control site. Statistical analysis did not determine a significant difference between the liver tumor prevalence in brown bullhead fish from the Buffalo River compared to the control site at LPIB. The weight of evidence considerations included the absence of tumors in younger Buffalo River fish, the declining trend in tumor incidence on Buffalo River fish, the incidence of tumors in fish from relatively pristine waters generally, and the statistical evidence. Based on this evidence, the *Fish Tumors and Other Deformities* BUI removal criteria has been met.

5. Public Outreach

DEC, in partnership with BNW, Erie County Department of Environment and Planning, EPA, and the Buffalo River RAC, hosted a hybrid in-person and virtual public meeting on XXXX, to present the case for removing *the Fish Tumors and Other Deformities* BUI to local stakeholders. The meeting was held during the 30-day public review period from XX to XX, during which the public was invited to review and provide input on a draft version of this BUI removal report. A summary of the public review period is found in Appendix C.

6. Conclusions

6.1 BUI Removal Steps

6.2 Removal Statement

Based on the analysis demonstrating Buffalo River tumor prevalence in brown bullhead is not statistically higher than those found in the LPIB control site, and the additional weight of evidence of age and environmental factors, the removal criteria for the *Fish Tumors and Other Deformities* BUI has been met. Accordingly, DEC and the RAC fully support the redesignation of its status from "impaired" to "not impaired". A letter of support is provided in Appendix D.

6.3 Post-Removal Responsibilities

6.3.1 New York State Department of Environmental Conservation

Through the State Pollutant Discharge Elimination System (SPDES), DEC will continue to regulate point source discharges of industrial and municipal wastewater and stormwater in accordance with the federal Clean Water Act. There are several point-source discharges in the AOC as well as outside of the AOC upstream the Buffalo River. Additionally, DEC will continue to provide regulatory oversight for inactive hazardous waste sites within the Buffalo River watershed.

6.3.2 United States Environmental Protection Agency

The USEPA will continue to provide funding for RAP/RAC Coordination and technical resources to the extent resources are available to support the removal of remaining BUIs and ultimately the delisting of the AOC.

6.3.3 Buffalo Niagara Waterkeeper

BNW will continue to serve as the RAP coordinator for the Buffalo River AOC until EPA/GLRI grant funding expires. As RAP coordinator, BNW facilitates RAC meetings, provides technical and administrative assistance for AOC documentation, serves as the primary point of contact for the AOC, and coordinates the overall implementation of the RAP for the Buffalo River AOC.

6.3.4 Erie County Department of Environment and Planning

Erie County Department of Environment and Planning will continue to partner with BNW in implementing responsibilities associated with the Buffalo River RAP until EPA/GLRI grant funding expires. Erie County staff participate in RAC meetings, provide feedback on AOC-related documentation and progress reports, and capacity support for the Buffalo River AOC.

6.3.5 Remedial Advisory Committee

The RAC will continue to forward the objectives of the RAP by evaluating, supporting, and documenting the restoration of the Buffalo River AOC, until all the Beneficial Use Impairments are restored and the long-term goal of delisting the AOC can be achieved.

6.4 Future Recommendations

In addition to post-removal responsibilities mentioned above, it is recommended that an adaptive management approach is taken to monitor the areas of restoration and identify potential threats that may occur after BUI removal so that success of restoration activities can be sustained in the future. These threats may include impacts from invasive species, point and non-point source pollution, climate change, and other factors that may negatively impact the benthic community.

The Regional Niagara River Lake Erie Watershed Management Plan was developed by Buffalo Niagara Waterkeeper and the Plan assesses sub-watersheds within the Niagara River/Lake Erie watershed and develop implementation plans for five priority sub-watersheds, including the Buffalo River sub-watershed (BNW 2017). The implementation plan provides short-term and long-term recommended actions, best management practices, and programmatic suggestions for addressing waterbody impairments and conserving lands contributing to good water quality. Implementation of the plan would improve riparian habitat and water quality.

The Lake Erie Nine Element Watershed Management Plan (Lake Erie 9e Plan), currently being drafted, details water quality concerns and a strategy to address those concerns. The nine elements are intended to ensure that the contributing causes and sources of nonpoint source pollution are identified, and that restoration and protection strategies are identified that will address the water quality concerns. Implementation of the Lake Erie 9e Plan is expected to result in improved water quality in the tributaries that are within New York's portion of the Lake Erie watershed, including the Buffalo River.

As feasible and as funding allows, DEC will work with local partners to develop a plan for continued monitoring of conditions within the AOC after delisting, and to maintain the improved conditions leading to the removal of the *Fish Tumors and Other Deformities* and other BUIs. DEC will also continue to work with other federal, state, and local partners to pursue projects under the binational Lake Erie Lakewide Action and Management Plan (LAMP) that will further contribute to restoration of the Buffalo River and its surrounding watershed.

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Appendix A

Statistical Analysis

Buffalo River Statistical Data Analysis

Michael A. Rutter, 5/7/2024

Methods

For Brown Bullhead, liver tumors were analyzed using logistic regression. The presence or absence of any liver tumor was the response variable while age, length, weight, and sex where possible predictor variables. Sample location was always included in the model as an intercept term in order to examine for differences in tumor incidence between locations. All possible combinations of the predictor variables were modeled, and the combination with the lowest AIC (Akaike's Information Criteria) was selected as the best combination of those predictor variables examined.

Data was used for Brown Bullhead only. After the best combination of predictor variables was determined, another logistic regression model using a Bayesian approach. Given the relatively small sample size and that only two locations were sampled for one year, a single term slope term for describing the increase in tumor incidence was shared between the locations for each predictor variable in the model. To model differences in tumor incidence for location, a separate intercept term was estimated for each location. Samples from the posterior distribution of the model parameters were used to compare locations and create intervals for tumor incidence rates on a typical fish from the sample data.

To establish a baseline rate of equivalence, the Buffalo River data was compared to itself to determine uncertainty in the tumor instance via a 90% highest posterior density interval (HPDI). To test for equivalence between the Buffalo River site and the reference site (Long Point, Inner Bay), a two one-sided test (TOST) was conducted using the 90% HPDI for the Buffalo River from above, with an additional 5% of tolerance added (see Rutter 2010 for details). If the 90% HPDI comparing the Buffalo River site to the reference cite is within specified TOST reference interval, the sites would be considered to have statistically equivalent tumor incidence rates.

Results

To determine the best predictor variable or variables, AIC values were compared. The model with the lowest AIC is considered the best fitting model of those compared.

Based on the above table, the model with age (in years) as the only predictor is the best model of those compared. For the data, the median age brown bullhead was 7 years old, and will be used as the reference age for comparing tumor incidence. Below is a table of the the 95% Bayesian HPDI tumor rates at each location.

In order to test for equivalence between the sites, a reference TOST interval is created by comparing the Buffalo River site to itself for an age 7 fish. The comparison results in a a 90% HPDI interval of (-9.5%, 9.3%). Adding 5% to each bound and making it symmetric results in a TOST reference interval of (-14.5%,14.5%). The difference in tumor incidence for age 7 fish between the Buffalo River and reference locations has a 90% HPDI of (-1.0%,13.1%), which is within the TOST reference interval. Therefore, the Buffalo River and reference site are considered to have statistically equivalent tumor incidences.

Appendix B

Brown Bullhead Data

Appendix C

Public Comment Summary

Appendix D Letter of Support