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Ms. Cheryl Niemi
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**Re: Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3**

Dear Ms. Niemi,

These comments are being submitted today by PRINTING United Alliance, representing the interests of those companies in the printing, publishing, and packaging industry. We appreciate the opportunity to offer observations and formal recommendations on the Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3 authored by the Washington State Department of Ecology November 2021.

As background, the printing, publishing, and packaging industry in State of Washington is a multi-billion dollar industry that provides employment for thousands of citizens. According to the 2016-2019 County Business Patterns and 2017 Economic Census collectively, there are approximately 892 establishments in the State of Washington that employ about 14,360 people. The value of goods shipped is estimated to be $3.514 billon. For the printing industry (NAICS 323) segment, 86 percent of the establishments employ 20 or fewer employees. Printing is a prime example of small business involved in manufacturing.

PRINTING United Alliance has been engaged with Department of Ecology (Ecology) since the beginning of this program and has found ECY's response to input and feedback to be nonproductive. The process used to identify printing inks as significant source of polychlorinated biphenyls that require a regulatory solution conflict with established scientific, technical, and economic laws and regulations governing products in commerce in the United States. When printing inks were identified for the program in 2020, Ecology conclusion that "colored pigments contained in inks are the largest source of inadvertent PCB contamination in consumer goods" is not supported by any specific references, studies, or other supporting documentation that we could locate.

Furthermore, Ecology came to this conclusion at the beginning of the Safer Products evaluation process prior to conducting tests on any inks for the presence of PCBs. Ecology referred to several sets of testing performed on printed products that were nonspecific regarding which components of the printed product was the source of PCBs. Based on this information, we believe that Ecology based its decision regarding ink based on assumptions rather than data. As ink sets vary dependent on print process, we were amazed to discover that there was no mention as to the specific printing process used to produce each printed product.

Actual testing of inks did not occur until late 2021, and the results of the ink testing were not available when this draft was released on November 17, 2021. The results did not become available until December 2, 2021, which prompted request for a comment extension that was subsequently granted.

**Misrepresentation of the Printing Industry**

Ecology's characterization and decision to focus on "process inks", those that are used for four color printing, poses several problems for the printing industry. Contrary to Ecology's statement, ink type, formulation, and use are not universal. The printing industry manufactures, through a wide variety of distinct printing processes, a wide variety of products including books, magazines, direct mail, envelopes, business cards, textiles, clothing, banners, billboards, flyers, rigid packaging, flexible packaging, electronics, flooring materials, and a multitude of other similar products.

While Ecology does acknowledge that there are different types of print technologies, the identified print technologies is neither complete nor comprehensive. Furthermore, Ecology has failed to appreciate that each one of the printing technologies has its own unique ink application method and drying or curing method.

From an ink formulation and application perspective, the most important and critical point that needs to be understood is that each technology uses its own distinct ink system. The inks must be formulated to the exact specifications required for the application approach and performance characteristics that are required for the product's end use. Inks that are formulated for one specific printing process cannot be used in another printing process. For example, an offset lithographic paste ink cannot be used to print on a flexographic printing press as the inks required for flexographic operations require a high level of viscosity. Similarly, a sheetfed offset lithographic printing ink cannot be used on a heatset web offset lithographic printing press or a nonheatset web offset lithographic printing press even though the application technology is common. While all are offset technology, the products produced require specific ink sets.

Given the rapidly accelerating growth of digital printing applications, it is also important to understand that each type of digital device (e.g., ink jet, dye sublimation, Indigo, Landa NanoInk, dry toner) requires its own specific ink formulation. In some instances, the pigments used in these systems are not the same as those in conventional systems. In addition, some of them use dyes and not pigments as the colorants.

The finished product requirements with respect to performance characteristics such as hue, tonal value, fade resistance, adherence to substrate, etc. all demand that each ink be specifically formulated in such a manner that achieves these desired results. There are thousands upon thousands of "process" ink formulations which are distinctly different based on printing technology application method and finished product performance characteristics. Printed products that fail to meet color or performance specifications will be rejected by the customer resulting in increased waste generation and financial loss to the printer or converter.

Unfortunately, Ecology's inappropriate oversimplification of the inks used by the printing industry has resulted in the sampling and testing of inks that are not representative of all the process inks used by the entire industry. Furthermore, the report does not identify the specific types of ink that were tested. This is critical information that needs to be shared to industry so that we avoid the issue of bad regulatory policy.

**Ink Sampling Methodology**

We also have questions regarding the ink testing and sampling methodology used. In analytical chemistry one of the common tenants and core techniques of any quality control program used for determining the precision of an analysis is the analysis of duplicate samples. Analyzing replicate samples provides assurance and confidence that any measured value is accurate, especially when using a method that is variable such as EPA Method 1668C. Duplicate samples are obtained by dividing a single gross sample into two parts or in some cases the duplicate samples are independently collected gross samples.

Ecology did not issue a formal report on the ink testing. It only released raw ink testing data. Additional explanation is required as to why the ink testing was only performed on one set of samples. At the time of these comments, the ink types identified in the raw data released on ink testing by Ecology could not be confirmed Replicate sampling is used to estimate sample variability and repeatability of results and was not used in the testing of printing inks. The history with PCB sampling by Ecology and City of Spokane has shown there can be wide variability in results obtained by using EPA Method 1668C, especially with the hydroseed sampling that was performed several years ago.

Without a formal report, another significant issue revolves around understanding what blanks were used for the testing and the results of the blank testing. EPA Method 1668C has an entire section dedicated to the determination of PCBs in blanks and without having information on blanks and blank testing results, it is difficult to fully understand the test results. At a minimum there should be a method blank, in which an analyte free sample is analyzed using the same reagents, glassware, and instrumentation. The method blank allows for the identification and correction systematic errors due to impurities in the reagents, contaminated glassware, and poorly calibrated instrumentation. In addition, an ink sample from an ink that has been carefully formulated to ensure no known sources of PCBs in the ingredients should also be prepared and analyzed.

Replication is used to increase confidence in the integrity of data generated by analytical methods. Only having one set of test results on unknown types of inks does not provide sufficient data to draw any conclusions regarding the concentration of PCBs found in inks, the range of PCBs, or the consistency of the concentrations of PCBs in inks. There needs to be a baseline of concentration established before a regulatory limit can be imposed. Until duplicate and additional testing on a wider range of ink types, Ecology does not have adequate data to propose a regulation limiting the concentration of PCBs in inks.

**Basis For Ink PCB Regulation**

Issuing a regulation as opposed to a recommendation is a serious step as it imposes legal obligations and significant costs on the part of regulated entities. Therefore, careful consideration needs to be paid to the justification for the regulation, hazard identification, hazard control, and compliance demonstration. While Ecology has stated a regulation is necessary, the basis for it has not been established and it has not shown that alternatives exist and are feasible.

<u>Use of EPA Method 1668C</u>

Ecology is relying upon the results of EPA's Method 1668C to identify and determine each PCB congener and its respective concentration in inks. It is also proposing to use the results of the method to set some type of regulatory limit in a separate future rulemaking. However, this is not the appropriate method to be used for setting regulatory requirements.

In EPA's Method 1668C, which can be found at this link, https://www.epa.gov/sites/production/files/2015-09/documents/method_1668c_2010.pdf, the scope of the method excludes its use for determining PCB content in inks or other similar materials.

> *1.2 EPA developed this Method for use in Clean Water Act (CWA) programs and for wastewater, surface water, soil, sediment, biosolids and tissue matrices. Other applications and matrices may be possible, which may or may not require modifications of sample preparation, chromatographic conditions, etc. Method 1668C is a revision of previous versions of Method 1668 all of which are based on a compilation of methods from the technical literature (References 3 and 4), and EPA's dioxins and furans Method, Method 1613.*

Another and perhaps more important limitation of EPA Method 1668C is that neither regulation nor guidance issued by EPA allow the use this method for compliance purposes. For example, approved analytical methods for NPDES permits are listed in 40 CFR Part 136. There are several methods that are approved, and it appears that the most common and most sensitive approved method is EPA Method 608.3. In addition, all the approved analytical methods for PCBs are for PCB Aroclors and they are not congener-specific methods. We understand some wastewater discharge permits can require the use of EPA method 1668C for effluent characterization purposes, however, the method is not used to determine compliance with an effluent limit for total PCBs.

Likewise, under 40 CFR 761, which governs the identification and disposal of PCB materials, no reference for the allowance of EPA Method 1668C can be located. Paragraph 761.6 does not have 1668C identified as an acceptable method.

EPA's Method 1668C offers several advantages over other EPA methods such as detection limit and monomer identification, it is clear it cannot be used for compliance purposes. This may be because of the limitations of the method at very low concentrations of PCBs. While 1668C can be used for investigation purposes to determine many individual monomers, it cannot be used as a basis for a regulation to set an acceptable limit of PCBs in inks.

In addition, the method cannot be used for compliance demonstration by regulated entities. Regulations need to specify what compliance demonstration procedures must be used and EPA's Method 1668C is not an acceptable method as it pertains to PCBs. Because this method is not to be used for compliance, it cannot be used to enforce a regulatory requirement that would set PCB limits below detection limits of those methods that are acceptable from a regulatory purpose.

PCB Hazards Associated with Inks

Ecology has not established an acceptable level of PCBs in inks and coatings. Ecology has just completed some initial testing of nonrepresentative inks with no acceptable data in which to compare the results and draw any conclusions. To establish an acceptable level, additional testing of inks is required to gain an understanding of the range of PCB concentrations that can be found in inks. There is no justification that can be made for a regulatory limit based on the limited testing data.

On page 59 of the report, it states the following:

*Ecology considered the hazards associated with PCBs and determined they do not meet our minimum criteria for safer, as outlined in our criteria for safer and described in the hazards of PCBs section of this chapter. Paints and inks that avoid or reduce the inadvertent generation of PCBs are considered safer alternatives in this case, because they are less hazardous. Reducing inadvertent PCBs represents a step toward eliminating them.*

*We identified paints and inks with lower PCB concentrations that are feasible and available (see the alternatives are safer, feasible, and available section(s) of this chapter). We also considered the presence of PCBs in paints and printing inks and determined that they are a significant source of PCBs to the environment and have the potential to expose people and wildlife to PCBs (see the reducing a significant source or use section of this chapter). A restriction on the presence of PCBs in paints and inks would reduce a significant current source of PCBs.*

Ecology has not demonstrated that there are inks with lower PCB concentrations are feasible and available because Ecology has not tested a representative sample of inks used by the printing industry. No information on the sampling methodology has been presented that would describe a systematic and comprehensive approach taken to describe how the inks tested were identified and chosen so that they would be considered representative of all inks used in the printing industry. The current sample is not a robust data set that leads to any conclusions regarding the range of PCBs that are present in ink systems.

Because Ecology has not established a range of PCB concentration in ink systems, it cannot conclude that placing a restriction on them would reduce the amount of PCBs being released into the environment or that the amount of reduction would be significant. Ecology needs to first establish a baseline of PCB concentrations in inks and then compare the results to the amount of PCBs found in a multitude of other PCB containing products to determine if inks are actually a significant source of PCBs. Ecology has failed to conduct this analysis, so it is not known if inks even warrant being regulated. Additional data and investigation are also needed to establish a limit that is both technically and economically feasible achievable before Ecology can conclude placing a regulatory limit would reduce PCBs being released into the environment. A single set of ink test results of nonrepresentative inks does not qualify as a robust enough dataset to support a regulation.

On page 68 of the report, it states the following:

*We determined that for CMYK inks, safer alternatives to PCBs in ink are feasible and available (Table 18). We identified insufficient data for other ink colors, so at this time, we are limiting our draft determination to CMYK inks. Restricting PCBs in inks would reduce a significant source of PCBs to people and the environment.*

From Appendix D on page 251:

*To be feasible, an alternative must meet at least one of the following criteria:*

- *Already used for the application of interest or a similar application.*
- *Marketed for the application of interest or a similar application.*
- *Identified as feasible by an authoritative body.*

*To be available, an alternative must meet at least one of the following criteria:*

- *Currently used for the application of interest.*
- *Offered for sale at a price that is close to the current.*
- *If needed, we will define "close to the current" on a case-by-case basis—relying on existing alternatives assessments and frameworks, as well as stakeholder input.*

The responses to the criteria used in Table 18 and identified in Appendix, is not appropriate to determine if safer alternatives to PCBs in inks are feasible and available. The limited testing conducted by Ecology does not support the conclusion drawn that a safer alternative for inks that are feasible exist. No information on the sampling methodology has been presented that would describe a systematic and comprehensive approach taken to describe how the inks tested were identified and chosen so that they would be considered representative of all inks used in the printing industry.

On page 69 of the report, it states the following:

*While many PCB congeners can be inadvertently generated, PCB 11 is considered a hallmark of iPCB contamination, specifically from pigments and dyes (Guo et al., 2014). PCB 11 is known to be present in many painted and printed materials, and it is not found in legacy PCB products (Heine & Trebilcock, 2018). A biomonitoring study for PCB 11 showed 65% of 85 women in the Midwest had trace levels of PCB 11 in their blood (Marek et al., 2014). In 2013, studies reported the presence of PCB 11 in air samples and in the blood of children and mothers (Marek et al., 2013; Zhu et al., 2013). A 2015 study reported PCB congeners 11, 14, 35, 133, and 209 as the most frequently detected non-Aroclor congeners in the blood of study participants (Koh et al., 2015).*

*Studies detect PCBs in residential environments from indoor air and house dust (Takeuchi et al., 2017). A study reported concentrations of PCBs in indoor air in homes and schools in East Chicago and Columbus Junction, and estimated exposures in mothers and their children (Ampleman et al., 2015). In this study, inhalation exposure was greater in indoor environments than outdoor environments, and included contributions from PCB 11, which the authors attributed to pigments and paint. PCB 11 concentrations have not decreased since 2004. In 2007, PCB 11 was found in 91% of air samples taken near 40 Chicago area elementary schools (Hu et al., 2008).*

*We determined that restricting the levels of PCBs in printing inks would reduce a significant source of PCBs and reduce the potential for human exposure.*

The statement that PCB 11 is a hallmark of iPCB contamination, and it not found in legacy PCB products is not well supported. PCB 11 is found in some Aroclors. Here is one source that contradicts the statement:

*Discovery of Non-Aroclor PCB (3,3'-Dichlorobiphenyl) in Chicago Air Dingfei Hu, Andres Martinez, and Keri C. Hornbuckle (Environmental Science & Technology 2008 42 (21), 7873-7877 DOI: 10.1021/es801823r). Here are some statements from the paper:*

- *PCB11 is reported to be nondetectable (<0.05%) in most Aroclor mixtures except in Aroclor 1221, where PCB11 is as high as 0.16% (14, 15). Using our analytical method, we found less than 0.08% PCB11 in Aroclors 1016, 1242, 1254, and 1221.*

- *The same paper reported that Non-Aroclor PCB congeners including PCB11 can be produced through reductive dechlorination (16). Zanaroli et al. found that PCB11 is one of the major metabolites of PCBs 77, 118, 126, 156, and 169 in spiked Venice Lagoon sediment microcosms (17). Rhee et al. also reported PCB11 was the only metabolite of PCB77 in Hudson River sediment incubations (18).*

Another excellent reference is the November 2020 review paper produced by Dr. Mark Vincent that was published in Ink World entitled "*PCB-11 and its Presence in the Environment*", which can be accessed at https://www.inkworldmagazine.com/contents/view_online-exclusives/2020-11-11/pcb-11-and-its-presence-in-the-environment/?userloggedin=true The paper identifies numerous mechanisms and pathways that PCB-11 can be generated, all of which are not related to it being created during certain pigment manufacturing processes.

The work being performed by the Spokane River Regional Task Force has also confirmed that pigments are not the only source of PCB-11. There was some speculation that the PCB-11 Spokane River concentration originates from discarded/landfilled printed matter or from a paper recycling operation discharging to the Spokane River. An investigation of the sources of PCB-11 was initiated culminating in a preliminary report being presented at the Task Force meeting on September 1, 2021. The preliminary reported had two significant conclusions:

- PCB11 concentrations are essentially indistinguishable from blanks in upper portion of study area (i.e., Upriver Dam and upstream).

- PCB11 concentrations in lower portion of study area are at levels greater than can be explained by known loading sources.

- The magnitude of the unexplained load appears large relative to known sources
    - Largest individual known load is 5.7 mg/day
    - Unexplained load ranges from 4 to 40 (or 72) mg/day

The presence of PCB-11 in the Spokane River wastewater from the known sources is far surpassed by the unknown sources which provides a strong indication that other sources of PCB-11 exist such as incineration, photolysis and its inadvertent presence in other non-pigment containing products. Additional work is planned to try and determine the large unexplained source of PCB-11 or if some if it is due to how the concentrations in the blanks are being applied to the test results. Interesting enough, this is another primary reason why EPA Method 1668C is not used for regulatory compliance purposes.

Regarding the indoor air quality studies cited, there seem to be some missing references. One important 2020 study *Comprehensive Subchronic Inhalation Toxicity Assessment of an Indoor School Air Mixture of PCBs* by Wang et.al. (Environ. Sci. Technol. 2020, 54, 24, 15976–15985, Publication Date: November 30, 2020, https://doi.org/10.1021/acs.est.0c04470) examined in vivo inhalation studies explored the toxicity of environmentally relevant mixtures of polychlorinated biphenyls (PCBs). The study looked at exposing rats to various concentrations and blends of PCBs including some individual PCB monomers (i.e., PCB-11 and PCB-3).

The study made several important statements regarding the source of PCBs in indoor air and PCB-11:

- Slow and continuous volatilization of PCBs from light ballasts, caulks, and sealants is the principal source of indoor PCBs.

- Hu et al.47 also compared the toxicity of a Chicago air mixture (vapor from A1242, A1254, and PCB 11) by nose-only and whole-body inhalation regimens at doses of 1320 and 1980 µg/kg bw, respectively. Diminished weight gain and decreased thyroid hormone T4 were observed in both regimens. Increased liver lipid peroxidation was only shown with the higher dose delivered nose-only. At a lower dose of 446 µg/kg bw, the effects on weight gain and T4 were no longer present, but we still observed minor changes in blood GSH/GSSG.17 Casey et al.58 observed adverse outcomes of A1242 at a much lower stated dose of 19.2 µg/kg bw, including histopathological changes in the thyroid and thymus, increases in serum T3 and T4, decrease in exploratory behavior, and diminished weight gain. However, as discussed previously,47 the Casey et al.58 study had significant shortcomings in its experimental design. Lombardo et al.59 reported hyperactivity in male rats after whole-body inhalation of A1248 at ∑PCB dose of 8.72 µg. No overt toxicity was found in our low-dose studies exposing rats to individual PCB congeners, e.g., PCB 11 (7.2 µg/kg bw) and PCB 3 (150−180 µg/kg bw).60,61

Regarding the Ampleman et al., 2015 study that attributed the presence of PCB 11 to pigments and paint, there was no direct measurement of pigments and paint to determine if they were a source of PCB-11. The authors reference a study by Hu D.; Hornbuckle K. C. Inadvertent polychlorinated biphenyls in commercial paint pigments. *Environ. Sci. Technol.* 2009, 4482822–2827. [PMC free article]. In addition, the study concluded that dietary PCB exposure was greater than inhalation exposure. Below are the key statements and conclusions from the paper:

- Sum (∑) PCB dietary exposure was greater than ∑PCB inhalation exposure for most individuals (Figure (Figure4),4), except for the EC household with highest airborne PCB concentrations (74 ± 40 ng m–3). Dairy and meat contributed the greatest amount to ingested ∑PCB, depending on the age, location, and sex of the subjects (Figure (Figure4).4). Meats contributed the greatest amount of PCBs to dietary exposure in EC, whereas dairy contributed the greatest amount of PCBs to dietary exposure in CJ (Figure (Figure4).4). Male children appear to ingest more PCBs than female children or mothers (Figure (Figure4,4, SI, Table S3). These differences arise from different food ingestion rates for males vs females and for mothers vs children.26

- Congener profiles for inhalation exposure resemble Aroclor 1248 with additional contributions from Aroclor 1254 and the non-Aroclor PCB 11. The latter congener is produced as a byproduct of paint pigment manufacturing[11] and is thus likely ubiquitous in residential and commercial buildings, especially those with green, yellow, or other organic paint pigments. Given the presence of paint in virtually all indoor environments, we expect these results to be generalizable within the U.S.

- Regarding the referenced paper by Hu and Hornbuckle, they did not perform any volatilization measurements of PCBs from the pigments tested. The methodology used to test the pigments was performed via extraction. Among the conclusions, there was a statement regarding the potential volatilization of PCB-11 that was purely speculative. In addition, it also reiterated that PCB-11 can be found in commercial Aroclor mixtures. Here is the statement from the paper:

- PCB11 is consistently detected in almost all azo and phthalocyanine pigments, and it is absent or in very low relative concentrations in commercial Aroclor mixtures. Therefore, PCB11 can be regarded as a key indicator of PCB emission from de novo synthesis as by-products of industrial synthetic process of paint pigments. PCB11 is the fifth highest congener and ubiquitous in Chicago air (4). Although we do not know the contribution of PCB congeners from paint pigments to the airborne PCBs in the environment, these congeners, especially low chlorinated congeners, might contribute a significant portion as PCB11 because of their high volatility.

In reviewing the references provided by Ecology to demonstrate the need to regulate inks and coatings due to the presence of inadvertent PCBs, due to PCB-11 being found in various environments, the references are incomplete and do not support the conclusion that inks, and coatings are the only source of PCB-11. First and foremost, contrary to the statement that PCB-11 is not present in Aroclors, two papers distinctly state the opposite that it can be found in low concentrations in some Aroclors.

Despite the speculation in some of the papers that PCB-11 is only found in inks and coatings, other research not considered by Ecology clearly indicate that this is not the case. While PCB-11 could volatilize from inks and coatings, it has not been shown by any of the researchers to occur. The researchers are only speculating based on the volatility of PCB-11. What the researchers seem to have failed to recognize is that as the pigments in the inks and paint are encapsulated by the resins that form the protective coating that prevents them from being rubbed off. It could easily be anticipated that if volatilization were to occur it would not be 100% due to the nature of dried ink and paint films.

**Safer Alternatives**

In the report, Ecology is requesting feedback on the following two items:

- Whether the safer alternatives we identified will work for the intended purpose in the products you manufacture, sell, or use.
- How these draft determinations could be implemented if we finalize them—time for compliance, existing product stocks, concentration limits, testing methods, etc.

At this time, specific feedback cannot be provided on either. Ecology has not identified any specific alternative for all ink systems used by the industry. The ink testing that has been conducted does not support nor provide any relevant or pertinent information.

Ecology also needs to be cognizant of the impact of any regulation will have on the printing industry. If the safe level is set so low based on nonrepresentative ink sampling, it could jeopardize billions of dollars of economic activity generated in the state as printing operations, publishers, and packaging operations will not be able to obtain process inks so they can produce products for their customers. Shutting down three industry segments is not a viable option to solving a perceived problem with PCBs in inks.

**Summary and Conclusion**

Based on the review of the data provided by Ecology, PRINTING United Alliance does not believe that Ecology has presented sufficient information to justify moving forward with a regulation to set PCBs levels in inks.  Nor does Ecology have the data to establish a “safer alternative” for all inks. Through the limited testing performed, Ecology misrepresented inks used by the printing, publishing, and packaging industry. Before moving forward with a regulation that could tremendously impact the Washington State printing industry sector, Ecology needs to clearly and accurately demonstrate that inks, all inks used by the industry, pose a threat to human health and the environment.

In conclusion, PRINTING United Alliance appreciates the opportunity to provide comments on Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3. If you have any questions regarding these comments, please feel free to reach out to me. My contact information is below.

Sincerely,

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