PRINTING United Alliance

December 23, 2024

Ms. Kim Morley
State of Washington, Department of Ecology
Hazardous Waste and Toxics Reduction Program
P.O. Box 47600
Olympia, WA 98504-7696

Re: Comments on Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2

Dear Ms. Morley,

These comments are being submitted today by PRINTING United Alliance (Alliance), representing the interests of those companies involved in the printing, publishing, and packaging industry. We appreciate the opportunity to offer observations and formal recommendations on the *Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2*.

As background, the printing, publishing, and packaging industry in the State of Washington is a multibillion-dollar industry that provides employment for thousands of citizens. According to the County Business Patterns 2022, published June 2024 and 2017 Economic Census collectively, there are approximately 795 establishments in Washington that employ about 12,567 people. The value of goods shipped is estimated to be $3.057 billion. For the printing industry (NAICS 323) segment, 86 percent of the establishments employ 20 or fewer employees making printing a prime example of small businesses involved in manufacturing.

The Alliance has been engaged with the Department of Ecology (Ecology) since the beginning of the Safer Products for Washington program (Safer Products) when printing inks were identified in 2020. We want to formally express our opposition to the inclusion of inks in the *Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2.* As an industry stakeholder and advocate for sustainable practices, we believe that the inclusion of inks as a priority product for further regulatory scrutiny is not warranted based on the reasons stated below.

EXECUTIVE SUMMARY

1. Inks Have Already Demonstrated Significant Safety and Environmental Improvements

> Compliance with existing and stringent regulations along with the sustainability movement have already resulted in a wide adoption of safer formulations. The narrow and limited testing performed by Ecology in *Final Regulatory Determinations Report*, *Regulatory Determinations Report to the Legislature: Safer Products for Washington Cycle 1 Implementation Phase 3*, confirmed that inks comply with EPA's very stringent limit on trace concentrations of inadvertent polychlorinated biphenyls (iPCBs).

2. Inks Are Not a Significant Contributor to Hazardous Chemical Exposure

> Ecology has not demonstrated that inks are a significant contributor of iPCBs. EPA's response to Ecology's January 4, 2024 petition clearly stated that Ecology did not present any compelling evidence that the current limit is not protective of human health or the environment. Ecology's

petition was simply a review of the current opinion of the agency and was not supported by any direct evidence that inks with iPCBs pose a threat to human health or the environment.

3. Ecology Has Not Demonstrated There Are Acceptable Non-iPCB Containing Ink Alternatives

It has taken many decades of experience and innovation to develop the inks that are being used in today's high technology printing presses. This includes resins, solvents, surfactants, additives and pigments across the multitude of ink systems that are specifically designed for printing application technologies. This means that inks are not universally interchangeable. The National Association of Printing Ink Manufacturers comments on the *Final Regulatory Determinations Report*, *Regulatory Determinations Report to the Legislature: Safer Products for Washington Cycle 1 Implementation Phase 3*, stated: "*The very limited number of inks tested for this report were of indeterminate type and are not representative of the range of commercial and packaging ink systems currently being sold. In addition, assumptions within the report about pigment compatibilities across inks systems is incorrect.*"

4. TSCA Preempts Additional Regulation of iPCBs in Inks

The contention that iPCBs present in pigments is intentional because they are present as byproducts is not based on a full understanding of the pigment manufacturing process. PCBs are not additive to this process. Rather, their presence is the result of a chemical reaction that occurs during the process, which makes them, by definition, inadvertent and not intentional. TSCA's existing ban on intentionally manufactured PCBs and limits on inadvertently created PCBs, prevents Ecology from regulating iPCBs in inks that are present as a byproduct resulting from the pigment manufacturing process.

5. Ecology's Incorrect Focus on Regulating iPCBs in Inks

The Safer Products for Washington program incorrectly assumes that any pigment used in an ink formulation that contains a chlorine atom is equivalent to one that contains iPCBs.

6. Unproven that iPCBs are the Cause of Spokane River Water Quality Issues

The inability of a paper recycling mill and other dischargers to the Spokane River and other waterways to meet the water quality standard of 7 parts per quadrillion (ppq) is not because inks are the most significant source of iPCBs in consumer products. All sources of PCBs have not been identified in the discharge of the effluent from paper recycling mill. As such, it cannot be determined that inks are the significant source. Further compounding the issue is that the 7 parts per quadrillion standard cannot be met with any existing or reasonably foreseeable future wastewater treatment technology.

7. Potential Economic and Operational Impact on Local Small Businesses

Many printing businesses have already made the transition to safer, more environmentally friendly inks voluntarily. Introducing further mandatory regulations will undoubtedly create additional financial and operational burdens without clear public health benefit. Such regulations will have a catastrophic impact on the State's economy.

DISCUSSION

1. Inks Have Already Demonstrated Significant Safety and Environmental Improvements

The printing and ink industries have long been committed to continuous improvement in terms of sustainability and chemical safety. Many companies have implemented rigorous safety protocols, including regular chemical safety assessments, third-party certifications (such as Green Seal, EcoLabel, Sustainable Green Printing Partnership, and others), and adoption of environmentally friendly processes.

Inks have undergone significant advancements in terms of both safety and environmental impact over the past several decades. Modern inks, such as digital, water-based, soy-based, and other low-volatile organic compound formulations are widely used and have resulted in substantial reductions in harmful emissions, which have benefited both the environment and public health.

Both industries are already regulated under several federal and state programs, including OSHA's hazard communication standards, EPA regulations, and state-level programs addressing chemical exposure. Furthermore, many ink manufacturers already comply with stringent environmental regulations and industry standards, such as the European Union's REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) and other U.S. regulations regarding toxic substances, especially the Toxic Substances Control Act (TSCA).

EPA's regulations under TSCA, outlined in 40 CFR Part 761, address the manufacturing, handling, remediation, and disposal requirements for polychlorinated biphenyls (PCBs), including iPCBs that are unintentionally created during industrial processes, in products and waste. Under Section 6(e) of TSCA, iPCBs are subject to strict limits allowing 25 parts per million concentration on average, not to exceed 50 parts per million. These concentrations are considered trace amounts and are designed to minimize human and environmental exposure to PCBs.

Inks and their components are manufactured to comply with the TSCA limits set out at 40 CFR 761.1(d). The presence of iPCB's in pigments and inks has been reduced over time. The narrow and limited testing performed by Ecology and reported in *Final Regulatory Determinations Report*, *Regulatory Determinations Report to the Legislature: Safer Products for Washington Cycle 1 Implementation Phase 3*, confirmed that inks comply with EPA's very stringent limit on trace concentrations of iPCBs.

EPA's website on inadvertent pigments contains a statement from the Food and Drug Administration (FDA) regarding its position about iPCBs:

> *The concentrations of iPCBs found in products are generally lower than the Food and Drug Administration's tolerances for PCBs in food and food packaging. The FDA recognizes PCBs as an unavoidable, environmental contaminant and set temporary food tolerances for PCBs ranging from 0.2 to 1.5 ppm, and a tolerance of 10 ppm in paper packaging in direct contact with food. Refer to 21 CFR 109.30(a).*

Compliance with existing and stringent regulations along with the sustainability movement have already resulted in a wide adoption of safer formulations. Given the progress made, further regulatory interventions may be unnecessary and could undermine the innovation already in motion.

2. Inks Are Not a Significant Contributor to Hazardous Chemical Exposure

Ecology contends that inks are a "significant" source of PCBs to the environment, as reiterated in this report. As noted in prior comments submitted by the Alliance and the National Association of Printing Ink Manufacturers (NAPIM), we do not believe that Ecology has met its obligation to identify inks as a "significant source" of PCB contamination. Those comments are attached for reference and are to be considered part of this submission.

When printing inks were identified for Safer Products in 2020, Ecology concluded that "colored pigments contained in inks are the largest source of inadvertent PCB contamination in consumer goods". However, to the best of our knowledge and research, Ecology's conclusion was not supported by any specific references, studies, or other supporting documentation. It appears that Ecology did not follow any recognized scientific protocol(s) that examine the multitude of products and other sources that contain iPCBs, evaluate potential releases from these sources, or perform a ranking based on a true risk assessment. Ecology also did not ascertain if the presence of the iPCBs in inks poses a threat to human health or the environment.

There is a reference in Ecology's PCB Chemical Action Plan to pigments and dyes along with a variety of other sources of PCBs. The estimate of annual releases from pigments and dyes was based on PCB-11 and the amount released was stated to be significantly less than other sources. For example, the category "Other Inadvertent" generation had an estimated annual release of 900 kg/yr compared to an estimated range of 0.02 to 31 kg/yr for pigments and dyes. There was no methodology provided for how the estimated releases were determined.

The pigments and dyes category are not limited to the incorporation in inks. Pigments and dyes are used in many products, not just inks. As such one can only conclude that the amount released due to inks, a component of the category, is much less than what is included in the estimated amount. Further, the releases identified in the report are only estimates and not measured values.

Ecology reached the aforementioned conclusion at the beginning of the Safer Products evaluation process in 2020 prior to conducting tests on any inks for the presence of PCBs. Ecology did not test any inks for the presence of iPCBs until late 2021 and then only tested a limited number of inks which means that the evaluation and related reported results are not representative of the wide range of inks used in printing applications.

The process that Ecology uses to determine if a chemical or a chemical in a product is "significant" is based on the criteria specified in Chapter 70A.350.030 RCW which includes:

> *(a) The estimated volume of a priority chemical or priority chemicals added to, used in, or present in the consumer product;*
>
> *(b) The estimated volume or number of units of the consumer product sold or present in the state;*
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> *(c) The potential for exposure to priority chemicals by sensitive populations or sensitive species when the consumer product is used, disposed of, or has decomposed;*
>
> *(d) The potential for priority chemicals to be found in the outdoor environment, with priority given to surface water, groundwater, marine waters, sediments, and other ecologically sensitive areas, when the consumer product is used, disposed of, or has decomposed;*
>
> *(e) If another state or nation has identified or taken regulatory action to restrict or otherwise regulate the priority chemical in the consumer product;*
>
> *(f) The availability and feasibility of safer alternatives; and*
>
> *(g) Whether the department has already identified the consumer product in a chemical action plan completed under chapter **70A.300** RCW as a source of a priority chemical or other reports or information gathered under chapter **70A.430**, 70A.405, 70A.222, 70A.335, 70A.340, 70A.230, or **70A.400** RCW.*

Ecology stated that it is not required to weigh each criterion equally or consider all of them. No specific information has been shared regarding how each or any of these criteria have been weighted in determining if inks are a "significant" source of iPCBs. Consequently, there is considerable latitude with no predictability regarding how a product is deemed to be a "significant contributor" of a specific chemical.

The criteria for selection of consumer products requires Ecology to consider both exposure potential and potential for contamination in the environment. These aspects are critical to the determination of significance, but Ecology has not identified actual release or exposure to iPCBs caused by inks. The references cited by Ecology in *Final Regulatory Determinations Report, Regulatory Determinations Report to the Legislature: Safer Products for Washington Cycle 1 Implementation Phase 3*, do not show a direct relationship between the presence of iPCBs in inks and exposure to humans. The references cited by Ecology as a basis for exposure appear to be largely theoretical and not based on any measured values. There are no studies that show any direct exposure of iPCBs that are contained in ink.

During the 2023 legislative session, the legislature, pursuant to RCW 70A.350.100, required Ecology to develop and submit a petition to EPA. The TSCA Section 21 petition requires Ecology to demonstrate that iPCBs in ink, coatings, and other consumer products present a threat to human health and the environment. Specifically, the entity filing a TSCA Section 21 petition under 15 USC 2620 (b)(1) is required to:

> "*set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title."*

EPA's response to Ecology's January 4, 2024 petition and ultimate denial confirms that Ecology failed to establish a compelling argument and presented only limited justification for choosing inks as a significant source of iPCBs. In the denial of the petition, published on April 9, 2024 in the Federal Register (89 FR 24824), EPA concluded that Ecology failed to identify specific deficiencies in EPA's previous rulemaking when it set the TSCA PCB limits. Ecology did not meet the burden of establishing the necessity to amend the existing rule. EPA did acknowledge the concerns regarding PCBs but will continue to gather information and assess the risks associated with inadvertently generated PCBs:

> *"…the petition failed to point with any specificity to deficiencies in the Agency's promulgation of the 1984 final rule and determination of no unreasonable risk under TSCA section 6(e). As a result, the petitioner has not provided adequate justification – based on the rulemaking process and record for the 1984 final rule, as well as information provided or otherwise available to the Agency – for the requested actions. Thus, the EPA finds that the petition is insufficiently specific and that the petitioner did not meet their burden under TSCA section 21(b)(1) of establishing that it is necessary to amend the 1984 final rule under TSCA section 6(e). Therefore, after careful consideration, the EPA has denied the petition for the reasons set forth in this notice."*

Ecology's petition was more of a summary and review of existing studies which lack direct evidence that inks with iPCBs pose a threat to human health or the environment. There was no new supporting risk assessment that indicated iPCBs in ink require further regulation.

A critical missing component of Ecology's assessment of inks is the presentation of a comprehensive review of all iPCB containing products and sources. To clearly identify sources of PCB levels in waterways, Ecology needs to conduct a source-to-receptor assessment using widely accepted protocols. Without an assessment, major sources, including legacy sources, are not addressed as part of the Safer Consumer Products regulatory process. This removes any real protection of aquatic species and results in regulation that does not significantly reduce PCBs in the environment.

Ecology has not satisfied its statutory obligation to select a product(s) with any level of priority, chemical and/or low exposure potential. The failure to identify the largest contributors of PCB contamination creates a deficiency in Ecology's investigation. It is further concerning that a conclusion was reached without full analysis and related data supporting such a conclusion that inks are the most significant source of iPCBs in consumer products. Additional work on ink without completing the appropriate investigation should be suspended.

3. Ecology Has Not Demonstrated There Are Acceptable Non-iPCB Containing Ink Alternatives

70A.350.030 RCW requires Ecology to consider the safety, feasibility and availability of alternatives. Ecology's *Final Regulatory Determinations Report*, *Regulatory Determinations Report to the Legislature: Safer Products for Washington Cycle 1 Implementation Phase 3*, states that such alternatives to PCB-containing printing inks exist and are readily available in the marketplace. However, Ecology has not provided any supporting information or data to support this statement. Ecology has not revealed what factors were used to determine that an "acceptable safer, feasible, and available alternative" exists. While some of the factors required for the determination were identified in the PCB Chemical Action Plan, no discussion of any of them were presented for review and comment.

NAPIM offers further confirmation in its previous comments:

> *In our view, the conclusions outlined in Chapter 2 – Priority Product: Printing Inks of the subject draft report show a fundamental misunderstanding of ink formulation, color science and production of commercial and packaging printing.* ***Specifically, there is no valid, scientific basis for the subject report's conclusion that non-inadvertent polychlorinated biphenyl (iPCB) containing inks are feasible and available as total market replacements for all current ink systems****. The very limited number of inks tested for this report were of indeterminate type and are not representative of the range of commercial and packaging ink systems currently being sold. In addition, assumptions within the report about pigment compatibilities across inks systems is incorrect.*

There are many factors involved in determining an acceptable alternative pigment that include its physical characteristics, performance characteristics, level of fastness (resistance to light, solvents, heat, chemicals, etc.), optical qualities, ability to be printed using all the printing technologies, and economic considerations. Given the vast differences in printing application technologies, inks and their components are not universally interchangeable. As such, if a given pigment is in a certain color class such as yellow, it cannot be assumed that any yellow pigment can serve as a universal alternative.

A single attribute such as visual appearance cannot be the sole basis for identifying alternatives. Rather a proper evaluation requires extensive testing and measurement of critical parameters which requires significant investment in research and development, evaluation, and testing to ensure that the inks will perform across a multitude of printing applications/technology and use of the finished product. Printing inks must be designed for specific applications and some of them are driven by regulations under the Food and Drug Administration, Consumer Product Safety Commission, Department of Defense, and other agencies. For example, warning stickers printed for lawn mowers and other similar power equipment must be able to withstand the conditions of use for the equipment and not fade.

The Spokane River Regional Task Force, disbanded, proposed to conduct an evaluation of two yellow inks. The purpose was to compare the "performance characteristics" of an ink with a pigment containing iPCBs to one that would have "minimal", defined as less than 500 parts per billion, iPCBs. While a protocol was not developed, a Quality Assurance Project Plan (QAPP) was created in 2023. The QAPP plan provided an outline of the evaluation but did not contain any meaningful details or specifics regarding the conduct of an evaluation such as the type of ink to be used, the printing process used to print the product, the type of product to be printed and, most importantly, the parameters, except for a visual comparison, to be recorded and analyzed.

Valid testing requires numerous parameters to be measured, observed, recorded, and analyzed in addition to a visual comparison. Furthermore, yellow ink is not an ideal ink to use for such a comparison due to the visual characteristics of yellow ink. While the QAPP indicated that the inks would be tested for the presence and concentration of iPCBs, it did not indicate if other input materials such as other ink components, substrate, fountain solution (if offset lithographic printing will be used) would be tested for the presence of iPCBs. Extensive comments were submitted on the QAPP in 2023.

If Ecology wants to use the results as a basis to support its assertion that "alternative" pigments and inks are feasible and available, the QAPP requires revision. Most importantly, any resulting conclusion regarding the pigment used in the low iPCB containing ink must be qualified as a single evaluation which cannot be universally applied to all ink used to print all products. If a "successful evaluation" is achieved, it must be qualified to clearly state that the evaluation was limited to one type of ink with one specific product printed. For example, using news ink, which is an ink formulated to print on newspaper via the offset lithographic printing process, is limited to that specific ink formulation printing on the relatively unique light weight paper made for newspapers. The results cannot be extrapolated to any other product printed with a different ink type such as sheetfed or heatset web offset lithographic ink due to the significant differences in ink formulation and performance characteristics required by each of the different presses and products produced. Furthermore, the single evaluation results cannot be extrapolated to a product produced with any other printing process such as flexographic, screen, digital, etc. due to the unique characteristics associated with each printing ink and printing technology.

4. TSCA Preempts Additional Regulation of iPCBs in Inks

In June 2022, Ecology published its interpretation in its *Final Regulatory Determinations Report*, *Regulatory Determinations Report to the Legislature: Safer Products for Washington Cycle 1 Implementation Phase 3* regarding its implementation of Safer Products for Washington, that iPCBs inks and coatings could not be regulated due to preemption by the Toxic Substances Control Act (TSCA). In the *Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2,* Ecology reverses its previous position stating that it now believes that it is not preempted by TSCA and has the authority to regulate iPCBs in inks.

The June 2022 report states the following (page 90):

> *Reducing PCBs in these inks to a level closer to what we identified in this report would reduce a significant source of PCBs to people and the environment. However, because we believe we are preempted by federal Toxic Substances Control Act (TSCA) regulations, our regulatory determination on PCBs in printing inks is no action.*

In the 2024 report, *Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2,* Ecology provides no specific analysis or legal review to support its new interpretation. The report provides two statements in support of its new position (page 30):

> PCBs in Washington waterways impact sensitive species. In our 2022 Regulatory Determinations Report to the Legislature, 47 we found that lower concentrations of PCBs were feasible and available, but we believed the way we defined the category limited our ability to set a *different limit* than EPA and we declined to take regulatory action at that time. *However, we don't believe we're pre-empted from prohibitions on the use of PCBs in products. 48*
>
> Since our 2022 report, several factors have led us to reconsider PCBs in printing inks:
>
> > • *During the 2023 legislative session RCW 70A.350.10049 was amended to include a legislative finding that the "use of manufacturing processes resulting in products with*

PCB by-products isn't inadvertent, but intentional, and constitutes a use of the chemical within the product."

• Washington's current water quality standard for PCBs is 7 parts per quadrillion and EPA is proposing a limitation on discharges to the Spokane River at 1.3 ppq (US EPA, 2024).

• These water quality standard levels are extremely low compared to EPA's 25 ppm annual and 50 ppm maximum limits on PCBs in pigments used in inks. Based on the definition of PCBs by EPA, a dichlorinated PCB found in yellow pigments, PCB-11, is allowable at up to 250 ppm in pigments if it is the only PCB present.

• Wastewater treatment technology hasn't kept up with efforts to limit PCBs in the environment and therefore pollution prevention is necessary (Association of Washington Business et al., 2022).

Footnote 48 (page 30) states:

The US Environmental Protection Agency's rule exempting inadvertently generated PCBs below specified concentrations from the Toxic Substances Control Act's (TSCA's) ban on PCBs was promulgated under 15 USC Sec. 2605. 15 USC Sec. 2617(d)(2)(B), preserves state preemption as it was in effect under the TSCA prior to the Frank R. Lautenberg Chemical Safety for the 21st Century Act with respect to rules promulgated by the Environmental Protection Agency under 15 USC Sec. 2605. Pre-Lautenberg Act TSCA Sec. 18(a)(1)(B) saved from preemption state requirements applicable to an article containing a chemical substance for which the EPA Administrator prescribed a rule under 15 USC Sec. 2605 if the State "prohibits the use of such substance or mixture in such State . . .."

Pursuant to RCW 70A.350.100 the legislature ordered Ecology to submit a petition to EPA to request them to revise the iPCB limits. This legislation that includes:

(5) While previous industry analysis of toxic substances control act rule making has asserted negative impacts and infeasibility in disallowing by-product PCBs, the legislature finds that safer, feasible, and available alternatives to PCB-containing paints and printing inks now exist, as determined by the department in its June 2022 Safer Products for Washington report. Moreover, since safer and available products and processes to produce paints and printing inks do exist, the legislature finds that use of manufacturing processes resulting in products with PCB by-products is not inadvertent, but intentional, and constitutes a use of the chemical within the product.

A footnote is intended to provide additional interpretation to legislative intent but is not to be confused with legal authority to regulate iPCBs in ink. The footnote is not relevant to the legislation directing Ecology to petition EPA to reduce or eliminate the presence of iPCBs in "excluded manufacturing processes". Further, the note is contradictory. By definition, "excluded manufacturing processes" are those that generate inadvertent PCBs. The note states that the legislature does not think the PCBs found in ink are inadvertent but are deliberate. However, if this is the case, the ink would be prohibited from being sold pursuant to Section 6(e) of TSCA which prohibits the sale of products that contain intentionally manufactured PCBs.

The issue of inadvertently generated PCBs was addressed by EPA in the definitions found in 40 CFR 761.3 in which EPA clarifies that incidental formation of PCBs during a manufacturing process, or an excluded PCB product means that it is an undesired byproduct or impurity, as opposed to PCBs that were made for their commercial value (i.e., aroclors). Excerpts from the key EPA definitions:

- *Excluded manufacturing process means a manufacturing process in which quantities of PCBs, as determined in accordance with the definition of inadvertently generated PCBs, calculated as defined, and from which releases to products, air, and water meet the requirements of paragraphs (1) through (5) of this definition, or the importation of products containing PCBs as unintentional impurities, which products meet the requirements of paragraphs (1) and (2) of this definition.*

  > *(1) The concentration of inadvertently generated PCBs in products leaving any manufacturing site or imported into the United States must have an annual average of less than 25 ppm, with a 50 ppm maximum.*

- *Excluded PCB products means PCB materials which appear at concentrations less than 50 ppm, including but not limited to:*

  > *(1) Non-Aroclor inadvertently generated PCBs as a byproduct or impurity resulting from a chemical manufacturing process.*

- *Byproduct means a chemical substance produced without separate commercial intent during the manufacturing or processing of another chemical substance(s) or mixture(s).*
- *Impurity means a chemical substance which is unintentionally present with another chemical substance*
- *PCB and PCBs means any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees or any combination of substances which contains such substance. Refer to § 761.1(b) for applicable concentrations of PCBs. PCB and PCBs as contained in PCB items are defined in § 761.3. For any purposes under this part, inadvertently generated non-Aroclor PCBs are defined as the total PCBs calculated following division of the quantity of monochlorinated biphenyls by 50 and dichlorinated biphenyls by 5.*

40 CFR 761.3's definitions of Excluded Manufacturing Process and Excluded PCB Products define inadvertently generated PCBs as being byproducts or impurities resulting from the manufacturing process. PCBs are not used in the manufacturing process of any pigment. Their presence is due to a chemical reaction that occurs during the manufacturing process, which makes them, by definition, inadvertent. The PCBs created are a byproduct of the process and cannot be characterized as intentional.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law on June 22, 2016. The law contained many provisions including one that preempts states from taking action if EPA has started or completed an action on a chemical. Section 6(e) of TSCA, basically unchanged by the Lautenberg amendments, instructed EPA to ban the manufacture, processing, distribution, or use of PCBs by 1979, subject to activities that do not pose an unreasonable risk. In the regulations, EPA allowed for the inadvertent generation of PCBs in "excluded manufacturing processes" [40 C.F.R. § 761.1(f)(1)].

The Lautenberg amendments made dramatic changes to Section 18 of TSCA preempting states from regulating or banning chemicals once they are subject to EPA action. States are not allowed to impose more stringent requirements unless they are authorized by specific federal action or are consistent with federal regulations. While there are some exceptions to the preemption, none are applicable to Ecology's desire to regulate iPCBs in ink. The State had not regulated or passed legislation prior to EPA's regulations on PCB, which would be the most applicable exemption. The intent behind this provision is to establish a uniform standard for chemical safety across the country, preventing a patchwork of state regulations that could create inconsistencies and barriers to commerce.

Section 18 also restricts state authority to adopt stricter chemical regulations than those established by the EPA once the Agency has acted on a chemical under TSCA. EPA's existing ban on intentionally manufactured PCBs and limits on inadvertently created PCBs, prevents Ecology from regulating iPCBs in inks that are present as a byproduct resulting from the pigment manufacturing process. The preemption by Section 18 TSCA covers both situations.

5. Ecology's Incorrect Focus on Regulating iPCBs in Inks

PCBs are not used in the manufacturing of any pigment. While a pigment may contain a chlorine atom in its chemical structure, it cannot be assumed that it contains iPCBs because they are different chemical entities. iPCBs are created as a byproduct during the manufacture of certain pigments that contain chlorine. Consequently, the Safer Products for Washington program incorrectly assumes that any pigment used in an ink formulation that contains a chlorine atom is equivalent to one that contains iPCBs.

Nearly 150 pigments contain chlorine in their chemical structure, including those used in four-color process printing. Banning chlorine containing pigments or inks with iPCBs will effectively shut down the printing and packaging industry in the State. Ecology's limited testing of certain inks indicates that iPCBs are found in inks that have pigments that do not contain chlorine. The best example is the test results for red ink. The pigment used in process red ink does not contain chlorine in its pigment chemical structure, yet Ecology's test results show that red ink contains iPCBs. Since iPCBs should not be present in the pigment, additional investigation regarding the source is warranted. Until the source of iPCBs is known, Ecology would not be able to demonstrate a definitive understanding of what ink component needs to be regulated, if at all, because the source of iPCBs could be due to contamination.

Ecology appears to be concerned about a potentially theoretical concentration of PCB-11, a known PCB congener which can be found in some diarylide yellow pigments. The statement found on Page 30 of the *Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2* report (page 30) states:

> *These water quality standard levels are extremely low compared to EPA's 25 ppm annual and 50 ppm maximum limits on PCBs in pigments used in inks. Based on the definition of PCBs by EPA, a dichlorinated PCB found in yellow pigments, PCB-11, is allowable at up to 250 ppm in pigments if it is the only PCB present.*

Pigments that have inadvertent PCBs do not contain only a single iPCB. Ecology's test data on inks found that none of them contained iPCBs approaching 250 ppm. The testing showed that all inks met EPA's TSCA limit of 25 ppm not to exceed 50 ppm on average.

PCB-11 is commonly used as an indicator that the source of contamination must only be diarylide yellow pigment, but it has not been proven. Ecology's petition to EPA includes several references that speculate that this is the case, but neither the papers nor the information presented by Ecology are definitive. In fact, an article written by Dr. Mark Vincent published in Ink World and previously provided to Ecology, identifies numerous pathways as to how PCB-11 can be found in the environment.

Not all PCB congeners exhibit the same behavior regarding bioaccumulation, especially PCB-11. Ecology's own fish tissue testing data (personal correspondence with, Brandee Era-Miller, Freshwater Fish Contaminant Monitoring Program: 2012 Results, SRRTTF_FishTissuePCBReport_07-30-2021_final.pdf, and http://srrttf.org/wp-content/uploads/2023/05/4-SRRTTF_2022_FishTissuePCBReport_05-17-2023_ProvisionalFinalDraft.pdf) indicates that PCB-11 does not appreciable bioaccumulate, if at all.

6. Unproven that iPCBs are the cause of Water Quality Issues

Ecology's focus on iPCBs in inks stems from the inability of a paper recycling mill and other dischargers to the Spokane River and other water bodies to meet the water quality standard of 7 parts per quadrillion (ppq) and not because inks are the most significant source of iPCBs in consumer products. The paper recycling mill claims that it cannot comply with the limit because of the iPCBs in the ink on the paper being recycled. However, this is still unproven because not all sources of PCBs have been identified in the discharge of the effluent from paper recycling mill. For example, titanium dioxide can contain iPCBs and this chemical can be used in the paper manufacturing process to make certain types of papers. Since it is present in some papers, it can also be a source of PCBs in the mill's effluent. There are other possible sources of PCBs as well such as incoming water. Even though the PCB concentration in incoming water cannot be utilized in determining compliance, it is still a source of PCB and a complete accounting of all sources needs to be prepared

Nevertheless, the issue is the water quality standard and not the presence of trace concentrations of iPCBs in ink or the treatment technology being used by the paper recycling mill to treat its effluent. The paper mill has installed the most advanced treatment technology for its wastewater discharges, and it still fails to meet the standard. This is because the water quality standard is not reliably measurable or enforceable. At 7 ppq, the standard is not possible to meet.

In December 2023, a lawsuit was filed to challenge the water quality standard. The lawsuit, *Association of Washington Business, et al. v. United States Environmental Protection Agency*, et al.,1:23-cv-03605 (D.D.C. 2023) was brought because EPA created an unattainable standard with no reasonable path to compliance. EPA adopted a standard that cannot be met with any existing or reasonably foreseeable future wastewater treatment technology.

Regulating the level of iPCBs in ink or other products to zero is not an achievable standard due to the ubiquitous presence of PCBs in the environment. The level of iPCBs in printing ink that would theoretically allow the paper recycling mill to achieve compliance with the water quality standard is unknown. To justify a limit other than "less that is allowed by EPA under TSCA", Ecology is tasked to provide an analysis complete with supporting technical data indicating the concentration of iPCBs in inks that would allow the paper recycling mill to meet the 7 ppq standard. It is quite possible that even if there was no iPCB in the printed paper being recycled, the mill would still not meet the 7 ppq standard.

7. Potential Economic and Operational Impact on Local Small Businesses

Banning approximately 150 pigments that contain chlorine based on unproven assumptions would cripple the printing industry. Also caught in the ban will be titanium dioxide, a pigment that is used in many inks, either alone in white inks or as an additive to other inks. A ban on these pigments will completely shut down the printing and packaging industry in the State of Washington which ships goods valued at approximately $3.057 billion. The resulting loss of employment and negative impact to the State's economy, by any measure, will be significant.

The total impact on the State's economy is almost incalculable as it will destroy established supply chains. The printing and packaging industry's products are used by its customers in the pursuit of their business. For example, a packaging converter only makes the package, which is sent to its customer, who fills the package with their product to be distributed into commerce. If the converter's customer cannot have their package printed with the contents, images, directions, etc., they cannot sell their product. The amount of loss to the economy pales in comparison with the value of the goods shipped by the printing and packaging industry. It is not clear how consumers would be able to obtain essential goods.

Many printing businesses have already made the transition to safer, more environmentally friendly inks voluntarily. Introducing further mandatory regulations will undoubtedly create an additional financial and operational burden without a clear public health benefit.

CONCLUSION

The Alliance fully supports efforts to improve the safety and environmental footprint of products in the State of Washington; however, we respectfully oppose the continued inclusion of inks as a priority product under the *Safer Products for Washington Cycle 2 Implementation Phase 2*. Ecology has not fulfilled its obligations under the Safer Products Program by concluding that iPCBS in inks are a priority chemical that requires regulation. Ecology did not fully consider the required factors of exposures, potential exposures, sensitive populations, feasibility and availability of alternatives, estimated volumes of the priority chemical in priority products, volumes of priority product sold in the state and regulatory actions in other jurisdictions and by the agency in their entirety. Lastly, Ecology is prohibited by TSCA from regulating iPCBs in inks. TSCA is very explicit in defining the actions and limitations that regulatory authorities can take regarding iPCBs.

If you have any questions regarding these comments, please feel free to reach out to me. My contact information is below.

Sincerely,

Gary Jones,
Vice President, Environmental Health & Safety
gjones@printing.org
(703) 359-1363

January 27, 2022

Ms. Cheryl Niemi
Hazardous Waste and Toxics Reduction Program, Washington Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7696
cheryl.niemi@ecy.wa.gov

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.

<u>PCB Hazards Associated with Inks</u>

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.

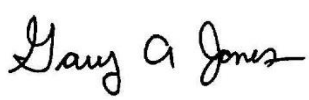
Ecology also needs to be cognizant of the impact of any regulation will have on the printing industry. If the safe level is set so low based on nonrepresentative ink sampling, it could jeopardize billions of dollars of economic activity generated in the state as printing operations, publishers, and packaging 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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Cheryl A. Niemi
Hazardous Waste and Toxics Reduction Program
Department of Ecology
P.O. Box 47600
Olympia, WA 98504

Ref: Safer Products for Washington program – Printing Inks

Dear Cheryl,

Following is relevant information which may be helpful to your team in reaching an accurate, reliable assessment of typical inadvertent PCB (iPCB) concentrations in printing inks. Overall, the apparent simplicity of ink on substrate belies its complexity. An enormous amount of research, development, technology and customization is required to produce these specialty chemical products to meet exacting and specific requirements.

- There are multiple, major Ink types: lithographic, letterpress, flexographic and gravure. Within each of these categories there are subcategories including conventional, energy curable, water based and solvent based. Each one of these categories and sub-categories represent substantial formulation/composition differences.
- Formulation differences: (differences in pigment types and loading, solvent, vehicles, binders, additives based on print process, substrate, color specifications, costs, etc.). The formulation differences are required to provide specific end use properties (e.g. lightfastness, heat resistance, abrasion resistance, product resistance, weathering, etc.)
- Differences between ink manufacturers: (There are approximately 240 US ink companies. Small companies can have thousands of significantly different formulations, larger companies 10 times that number or more)
- Printing ink input raw materials are sourced from multiple suppliers who themselves have multiple suppliers for input raw materials. Input raw material suppliers are changed routinely based on costs, quality and other factors.
- The ink industry conducts commonly accepted, routine quality testing of input raw materials. Testing of each ink formulation is not possible or practical.
- Printing Applications (e.g. lithographic, flexographic, gravure, etc.): Application rates and coverage differ among print jobs based on color. performance requirements and other factors.
- Color specification: Color reproduction is critically important. Print jobs are spectrophotometrically measured; print jobs that do not meet predetermined color specification requirements are rejected.
- Small one-off products (5 gallons or less), custom formulated products are common within the industry.

In our view, consideration (and incorporation) of the factors noted above is essential in developing and conducting any testing program designed to establish and accurate assessment of iPCB concentrations in printing inks.

Please feel free to contact us if you have any questions.

Best Regards,

George R. Fuchs

Director – Regulatory Affairs and Technology

NATIONAL ASSOCIATION OF PRINTING INK MANUFACTURERS
napim
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Ref. Washington State Department of Ecology – Draft Regulatory Determinations Report to the Legislature – Safer Products for Washington Implementation Phase 3

Overview/Summary

In our view, the conclusions outlined in Chapter 2 – Priority Product: Printing Inks of the subject draft report show a fundamental misunderstanding of ink formulation, color science and production of commercial and packaging printing. Specifically, there is no valid, scientific basis for the subject report's conclusion that non-inadvertent polychlorinated biphenyl (iPCB) containing inks are feasible and available as total market replacements for all current ink systems. The very limited number of inks tested for this report were of indeterminate type and are not representative of the range of commercial and packaging ink systems currently being sold. In addition, assumptions within the report about pigment compatibilities across inks systems is incorrect.

Discussion

There are multiple, major Ink types: lithographic, letterpress, flexographic, gravure, screen and digital. Within each of these categories there are subcategories including conventional/oil-based, energy curable (both ultraviolet cured and electron beam cured), water based and solvent based systems. Major ink types are not interchangeable (e.g. a flexographic ink cannot be used on an lithographic press, etc.) and have very different chemical compositions.

The raw material selection process for each of these ink systems is critically important and different for each system. Minimally, the selection of the component raw materials is driven by the print process to be used, printing substrate, color specifications, printed article performance properties, end use requirements, costs, etc. In the design of any multi-component system individual materials compatibilities is a critically important consideration. Input raw materials, including pigments, that function well in water-based inks cannot generally be used effectively in oil-based or solvent based systems.

Printing ink pigments are organic chemicals and while they are synthesized to be inert – the synthesis is predicated on a specific target medium (described above). Paste inks use oils for solvents, fluid inks may use water or alcohols for solvents, energy cured inks use monomers as solvents. A pigment that is stable in an oil (e.g. PY12, etc.) will be dissolved and lose all color in alcohol. This is similar for blues and particularly so for magentas.

Following are descriptions from the *Printing Ink Manual* on the pigment selection process for gravure and flexographic inks:

Gravure ink pigment selection - "The initial factor in pigment selection is that it should be chemically suitable for the end use application e.g. an acidic pigment should not be adopted for a design requiring alkali resistance. Secondly, the pigment should disperse readily in the selected vehicle system giving an ink with near Newtonian flow properties which when reduced to press viscosity will give good gravure printability. Thirdly, the pigment must exhibit good dispersion stability both as ink supplied and also at press viscosity since press returns may be stored for lengthy periods prior to reuse[1]."

Flexographic ink pigment selection - "Pigments used in flexographic inks will have similar specification requirements to those used for other processes. Irrespective of the properties required by the end use of the print, suitable pigments will be chosen for their wettability and dispersion characteristics in the various solvents and resins systems that are used[2]."

Another important pigment consideration is surface chemistry. Ink system pigment concentrations (especially in the 15% - 25% range) require critical adjustments to pigment surface chemistry necessary to keep the pigments in solution. Pigments do not like to be separated they want to flocculate and agglomerate. These surface chemistries differ between pigment type and ink system which means each ink and pigment combination are unique to that application.

Furthermore, the pigment selection characteristics and processes noted above are similar for all types of commercial and packaging inks, which cover a range of printing application technologies.

In consideration of Ecologies statements in the draft report regarding composition similarity of ink systems please note that the reference, (NAPIM, 2019 p.67), in the draft report points to a presentation made to the DoE in 2019 by NAPIM. This presentation was intended as an introduction to printing ink and printing ink manufacturing. It made of use of simple, example ink formulations intended to illustrate the basic structure and composition of various ink types. These basic examples were meant to show the basic chemical types and percentages and in no way intended to represent any production ink system.

<u>Conclusion</u>
There are critical, functional differences among commercial and packaging ink types. Commercial and packaging printing inks are complex, multi-component systems which are specifically formulated to meet critical end-use properties and requirements. They are not generic, interchangeable commodity products.

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[1] "Printing Ink Manual Fifth Edition" ed. R.H. Leach, R.J. Pierce, (Blueprint – an Imprint of Chapman and Hall), 491

[2] Ibid, 562

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There are approximately 240 US ink companies. Small ink companies can have thousands of significantly different formulations for multiple ink types, larger companies can have 10 times that number or more (see October 18, 2021 memorandum Fuchs to Niemi attached). DoE's test sample of twenty ink systems is not sufficient as the basis for regulating commercial and packaging ink systems. Therefore, additional sampling and testing of representative inks needs to occur before a complete understanding of the range of potential PCBs in ink systems can be correctly understood. Ecology has not established sufficient data to move forward with a regulation.

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