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;*
>
> *(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.

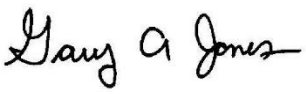
Many printing businesses have already made the transition to safer, more environmentally friendly inks voluntarily. Introducing further mandatory regulations will undoubtedly create an additional financial and operational burden without a clear public health benefit.

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,



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