American Coatings ASSOCIATION℠

July 30, 2021

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RE: Safer Products for Washington – ACA Comments on June 1, 2021, Inadvertent Polychlorinated Biphenols in Paint Webinar

Dear Ken:

As a follow-up to the June 1, 2021, State of Washington Department of Ecology (Ecology) paint webinar, the American Coatings Association (ACA)[1] is providing this comment letter to continue to assist Ecology in preparation of its report to the State Legislature on potential restrictions on inadvertent polychlorinated biphenols (iPCBs) in paints. As we've noted in our conversations, ACA would like to work with Ecology towards implementing an effective program that is based on a clear and accurate understanding of products causing contamination and their impact on health and the environment. We are hopeful that, with continued communication, we can achieve this common goal. We look forward to discussing these comments in detail during our August 5 call.

A brief summary of ACA's key points are listed here, followed by further detail below.

- The federal U.S. Environmental Protection Agency (EPA) already has established protective risk-based limits on iPCBs in products and has reviewed several paint pigments. In addition, the U.S. Food and Drug Administration (FDA) has set risk-based limits for PCBs in food and packaging.

- Additional risk assessment/source assessment activities should be conducted before proposing state restrictions that are significantly lower than current international and federal levels for PCBs.

[1] The American Coatings Association (ACA) is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory, and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services.

- EPA Safer Choice concludes that pigments that contain iPCBs and are used in the paint industry are of low concern. ACA suggests Ecology take follow the risk-based criteria used by Safer Choice Program and conclude these pigments "safer."

- A June 15, 2021, report by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) provides new and relevant data and conclusions regarding iPCBs in pigments that Ecology should consider prior to enacting iPCB restrictions in paint.

- Even though many of the paint products that Ecology cited in the Legislative report may have met the suggested10 and 25 ppb prohibition levels, ACA believes that the testing data is not representative nor reliable since it likely did not include deep tone paint products containing higher amounts of pigments. As a result, the 10 and 25 ppb prohibition levels are too low.

- The potential restrictions of 10 ppb or 25 ppb discussed on the June 1 webinar should be revised based on this new data. Based on the ETAD data, batch-to-batch pigment variations, test method 1688c issues, and unavailability of pigment supply issues, ACA suggests Ecology adopt a 350 ppb prohibition level in paints, which equates to 5 ppm in pigments and is a nearly 80% reduction from the current EPA limit of 25 ppm (average).

- To properly account for the differing levels of concern for the various PCBs, the concentration is calculated following division of the quantity of monochlorinated biphenyls by 50 and dichlorinated biphenyls by 5. Ecology always should follow this established approach to calculating iPCB concentrations.

- Regarding scope, ACA suggests Ecology exempt any paints that are certified or regulated by the Federal Aviation Administration or Department of Defense or that are used to manufacture or maintain on-highway or off-highway vehicles (including automobile construction equipment, all-terrain vehicles, motorcycles, side-by-side vehicles, farm equipment, and personal assistive mobility devices), or that are used in the production of electronic products.

- Ecology should consider that there are feasibility and availability concerns regarding the necessary dry pigments to meet the suggestedrestrictions. From a feasibility perspective, moving to the suggestedlimits would require additional development of new yellow colorants and cause a shift in pigment sources to dry pigment suppliers that can meet the suggestedlimits of iPCBs. The cost impact to both raw material suppliers and paint manufacturers is in the hundreds of thousands to millions of dollars per company, which will be passed onto the consumers in Washington State.

- While Ecology noted during the June 1 webinar that no restrictions would be enacted prior to 2024, ACA recommends that if restrictions are to be below the current federal levels then more than 2 years compliance time is needed. Colorant suppliers need at least 3 years to develop and approve an alternative for some colorants (such as yellow) and find adequate suppliers of low-iPCB green colorant. Paint manufacturers need another 2 years to reformulate paint formulas and refresh color collateral.

Federal iPCB Risk-Based Regulations Are Sufficiently Protective While Ecology's Approach Lacks Risk and Source Assessments

During the June 1, 2021, paint webinar, Ecology presented potential iPCB restrictions for paint of 10 ppb and 25 ppb based on the range of concentrations previously observed in limited data and by setting a cutoff rather than a risk-based approach with evidence that the action is anticipated to have an impact on human health or the environment. RCW 70A.350 requires "reducing exposure" and that any restrictions "reduce a significant source or use of the priority chemical." Without adequate source-to-receptor assessments that adequately document the source of increased PCB levels in Washington waterways, there is no way to know that any restrictions beyond current international and federal standards will result in additional protections for Washington consumers and biota.

We believe that it is important that Ecology complete a source-to-receptor assessment to adequately document the source of PCBs levels in the Washington State waterways. We continue to be concerned that other potential sources (including legacy sources, such as transformers and light ballasts) of PCBs are not being addressed as part of the safer consumer product regulatory process.

The criteria for selection of consumer products, provided in RCW 70A.350.030, requires Ecology to consider both exposure potential and potential for contamination in the environment, amongst several other considerations. Specifically, the section requires Ecology consider:

> The potential for exposure to priority chemicals by sensitive populations or sensitive species when the consumer product is used, disposed of, or has decomposed. (RCW 70A.350.030(2)(c)); and
>
> 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. (RCW 70A.350.030(2)(d)

Ecology reads these sections to mean that even a trace, inconsequential level of release of a priority chemical from a product justifies its listing as a consumer product. Ecology's approach undermines the purpose of the statute articulated in the preamble to the act as, "preventing toxic pollution that affects public health or the environment."[2] By failing to identify the largest contributors of PCB contamination, Ecology minimizes potential benefits of the program, subverting its legislative purpose.

Section 3 of the act indicates that Ecology must consider the extent of environmental and health related effects caused by the presence of a priority chemical in a product, when selecting a priority product.

Ecology must consider:

- Estimated volume of the priority chemical in the proposed priority product;
- Estimated volume or units of the priority chemical sold in the state;
- Potential for exposure to the priority chemical in sensitive populations and species;

[2] Substitute Senate Bill 5135 ("Safer Products for Washington Act"), 2019 Legislative Session, available online at: http://lawfilesext.leg.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/Senate/5135-S.SL.pdf.

- Potential for priority chemicals to be found in the outdoor environment;
- Actions taken by another state or nations towards the priority chemical in a priority product;
- Availability and feasibility of safer alternatives;
- Whether the department has already identified the consumer product in a chemical action plan.

Ecology must consider these factors together. Ecology does not meet these criteria merely by selecting a product with any level of a priority chemical and/or low exposure potential. ACA is concerned that identifying paints as a priority product will not address PCB contamination at issue while imposing a high cost to the paint industry.

In its Priority Consumer Products Report to the Legislature (July 2020), Ecology concludes that paints and printings inks are a significant source of PCB contamination in Washington State, based on the number of paints and printings inks used in the state.[3] Ecology has not presented specific scientific evidence that paints and coatings present a risk to human health or the environment due to iPCBs. Ecology's response is that selection criteria for priority products has been met by demonstrating the presence of iPCB contamination coupled with Ecology's rough estimates of volume of paint and printing inks used in the state containing some level of iPCBs. However, Ecology has not shown that iPCBs from paint is the source of contamination. Further, Ecology has not provided specific information related to the health and/or environmental effects of iPCB exposure associated with contamination from paint. Following down Ecology's current path of general inferences will potentially minimize any benefits of the Safer Products for Washington program.

It is important to note that the most common iPCB in paints and coatings (PCB-11) has little if any impact on fish tissue in the Spokane River. At the June 30, 2021, Spokane River Regional Toxics Task Force (SRRTTF) Positive Matrix Factorization (PMF) Workgroup meeting, Dr. Lisa Rotenburg reviewed all the Spokane fish tissue and biofilm data and concluded that PCB-11 is frequently below the detection limit in the fish samples, and that PCBs in fish tissue are almost entirely from [legacy] Aroclors. Therefore, reducing iPCBs from paint will not make an improvement to human health or the environment.

In addition, a June 2021 Ecology report entitled "Contaminants of Emerging Concern and Wastewater Treatment Plants" provides further information. This paper explored new and traditional treatment options for wastewater treatment plants (WWTP), highlighted the potential co-benefits some of these technologies may bring, and provided information on options for reducing CECs in wastewater. The report identified all main contaminants in waterways in the state. Notably, PCBs were not mentioned in this report as an issue of concern. Indeed, evidence indicates that pursuing paint as a priority product will result in regulation that does not benefit sensitive populations and species or the environment.

[3] Priority Consumer Products Report to the Legislature (July 2020), p. 28 &32.

A report of the Southern Orca Resident Task Force from November 2019[4] notes recent losses of three adult orca from the Southern Resident population, leaving only 73 orcas. To reverse this trend, the task force emphasized the importance of:

1. Effectively addressing climate change, human population growth and human sources of nutrients to enable long-term orca survival;
2. Developing dedicated funding to support recovery efforts; and
3. Continuing the mission of orca recovery.

The task force made 49 recommendations (many of which focused on salmon recovery), and five addressed the threat of contaminants. Most of the five focused on monitoring, prioritizing, and clean-up of legacy sources of contaminants, including PCBs. One PCB-specific recommendation (#29) was to "accelerate the implementation of the ban on PCBs in state-purchased products and making information available online for other purchasers." A later statement claimed that the ban will "reduce PCBs entering Puget Sound from products such as paints, hatchery fish feed, adhesives, electrical equipment, caulking, paper products and lubricants" yet provides no information linking or matching the specific PCBs in those products to those found in Puget Sound. Without such a clear connection of PCB source to environmental concentration, such a ban is likely to provide no impact. A similar lack of impact awaits any establishment of restrictions Ecology on concentration limits on iPCBs in paint as part of the safer products program.

Federal, Risk-based, Concentration Limits Provide Effective iPCB Controls for Paints

Ecology must recognize that the federal U.S. Environmental Protection Agency (EPA) has already established risk-based limits on iPCBs in products, and it has reviewed several paint pigments. In addition, the U.S. Food and Drug Administration (FDA) has set a risk-based limit for PCBs in food and packaging. ACA strongly suggests that in Ecology's report to the legislature, required next year, it states that:

- iPCBs in paints are already regulated and have been evaluated by the federal government;
- Studies have not established a connection between trace levels of iPCBs in paint, contamination in the environment and a connection to aquatic species, particularly in orca;
- Any further actions on PCBs should focus on the remediation of legacy contamination rather than products that do not meaningfully contribute to contamination.

EPA has already set limits for iPCBs in products. In 1984, EPA reviewed and improved upon a joint consensus proposal[5] from the American Chemistry Council (then called the Chemical Manufacturers

[4] The Southern Orca Resident Task Force is an inter-governmental and NGO task force appointed by the Governor to develop plans for orca recovery and future sustainability. Its most recent recommendations are published in: Southern Orca Resident Task Force, 2019. Final report and recommendations. (November 7, 2019). More information about the task force and reports are available online at: https://www.governor.wa.gov/issues/issues/energy-environment/southern-resident-orca-recovery/task-force

[5] Environmental Defense Fund, Natural Resources Defense Council, Chemical Manufacturers Association, 1983. Recommendation of the parties for a Final EPA Rule on inadvertent generation of PCBs. April 13.

Association), the Environmental Defense Fund and the Natural Resources Defense Council. In setting the limits, EPA considered:

1. The effects of iPCBs on human health and the environment;
2. The magnitude of exposure of iPCBs to humans and the environment;
3. The benefits of using those products containing iPCBs; and
4. The economic impact of the rule upon the national economy, small business, technological innovation, the environment, and public health

The major difference between the criteria proposed by EPA and the consensus proposal criteria was the addition of a concentration limit of 5 ppm for iPCBs in consumer products with a high potential for exposure (i.e., detergent bars). All other products were limited to an annual average of 25 ppm with a 50 ppm maximum. To properly account for the differing levels of concern for the various PCBs, the concentration is calculated following division of the quantity of monochlorinated biphenyls by 50 and dichlorinated biphenyls by 5. Ecology should follow this established approach to calculating iPCB concentrations. Further, Ecology need not set a new limit on iPCBs in products, especially one that lacks a foundation in risk assessment.

In addition, the Food and Drug Administration (FDA) recognizes that PCBs are ubiquitous at minute levels throughout the environment. To protect human health, FDA set temporary food tolerances for PCBs ranging from 0.2 to 1.5 ppm (21 Code of Federal Regulations 109.30(a)). For paper packaging in direct contact with food, the PCB tolerance is 10 ppm. The Ecology proposal to regulate iPCBs in paint to levels many fold lower than those allowed for direct food ingestion in food is unnecessary and unfounded.

The testing results for iPCBs in paints and coatings documented by Ecology are well within North American and global regulatory standards deemed to be safe by national and international government agencies. Without further new studies by Ecology, it is evident that all paints currently sold in Washington State are "safe" and do not present a hazard to consumers.

Ecology should rely on EPA Safer Choice ingredients list to define "safer." EPA has reviewed several iPCB containing paint pigments under its Safer Choice[6] Program ingredients list. Of the 45 colorants reviewed, four iPCB pigments used in paint (C.I. Pigment Yellow 17 is not) and their ratings are:

- Green circle (low concern)
  - C.I. Pigment Blue 15
  - C.I. Pigment Green 7
- Green half-circle (low concern, additional data would strengthen confidence)
  - Copper phthalocyanine, sulfamoyl sulfo derivs., sodium salts
- Yellow triangle (met criteria but has some hazard profile issues)
  - C.I. Pigment Yellow 17 (generally not used in paints)
- Grey square (not acceptable for Safer Choice label)
  - None

[6] https://www.epa.gov/saferchoice/safer-ingredients

EPA Safer Choice concludes that several blue and green pigments that contain iPCBs and are used in the paint industry are of low concern. ACA suggests Ecology take follow the risk-based criteria used by Safer Choice Program and conclude these pigments "safer".

In summary, the federal government already regulates iPCBs using risk-based, health and environmentally protective approaches. Any additional regulation by Ecology to further limit iPCBs in paint, especially one that avoids risk and source-to-receptor considerations, is unlikely to benefit orca, humans or other receptors of concern.

The Ecological and Toxicological Association of Dyes and Organic Pigments Manufactures (ETAD) Position on the Presence of Unintentional Trace PCBs in Some Organic Pigments in the Context Regulation (EU) 2019/1021 (POPs recast Regulation) Should be Considered in Ecology's Next Steps

ACA refers Ecology to the ETAD Position Paper[7] (attached) developed in conjunction with the EU POP's Recast Regulation (EU 2019/1021). ACA notes the following key points from the document:

- The Position Paper demonstrates that ETAD members are in compliance with both EU and global PCB regulations.

- The position paper emphasizes to ECHA authorities that any discussion about changing existing PCB limits to a lower level BEGINS at a floor of 2 ppm (discussion about future regulatory changes lie somewhere between 2 ppm and 25 ppm).

- Even with appropriate manufacturing technology and pristine raw materials, "zero PCB" is not achievable and/or impossible for organic pigments.

- Further problems are expected regarding the supply of pigments, should the limit be changed suddenly, and ETAD doubts whether there would be enough lower iPCB-suitable pigments to fulfill all the needs of downstream users.

- In addition to PCB content, pigment products must satisfy many other requirements, many of which are influenced by shape, surface, crystal structure (polymorph), and particle size of the product.

- It is just not possible to change from one pigment chemistry to another overnight; significant resources in time and expertise all along the supply chain are required, ranging from the potential for investment in new organic pigment production facilities to reformulation by the downstream users.

[7] Note the ETAD Position Paper uses test method ISO 787-28:2019

Suggested Restrictions Discussed on the ,June 1, 2021 Webinar Should be Revised Based on the ETAD Data

Even though many of the paint products that Ecology cited in the Legislative report may have met the possible 10 and 25 ppb prohibition levels, ACA believes that the testing data is not representative nor reliable since it likely did not include deep tone paint products containing higher amounts of pigments. As a result, the 10 and 25 ppb prohibition levels are too low.

Table 1 of the ETAD position paper provides a summary of pigment iPCB testing in Europe. ACA suggests the ETAD data supports ACA concerns that the Legislative report testing data were not representative of deep tones paints. The Table 1 C.I. Pigment Yellow 83 pigment iPCB concentrations range from 0.5 to 15 ppm. C.I. Pigment Green 7 and 36 iPCB concentrations range from 1-3 ppm. For C.I. Pigment Yellow 83 (assuming 30% pigment loading in colorants and 14% colorant loading for deep tone paints), iPCB concentrations in deep tone paints may range from 21 ppb to 630 ppb and for the greens from 42 ppb to 126 ppb.

Based on the ETAD data, batch-to-batch pigment variations, test method 1668c issues, and lower level pigment supply issues, coating manufacturers could not reasonably assure compliance with the 10 ppb or 25 ppb prohibition levels – especially for deep tone paints.

Although ACA finds the current federal limits (25 ppm average, 50 ppm maximum) to be risk-based are sufficient to protect human health and the environment, if Ecology continues to pursue a different limit, ACA suggests Ecology adopt a 350 ppb prohibition level in paints and coatings to account for deep tone paint colors. The 350 ppb level equates to 5 ppm iPCB concentration in pigments, which is a nearly 80% reduction from the current EPA limit of 25 ppm. It is important to note that most consumers purchase mid tone or pastel colors, so a large percentage of paint will have iPCB concentrations well below the suggested 350 ppb prohibition level. To address test method issues, ACA strongly recommends that EPA method 8082A be used.

ACA Suggests Modification of Terminology to More Accurately Describe the Scope of paint Products while also Noting Necessary Exemptions

ACA suggests a change in how Ecology refers to paint products. This change would more clearly describe the scope of products covered by the program. ACA further notes that Ecology must exempt DOD and FAA-regulated paints (including spray paints and road/runway paints).

Interior and Exterior Decorative Paints

ACA suggests replacing “interior and exterior building paint” with “interior and exterior decorative paint” since this better defines paints that contain color pigments that were tested and described in the paint test results in the Report to the Legislature.

Exemption for Paints and Coatings Certified or Regulated by the Federal Aviation Administration or Department of Defense, On-highway or Off-highway Vehicles, and Electronic Products

RCW 70A.350.030 specifically excludes Ecology from identifying the following as priority consumer products:

- Finished products certified or regulated by the Federal Aviation Administration (FAA) or the Department of Defense (DOD), or both, when used in a manner that was certified or regulated by such agencies, including parts, materials, and processes when used to manufacture or maintain such regulated or certified finished products.

- Motorized vehicles, including on- and off-highway vehicles, such as all-terrain vehicles, motorcycles, side-by-side vehicles, farm equipment, and personal assistive mobility devices.

- Restrict or require the disclosure of a priority chemical in an inaccessible electronic component of an electronic product.

This section indicates several important exclusions for any restriction on iPCB's in paint. ACA suggests that:

- Ecology exempt any paints that are certified or regulated by the Federal Aviation Administration or Department of Defense;

- Ecology exempt paint used to manufacture or maintain or refinish on-highway or off-highway vehicles (including automobile, construction equipment, all-terrain vehicles, motorcycles, side-by-side vehicles, farm equipment, and personal assistive mobility devices); and

- Ecology exempt paint used on an inaccessible electronic component of an electronic product or that are used in the production of electronic products or FAA and/or DOD road/runway paints.

Adequate Supply of Pigments Within the Considered iPCB Ranges are not Available

RCW 70A.350 requires that Ecology determine that safer alternatives are "feasible and available" before restricting the use of a priority chemical. At the PCB limits Ecology is considering, supply of dry pigments will unduly strained and largely unavailable. ACA anticipates dry pigment shortages particularly for green and yellow pigments that meet the suggested limits.

For green pigments, it appears that only one phthalo-green pigment supplier is currently capable of meeting Ecology's suggested limits. One supplier would not be able to supply the entire paint manufacturing community without shortages as well as increased costs.

For yellow pigments, the industry primarily uses C.I. Pigment Yellow 83 (PY 83), which does not meet Ecology's suggested limits at current usage levels. It is likely that this pigment would need to be replaced, resulting in a shift in the color space that would require all paint formulas and downstream products that contained PY 83 based colorant to be reformulated. This may mean that color collateral (including marketing materials) will have to be disposed of and replaced with the new offerings both

online and at the store level. It is estimated that the colorant manufacturers would need approximately three years to develop, perform performance testing (including extended exposure testing) and approve a PY-83-free colorant. Another 2 years would be required by the paint manufacturers to then reformulate all of their paint formulas and refresh the color collateral.

It is important to note that the coatings industry has already been facing increased raw material (including pigment) costs and supply shortages for several years. Several years ago, an explosion in China limited pigment supplies and recent demand and supply shortages (due to ice storms in Texas) have increased global pigment costs. The suggested iPCB limits for paints will result in additional increased costs and supply shortages if Ecology implements the suggested iPCB limits.

From a feasibility perspective, moving to the suggestedlimits would require additional development of new yellow colorants and cause a shift in pigment sources to dry pigment suppliers that can meet the suggestedlimits of iPCBs. Development of a new yellow color space would incur increased costs for colorant manufacturers, which will likely be passed on. Paint manufacturers would be expected to have significantly higher costs in changing out thousands of paint formulas, changing out the color collateral, and increased colorant raw material costs. The cost impact to both raw material suppliers and paint manufacturers is in the hundreds of thousands to millions of dollars per company, which will be passed onto the consumers in Washington State.

ACA Requests an Adequate Compliance Timeframe and Sell-through Period

Ecology stated on the June 1 webinar that 2024 is the earliest potential restrictions would take effect. Assuming the commercial viability of reformulating, ACA urges at least 5 years for compliance with any new restrictions. Colorant manufacturers would need approximately three years to develop, performance test (including extended exposure testing) and approve an alternative yellow colorant and find adequate supplies of low iPCB green colorants. Another 2 years would be required by the paint manufacturers to then reformulate all of their paint formulas and refresh the color collateral.

ACA is very concerned that the limits could result in extensive amounts of "stranded" products – existing stock manufactured prior to any prohibition compliance date and that can't be sold since it may not meet the prohibition limit. In order to limit the negative financial and environmental impacts associated with disposing of "stranded" products that can no longer be sold, ACA requests that Ecology allow products manufactured prior to the compliance date to be wholesaled, distributed, sold and used after the compliance date. If, over our objection, Ecology does not allow products manufactured prior to the compliance date to be wholesaled, distributed, sold and used after the compliance date, ACA requests at least a three-year "sell through" period for products to be wholesaled, distributed, sold and used after the compliance date. This would limit the negative financial and environmental impacts associated with disposing of "stranded" products that can no longer be sold.

ACA's request is reasonable since RCW 70A.350.040(5) mentions that "A restriction or prohibition on a priority chemical in a consumer product may include exemptions or exceptions, including exemptions to address existing stock of a product in commerce at the time that a restriction takes effect." Moreover, immediate implementation of the lower limit is not necessary to address an urgent

environmental concern. As noted above, iPCBs from pigments in paints are not a primary source of contamination. An unlimited sell-through or a 3-year phase-in would not affect PCB in waterways.

Conclusion

Thank you for your willingness to work with ACA as you proceed through the regulatory process. In summary, ACA believes that additional risk/source assessments are needed; cited testing data is not representative nor reliable; EPA and FDA have already set protective limits on iPCBs; EPA Safer Choice iPCBs pigments should result in Ecology concluding these pigments are "safer"; and the suggested restriction levels will result in significant impacts to paint and coatings industry. ACA, therefore, recommends an action level of 350 ppb for paints and at least a 5-year compliance timeframe to take into account the sell-through needs of retailers/distributors (which is reasonable under RCW 70A.350.040(5)). We appreciate your consideration of our comments and concerns and look forward to speaking with you further on August 5, 2021. In the meantime, please do not hesitate to contact us if you have any questions.

Sincerely,

/s/
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ETAD Position on the Presence of Unintentional Trace PCBs in Some Organic Pigments in the Context Regulation (EU) 2019/1021 (POPs recast Regulation) [June 15th 2021]

Executive Summary

Polychlorinated biphenyls (hereafter: PCBs) are chemicals of global concern due to their potential for long range transport, persistence in the environment, ability to bio-magnify and bioaccumulate in ecosystems, and are toxic. Under the Stockholm Convention, their intentional manufacture, trade and use are banned globally. They are subject to release reduction provisions and waste consisting of or containing this substance is subject to specific provisions.

There is a growing amount of literature implying that the use of certain organic pigments may be dispersing PCBs throughout the environment,

Within the Stockholm Convention on Persistent Organic Pollutants (POP) the BAT/BEP Expert Meeting has also identified organic pigments as a source of unintentional POPs formation and release and pointed to the need for thorough identification and descriptions of the raw materials and technologies used in manufacturing processes, because these factors may greatly influence POPs formation and release.

Over the years ETAD member companies have carried out regular testing on their products placed on the market to ensure compliance with EU and global regulations. Our long-term Member Companies were asked to submit a random selection of their PCB historical testing results. Data was requested not only for pigments where PCBs could be present but specifically for the large volume pigments: C.I. Pigment Yellow 13, Monoazo pigments such as CI Pigment Red 57:1 and for Copper Phthalocyanines.

In this position paper we share our testing data, so that an open and informed discussion on the PCB/POPs issue can take place. This note also shows the data obtained in the (Japanese) METI study which are publicly available.

Without exception, the products placed on the market by the ETAD member companies have PCB contents less than 50 ppm, the limit given in Council Directive 89/677/EEC.

The data shows also that "zero PCB" is not attainable when chlorine atoms are present as part of the chromophore, present in a raw material or present in some form in the production process e.g as part of a solvent. Some brief consideration is given to some of the concerns that may arise when substituting a PCB containing pigment with a "zero PCB" pigment.

A proposal is made on the limit of unintentional trace PCB in organic pigments, along with a recommendation of test method specifically designed for organic pigments.

1. Introduction

PCBs are chemicals of global concern due to their potential for long range transport, persistence in the environment, ability to biomagnify and bioaccumulate in ecosystems, and affect human health. Their intentional manufacture, trade and use are banned globally.

In July 2011, ETAD published a position paper on the presence of inadvertent traces of PCBs in some organic pigments[1]. The Regulatory landscape was reviewed, and we confirmed that products placed on the market at that time by its member companies met the laws of the countries in which they marketed their products.

The Regulatory landscape has changed since then, e.g. within the EU Regulation (EU) 2019/1021)[2] (hereafter: POPs recast Regulation) was published. Additionally, there is a growing amount of literature[3] implying that the use of organic pigments may be dispersing PCBs throughout the environment, by manufacture, use or decay as part of waste. A study published in 2013 by the Japanese Ministry of Economy, Trade and Industry (hereafter: METI) lists a number of azo pigments with PCB concentrations above the Japanese, the EU (Council Directive 89/677/EEC[4] Art.1, par.1) and pre-2017 German 50 ppm limits, or the USA 40 CFR §761[5] limit of 25 ppm.

Within the Stockholm Convention[6] on Persistent Organic Pollutants, the Expert Meeting on Best Available Techniques and Best Environmental Practices held in Bratislava in 2015[7] has also identified organic pigments as a source of unintentional POPs formation and release and pointed to the need for thorough identification and descriptions of the raw materials and technologies used in manufacturing processes, because these factors may greatly influence POPs formation and release.

ETAD[8] is an international organization representing the dye and pigment industries committed to minimizing any adverse impact of organic colorants on health and the environment. Over the years ETAD members companies have carried out regular analyses on their products placed on the market. Further, ETAD and its member companies have been developing analytical methods on PCBs with respect to pigment peculiarities, e.g. ETAD Method No 229[9]. This method has subsequently been adopted as ISO 787-28:2019[10]a, and DIN EN ISO 787-28:2020-12[10]b. The adoption by CEN as EN ISO 787-28 is on the way.

Our long-term member companies were asked to submit a random selection of their PCB historical test results. Data was requested not only for pigments where PCBs could be present but specifically for the large volume pigments such as Pigment Yellow 13, Pigment Red 57:1 and for Copper Phthalocyanines. It is time both to update our earlier position paper and to share our test data, so that an open and informed discussion on this issue as well as on regulatory developments can take place.

2. ETAD Testing Data on PCBs

The PCB values shown in Table 1 are simply the summation of the individual test values of total PCBs. No exemptions (see Appendix I: EU Regulations) and no discounting factors for monochlorinated biphenyls and dechlorinated biphenyls (see Appendix I: USA legislation) have been used, and no adjustments for molecular weight (See Appendix I: CoE "AP(89)1").

Where several data sets for a specific pigment have been received, the values shown are simply the lowest and the highest and, in all likelihood, come from different member companies.

3. Discussion

Not every pigment shown in Table 1 is marketed by every ETAD member. These single data sets are indicated in the table.

For any one individual C.I. Generic name, the results are all similar, even though manufactured by different companies, and the analyses were carried out by differing institutions. They do not vary over orders of magnitude.

The data confirm that the values are lower than EU 50 ppm PCB limit set in the Council Directive 89/677/EEC. However, this Directive is no longer in force. It was repealed by Regulation (EC) No 1907/2006[11] (hereafter: REACH Regulation).

Table 1 Summary of PCB testing data generated by ETAD long-term member companies[1] as part of their monitoring program to ensure EU and global regulatory compliance.
(Data comes from testing of production material in the years 2013 to 2020)

C.I. Colour Index	Chemistry	Measured value of Total PCB (ppm)
Pigment Yellow 12	Diarylide	2.0 – 6.0
Pigment Yellow 13	Diarylide	< 0.5 - 10
Pigment Yellow 14	Diarylide	< 10
Pigment Yellow 17	Diarylide	0.5 to 8.0
Pigment Yellow 81	Diarylide	25 – 35
Pigment Yellow 83	Diarylide	0.5 - 15
Pigment Yellow 93	Disazocondensation	< 0.5
Pigment Yellow 95	Disazocondensation	< 0.5
Pigment Yellow 109	Isoindolinone	< 0.5
Pigment Yellow 110	Isoindolinone	< 1.0
Pigment Yellow 128	Disazocondensation	< 0.5
Pigment Yellow 168	Azo salt (Ca)	< 0.5
Pigment Yellow 183	Azo salt (Ca)	< 0.5
Pigment Yellow 191:1	Azo salt (Ca)	< 0.5
Pigment Orange 13	Diarylide Pyrazalone	0.5 - 5
Pigment Orange 34	Diarylide Pyrazalone	3.0 - 15
Pigment Orange 61	Isoindolinone	< 0.5
Pigment Red 2	Naphthol AS	10 - 20
Pigment Red 48:4	2B Toner (Mn) (azo lake)	< 0.5
Pigment Red 57:1[2]	Ca 4B Toner (azo lake)	Not detected
Pigment Red 112	Naphthol-AS	10 – 25
Pigment Red 144	Disazocondensation	< 10
Pigment Red 166	Disazocondensation	< 10
Pigment Red 202	Quinacridone	< 0.5
Pigment Red 214	Disazocondensation	< 10
Pigment Red 220	Disazocondensation	< 0.5
Pigment Red 221	Disazocondensation	< 0.5
Pigment Red 254	DPP	< 1 - 10
Pigment Red 264	DPP	< 0.5
Pigment Violet 19	Quinacridone	< 0.5
Pigment Violet 23	Dioxazine	<2.0
Pigment Blue 15; 15:1 -15:6	Phthalocyanines, different treatment and polymorphs	< 0.5
Pigment Brown 23	Disazocondensation	< 10
Pigment Green 7	Phthalocyanine chlorinated	< 3.0
Pigment Green 36	Phthalocyanine mixed halogenated (Br,Cl)	< 1.0

1) This table, a non-exhaustive list, shows the testing data received from our ETAD long-term member companies and is not to be taken as a guarantee of controlled values of ETAD member companies. All values are the simple summation of the individual analytical values for each of the congener groups including mono- and di-chlorinated biphenyls.
2) No chlorine in the molecule and no chlorinated solvents used in its manufacture. It was included in the data gathering as it is a large volume pigment (REACH phase 1)

Annex XVII to the REACH Regulation does not contain the expected limits for PCBs. Neither are PCB limits specified in POPs recast Regulation; but this regulation does contain a more general statement on unintentional trace contaminants, viz Article 4 "Exemption from Control Measures" which states that article 3 shall not apply in the case of a "substance present as an unintentional trace contaminant as specified in the relevant entries of Annex I or II in substances, mixtures or articles." Article 3 lists those substances that shall not be manufactured, placed on the market or used in substances, mixtures, or articles unless there are exemptions. (More details on POPs recast Regulation can be found in Point 1 of Appendix I).

At the workshop organized by German UBA/BMU "Untersuchung von Abfällen auf das Vorkommen nicht-technischer PCB-Kongenere und DecaBDE" on 22 October 2019 in Berlin[12] the presentations emphasised that without a concentration limit given in Annex I, which could be applied to point (b) of Article 4(I) for PCBs present as unintentional trace contaminants, it had to be assumed that this equated to an absolute ban for placing on the market any product containing PCBs ("zero limit"), an argumentation which we find difficult to follow and is complete contradistinction to the 50 ppm limit allowed for recycling (The final report on the studies – including an English Summary is also available.[13])

We find also the definition of Unintentional Trace Contaminant given in POPs recast Regulation very difficult to understand, at a practical level: viz: "unintentional trace contaminant means a level of a substance that is incidentally present in a minimal amount, below which the substance cannot be meaningfully used, and above the detection limit of existing detection methods to enable control and enforcement." The detection limit will be very method dependent, determined not only by the analytical equipment being used but also by the way the sample is treated before the actual analysis; it could range from as little as several ppb to as high as a few ppm. And for the case of PCBs is it the total PCB content or each congener family? A robust detection method, for enforcement, would need to be agreed and specified. See also a Q&A document from the Commission Services regarding a draft commission regulation amending Regulation (EC) No 850/2004[14]

Annex I of POPs recast Regulation contains 26 entries, and for 19 of them, no concentration limits are provided for their presence as unintentional trace contaminants in substances. These 19 substances include all the so-called "Dirty Dozen Chemicals" on the original listing in the Stockholm Convention, which were all included in Regulation (EC) No 850/2004[15]. Those substances where limits are included, with relevance to point (b) of Article 4(1), were essentially all added as amendments to this Regulation following decisions taken under the Stockholm convention resp CLRTAP Protocol; e.g. the limits for PFOS and for PBDEs were included in Regulation (EC) No 850/2004 following decisions taken by COP4 in May 2004. Until further information became available the thresholds specified reflected the values in Annex XVII to REACH Regulation.

About PCB Limit and Reality Check

However, in POPs recast Regulation, there is an additional specification for PCBs which refers to the requirement to remove from use mainly electrical equipment which contain liquid stocks with more than 0.005% PCBs. This 0.005% limit for PCBs is also given in Annex A Part II of the Stockholm Convention, where it asks that every effort should be made to identify other articles (cable-sheaths, cured caulk and painted objects) containing more than 0.005% of PCBs.

In the Regulation (EC) No 1272/2008/EEC[16] (hereafter: CLP Regulation) Annex VI merely requires products contaminated in excess of 50 ppm PCB to be labelled, inter alia using the Signal Word "Warning" (Table 2 below).

At a more recent WebEX Online UBA workshop, Dessau on 23.09.2020[17], "Wie werden wir unserer Verantwortung zu POP Gerecht? – Ein ambitionierter nationaler durchführungsplan 2020 zum Stockholmer übereinkommen" (*"How do we live up to our responsibility to POP? - An ambitious 2020 national implementation plan to the Stockholm Convention"*), inter alia the updating of the NIP (National Implementation Program) was discussed. It was again stated that as no limits were given for PCBs, this meant under current legislation NO PCB must be present in substances, preparations or articles. However, if from the perspective of enforcement it is felt there is a need to set a suitable concentration limit for unintentional trace PCB impurities in Annex I of EU-POP-VO, then an appropriate procedure could be initiated (page 29 of the conference summary by UBA[18]).

Table 2 Citation of updated ECHA 18 Sept., 2018

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes	ATP inserted / ATP Updated
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)			
602-039-00-4	polychlorobiphenyls;PCB	215-648-1	1336-36-3	STOT RE 2* Aquatic Acute 1 Aquatic Chronic 1	H373 ** H400 H410	GHS08 Environmt GHS09 Health Warning	H373 ** H410		STOT RE 2 H373: C ≥ 0,005%	C (= isomer / congener statement required)	CLP00

https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/128359

It has to be emphasised that the data shown in Table 1 was contributed by the long-term ETAD members. However, the majority of organic pigments are produced by non-ETAD members, much manufactured in what is often referred to as “low cost manufacturing” countries.

With this in mind, we should probably not just focus on the ETAD generated data; we should pay equal attention to other public data.

Recently Anh, Watanabe; Minh and Takahashi[28] have reviewed the literature spanning the last four decades of pigment derived PCBs. They present results for a wide range of organic pigments as well as *inter alia* discussing possible pathways for the formation of PCBs during pigment manufacture as well as emission routes and fate of the PCBs.

Results are presented for a broad spectrum of organic pigments: mono- and bis-azos, phthalocyanines, quinacridones, DPP, dioxazine, obtained from Asia, Europe and North America and show a wide scatter of results from a few ppb up to several hundred ppm.

In response to a report from the Japan Dyestuff and Industrial Chemicals Association (JDICA) in February 2012 that some organic pigments contained traces amounts of PCBs unintentionally generated as by products, METI, the Ministry of Health, Labour and Welfare (MHLW), and the Ministry of Environment (MOE) collectively requested businesses that manufacture or import pigments that might contain PCBs as by-products to analyse them for the presence of PCBs and to report them to these ministries. The results of which have been published in a number of METI press releases.

This publicly available METI data has already been published in the BAT/EP report[7] and also in slides at the BMU workshop[12] held in October 2019 and is shown in Table 3.

METI has also published compiled results of analyses submitted which includes results of some analyses and reanalyses where it was demonstrated that the analytical method including pretreatment process could influence the determined results (May 10,2013)[20] (Table 4).

The complied METI data shows that some relatively few batches of pigment (approx 3% based on the results data presented) have been placed on the market with PCB values exceeding 50 ppm. It is deeply to be regretted that such material has found its way into commerce and indicated that at a very minimum the final release processes need to be critically looked at. Since December 2012, every Japanese manufacturer/importer have agreed their self-managed upper limit values equal or lower than 50 ppm, and after that time no organic pigments containing more than 50 ppm PCB have been placed on the Japanese market.

The ETAD results (Table 1) show that low PCB content (below 50 ppm) organic pigment can be produced – using the right technology and the right raw materials. The results presented from the METI studies as well as by Anh et al would tend to back this conclusion but they show that it is possible to get it significantly wrong!

A value of less than 50 ppm should be achievable by every manufacturer and we would suggest serve as an initial goal as part of the on-going work to reduce emissions.

But even with good manufacturing technology and good raw materials the results clearly indicate that “zero PCB” is not achievable for organic pigments where chlorine atoms are part of the chromophore or part of a molecule involved in the process e.g. raw material, and/or a solvent.

Table 3. Pigment batches monitored by the Japanese Ministry of Economy and Trade (METI) exceeding 50 ppm limit for import or use in Japan (METI 2013)

Name of Pigment	Name of Product	Amount of PCB (ppm)
Pigment Red 2	ZA-855 Red	37-58
	PERMANENT RED G-87	52
	FAST RED F2R (PR-2) POWDER	61
Pigment Red 112	ZA-862 Red	16 -121 ppm
	Permanent Red GY	
Pigment Yellow 12	Pigment Yellow 1207	1500 ppm
	Disazo Yellow G 178 – 4	110 ppm
Pigment Yellow 13	DISAZO YELLOW 3GR-M	220 ppm
	DISAZO YELLOW 3GR-M-5	
Pigment Yellow 13	Orange BO-01	1000 ppm
Pigment Yellow 14	SUIMEI YELLOW GGNB	810 ppm
Pigment Yellow 17	SUIMEI YELLOW 7G	700 ppm
	SUIMEI YELLOW 7GKT	1000 ppm
Pigment Yellow 55	SUIMEI YELLOW DRO-10	1500 ppm
	SYMULER Fast Yellow 4539	
Pigment Yellow 81	SUIMEI YELLOW F10G	79 ppm
Pigment Yellow 83	SUMIKAPRINT FAST YELLOW HR-M	52 -280 ppm
	SUMITONE FAST YELLOW HR-M-5	
	SUMIKAPRINT FAST YELLOW HR-T-2	
	SUMIKAPRINT FAST YELLOW HR	
	PY-2GN	
	SUIMEI YELLOW ERT	2000 ppm
	SUIMEI YELLOW 5RT	
	Permanent Yellow HR-1183-2	59 ppm
Pigment Yellow 165 ($C_{16}H_{12}Cl_2N_4O$)	FAST YELLOW F5G	208 ppm
Pigment Orange 13	Orange BO-01	1000 ppm
Pigment Orange 34	SUIMEI PYRAZOLONE ORANGE GR-N	190 ppm

Table 4. Results of analyses, published by METI (May 10, 2013)

PCB content in ppm	To 0.5	Over 0.5 to 1	1 – 5	5- 10	10-15	15-20	20-25	25-50	Over 50	Total
Total (including the previous investigations)	359	51	89	29	13	7	10	13	17	588

Potential Consequences of "Zero PCB"

A "zero PCB" in substances would seem to be in distinct contradiction to the information in Annex IV of POPs recast Regulation where articles with a PCB concentration below 50 ppm qualifies waste as recyclable.

- In view of modern sensitive analytical chemistry and its tools, a "zero PCB" requirement would be impossible to meet.
- Besides our grave concerns regarding the analytical aspects of "zero PCB", we envisage further problems regarding the supply of pigments, should the limit be changed "suddenly" or indeed in a "step wise reduction" from 50 ppm to "zero". We doubt if there would be enough suitable such pigment available to fulfil all the needs of our downstream users.

Certainly, there are plenty of e.g. organic Yellow pigments commercially available. In the 4th, completely revised edition of "Industrial Organic Pigments"[21] just over 100 different Yellow organic pigments are listed. (C.I. Generic Names mean different chemical structures). But as pointed out by

CPMA in their presentation at the October 2019 Spokane Conference[22], it is not just the molecular chromophore that is important for pigment users, the product must satisfy many other requirements, many of which are influenced by shape, surface, crystal structure (polymorph), and particle size of the product. Additionally, pigments should be non-toxic to man and the environment.

It is just not possible to change from one pigment chemistry to another overnight – significant resources in time and expertise all along the supply chain are required, ranging from maybe investment in new organic pigment production facilities to reformulating by the downstream users. For automotive paints all the necessary weather fastness data would need to be gathered for all the formulations containing a change in pigment – a process taking several years, while a change in one of the standardised base colours used in four colour printing would not only require reformulation of that ink but would have potentially ramifications additionally for the other three inks.

A “ban” on the large volume and niche specialities would cause severe business disruption and would not stop the import of coloured articles into Germany resp the EU. Controlling with the necessary analyses of this import stream would present significant hurdles.

As mentioned above the concept of “zero PCB” raises severe analytical and conceptual concerns. Each analytical method has a detection limit and a slightly higher quantification limit; these limits are also matrix dependent. And conceptually what does “zero PCB” really mean in this discussion? Not even one molecule of one of the congener families present. Including a limit in a regulation requires both a value as well as a robust analytical procedure.

Additionally, there must be international agreement on the Regulatory definition of PCB, as it is necessary to ensure coherence regarding which congener groups are to be included resp excluded from the limit set. Appendix 1 gives a very brief overview of some representative PCB definitions given in regulations currently in force.

For PCBs, the essential aim of POPs recast Regulation is to minimize with a view to eliminate where feasible as soon as possible releases of this substance.

4. ETADs Proposal

We would suggest that total elimination of unintentional PCBs for organic pigments is not feasible; industry must consequentially minimize their production as an unintentional trace contaminant with all haste. As a first limit 50 ppm, as specified in Council Directive 89/677/EEC, in the CLP Regulation, and referred to in the Stockholm Convention for e.g. painted objects, could be set as a goal with the intention of reducing this to 25 ppm over an agreed time period. The 50 ppm limit is already stricter than the Council Directive 89/677/EEC limit as the mono-chlorinated and di-chlorinated biphenyls are included. In addition, an analytical method should be defined. We recommend ISO 787-28:2019[10]a or DIN EN 787-28:2020-12[10]b, as the both are the only method available which are specifically developed for organic pigments.

The PCB content of organic pigments manufactured by ETAD members has been shown to be less than the 50 ppm so under the POPs recast Regulation waste organic pigment would then be considered as “recyclable”.

In a final coloured article the PCB content would then be considerably lower due to the low dosage level ("pigmentation").

Appendix: Overview of Some Regulations Involving PCBs

1. Regulation (EU) 2019/1021 (POPs recast Regulation)

On a global basis, the risks posed by POPs are addressed by the United Nations; UN Environment sets the global environmental agenda, promotes the coherent implementation of the environmental dimension of sustainable development within the United Nations system and serves as an authoritative advocate for the global environment.

The EU is party to two major international agreements on POPs:

The regional UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP), which addresses POPs through the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (also known as the 1998 Aarhus POPs Protocol), which entered into force in 2003 and focuses on 16 substances.

The global Stockholm Convention on POPs, which entered into force in 2004. This initially regulated 12 substances, known as the 'dirty dozen'; with a further 16 having been added to the convention since 2009.

Both instruments were implemented in the EU through the Regulation on POPs, Regulation (EC) No (EC) No 850/2004[15]. This regulation has been amended on 12 occasions and the number of POPs under Part A of Annex 1 have evolved to 21 chemicals.

On June 25, 2019, the EU published Regulation (EU) 2019/1021, recasting the POPs Regulation ("POPs recast Regulation"). The POPs recast Regulation repealed the POP Regulations and became effective on July 15, 2019.

The essential aim of the POPs recast Regulation (See **Article 1**) is to protect human health and the environment by:

- Prohibiting, phasing out as soon as possible, or restricting manufacture, placing on the market and use ("trade") of products containing POP substances (see **Article 3** secs. 1 and 2, both subject to article 4)
- Minimising, with a view to eliminate where feasible as soon as possible releases of such substances (**Article 6**)
- Establishing provisions regarding waste consisting of, or contaminated by any of those substances (**Article 7**)
- PCBs are listed in the Regulation in
- Annex I. (List of substances prohibited from manufacturing, placing on the market and use whether on their own, in mixtures or in articles)
- Annex III (List of substances subject to release reduction provisions)
- Annex IV (List of substances subject to waste management provisions, with a PCB concentration below 50 ppm qualifying waste material as "recyclable")

2. Some Representative Regulatory Definitions of PCBs

2.1 Global (UN)

For global implementation of the Stockholm Convention – and also to ensure there are no deviations when implementing POPs recast Regulation into member state specific legislation – an agreed regulatory - rather than just chemical - definition of PCBs needs to be established.

In the Stockholm Convention "Polychlorinated biphenyls" means 209 aromatic compounds formed in such a manner that the hydrogen atoms of the biphenyl molecule (two benzene rings bonded together by a single carbon-carbon bond) may be replaced by up to 10 chlorine atoms. This is the same definition used in REACH and in CLP where CAS # 1336-36-3 is used.

However, PCBs are regulated differently in different regulatory regimes, a few examples of which are shown below:

2.2 European Union

Pre-REACH, the marketing and use of PCBs was regulated by Council Directive 89/677/EEC[4]. The content of PCB/PCT in preparations (including waste oils) was reviewed and the limit of 0.01% set down by Council Directive 85/467/EEC was replaced by 0.005%. According to 76/769/EEC mono- and di-chlorinated biphenyls are exempt[24].

So, with the implementation of POPs recast Regulation there is already a considerable additional restriction for PCBs as there is now no exemption for mono- and dichlorobiphenyls.

2.2.1 Council of Europe (CoE)

CoE, which is a non-EU-entity without legislative powers, adopted resolution "AP (89) 1"[25]. which*, inter alia*, gives a limit for PCBs in colorants for food contact applications as 25 ppm, to be calculated as "Equivalents Decachlorobiphenyl", primarily for historical reasons. A sort of worst-case reporting, re-calculating every homologue group sum into a fictive decachlorobiphenyl by multiplying with the ratio of molecular weights, and summing up. The system is basically a molar quantification of PCBs, multiplied with the molecular weight of decachlorobiphenyl.

2.3 USA

EPA issued regulations under TSCA 40 CFR §761.20[26] to prohibit manufacture, processing, and the commercial distribution of any product containing an annual average of 25 ppm PCB (with a maximum concentration at any time set at 50 ppm). The agency also required manufacturers or importers of products and processes associated with inadvertently produced PCBs to report any individual PCB congener concentrations greater than 2 ppm in such products or processes. In the US the monochlorinated biphenyls (mono-CBs) and dichlorinated biphenyls (di-CBs) are regulated, but there is a discounting factor for reporting purposes (refer to US 40 CFR 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 mono-CBs by 50 and di-CBs by 5.

2.4 Canada

According to The PCB Regulations SOR/2008-273[27], a colouring pigment shall contain PCBs produced incidentally less than 50 mg/kg, while an annual average concentration of 25 mg/kg. According to PCB definition laid down in this Regulation, mono- and dichlorinated biphenyls are exempt.

2.5 Japan

According to Japanese Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture[23], PCBs (defined by CAS No 1336-36-3) are categorized as Class I Specified Chemical Substances. The self-managed upper limit value is to set to a level of 50 ppm or less, which is considered to be the concentration at which international distribution is avoided, and within a range that is technically and economically achievable in industry. Every organic pigment manufacturer/importer must submit their own self-mananged upper limit to the competent authorities before marketing and must control them at all times and submit an anual report.

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