Application of EPA Method 1628 for PCB Congeners in Fish Tissue Analyses

Matching the Method to the Question to be Answered

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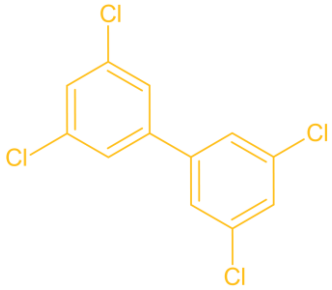
Disclaimer



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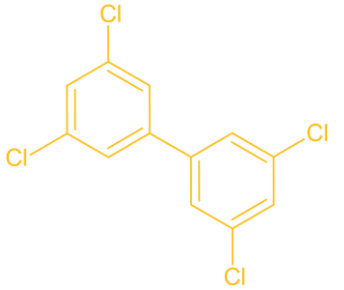
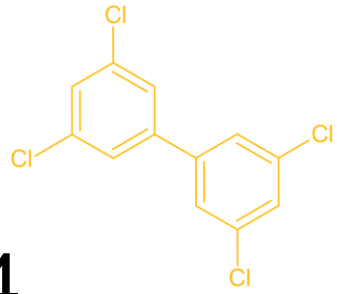
EPA Studies of PCBs in Fish Tissues



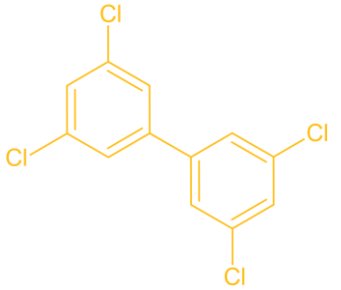
- Beginning with the 2000-2004 National Lake Fish Tissue Study, the EPA Standards and Health Protection Division (SHPD) has conducted eight national-level probabilistic studies of contaminants in fish likely to be consumed by humans.
- Among those contaminants are PCB congeners.
- In seven of those eight studies, the EPA specified that the commercial laboratories contracted for the studies use EPA Method 1668C, a high-resolution GC/MS procedure.

Method 1668



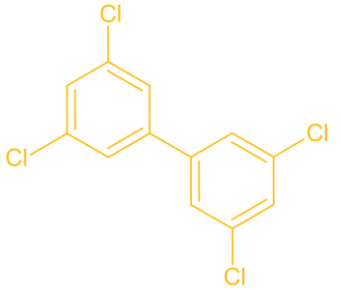
- Method 1668, Revision A was used in the 2000-2004 National Lake Fish Tissue Study in part because:
  - It explicitly incorporated procedures for tissue analyses.
  - It is highly sensitive, and EPA hoped that a national-level study would include fish with lower PCB concentrations than those found in many targeted studies of problem areas.
  - Its use in a large-scale study would provide performance data for future updates of the method.
- The method has been revised twice and since 2010, SHPD has used Method 1668C for the six most recent studies.

Challenges of Using Method 1668C



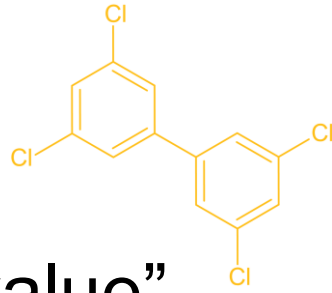
- Its high sensitivity can lead to low-level background contamination of method blanks that may call into question individual sample results. Typical MDLs in tissues are on the order of 0.1 to 0.8 picograms per gram (pg/g).
- SHPD required results for all contaminants be reported down to the laboratory's MDLs.
- Minimizing that background contamination requires careful efforts by the laboratories, leading to higher per-sample costs.
- There are also added costs associated with data review and validation to ensure that EPA can appropriately use the data to assess levels of PCBs on a nationwide scale.

How the EPA Assesses PCB Contamination in Fish

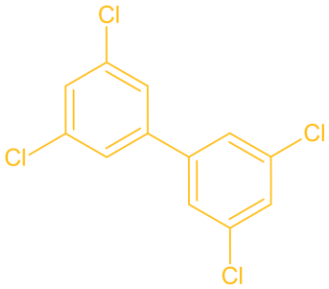


- The EPA's assessments of the human health risks of PCBs and other contaminants in fish are based on guidance developed in 2000 and updated in 2024.
- Prior to the 2000-2004 NLFTS, the EPA issued "*Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*" to help state, local, regional and Tribal programs responsible for developing and managing fish consumption advisories.
- That guidance includes concentrations of contaminants in fish above which a fish consumption advisory may be warranted.

Assessing PCB Contamination (cont.)

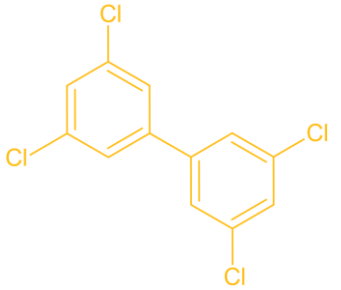


- For PCBs, the guidance indicates that above a “screening value” of 12 nanograms per gram (ng/g) of “total” PCBs, the risk of cancer in humans warrants an advisory.
  - Note that the screening value is in ng/g, while the typical tissue MDLs for Method 1668C are below 1 pg/g.
- Relative to concerns about method sensitivity, across the eight SHPD studies, 2811 samples were collected and analyzed for PCBs. Of those, 1386 (49%) had total PCB concentrations over 12 ng/g.
  - The exceedances varied by study, and ranged from 7% to 98%.
  - Three Great Lakes studies had exceedances in over 80% of the samples.



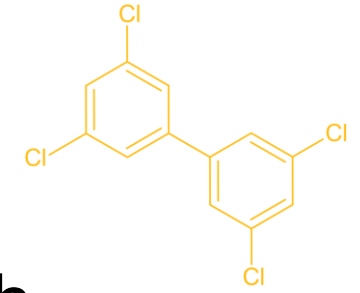
So, did we really need to use Method 1668C?

What About Method 1628?



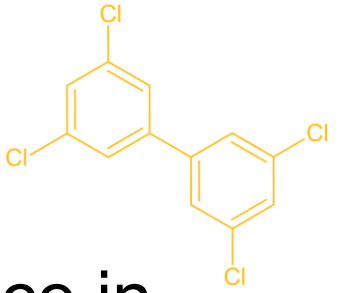
- There were 68,384 PCB congener results from the 413 fish tissue samples collected for the 2022 National Lakes Assessment (NLA), SHPD's most recent study.
  - 45,256 of those 68,384 results from Method 1668C were reported as non-detects by the 1668C laboratory and thus would not have been seen using Method 1628.
  - Of the 23,128 "hits" reported by the 1668C laboratory, 937 were considered to be non-detects because of method blank levels (e.g., <5 x the method blank result), leaving 22,191 hits that SHPD used to assess the original study results.

What About Method 1628? (cont.)



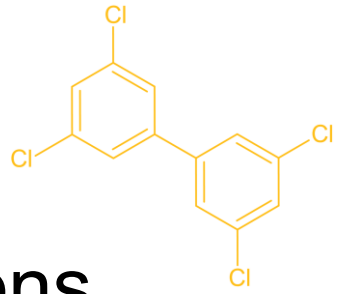
- I merged the 1668C PCB congener results from the 413 fish tissue samples with the pooled MDL values published in Method 1628 and made adjustments for differing co-elutions.
- I compared the 1668C hits against the 1628 MDL values and flagged all of the 2022 NLA detected results that Method 1628 would have "missed."
  - 19,550 of the 22,191 detected results from 1668C would have been non-detects using Method 1628.
  - That left 2,641 congener results that were theoretically detectable by Method 1628.

That Sure Sounds Like a Big Difference



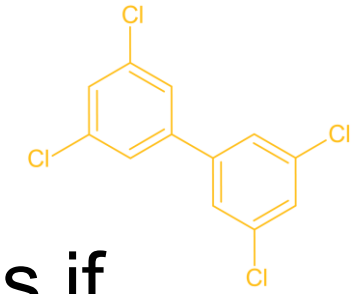
- But, in the context of the actual study, would it make a difference in the outcome?
  - Keep in mind that the EPA assesses the human health risk based on the "total" PCB concentration, even though the toxicological effects differ by congener.
  - For the purposes of the calculation, any results below the MDLs are treated as zeroes.
- I recalculated the total PCB concentrations for all 413 samples using only the 2,641 hits that theoretically would have been detectable using Method 1628.
- Then I compared those new totals to the 12 ng/g screening value.

How’d Things Turn Out?



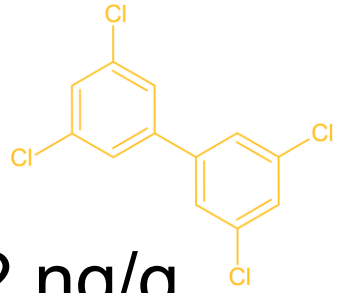
- All 413 samples had measurable total PCB concentrations using the original Method 1668C results.
  - 30 samples had total PCB concentrations over 12 ng/g.
- Only 251 of the 413 samples would have had measurable total PCB concentrations using Method 1628.
- However, comparing both sets of Total PCB results to the 12 ng/g screening value, only 5 of the 413 samples would have come to a different conclusion using the 1628 results (e.g., only a 1.2% decision “error” rate).
  - The 1668C totals for those samples ranged from 12.6 to 14.1 ng/g, while the corresponding 1628 results ranged from 10.9 to 11.3 ng/g.

How’d Things Turn Out? (cont.)



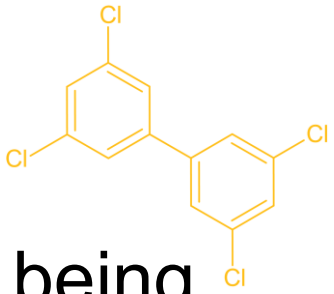
- Treating the two sets of results for those five samples as if they were “duplicates” and calculating the RPDs, the five RPDs ranged from 15.3 to 22.9%, largely within typical expectations for laboratory duplicates in most methods.
- For the fish samples over the screening value by both methods, the RPDs ranged from 15.6% just above the 12 ng/g level, to 1.4% at the highest observed Total PCB level of ~130 ng/g.
- Thus, from the point of view of assessing sample results against the 12 ng/g screening value, there would have been very little difference in the conclusions using Method 1628.

Other Uses of the Results by SHPD



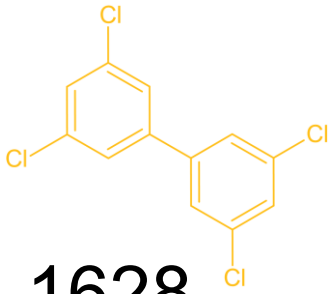
- In addition to evaluating the total PCB results against the 12 ng/g cancer screening value, SHPD works with ORD statisticians to calculate the nationally weighted average concentrations of the contaminants in each study.
  - The weighting factors include the kilometers of river length or the square kilometers of lake area represented by each sampling site, among others.
  - SHPD's goal for the weighted averages is to facilitate comparisons over time and across related studies.
- The reduced sensitivity of Method 1628 *will* affect those calculations, but so do changes in the exact sampling locations, fish species collected at each site, etc.

Other Impacts



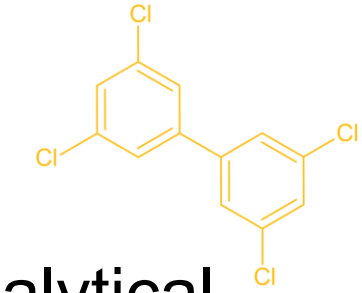
- The extreme sensitivity of 1668C often results in congeners being detected at similar levels in the method blanks and in some samples in the same extraction batch, often leading to reanalyses.
- During data validation efforts, those instances need to be evaluated on a congener-specific basis and sample results may be removed from further consideration.
  - For SHPD's fish studies, the rule has been that if the sample result is less than 5 times the blank result, the sample result is converted to a non-detect in the database.
  - As noted earlier, for the 2022 NLA, 937 of the 68,384 PCB results from 1668C were converted to non-detects (1.37%).
- While that is a small percentage of data loss, the validation effort takes more time and increases the cost of the study.

Cost Implications



- Although the per-sample costs for both Methods 1668C and 1628 will vary across laboratories based on numbers of samples, schedules, reporting requirements, etc., analyses by Method 1628 are likely to cost less than those by Method 1668C.
- While some sample results from Method 1628 will still be affected by method blank concerns, the initial number of hits will be lower and should translate to fewer reanalyses and slightly lower data validation costs.
- Lower per-sample costs may allow studies to analyze more samples.
- Conversely, use of Method 1628 may be needed to meet funding constraints.

Conclusions



- As with *any* data collection effort, it is important to match the analytical methods to the questions to be answered.
- In the case of PCB congener analyses used to establish fish advisories, the cancer screening level or “action limit” of 12 ng/g for total PCBs is high enough that Method 1628 could be the more appropriate and cost-effective choice.
- While its lesser sensitivity has implications for comparisons of results across different studies, the common refrain of “*but we’ve always done it that way*” must be examined in greater detail during project planning.
- For targeted studies of contaminated sites where the “action levels,” are often higher, Method 1628 may offer the ability to collect more samples for the same analytical cost.

Questions?