Chemicals Should be Proven Safe Before Use Rather Than Proven Toxic After Use *A Case Study on PCBs* 

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#### INTRODUCTION TO PCBS

Virtually everyone on the planet has some amount of man-made chemical in their body. Although chemical contamination is expected in people who live near industrial or agricultural areas, even the isolated Inuit people of Canada have high levels of synthetic chemicals in their bodies, including PCBs (Ronald Fein). PCBs were allowed to be made between 1929 to 1976, and were so deleterious that the effects are still seen today. The Hudson River, considered a superfund site due to PCB contamination, is still polluted. This specific example of PCBs alone should have been enough to convince politicians to enact stricter laws so this could not be repeated again. However, the law passed to regulate industrial chemicals, TSCA, was not enough, and the amendment made to TSCA in 2016 is still not enough; another PCB situation can still happen. The United States needs to amend TSCA once again to include the precautionary principle: stricter requirements for chemicals to be proven safe before they are allowed to be used in production.

PCBs is an acronym for polychlorinated biphenyls. The chemical was discovered in 1881 as a byproduct of benzene and started to be produced for industry in 1929 (*Polychlorinated Biphenyls 1929-1979: Final Report*). They were made for use in machines such as electronics and capacitors due to its high heat resistance (OLEM US EPA). Concerns of its toxicity started after an epidemic in a community in Japan which was determined to be caused by accidental ingestion of PCBs from rice oil, called Yusho Disease.

Polychlorinated biphenyls refers to a group of complex chlorinated organic compounds. They are produced from mixtures of chlorine, carbon, and hydrogen atoms, of which there are 209 possible forms of (Schierow). Each of these mixtures have different trade names. Monsanto's trade name, who was the sole producer of PCBs in the United States, was Aroclor (Bourne, Joanna W.). The variety and complexity of the chemical makes PCBs a difficult compound to study and understand the effects of, as different mixtures can lead to different reactions (Schierow).

PCBs are highly stable, and therefore degrade very slowly. The more highly chlorinated mixtures tend to be more persistent. Since the chemical stays in the environment for a long time, it cycles between atmosphere, land, and water. PCBs adsorb relatively rapidly onto various surfaces such as plastic, glass, silt, and sand, and therefore tend to accumulate in sediments of water bodies (Bourne, Joanna W.).

"PCBs do not readily break down once in the environment. They can remain for long periods cycling between air, water and soil. PCBs can be carried long distances and have been found in snow and sea water in areas far from where they were released into the environment. As a consequence, they are found all over the world." (OLEM US EPA).

The solubility of chloro-biphenyls in water is low but they are quite soluble in hydrocarbon solvents and in lipids, or fat. This is what makes PCBs bio-accumulative, meaning the presence of the chemical increases as it accumulates up the food chain in the fatty tissues of animals. Carnivores higher in the food chain have higher PCBs levels than found in the surrounding environment (Bourne, Joanna W.). The fact that PCBs are persistent and bioaccumulative makes this chemical highly detrimental to the environment and it is the reason why the effects of PCB production are still seen today.

Their bioaccumulation and persistence is especially an issue since PCBs are toxic to animals. The estimate for an allowable daily intake of PCBs for people ranges between 35 and 140 microgram per day, depending on weight, with specific populations who are more at risk being young children and fetuses (Bourne, Joanna W.). Symptoms of PCB poisoning include darkening and thickening of the skin, severe chemical acne, eye discharge, nausea, loss of appetite, joint or muscle pain, abnormal liver function, and much more. Infants exposed before birth have had abnormalities of the gums, skin, nails, teeth, and lungs, and have been observed to be slower to develop (Schierow). Human health effects have been documented after the Yusho Disease incident, which occurred in 1968 and gave a grim understanding of the severe effects of PCBs to humans. A total of 1,291 people were recorded to have been affected, with symptoms noted to be slowed growth, neuro-endocrine issues, enzyme metabolism issues, chloracne, ocular issues, fatigue, headaches, and much more. The concentration of PCBs in the oil was gauged at 1000 or 2000 ppm, with effects seen at around 2000 mg of digested PCBs (Bourne, Joanna W.). Effects of this incident can still be observed, as mortality from cancer in the exposed individuals is higher compared to average citizens in Japan fifty years later (Onozuka et al.).

In addition to these effects there are also reproductive, immune, neurological, and cancerous effects. PCBs in animals have been shown to increase mortality rates of offspring, reduce birth weight, reduce conception rates, suppress the immune system, and more (OLEM US EPA). The chemical is a B2 classified carcinogen, a probable human carcinogen, from high evidence of carcinogenicity in animals. PCB workers had higher cases of rare liver cancers and malignant melanoma then the average citizen. The estimated dose associated with only a 10 percent increase of cancer is between .086 to 2.4 milligram dose per kilogram of weight (Jim Cogliano).

Since PCBs bioaccumulate in the food chain, the general population is most likely to be contaminated with it through food and in particular, fish. Workers are exposed if handling PCBs or handling electrical equipment that has PCBs. The ATSDR has suggested that indoor air is an exposure source to PCBs from older fluorescent lights and appliances (Schierow).

An example of PCB contamination is the Hudson River Superfund site, a 200 mile stretch of the river polluted by PCBs because of General Electric. Between 1947 and 1977, GE discharged as much as 1.3 million pounds of PCBs from 2 manufacturing plants located about 50 miles above Albany (R. 02 US EPA). A 40 mile stretch of the Hudson River between Fort Edward and just above Albany was determined to be the most polluted area with 40 hotspots, defined as sediment containing greater than 50 parts per million of PCBs ("Hudson River PCBs"). Under the Superfund Law, GE was required to pay for dredging to clean this section up, which cost over one billion dollars (McKinley). Fortunately, the dredging project was an enormous success and historical achievement with more than 300,000 pounds of PCBs removed (*EPA: Dredging Effective in Reducing PCB Levels*).

Overall, PCBs are highly dangerous to the environment and to human health, as they do not biodegrade quickly and accumulate in the environment. Prior to 1976, during production of PCBs, concerns over various toxic chemicals increased and finally accumulated to the creation of the Toxic Substances Control Act in 1976. The TSCA was the first legislation to extend regulation to industrial chemicals and fully banned the production of PCBs for being bioaccumulative and long lasting in the environment. Although the TSCA was passed to protect human health and the environment, it is largely considered a massive failure.

## TOXIC SUBSTANCES CONTROL ACT

TSCA law excludes pesticides, food and additives, drugs, and cosmetics from the law's definition of a chemical substance, since these chemicals each have separate regulation. The main purpose of TSCA is written in the introduction of the law: (1) adequate data should be developed on the effects of the chemical substance to health and the environment by the

manufacturer; (2) authority should exist to regulate chemical substances found to present unreasonable risk of injury to health or the environment; and (3) the authority over chemical substances should not impede economic or technological growth (*Public Law 94-469 [S. 3149]*).

In order to determine which chemicals had to be tested, two groups, new and existing, was created. Existing chemicals, starting at around 62,000 chemicals in total, were exempt from regulation under the law simply because they were in use before 1976 (Schmidt). If an existing chemical was suggested to be toxic, like formaldehyde, the EPA had to prove the chemical had unreasonable risk to human health or the environment in order for the EPA to regulate it. This caused an unbeatable paradox. The EPA had to demonstrate the need for data by determining an unreasonable risk, but needed data to determine unreasonable risk. On top of this, the court case Corrosion Proof Fittings v EPA in 1991, which revoked the EPA's ban on asbestos, determined that the interpretation for the 'least burdensome requirements' in TSCA requires the EPA to conduct a comprehensive benefit-cost analysis with comparisons to several other possible approaches in order to validate the chosen risk management approach (Schmidt). Such an extensive evaluation was just not feasible for the EPA to conduct on every substance that was suggested to be toxic (Bergkamp and Abelkop).

As for new chemicals, TSCA did require companies to submit applicable health and environmental data via premanufacture notices (PMNs) (Schmidt). However, these PMNs were not required to include toxicity, health, or safety data. The EPA did have the authority to prohibit the manufacturing of a new chemical only if the information given in the PMN was insufficient or presented unreasonable risk to public health or the environment (Jellinek). The EPA only had 90 days to review a PMN submission. If EPA took no action within the 90-day review period, the new chemical was added to the TSCA inventory. The TSCA inventory started at about 62,000, from existing chemicals that were not required to be tested, and now contains 86,557 chemicals (OCSPP US EPA, "How to Access the TSCA Inventory"). Once on the inventory, the chemical was rarely reviewed due to the regulatory hurdles and unbeatable paradox written into the law. Therefore, TSCA was designated as broken. It failed to protect public health and the environment and overall, undermined the public's trust in chemical industries (Bergkamp and Abelkop).

In 2016, TSCA was finally amended by the Frank Lautenberg Chemical Safety Act. This act prohibits the manufacturing of a new chemical and the manufacturing of a significant new use chemical. Although still highly still reminiscent of the pre-amended TSCA, the act developed a structured process to chemical risk assessments by creating deadlines for the evaluations and requirements for new chemicals to be assessed prior to industrial use. The EPA can more easily and quickly collect test data from industry on a case-by-case basis, thereby getting rid of the paradox (Botos et al.).

Since simply going down the TSCA inventory list of chemicals already in use and doing a risk evaluation process for each is onerous, this act specifies the regulatory requirements to split chemicals into two groups, high priority and low priority. The prioritization process is much more structured, and the timeline requirement is at least nine months but not more than twelve. If evidence is still uncertain after the 12 months of review, the EPA moves the substance to highpriority designation for further evaluation. High priority is based on hazard and exposure potential, including whether the substance is persistent or bio-accumulative, whether there may be a susceptible subpopulation, potential for contamination of drinking water, the conditions of use for this chemical, and production volume (Bergkamp and Abelkop). If a substance is flagged as high priority, it will move into the risk evaluation stage, and a final risk determination must be made within three years. Otherwise, the chemical will be allowed to be produced and used by industry (OCSPP US EPA, "Risk Evaluations for Existing Chemicals under TSCA").

This amendment was highly necessary since the pre-amended TSCA was not a strong or safe regulation. However, this act does have flaws which prevent the law from reducing risk to a reasonable level. The nine-month timeline in the amended TSCA is still not long enough to fully determine the safety of a chemical. This is true for newly developed chemicals, which are typically created to replace unsafe older chemicals, but do not have enough data to fully ascertain their safety. Nine months is especially not long enough to determine carcinogenicity. Taking PCBs as an example, the first assessment of carcinogenicity was in 1987, 11 years after their ban (OLEM US EPA). Furthermore, risk evaluations are highly tedious and time consuming. For example, the risk assessment published for trichloroethylene took four years and is 803 pages long (OCSPP US EPA, "Risk Evaluation for Trichloroethylene (TCE)"). A similar length of risk assessment has occurred for the 10 chemicals substances that were subject to a required risk evaluation under the amended TSCA (OCSPP US EPA, "Risk Evaluations for Existing Chemicals under TSCA"). The length, scientific aptitude, technical expertise, and data required is impressive and unmatched. However, it is for this reason it is highly implausible to apply this process to every chemical.

Overall, the amended TSCA is still not well developed enough to precautionarily catch deleterious chemicals before their use in industry. A nine-month timeline in the amended TSCA is not long enough to fully determine the safety of a chemical, particularly not for newly developed chemicals. Thus, the answer to the question of "Can another PCB situation happen again?" is yes. There are 700 new chemicals being created every year, and nine months for each is not long enough to issue a proper determination on chemical safety (Bergkamp and Abelkop).

## COMPARABLE RISK ASSESSMENT LAWS

By learning from other risk assessment laws, ideas that could be implemented in TSCA can be generated. To start, REACH is a highly ambitious law passed by the European Union in 2007. REACH stands for Registration, Evaluation and Authorization of Chemicals. REACH (1) registers chemicals, (2) evaluates industries risk assessment, (3) phases out substances of very high concern, and (4) restricts certain chemicals of concern. The requirement for new chemicals to be manufactured in the EU is based on the idea of no data, no market. If a substance is not registered, it may not be manufactured or placed on the market. This is done through a Chemical Safety Report (CSR) produced by the manufacturer, which details potential exposure scenarios and risk management measures. A dossier must include information on the identity of the manufacturer; the identity of the substance, which includes chemical and physical properties; how the manufacture uses the substance; the environmental fate and pathways; toxicological information; guidance on safe use; and research summaries. REACH allows multiple manufacturers of the same chemical to submit a single dossier, 'one substance, one registration', which reside on the Substance Information Exchange Forums (SIEFs) (Bergkamp and Abelkop). This method reduces repetitive risk assessments for the same substance.

It must be noted that there are many cons to REACH as well. Risk assessments will differ for every chemical and every organization, and consequently it is very confusing to understand the requirements (Niva Kramek). Additionally, ECHA has only evaluated around 30% of the registered substances for compliance of the dossier requirements (*Progress in Evaluation -ECHA*). Discussing the flaws of REACH is important to understand that an exact replica of REACH in America is not ideal, although lessons and ideas can be drawn from this unparalleled and visionary law. There is a statute that America has ratified which is more precautionary than TSCA. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the federal law that regulates pesticides (OP US EPA). Pesticides must be registered under FIFRA in order to be distributed, sold, or used in the United States. Similar to REACH, this law places the burden of proof onto manufacturers (Li). A pesticide may not be used if it poses "unreasonable adverse risks" to humans and the environment, which also encompasses the cost and benefits of using the chemical. A pesticide will be approved for use if it complies with FIFRA, it does not have unreasonable adverse effects on the environment, and it will not cause unreasonable adverse effects when used in accordance with widespread practice (Li). Although this is similar to TSCA, FIFRA is a licensing law, and TSCA is not (Jellinek). This distinction allows FIFRA to require an application to register a pesticide that includes the labeling of the product and the scientific data.

The data requirements, called the Pesticide Assessment Guidelines, have a robust set of requirements for test guidelines. Test guidelines include product chemistry, residue chemistry, environmental fate, wildlife and aquatic organisms, toxicology, and more. One interesting idea in FIFRA to deal with lack of scientific data for new substances is a 'Me Too' registration, similar to the REACH idea of 'one substance, one registration'. This type of registration allows for a manufacturer to rely upon data previously submitted by other applicants (Jellinek).

Additionally, FIFRA requires pesticides to be re-registered to fill in data gaps and update pesticides to meet new regulation requirements. The re-registration process has five-phases which are carried out over 9 years. The first three phases of the re-registration process require the manufacturer to identify and submit new data, and phase 4 and 5 require the EPA to conduct

their own review of the data and make the decision to re-register or take other appropriate regulatory action (Jellinek).

## **RECOMMENDATIONS FOR TSCA**

Reach has a 'stronger' precautionary approach than TSCA, as the narrative is no data, no market (Botos et al.). The dogma of proving a chemical is safe before use is not included in the amended TSCA. Rather, TSCA designates chemicals into low and high priority. A method to shift TSCA into a precautionary approach is to implement the REACH risk assessment concept of requiring industry to conduct a simple risk assessment with their data. In this way, risk assessments would be conducted for each chemical on the market and the EPA would not bear the burden. The EPA could still continue to prioritize chemicals on high and low priority and conduct full risk evaluations for high priority substances; however, it is more precautionary to conduct a simple risk assessment that is on the market.

FIFRA is highly robust and can be applied to TSCA. There should be more testing for all chemicals. Since the long-lasting effects of chemicals cannot be discovered in only nine-months, especially cancerous effects, TSCA could add a re-review every 15 years similar to FIFRA. A nine-year period with 5 phases can be replicated, and would create more robust data sets to further understand toxicity. Like FIFRA, test guidelines for registering chemicals could be included, such as toxicity, aquatic effects, environmental fate, and more. This re-registration with guidelines will reduce the pollution of a chemical if it is proven toxic when previously designated as safe. Additionally, FIFRA requires industry to gather data but still requires the EPA to make the final decision to re-register the chemical. This is an important function of FIFRA that should be kept if amending TSCA to match, since public servants should be the ones to make the decisions on public health (Niva Kramek).

One massive issue which is not addressed in TSCA is a lack of applying foreign health and environmental effects to chemical risk assessment. The requirement to consider foreign effects is not explicitly stated in TSCA and therefore not enforceable. Chemicals can travel far from the point of entry into the environment via air, water, and animal species. Regarding PCBs specifically, Inuit populations of the Canadian arctic have among the highest levels of chemical exposure due to their heavy fish and sea-animal oriented diet. Considering the smallest amount of exposure has profound effects on people, especially young children, this is markedly alarming. By learning from the mistakes of PCBs, chemicals regulated under TSCA should consider the transboundary effects as well. The EPA worked cooperatively with Canada regarding the persistent toxic chemical contamination in the Great Lakes, called Great Lakes Binational Toxics Strategy, proving that international cooperation for chemical regulation is feasible (Ronald Fein). Multilateral regulation on toxic chemicals is ideal to fully reduce humanities impacts on the world.

Following the international concept, another idea to achieve better chemical regulation and understanding is to set up a transparent data sharing service. The chemical data the EPA is amassing can be verified against data from Canada and the European Union. If every country's data on chemicals is shared, there is less likely of a chance for a company to alter the data in some way that benefits them. In the US, there is a Chemical Abstract Service (CAS), which is a subsect of the American Chemical Society, and has harmonized the rules for chemical substance identification. It is a registry base and is the largest chemical substance database in the world (Botos et al.). Publicizing data ought to be a requirement for industry for a means of accountability, which is currently lacking under TSCA.

#### CONCLUSION

Scientific uncertainty will always exist regarding chemical toxicity, especially for new substances. The underlying message in TSCA is a desire to place economic benefits above environmental hazard, symbolized by the extremely late reform. Congress ought to lean more towards precautionary measures if a chemical poses even the slightest toxicity towards the earth rather than considering the economic effects. Doing so would not destroy America's economic power, rather would force the industry to adapt and engineer greener and safer chemicals. In this way, America could instead become a leader in developing safer chemicals. Placing greater precautionary buffers to deal with scientific uncertainty ought to be a higher priority over economic consequences. If companies invest more in ecological safety currently, future hazardous clean-up requirements can be avoided. As with General Electric and the Hudson River, if the precautionary principle was considered, GE may not have had to pay over a billion dollars in clean-up under CERCLA (McKinley).

This issue of prioritizing economic effects above health and environmental effects can be seen in the results of Corrosion Proof Fittings v EPA in 1991. This hearing repealed the EPAs ban on asbestos due to the EPA failing to select the least burdensome regulation (Stadler). The requirement for the EPA to justify the chosen risk management approach for asbestos along with a thorough cost-benefit analysis proves the American narrative of placing the economic welfare above environmental or health. This ideological thought in TSCA is proven through PFAS. Currently, there are no maximum contaminant levels set for PFAS in drinking water in America whereas REACH in Europe includes a limit of 0.5  $\mu$ g/l for all PFAS in drinking water (*Perfluoroalkyl Chemicals (PFAS) - ECHA*). This is a fundamental flaw within the American

ideology and is the reason a PCB situation can occur again under TSCA. A fundamental philosophical shift in principles will be required to implement a precautionary approach.

The deleterious effects of PCBs should have been the wake-up call to initiate stronger precautionary regulations. Although TSCA at the time was revolutionary, it failed to adequately protect human and environmental health and allowed for the production of PFAS. The amendment made to TSCA in 2016 is still not enough; another PCB situation can still happen. The United States should amend TSCA once again to include the precautionary principle: stricter requirements for chemicals to be proven safe before they are allowed to be produced.

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