Toxic Free Future

Kara:

Please find our comments on the Children's Safe Products Act Reporting Rule attached.

Thank you!

Laurie
Laurie Valeriano
Executive Director
Toxic-Free Future (Formerly WA Toxics Coalition)
206-632-1545x114 (o)
206-200-2824 (c)
lvaleriano@toxicfreefuture.org

TOXIC-FREE FUTURE
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4649 Sunnyside Avenue N
Suite 540
Seattle, Washington 98103

May 12, 2017

Kara Steward
Washington Department of Ecology
Hazardous Waste & Toxics Reduction Program
P.O. Box 47600
Olympia, WA 98504

Comments in response to CSPA rulemaking proposal dated March 22, 2017

Dear Ms. Steward:

Toxic-Free Future (TFF) is in strong support of the proposed addition of 21 chemicals to the high priority list of chemicals of high concern to children (the CHCC list). The data collected under the Children's Safe Products Act has been extremely valuable in learning about specific uses of toxic chemicals in children's products. The 66 chemicals currently on the list are a fraction of the estimated 80,000 chemicals on the market. More disclosure is clearly needed and the addition of these 21 chemicals is a great step.

However, TFF respectfully requests the Department of Ecology (Ecology) reconsider its decision to omit several chemicals that are a health concern for children from the CHCC list, including two toxic flame retardants, several phthalates, D4, and chemicals that break down into PFOA. Specifically, TFF requests that Ecology:

1. *Include the highly toxic and persistent Perfluorooctanoic acid (PFOA) and Related Substances on the CHCC list:* This is an important class of hazardous chemicals that are used in a range of products and are now threatening drinking water supplies in several Washington communities. It is simply not adequate to only list PFOA when there are numerous chemicals in this class that can be a health risk to children. TFF requests that Ecology expand the proposed listing of PFOA to PFOA and related substances. It is important to include "related substances," which have the potential to degrade to form PFOA. By expanding the listing in this way, Ecology would obtain information on the compounds that are intentionally used in products, and not just

the final degradation product, PFOA. This approach would be consistent with the one used in the European Union and would provide much-needed information as the agency develops and implements a chemical action plan on PFAS chemicals.

2. *Include all of the toxic flame retardants currently proposed as well as two additional ones, on the CHCC list.* TFF strongly supports the addition of all of the flame retardants proposed by Ecology for addition to the CHCC list. We also request that Ecology add Dechlorane Plus (CAS # 13560-89-9) and BDBPE (CAS # 37853-59-1) to the list as we requested in 2013 and 2016. There is new information showing that a breakdown product of BDBPE is bioaccumulating in people and affecting thyroid hormone levels (Leonetti, Butt et al. 2016). Researchers found the breakdown product 2,4,6- tribromophenol in human placenta at levels higher than those of PBDEs. Both of these chemicals meet the toxicity and exposure criteria for listing, and information on their use is needed.

3. *Include three additional phthalate chemicals in addition to the ones already proposed to the CHCC list.* TFF strongly supports the proposed addition of three phthalates to the CHCC list: DCHP, DIBP, and DNPP. However, we also request that Ecology add three more phthalates that were included in TFF's 2016 petition: DEMP, DIOP, and DIPP. As industry moves away from phthalates that have already been restricted, it is critical that we obtain information about likely substitutes.

4. *Keep D4, a hormone disrupting chemical on the CHCC list.* TFF strongly opposes the de-listing of D4. D4 is clearly used in children's products and has already been reported over 2,300 times by manufacturers. D4 is considered by the EU to be a Category I chemical on its priority list of suspected endocrine-disrupting chemicals. There are ample studies showing D4 endocrine disruption and it is not defensible to remove the chemical from the list based on results from one assay (utertrophic) that does not provide the only evidence of endocrine disruption. There is no reason to remove D4 from the list. TFF requests Ecology retain D4 on the CHCC list.

TFF thanks Ecology for its important work protecting our health and environment from harmful chemicals and for the opportunity to provide the attached additional scientific evidence to support our position.

Sincerely,

Laurie Valeriano
Executive Director

Perfluorooctanoic Acid (PFOA) (CAS # 335-67-1) and Related Substances

TFF strongly supports the proposed addition by the Department for Ecology of perfluorooctanoic acid (PFOA) to the CHCC; however, TFF respectfully requests that the Department of Ecology change the proposed listing of PFOA to include PFOA and related compounds.

PFOA and related compound are used in the production of stain-resistance compounds used on textiles, polymers with numerous applications, fire-fighting foams, coatings, surfactants, and other products. The European Chemical Agency (ECHA) has classified PFOA as toxic for reproduction (ECHA, 2015b) and the International Agency for Research on Cancer has designated PFOA as a possible carcinogen based on epidemiological evidence linking exposure to kidney and testicular cancer (IARC, 2016), (Lau et al. 2007), (Barry et al. 2013), (Benbrahim-Tallaa et al. 2014). These compounds are widespread in the environment as a result of industrial releases and from their use in consumer products. Precursor chemicals used commercially can degrade to PFOA biotically and abiotically after their release during production or from in-use products (Butt et al. 2013) (D'eon and Mabury 2011). PFOA does not degrade in the environment and has been designated by the European Union as persistent, bioaccumulative, and toxic (PBT) (ECHA, 2013b). Despite the US EPA PFOA Stewardship Program challenging manufacturers to end releases of PFOA, recent testing has detected the compound in consumer products. PFOA has been detected in house dust, surface water, drinking water, sediment, outdoor air, fish, marine mammals, polar bears and other biota, and human blood (Calafat et al. 2007) (Furl et al. 2011) (Fraser et al. 2013) (Houde et al. 2011) (Ahrens and Bundschuh 2014) (Dinglasan-Panlilio et al. 2014).

There is precedent on the CHCC list for listing chemicals and related compounds. For instance, several metals, including arsenic and cadmium, are listed along with related compounds, and 3,3'-dimethylbenzidine is listed with dyes metabolized to 3,3'-dimethylbenzidine. For a sufficient understanding of the use of chemicals likely to degrade to PFOA, it is necessary to list PFOA along with related compounds. This is the approach taken in restrictions being considered by the European Union Committee in September, 2015. The approach was to restrict "manufacturing, use, and placing on the market of Perfluorooctanoic Acid (PFOA) and its salts, also including substances that may degrade to PFOA (PFOA-related substances) (ECHA, 2015b)."

The use of PFOA-related substances in consumer products is largely unknown by the public and by policymakers. By requiring disclosure of PFOA related compounds, the Department of Ecology would obtain information on the presence of chemicals in children's products that break down into PFOA. This approach would provide the public and policymakers critical information on potential exposure routes for kids, and be consistent with the European Union.

Toxic Flame Retardants

TFF is in full support of the addition of DBDPE, TCP, and SCCP to the CHCC list, as we requested in our petition dated August 5, 2016. These flame retardants should be included on the CHCC because of their toxicity characteristics and their known exposures to children which are summarized below:

Decabromodiphenyl ethane (DBDPE) (CAS # 84852-53-9)

Uses: DBDPE is used as a substitute for deca-BDE as an additive flame retardant, primarily in housings for electronics. According to industry marketing materials, it can be used in multiple plastic resins.

Children's exposure: DBDPE has been detected widely in house dust, including in Washington state (Stapleton et al. 2008) (Dodson et al. 2012) (Schreder and La Guardia 2014). Washington Department of Ecology testing has found DBDPE in children's products including a tablet, pajamas, furniture, and car seat (Department of Ecology 2016b). A study of Canadian mothers detected DBDPE in serum and breast milk (Zhou et al. 2014). It has been detected in children's toys in China at levels up to 237 µg/g (Chen et al. 2009). In a survey of sewage sludge from 12 countries, DBDPE was found in sludge from all countries (Ricklund et al. 2008). It has also been detected in outdoor air in the Great Lakes basin as well as the Arctic, and in tree bark (Salamova and Hites 2011) (Salamova and Hites 2013) (Salamova et al. 2014).

Toxicity: DBDPE was rated as high or very high hazard by the US EPA for developmental effects, persistence, and bioaccumulation (US EPA 2014c).

Developmental effects: EPA estimated a LOAEL of 6 mg/kg-day for decreased levels of T4 in male mice and locomotor effects; a LOAEL of 6.7 mg/kg (single dose gavage) for disruption in habituation in male Sprague Dawley rats; and 20.1 mg/kg (single dose gavage) for disruption in habituation in male mice (US EPA 2014c).

Hormone disruption: Rats orally exposed to DBDPE for 90 days had significantly increased levels of T3 (Wang et al. 2010).

Repeated dose effects: The 90-day oral study in rats determined a LOAEL of 100 mg/kg-day (only dose tested) for hepatotoxicity indicated by changes in serum chemistry (also cited by EPA) (Wang et al. 2010) (US EPA 2014c).

Persistence: EPA designated DBDPE "very high" for persistence based on studies that found it was not inherently biodegradable in activated sewage sludge or anaerobic sewage sludge and an estimated environmental half-life of more than one year (US EPA 2014c).

Bioaccumulation: EPA designated DBDPE "high" for bioaccumulation hazard based on "monitoring data reporting detections in many different species including those higher on the food chain." EPA cites detections in five fish species in Lake Winnipeg, Canada; giant

and red pandas in China; in the muscle of wild water birds from China's Pearl River Delta as well as bird eggs from North China; in herring gull eggs from the Laurentian Great Lakes; in falcon eggs from Canada and Spain; sole from the French Atlantic coast; in polar bears from Canada; in mussels from Japan and Korea; prawns, birds, and fish from Asia; and bird eggs in the Norwegian Arctic (US EPA 2014c).

Tricresyl Phosphate (TCP) (CAS # 1330-78-5)

Use: TCP is a flame retardant used in PVC and other plastics as well as in hydraulic fluids.

Children's Exposure: TCP has been detected in house dust in California and Canada as well as in other countries (Zhu et al. 2007) (Dodson et al. 2012) (Webster and Dodson 2014). It has not been widely analyzed in biota, but was detected in a Swedish study in perch, mussels, eelpout, and salmon (Sundkvist et al. 2010).

Persistence and Bioaccumulation: The USEPA rated TCP as High hazard for bioaccumulation (US EPA 2015). Bioconcentration factors between 385 and 2,768 have been measured for fish (Environment Agency 2009). Biodegradation appears to occur in the aquatic environment, but TCP persists in sediment with a projected half-life of 300 days (Environment Agency 2009).

Reproductive Toxicity: The USEPA has rated TCP as High hazard for reproduction based on a Bi of 7 mg/kg/day for ovarian lesions (US EPA 2015). In rats exposed by gavage, sperm concentration, motility, and progressive movement were lower than in control rats, and a dose-dependent increase in abnormal sperm morphology was observed; fewer exposed females delivered live young; the LOAEL was established at 100 mg/kg/day based on abnormal sperm morphology (US EPA 2015) (Carlton et al. 1987). From a dietary exposure study in mice, EPA estimated a LOAEL of 62.5 mg/kg/day based on decreased sperm motility (US EPA 2015). Histopathologic changes were observed in both male and female reproductive organs. A National Toxicology Program 2-year feeding study in rats found those exposed to 300 ppm (estimated equivalent 15 mg/kg) had increased incidence of ovarian lesions (NTP 1994)

Organ Toxicity: The USEPA has rated TCP as High hazard for repeated dose toxicity (US EPA 2015). A 9-week feeding study of Wistar rats found increased absolute and relative liver weights as well as changes in levels of protein, cholesterol, and other compounds in rats exposed to 5 g/kg TCP in their diets (Environment Agency 2009).

Neurotoxicity: In the National Toxicology Program's 13-week gavage study in mice, neuronal degeneration was observed in mice exposed to doses of 100 mg/kg and above (NTP 1994).

Short-Chain Chlorinated Paraffins (SCCPs) (CAS # 85535-84-8)

Use: SCCPs are used in lubricants, as coolants in metal operations, and as flame retardants in plastics, particularly PVC (US EPA 2009). According to the industry, they are commonly

used as secondary plasticizers together with phthalates or phosphate esters; they can also be used in other plastics including ABS, polyester, polyethylene, polypropylene, and urethane foam (Chlorinated Paraffins Industry Association 2009). US production has ceased, but they are also produced in China.

Children's Exposure: SCCPs have been detected in breast milk as well as other human tissues (Thomas et al. 2006) (US EPA 2009). They have also been detected in indoor air as well as household dust, and researchers have identified both inhalation and dust as important sources of exposure (inhalation greater for adults and dust greater for young children) (Friden et al. 2011). SCCPs have been detected in food including oils, butter, animal fat, fish, and shellfish (Bayan et al. 2006). They have been found in outdoor air in Norway at up to 10.6 ng/m^3 as well as in the UK; in river water in Europe and Canada; and in sediments in Europe, Japan, and Canada (Bayan et al. 2006).

Persistence and Bioaccumulation: The US EPA has stated that SCCPs are "persistent, bioaccumulative, and toxic to aquatic organisms at low concentrations. They can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, increasing the probability and duration of exposure" (US EPA 2009). The Washington Department of Ecology and the European chemical Substances Information System (ESIS) have listed SCCPs as a PBT (Washington state Department of Ecology). The Persistent Organic Pollutant Review Committee of the Stockholm Convention concluded that SCCPs meet the criteria for listing under the convention, stating that they "are likely as a result of long-range environmental transport to lead to significant adverse human health and environmental effects such that global action is warranted" (Persistent Organic Pollutants Review Committee). Chlorinated paraffins have been detected in fish and aquatic invertebrates, Beluga whales, and earthworms (Bayan et al. 2006).

Toxicity: SCCPs are listed as a Substance of Very High Concern by the European Chemicals Agency (ECHA 2010).

Cancer: SCCPs have been identified by the State of California as carcinogenic under the Safe Drinking Water and Toxic Enforcement Act (Prop 65) (Office of Environmental and Health Hazard Assessment. 2015). The National Toxicology Program has listed chlorinated paraffins as "reasonably anticipated to be human carcinogens" (NTP 2014).

Additional Flame Retardants

On September 6, 2013 TFF (then known as Washington Toxics Coalition) submitted a petition to the Department of Ecology requesting that the flame retardant Dechlorane Plus (CAS # 13560-89-9) and several other chemicals be added to the CHCC list. On August 5, 2016 TFF (then known as Washington Toxics Coalition) submitted a petition to Ecology requesting that the flame retardant BTBPE (CAS # 37853-59-1) and several other chemicals be added to the CHCC list. TFF respectfully requests that Ecology consider adding Dechlorane Plus and BTBPE to the CHCC list in this rule update. TFF's rationale for listing Dechlorane Plus and BTBPE are given below:

Dechlorane Plus (CAS # 13560-89-9)

Dechlorane Plus is a chlorinated flame retardant used in wires, cables, and connectors and in paper laminates, with typical levels in the range of 20-25% (Weil and Levchik 2004). It can be used in multiple polymers including ABS, HIPS, epoxy, nylon, and polypropylene (Oxychem 2007). A significant use is reported to be in television enclosures (Weil and Levchik 2007).

Children's Exposure: Dechlorane Plus is used in consumer products and has been detected in house dust in California and Canada (Dodson et al. 2012) (Shoeib et al. 2012). It has also been detected in outdoor air in the Great Lakes region as well as in Europe and the Arctic (Peverly et al. 2015) (Salamova et al. 2014) (Sverko et al. 2011). A Canadian study detected the compound in breast milk, and European and Chinese studies have detected it in human serum (Siddique et al. 2015) (He et al. 2013) (Cequier et al. 2015). It has also been found to cross the placenta (Ben et al. 2014).

Persistence and Bioaccumulation: The predicted half-life of Dechlorane Plus is 360 days in soil and 1600 days in sediment (Office of Environmental and Health Hazard Assessment 2008). The bioaccumulation appears to differ between the two isomers (syn- and anti-), but the predicted bioconcentration factor (BCF) is 3.2 (Office of Environmental and Health Hazard Assessment 2008). Modeling and detections in sediment and biota suggest that Dechlorane Plus may be persistent, bioaccumulative, and subject to long-range transport (Sverko et al. 2011).

Reproductive Toxicity: In a 28-day dermal toxicity study in rabbits, there was a significant decrease in absolute ovarian weights at the lowest dose tested, 500 mg/kg-day. This result places Dechlorane Plus in the "severe" category for reproductive toxicity (US EPA 2011).

Endocrine Disruption: Serum levels of Dechlorane Plus were associated with higher total T3 levels in women living more than 20 years in an e-waste recycling region of China (Ben et al. 2014).

Organ Toxicity: In a 28-day day inhalation study in rats, at the lowest dose tested, 0.64 mg/L (dust), both male and female rats showed significant increases in absolute liver weights. Females also had significantly greater lung weights and slightly increased numbers of macrophages in the alveoli (US EPA 2011).

Additional Considerations: Dechlorane Plus has a high degree of structural similarity to organochlorine pesticides including heptachlor, chlordane, nonachlor, and aldrin, substances restricted due to persistence, bioaccumulation, and toxicity (Zhu et al. 2007).

1,2-bis(2,4,6-tribromophenoxy)ethane (BTBPE) (CAS # 37853-59-1)

TFF requested the addition of 1,2-bis(2,4,6-tribromophenoxy)ethane (BTBPE) in our August 2016 petition. BTBPE is an additive flame retardant introduced to replace octa-BDE and used in various plastic resins including polystyrene and thermoplastics.

This compound has been detected in house dust, in children's toys, and in human serum. We again request the addition of this compound, which appears to disrupt thyroid hormone. Evidence of thyroid impacts include the following: tests on chicken eggs and hepatocytes found that BTBPE exposure depressed expression of a key enzyme related to thyroid hormone (Egloff et al. 2011). In addition, BTBPE's metabolite 2,4,6-tribromophenol (2,4,6-TBP) is a thyroid-disrupting compound (Hamers et al. 2006, Butt et al. 2011, Lee et al. 2016). In an epidemiological study, dust concentrations of BTBPE were positively and significantly associated with levels of T3 in adult men (Johnson et al. 2010).

Children's Exposure: BTBPE has been detected in household dust in Washington state as well as Boston, California and the UK (Harrad et al. 2008) (Stapleton et al. 2008) (Dodson et al. 2012) (Schreder and La Guardia 2014). It has been detected in children's toys in China at levels up to 117 μg/g as well as in food samples in Sweden and Ireland (Chen et al. 2009) (EFSA Panel on Contaminants in the Food Chain 2012) (Sahlstrom et al. 2015). BTBPE has been detected in human serum in two studies, in Norway and in Canada (Zhou et al. 2014) (Cequier et al. 2015). Sampling in the Great Lakes region and the Arctic has detected BTBPE in outdoor air at levels up to 1 pg/m^3 (Salamova and Hites 2011) (Salamova et al. 2014). Higher concentrations in air were seen in Louisiana, up to 70 ng/m^3 (EFSA Panel on Contaminants in the Food Chain 2012).

Persistence and Bioaccumulation: In its analysis, the European Food Safety Authority identified BTBPE as having high persistence and high potential for bioaccumulation (EFSA Panel on Contaminants in the Food Chain 2012). BTBPE has been detected in various biota, including marine mammals in the South China sea and the Canadian Arctic as well as in Glaucous gulls from the Norwegian Arctic, juvenile sole from the French Atlantic coast, and trout and other fish in Lake Ontario (EFSA Panel on Contaminants in the Food Chain 2012) (Zhu et al. 2014). A study in juvenile trout given an environmentally relevant dose of BTBPE found fish accumulated the compound and concluded it has a high potential for biomagnification in aquatic food webs (Tomy et al. 2007). Researchers also found BTBPE accumulated in fathead minnows (de Jourdan et al. 2014).

Other effects: Inhalation exposure of rats to BDBPE resulted in behavioral, respiratory, and gastrointestinal effects as well as dermatitis (Harju et al. 2009). Dermal exposure of rabbits resulted in "nutritional and gross metabolic changes" (Harju et al. 2009).

Since the submittal of the petition, additional research has been published raising the level of concern about the potential health impacts of this chemical. In November 2016, Leonetti et al. published a paper titled "Brominated flame retardants in placental tissues; associations with infant sex and thyroid hormone endpoints" in Environmental Health (Leonetti et al. 2016). In the analysis of placental tissues (n=102), the authors found PBDEs as well as 2,4,6-TBP in all placentas; suprisingly, mean 2,4,6-TBP levels were higher than those of ∑PBDEs, an unexpected finding. These results indicate that 2,4,6-TBP bioaccumulates in placenta and suggest there are substantial sources of this compound. The study also found lower T3 levels in placentas with greater brominated flame retardant levels. The authors conclude that brominated flame retardants may be associated with

thyroid hormone changes that differ between the sexes, which may explain the sex-specific manner, which may explain the sex-specific associations seen in other epidemiological studies. Thus, available studies show that exposure occurs in children and that the metabolite has endocrine activity that may be detrimental to developing children.

TFF also supports the proposed additions of the following flame retardant chemicals to the CHCC reporting list:

- Isopropylated triphenyl phosphate (IPTPP) (CAS # 68937-41-7).
- 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB) (CAS # 183658-27-7).
- Bis (2-ethylhexyl) tetrabromophthalate (TBPH) (CAS # 26040-51-7).
- Tris (1-chloro-2-propyl) phosphate (TCPP) (CAS # 13674-84-5).
- Triphenyl phosphate (TPP) (CAS # 115-86-6).
- Bis(chloromethyl)propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate (V6) (CAS # 38051-10-4).
- Tris (4-tert-butylphenyl) phosphate (TBPP) (CAS # 78-31-1 and 220352-35-2).
- Tris (2,3-dibromopropyl) phosphate (TDBPP) (CAS # 126-72-7).
- Ethylhexyl diphenyl phosphate (EHDPP) (CAS # 1241-94-7).
- Tri-n-butyl phosphate (TNBP) (CAS# 126-73-8).

Phthalates

TFF is in full support of the addition of DCHP, DIBP, and DPP to the CHCC list. These phthalates should be included on the CHCC list because of their toxicity characteristics and their known exposures to children, which are summarized below:

Dicyclohexyl phthalate (DCHP) (CAS # 84-61-7)

Use: Dicyclohexyl phthalate (DCHP) is used in the manufacture of plastisol, which is used in sealant compounds and textile printing, and is used as a co-plasticizer in manufacturing PVC, rubber, and plastic compounds, and is used in the formulation of organic peroxide as a phlegmatizer and dispersing agent (ECHA 2015a). DCHP is included in fabrics, textiles, and apparel, and in plastic articles (ECHA 2015a) (NICNAS 2008a). It is used in screen printing inks (NICNAS 2008a).

Children's Exposure: In the US, DCHP has been found in bar soap, modeling clay (4000 mg/kg), pajamas (3400 mg/kg), and perfume (3 mg/kg) in 1 of 36 perfume samples (ECHA 2015a). DCHP was found in household dust in Kuwait (median 2.9 µg/g). An exposure estimate of daily DCHP intake from the dust indicated that toddler's exposure was 9 fold higher than that of adult's. DCHP was found in household dust in China and USA (upper limit of 0.3 µg/g) at a frequency of 15% and 18%, respectively. DCHP was found in indoor air in Norway (4 – 5 ng/m^3). DCHP was found in indoor air samples in Tokyo (0.07 µg/m^3). Exposure to dicyclohexyl phthalate can occur via inhalation of ambient air, ingestion of food and beverages, and dermal contact with consumer products containing it (Toxnet HSDB).

Toxicity: DCHP is found on the following authoritative lists:

- EU – Annex VI CMRs: Reproductive Toxicity Category 1B (ECHA Annex VI CLP spreadsheet).
- EU – REACH Annex XVII CMRs – Reproductive Toxicity Category 1B (ECHA Annex VI CLP spreadsheet).
- EU GHS H-statements: H360D May damage the unborn child (ECHA Annex VI CLP spreadsheet).
- EU Priority Endocrine Disruptor Group III (European Commission DG ENV, 2000).

Reproductive and Developmental Toxicity: In a key oral DCHP exposure study the most sensitive endpoints were lowered prostate weight, reduced anogenital distance and retained areola mammae in rats (LOAEL 80-107 mg/kg bw/day, NOAEL 16-21 mg/kg bw/day) (ECHA 2015a). In another study DCHP exposure in utero (0, 20, 100 and 500 mg/kg bw/day) resulted in an increased number of litters with resorptions at all doses, in a decrease in male fetal pup anogenital distances, and in increased inhibin B levels in all dose groups. Testosterone and anti-Mullerian hormone (AMH/MIS), as well as the follicle stimulating hormone (FSH) to Inhibin B ratio decreased in the mid-and high dose group. Histopathological effects in the testes were also evident in a dose dependent manner (ECHA 2015a). In another study histopathological changes were observed in testes, epididymis and prostate at all dose levels with a LOAEL of 20 mg/kg bw/day. The percentage of abnormal epididymal sperm was significantly increased at all doses (0, 20, 100 and 500 mg/kg/day) in the adult animals (ECHA 2015a).

Endocrine Activity: The overall weight of evidence analysis shows that the male reproductive effects observed following in utero exposure to DCHP are mediated via an endocrine (antiandrogenic) mode of action that involves irreversible effects induced by interference with steroidogenesis during fetal development (ECHA 2015a).

Additional Considerations: The Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (CHAP) recommended to the U.S. Product Safety Commission in July, 2014 that DCHP should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 % (CHAP 2014). DCHP is on EPA's TSCA Work Plan List, however the hazard criteria met for inclusion on this list is DCHP's acute and chronic aquatic toxicity (EPA 2014a).

Diisobutyl phthalate (DIBP) (CAS # 84-69-5)

Use: DIBP is considered a specialty plasticizer and is often combined with other phthalates. It has been used as a plasticizer for PVC, nitrocellulose, cellulose ether, and polyacrylate and polyacetate dispersions. It is used in nail polish, cosmetics, lubricants, floor carpets, tapestry, clothing treatments, rubber dentistry settings, as a fuel stabilizer, in leather varnishes and lacquers, as a concrete additive, as an adjusting agent for lead chromate paint pigments, lacquer manufacturing, and methyl methacrylate applications. DIBP is also used in printing inks for paper and packaging. Because DIBP has similar properties as dibutyl phthalate (DBP), it can be used as a substitute for DBP (CPSC 2010a). DIBP is used as a plasticizer in a wide range of materials including polyvinyl chloride (PVC) formulations, as a softener, in viscosity adjustment, in clothing treatments, as a fuel

stabilizer, as a concrete additive, etc. DIBP has also been classified by the Food and Drug Administration (FDA) as an indirect food additive through its use as a component of adhesives (EPA 2014b).

Children's Exposure: DIBP has been detected in crayons, bar ends of run bikes, erasers, school bags, selected toys and childcare products produced from foam plastic in Denmark and in dolls and figures in Germany (CPSC 2010a). DIBP has also been reported in house dust and in indoor air in Germany (CPSC 2010a). DIBP metabolites (MIBP) have been detected in human urine samples in the US general population, and in Germany (EPA 2014b). Urinary MIBP levels have increased over the past four surveys in all age groups, genders, and races, and in total. CHAP calculations estimate that the median/high (95th percentile) intake from NHANES biomonitoring data for DIBP is 0.17/1.0 μg/kg-day, respectively, in pregnant women (CHAP 2014).

Toxicity: DIBP is found on the following authoritative lists:

- EU REACH Candidate List of Substances of Very High Concern for Authorization (SVHC list), Reason for listing: Toxic for Reproduction (ECHA 2010).
- EU – CLP Classification: Reproductive Toxicity Category 1B (ECHA 2008a).
- EU GHS H-statements: H360Df- May damage the unborn child, suspected of damaging fertility (ECHA 2008a).
- EPA 2014 TSCA Work Plan list for meeting the criteria for Reproductive Toxicity (EPA 2014a).

Reproductive Toxicity: Several studies report reproductive toxicity for DIBP in animals. For example short-term oral exposure to DIBP caused significant adverse testicular effects in male adolescent rats including decreased testes weights, increased numbers of apoptotic spermatogenic cells, disorganized or reduced vimentin filaments in Sertoli cells, elevated testicular testosterone levels, decreased testicular zinc levels, and marked inhibition of spermatogenesis and desquamation of spermatocytes with effects seen at doses as low as 500 mg/kg-day. Similar findings were reported in rats treated with MIBP (a DIBP metabolite). A similar study in mice found a significant decrease in testes weight at 1,000 mg/kg-day (CPSC 2010a). Subchronic oral exposure to DIBP resulted in marked significant reductions in absolute and relative testes weights of adult male rats fed 5% in the diet for 4 months in another study (CPSC 2010a).

Developmental Toxicity: One study found postnatal effects of in utero exposure to DIBP on male reproductive development. DIBP was administered via gavage to pregnant Sprague-Dawley rats at 0, 125, 250, 500, or 625 mg/kg-day on gestation days 12–21. Effects observed in male offspring included reduced anogenital distance, decreased pup weight, delayed separation of the prepuce from the glans penis, increased thoracic areolas and/or nipples, decreased testes and epididymis weights, increased incidence of testicular tubular degeneration-atrophy/hypoplasia, and increased incidence of external malformations, including hypospadias, exposed os penis, nonscrotal testes, and azospermia. 250 mg/kg-day was identified as the LOAEL. The NOAEL was 125 mg/kg-day (CPSC 2010a). Other studies of pregnant rats exposed orally to DIBP during gestation have reported that DIBP exposure in utero results in significant adverse effects to the offspring of the exposed dams.

For example in one study DIBP was administered via gavage to pregnant Sprague-Dawley rats resulting in significantly more resorptions at ≥500 mg/kg-day and significantly fewer live fetuses per litter and lower fetal body weight at ≥750 mg/kg-day. Internal examination revealed undescended testes in 56 and 70% of the male fetuses at 750 and 1,000 mg/kg-day, respectively. These results indicate developmental NOAEL and LOAEL values of 250 and 500 mg/kg-day, respectively (CPSC 2010a). In another study researchers exposed pregnant Sprague-Dawley rats to DIBP via gavage resulting in a marked increase in resorptions, a significant reduction in the number of live fetuses per litter, and a significant decrease in fetal body weight at ≥500 mg/kg-day and greater incidences of external, visceral, and skeletal malformations at ≥750 mg/kg-day (CPSC 2010a). Several epidemiologic studies measured urinary concentrations of MIBP (a DIDP metabolite). Of those that did, there were associations of maternal urinary MIBP concentrations with measures of male reproductive tract development (specifically, shortened anogenital distance (CHAP 2014). And in humans several studies reported associations of MBP with poorer scores on neurodevelopment tests (CHAP 2014).

Additional Considerations: The Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (CHAP) recommended to the US Product Safety Commission in July, 2014 that DIBP should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 % (CHAP 2014).

Dipentyl phthalate (DPP, DNPP or DPENP) or Di-n-pentyl phthalate (CAS # 131-18-0)

Use: Dipentyl phthalate (DPP or DNPP) is used as a plasticizer in PVC (Bureau of Chemical Substances 2013).

Children's Exposure: DNPP was detected in 8 out of 10 samples of house dust in Austria (Bureau of Chemical Substances 2013). The general population may be exposed via dermal contact with consumer products such as textiles, paper or paints containing DNPP (Bureau of Chemical Substances 2013). The DNPP metabolite MHPP has been detected in human urine (29% of people sampled) (Silva et al. 2011).

Toxicity: DNPP is found on the following authoritative lists:

- EU REACH Candidate List of Substances of Very High Concern for Authorization (SVHC list), Reason for listing: Toxic for Reproduction (ECHA 2013a).
- EU – CLP Classification: Reproductive Toxicity Category 1B (ECHA 2008b).
- EU R-phrases: R61 May cause harm to the unborn child (ECHA 2008b).
- EU R-phrases: R60 May impair fertility (ECHA 2008b).
- EU GHS H-statements: H360FD May damage fertility, may damage the unborn child (ECHA 2008b).

Reproductive and Developmental Toxicity: In one study pregnant Sprague-Dawley rats were treated by gavage daily from gestational days 12 – 19 with corn oil (control) or with 500 mg/kg per day dipentyl phthaltate (DNPP) (treatment). Anogenital distances were significantly reduced in male fetuses exposed to DNPP. DNPP exposure also significantly altered expression of 391 genes that affect molecular pathways in testicular development

(Liu et al. 2005). In another study pregnant female Sprague-Dawley rats were dosed by gavage with either corn oil (control) or doses of 25, 50, 100, 200, 300, 600, and 900 mg/kg/day during gestation days 8 – 18. Midgestation pregnancy loss leading to 100% fetal mortality was experienced by dams given doses of 300, 600, and 900 mg/kg/day DNPP. The NOAEL for reproductive and maternal effects was 200 mg/kg/day while the LOAEL was 300 mg/kg/day with 100% fetal mortality. DNPP reduced fetal testosterone production at doses as low as 100 mg/kg/day (Howdeshell et al. 2008).

Additional Considerations: The Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (CHAP) recommended to the U.S. Product Safety Commission in July, 2014 that DNPP should be permanently banned from use in children's toys and child care articles at levels greater than 0.1% (CHAP 2014). The CHAP also describes DNPP as among the most potent phthalates regarding developmental effects, that the toxicological profile of DPENP is very similar to that of the other antiandrogenic phthalates, and that DNPP exposure contributes to the cumulative risk (CHAP 2014).

Additional DPP Exposure Information: Toxic-Free Future submitted additional information on the exposure potential of DPP to the Department of Ecology. This additional information meets the following criteria communicated by Ecology as demonstrating exposure potential: peer reviewed scientific study of the chemical reported in humans, peer reviewed scientific study of the chemical reported in house or daycare dust or indoor air:

- (Chi et al. 2016) looked at 15 phthalates in indoor air of traffic micro-environments in Hangzou, China. Phthalate esters are semi-volatile and exist in both gas- and particle-phases in indoor air. DPP was detected in all gas and particle air samples detected in buses, subways, taxis, and private cars in levels ranging from 468.61 – 163,503 ng/m^3 in gas and from 403.67 – 2411.8 ng/m^3 in particle phase. The number of air samples collected from busses, subways, taxis, and private cars was 105, 40, 30, and 60 respectively.
- (Dodson et al. 2015) analyzed 49 house dust samples from different homes in northern California for 58 target analytes. DPP was detected in 12% of the samples over the method reporting limit, with concentrations ranging up to 2.2 ug/g (ppm).
- (Hartmann et al. 2015) looked at phthalates in the urine of Austrian children and adults, including DnPeP (DPP) and its metabolite MnPeP. MnPeP was detected in 6.5% of one group of 31 children, in 5.5% of another group of 220 children, however the levels were below the level of quantification. MnPeP was also detected in 4.4% of a group of 272 adults with levels ranging up to 2.9 ug/L and in 4.1% of a group of senior citizens with levels ranging up to 2.0 ug/L. Dipentyl phthalate (CAS # 131-18-0) is banned from cosmetics in the EU. This ban was published in 2009, and effective in 2013. Recruitment for the (Hartmann et al. 2015) study took place in 2010 and 2012 after the ban was published.
- (Kasper-Sonnenberg et al. 2014) looked at a metabolite of DnPeP (DPP), MnPeP, in two groups of German children. MnPeP was detected in urine samples of 7.4% of 465 children tested (concentration range not reported). Recruitment for the (Kasper-Sonnenberg et al. 2014) study occurred from 2006 – 2010.
- (Silva et al. 2011) looked at urinary biomarkers for DPP metabolism in rats and humans. MHPP was the major urinary metabolic byproduct of DPP in experiments

in rats; rats and humans metabolize phthalates in a similar way. MHPP is considered a suitable biomarker of DPP. In urine samples from 45 adult humans (United States) MHPP was identified in 29% of the samples at levels of <LOD to 8 ng/mL.

Additional Phthalates

TFF also petitioned Ecology to add DEMP, DIOP, and DIPP to the CHCC list, and respectfully requests that Ecology reconsider their decision not to add them. These phthalates should be included on the CHCC list because of their toxicity characteristics and their known and potential exposures to children. TFF has included in the summaries below additional peer-reviewed studies on exposure to DEMP and on toxicity and exposure to DIOP that have not been submitted in prior materials.

Bis (2-methoxyethyl phthalate) phthalate (DEMP) (CAS # 117-82-8)

Use: Bis (2-methoxyethyl phthalate) (DEMP) is used as a plasticizer in cellulosic resins, some vinyl ester resins, PVC, and as a solvent, a molding component in adhesives, and laminating cements (CPSC 2011).

Children's exposure: DEMP can be present at up to 40% (possibly in combination with other phthalates) in toys, including inflatable water products, hoppers, play and exercise balls according to Australian industry sources (NICNAS 2008b). In children's toys and childcare articles made from polyvinyl chloride (PVC), DEMP may also be used as a secondary plasticizer or be present as a contaminant (NICNAS 2008b). DEMP was detected in indoor dust in Hamburg, Germany, between 1998 and 2000 (BAuA Bis(2-methoxyethyl)phthalate). It was also detected in indoor air in Australia (BAuA Bis(2-methoxyethyl)phthalate). DEMP was detected in Germany in T-shirts (10–30 µg/kg), diapers (10–20 µg/kg) and house carpets (10–50 µg/kg) (Environment Canada 2009).

Toxicity: DEMP is found on the following authoritative lists:

- EU REACH Candidate List of Substances of Very High Concern for Authorisation (SVHC list), Reason for listing: Toxic for Reproduction (ECHA 2011).
- EU – Annex VI CMRs: Reproductive Toxicity Category 1B (ECHA 2008c).
- EU R-phrases: R61 May cause harm to the unborn child (ECHA 2008c).
- EU R-phrases: R62 Possible risk of impaired fertility (ECHA 2008c).
- EU GHS H-statements: H360Df May damage the unborn child. Suspected of damaging fertility (ECHA 2008c).
- EU – REACH Annex XVII CMRs: Repr. Category 1B (ECHA Annex VI CLP spreadsheet).

Reproductive Toxicity: In an oral exposure (gavage) repeated dose study in Sprague-Dawley rats DEMP metabolite 2-methoxyethanol (2-ME) was reported to have an LOAEL of 100 mg/kg bw-day for degeneration of spermatocytes, and an LOAEL of 250 mg/kg bw-day for decreased relative testis weight, seminal tube atrophy and sperm degeneration (NICNAS 2008b). In two DEMP oral exposure by gavage studies in rats an LOAEL of 1000 mg/kg bw-day was reported for decreased testes weight and an LOAEL of 1000 mg/kg bw-

day was reported for decreased testes weight and abnormal sperm heads (NICNAS 2008b). In a study on oral exposure of Sprague-Dawley rats to DEMP metabolite methoxyacetic acid (MAA) an LOAEL of 592 mg/kg bw-day was reported for decreased testes weight, however this was the lowest dose tested (NICNAS 2008b).

Developmental Toxicity: In a study in which Wistar rats were exposed to DEMP metabolite 2-methoxyethanol (2-ME) orally by gavage an LOAEL of 158 mg/kg bw-day was reported for the effect of increased fetal resorptions and increased gross and skeletal malformations (NICNAS 2008b). In another study in which female monkeys were exposed to 2-ME orally by gavage an LOAEL of 12 mg/kg bw-day was reported for increased intrauterine death with 100% intrauterine death at 36 mg/kg/bw-day (NICNAS 2008b). In a study in which Sprague-Dawley rates were exposed orally by gavage to DEMP metabolite MAA an LOAEL of 187 mg/kg bw-day was reported for increased fetal resorptions and increased gross and skeletal malformations (NICNAS 2008b). Developmental effects of DEMP were observed in rats following oral (gavage) administration on gestation days 6 to 16. Significantly reduced pup body weight gain and slightly reduced pup survival were observed at the lowest dose tested (60 mg/kg-bw per day, LOAEL). At a higher dose level (180 mg/kg-bw per day), significantly reduced pup survival and pup body weight gain as well as pup abnormalities, including a shortened lumbosacral region, acauda and filamentous tails, were observed (Environment Canada 2009).

Since the submittal of Toxic-Free Future's petition in 2016 requesting DEMP be added to the CHCC list, additional sources on DEMP exposure in humans were located. Researchers in Hong Kong published a study in which 153 samples of blood were collected from 153 individuals (Wan et al. 2013). DEMP was detected in 100% of the individuals sampled with a mean concentration of 11.01 ng/ml. In comparison DEHP was detected in 96% of the individuals sampled with a mean concentration of 11.13 ng/ml. DEMP is generally not included in the list of analytes in human biomonitoring studies. In another study (Bao et al. 2015), researchers detected DEMP in 1 out of 7 samples of baby shampoo at a concentration of 24.3 mg/kg. DEMP is infrequently included in consumer product and house dust testing. This new information raises concern about DEMP exposures, and with data gaps in the literature, Toxic-Free Future requests further consideration of this chemical for inclusion on the CHCC list.

Diisooctyl phthalate (DIOP) (CAS # 27554-26-3)

Uses: Plasticizer for vinyl, cellulosic and acrylate resins, and synthetic rubber, additive in plastics that will come into contact with food (HSDB 2009).

Exposure: In one study the use of DIOP has been reported in teethers (10.2%) and pacifiers (17.1%) (Stringer et al. 2000). In the US, it is also reported in shower mats. The FDA has approved DIOP for use in adhesives or surface resin and polymer coatings for products that have contact with food (products intended to be used in production, manufacturing, packing, transport, or holding of food) (CPSC 2010b).

Reproductive and Developmental Toxicity: Female CD-1 mice were exposed to 0, 44, 91, 190.6, or 292.5 mg/kg bw DIOP in their diet during gestation. The number and percent of resorptions, late fetal deaths, and dead and malformed fetuses were all increased in response to 190.6 and 292.5 mg/kg bw treatments. Female fetal weight and the number of live fetuses per litter for both sexes were significantly reduced at 190.6 and 292.5 mg/kg bw doses. A significant increase in both the percentage of fetuses with external, visceral, and skeletal malformations and the percentage of malformed fetuses per litter were observed with dosing as low as 91 mg/kg bw (HSDB 2009). In a two-generation study, male/female Swiss CD-1 mice were exposed daily to 0, 14, 140, or 420 mg/kg of DIOP in their diet throughout a cohabitation period. When the F1 litters were sexually mature, they were mated with animals from different litters within the same group. At necropsy the F1 animals showed a significant decrease in the number of litters/pair, live pups/litter, mean live pup weight and proportion of live pups at 140 mg/kg/day. Exposure to 420 mg/kg/day resulted in significant infertility during the continuous breeding phase of the study which was seen in both sexes. Exposure to the high dose in the crossover study also resulted in male specific effects including reduced testis, epididymis, prostate weights, percentages of motile sperm and abnormal sperm, and sperm concentration in the males. In females effects included reduced combined weight of ovaries, oviducts and uterus. Both sexes exhibited increased liver weights. The majority of high-dose male mice evidenced some degree of bilateral atrophy of the seminiferous tubules (HSDB 2009).

Additional Considerations: The Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (CHAP) recommended to the U.S. Product Safety Commission in July, 2014 that DIOP should be subject to an interim ban from use in children's toys and child care articles at levels greater than 0.1 % (CHAP 2014).

Since Toxic-Free Future submitted a petition in 2016 requesting Ecology add DIOP to the CHCC list, additional information on DIOP toxicity and exposure has been located. A study published in 2013 (Saillenfait et al. 2013) show that in utero exposure of Sprague-Dawley rats produced fetal growth retardation at 500 and 1000 mg/kg/day as evidenced by reduced body weight and/or ossification delay. Short supernumerary lumbar rib skeletal variant was significantly increased at 500 and 1000mg/kg/day. In addition there was abnormal position of the testes in DIOP-exposed fetuses, a dose-dependent decrease in ex vivo testosterone production by the fetal testis with the NOAEL and LOAEL for this endpoint being 10 and 100 mg/kg/day, permanent postnatal alterations in androgen-dependent structures of male offspring, and reproductive tract malformations in a few adult males at 500 mg/kg/day and at higher incidences at 1000 mg/kg/day. A recent study on phthalates in house dust carried out in Canada (Kubwabo et al. 2016) reported detections of DIOP in 87% of 126 house dust samples taken from 38 Canadian homes. Reported DIOP levels ranged from <MDL to 1170 ug/g, with a median of 6.6 ug/g. Phthalates not commonly monitored were focused on in this study. These papers confirm exposure to DIOP and provide additional toxicity evidence.

Diisopentyl phthalate (DIPP) (CAS # 605-50-5)

Use: DIPP is a plasticizer used to ensure flexibility of PVC (Environment Agency Austria, DIPP). It is also used in the manufacture of propellants and explosives, and has been found in cosmetics (Environment Agency Austria, DIPP) (Llompart et al. 2013). It is considered to be a potential substitute for other C4 – C6 phthalates and is similar in structure to other banned phthalates known for their toxicity effects (especially to DNPP CAS # 131-18-0) (Environment Agency Austria, DIPP).

Children's exposure: An Austrian environmental agency study of consumer products detected DIPP in one sample; since it has not routinely included in phthalate measurements in products, its presence may be underestimated (Environment Agency Austria, DIPP).

Toxicity: DIPP is found on the following authoritative lists:

- EU REACH Candidate List of Substances of Very High Concern for Authorisation (SVHC list). Reason for listing: Toxic for Reproduction (ECHA 2012).
- EU - Annex VI CMRs – Reproductive Toxicity Category 1B (ECHA 2008d).
- EU R-phrases: R61 May cause harm to the unborn child (ECHA 2008d).
- EU R-phrases: R60 May impair fertility (ECHA 2008d).
- EU GHS H-statements: H360FD May damage fertility, may damage the unborn child (ECHA 2008d).

Developmental effects: In a toxicity study in which an oral mixture of Di-n-pentylphthalate (DNPP) with di-iso-pentylphthalate (DIPP) was administered to pregnant Wistar rats in doses of 40, 200 and 1,000 mg/kg, results showed at the highest dose all fetuses were resorbed (100% post-implantation loss). No effects were observed at the lower doses (ECHA Support Document DIPP). Two other studies provide strong evidence that dipentylphthalate (DIPP) (CAS 131-18-0) is an equal or even more potent testicular toxicant than DEHP. This is likely to be valid also for other structurally related pentyl phthalates, like DIPP (ECHA Support Document DIPP). This is supported by the study on the mixture of DNPP and DIPP mentioned above. This mixture of pentyl phthalates caused a 100% resorption at 1000 mg/kg/day while DEHP caused malformations in 70% of the litters at the same dose (ECHA Support Document DIPP).

Reproductive effects: A fertility reducing action is suspected because of the structural relationship of DIPP to di-n-pentyl phthalate (DNPP) and dibutylphthalate (DBP) and the findings available for these substances. The monoesters of phthalic acid esters of medium chain length (C4 – C6) cause damage to the germinal epithelium in the testis. Sertoli cells in the seminiferous tubules are the primary site of attack. They exhibit considerable vacuolization of the smooth endoplasmatic reticulum resulting in a reduced fertility. As a consequence the germinal epithelium may be lost (ECHA Support Document DIPP).

Octamethylcyclotetrasiloxane (D4) (CAS # 556-67-2)

TFF urges the Department of Ecology to reconsider its proposal to remove octamethylcyclotetrasiloxane (D4) from the CHCC reporting list. There is evidence that this chemical has endocrine-disrupting properties in industry-sponsored as well as in government and independent studies (McKim et al. 2001) (Quinn et al. 2007) (Quinn et al. 2007) (Meeks et al. 2007) (Siddiqui et al. 2007) (He et al. 2003) (Lee et al. 2015) and there is new evidence of D4 exposure to children through CSPA reporting itself. D4's presence in children's products reported under CSPA indicates that products other than personal care products are a significant and unexpected source of D4 exposure to children. Washington's families and policymakers need the continued presence of D4 on the CHCC list while this exposure is evaluated.

Toxicity: D4 is described as having been placed on the CHCC list in 2011 because it is classified as a Category 1 endocrine disruptor by the European Union, it has been demonstrated to have estrogenic activity in rat and mice uterotrophic assays, and because it was identified by the Danish EPA as a listed ingredient in personal care products marketed to children (DOH, 2011).

TFF supports the continued listing of D4 on the CHCC list for its endocrine-disrupting properties:

- Washington's Department of Ecology confirmed the use of the European Union's priority list of chemicals identified as suspected endocrine disruptors, specifically those designated as Category 1, for this current CSPA rule update (Ecology, 2016a). D4 is identified as a Category 1 chemical (DHI 2007) because there is evidence that it has endocrine-disrupting effects in intact organisms.
- New evidence (Lee et al. 2015) gives evidence of D4's disrupting properties in an vivo study. In one of several studies reported on in this paper, an uterotrophic assay (an in vivo estrogenicity assay) was carried out by administering subcutaneous injections of 500 mg/kg (ppm) D4 or 1,000 mg/kg to immature rats for 4 days. Treatment uterine weights were not significantly different from control uterine weights in the uterotrophic assay. Having seen significant results in an in vitro estrogenicity assay prior to the uterotrophic assay, the authors stated that, "Since the estrogenic effect of D4 was not shown by UT assay, we used a more sensitive method." They looked at CaBP-9K, ER alpha, and PR expression in immature rats' uteruses. Results demonstrated that the estrogenic biomarker CaBP-9K mRNA expression was significantly increased by D4 in a dose-dependent manner. CaBP-9K mRNA expression was up-regulated 2- or 3- fold by 500 and 1000 mg/kg D4. The authors concluded from their research that D4 has estrogenic potential proven under both in vitro and in vivo experimental conditions. This paper shows mixed in vivo evidence, which is not compelling new evidence, and does not provide proof that D4 is no longer estrogenic.

D4 also shows evidence of reproductive toxicity and therefore should remain on the CHCC list:

- A European Union Harmonized Classification and Labelling has been assigned to D4: Reproduction Category 2 with a hazard statement code H361f (suspected of damaging fertility) and R62 (possible risk of impaired fertility) and R63 (possible risk of harm to the unborn child) risk phrases (EHCA 2008e).
- (Siddiqui et al. 2007) reports results on the reproductive toxicity of D4. This study evaluated the reproductive toxicity in two generations of Sprague-Dawley rats (30/sex/group) exposed to whole body vapor inhalation of D4 at concentrations of 0, 70, 300, 500, or 700 ppm 6 hours per day for 70 consecutive days prior to mating and lasted through weaning. Prolonged estrous cycles, decreased mating and fertility indices were observed in the F1 generation exposed to D4. Significant reductions in the mean number of pups born and mean live litter size were observed in the 500 and 700 ppm groups for both the F0 and F1 generations. Implantation sites were also reduced at 700 ppm for both F0 and F1 generations. The NOAEL for male reproduction was considered to be 700 ppm and the NOAEL for female reproduction was considered to be 300 ppm.
- (Meeks et al. 2007) exposed rats to D4 by whole body vapor inhalation and evaluated the phase of the female reproductive cycle affected by D4. For the overall phase study female rats were exposed to 0, 70, 300, 500, or 700 ppm D4 in vapor for 6 hours per day. A statistically significant decrease in maternal body weight was observed in the 700 ppm group during gestation. Mean absolute adrenal gland weight was significantly increased in the 700 ppm group. The mean numbers of corpora lutea were statistically significantly reduced in the 300 and 500 ppm exposure groups. There was increased implantation loss at 500 and 700 ppm. There was a significant reduction in the mean number of viable fetuses in the 500 and 700 ppm exposure groups. In the fertilization phase study (exposures were 0 and 700 ppm only), absolute maternal ovarian weight was decreased at 700 ppm. There were also lower numbers of implantation sites and a significant increase in early resorptions and significantly reduced mean number of viable fetuses.

Exposure: The argument for delisting D4 is also based on the assumption that D4 is no longer in use in personal care products. However, evidence does exist for D4's presence in personal care and other products that children are exposed to:

- There have been over 2,300 reports to date of D4 in children's products reported to the state of Washington under the Children's Safe Products Act in concentrations up to 500 ppm. Most of these reports are of products other than personal care products such as clothing, footwear, toys, baby care items, and bedding (Ecology 2017). Companies reporting these products include large companies such as Walmart, Carter's, Nike, Gap, Gymboree, and VF Corporation. Based on this evidence alone children's exposure to D4 is widespread and in products not generally associated with D4. This points to the need to investigate more fully the sources of exposure of children to D4, as well as to the importance of keeping D4 on

the CSPA reporting list in order to continue collecting important information about the chemical.

- (Capela et al. 2016) analyzed for D4 in cosmetics and personal care products purchased in Portugal. 6 out of 6 baby and children lotion/milk/cream moisturizer samples contained D4 with levels ranging from 0.03 – 0.14 ug/g (ppm). 8 out of 9 baby and children shower gels contained D4 with levels ranging up to 5.34 ug/g (ppm). 5 out of 8 baby and children shampoo contained D4 with levels ranging up to 20.13 ug/g (ppm). 6 out of 6 baby and children toothpaste samples contained D4 with levels ranging from 0.02 – 0.30 ug/g (ppm).

Additional Chemicals

Toxic-Free Future supports the proposed additions of the following chemicals to the CHCC reporting list:

- Bisphenol S (BPS) (CAS # 80-09-1)
- Bisphenol F (BPF) (CAS # 620-92-8.

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