

Summary of 10 chemicals reviewed by Dourson and his firm TERA, paid for by private industry, arguing for less protective standards

Chemical	Some use(s)	Some hazards	TERA funding source(s)	Where published	TERA vs. established standard(s)⁵
1,4-Dioxane¹	solvent, stabilizer; impurity in certain consumer products	likely carcinogen	PPG Industries	<i>Regulatory Toxicology and Pharmacology</i>	875 to 1,166 times less protective
1-Bromopropane¹	solvent, used in cleaning, adhesive, sealant, furniture care, products, etc.	developmental, reproductive, neuro toxicity	Albemarle and Ameribrom, Inc.	Unpublished report posted on TERA website	2 times less protective than 2005 standard in place at time of TERA report; 200 times less protective than 2013 standard ²
PFOA	Water/stain-proofing agent in textiles, packaging	Developmental toxicity, thyroid disruption	West Virginia Department of Environmental Protection based on DuPont recommendation	WV DEP Report	50-150 times less protective than DuPont's own standard at the time; 2,143-7,500 times less protective than 2016 standards ³
Trichloroethylene¹	solvent, intermediate, degreaser, etc.	known carcinogen	American Chemistry Council	<i>Regulatory Toxicology and Pharmacology</i>	1.5 to 15 times less protective
Perchlorate	rocket fuel ingredient	thyroid hormone disruption	Kerr-McGee Chemical Corporation, Goodrich Corp., Aerojet, Lockheed Martin, American Pacific, Alliant, Boeing	<i>Regulatory Toxicology and Pharmacology</i> ; unpublished report submitted to EPA	3 to 8.6 times less protective
Chlorpyrifos	insecticide	neurotoxicity, developmental neurotoxicity	Dow AgroSciences	<i>Regulatory Toxicology and Pharmacology</i>	33 times less protective than standard in place at time of TERA paper; 5,882 times less protective than 2016 standard ⁴
Alachlor degradates	Herbicide	liver, kidney, spleen toxicity	Monsanto and Dow AgroSciences	<i>Regulatory Toxicology and Pharmacology</i>	80 to 280 times less protective than standards in place at time of TERA paper
Acetochlor degradates	herbicide	thyroid disruption, male reproductive effects	Monsanto and Dow AgroSciences	<i>Regulatory Toxicology and Pharmacology</i>	4.7 to 14 times less protective than standards in place at time of TERA paper

Diacetyl	artificial popcorn butter flavor	severe lung damage	Cargill Inc., The Coca-Cola Co., ConAgra Foods Inc., Frito-Lay North America, Inc., General Mills Inc., The J.M. Smucker Co., Land O'Lakes Inc., Procter & Gamble, Unilever	<i>Regulatory Toxicology and Pharmacology</i>	20 to 40 times less protective
Acrylamide	formed in fried foods	Neurotoxicity, probable carcinogen	Burger King Corporation, Frito-Lay, Inc., H.J. Heinz Company, KFC Corporation, McDonald's Corporation, The Procter & Gamble Manufacturing Company, The Procter & Gamble Distributing Company, Wendy's Int'l.	<i>Regulatory Toxicology and Pharmacology</i>	10 to 25 times less protective

- 1 One of the [first 10 chemicals](#) undergoing review under reformed TSCA.
- 2 ACGIH lowered its standard in 2013; TERA's standard is 200 times less protective than ACGIH's current standard.
- 3 EPA set a lifetime health advisory level, and Vermont set a drinking water health advisory level; TERA's standard is 2,143 and 7,500 times less protective, respectively.
- 4 EPA lowered its standard in 2016; TERA's standard is 5,882 times less protective than EPA's new standard.
- 5 Comparisons are generally between Dourson's and others' values for the endpoints each designates to be the most sensitive, which means they may not always necessarily be between values for the same endpoint or same type of risk value. This is because what is most relevant here regarding the "safe" level is that for the most sensitive endpoint.

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1,4-Dioxane

- Used in a variety of manufacturing processes (typically as a solvent or stabilizer) and products (including greases, dyes, and varnishes). Also found as an impurity in some consumer products (personal care products, cosmetics, and food).
- Various acute exposure health effects: nausea, headache, respiratory irritation, drowsiness; Chronic exposure effects: dermatitis, eczema, liver and kidney damage
- Weakly genotoxic and classified as a likely carcinogen in humans

([US EPA 2014 Technical Fact Sheet](#))

[2014 paper by Dourson et al.](#)

- Maximum contaminant level goal (MCLG): **350 µg/L**
 - Value for hepatic necrosis (which Dourson's asserts is the most sensitive endpoint)
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: "PPG Industries, Inc. was the sponsor of the review conducted by EM and TERA."

[EPA \(2014\)](#)

- Drinking water guideline: **0.35 µg/L** (representing a 1×10^{-6} cancer risk level)
 - 1,000 times lower than Dourson et al. value
- Drinking water guideline: **35 µg/L** (representing a 1×10^{-4} cancer risk level)
 - 10 times lower than Dourson et al. value

[Massachusetts](#)

- Drinking water guideline level of **0.3 µg/L**
- 1,166 times lower than Dourson et al. value

[Colorado](#)

- Groundwater cleanup standard of **0.35 µg/L**
- 1,000 times lower than Dourson et al. value

[New Jersey](#)

- Ground water quality standard: **0.4 µg/L** [rounded to one sf from 0.35 µg/L]
- 875 times lower than Dourson et al. value

1-bromopropane

- Solvent used in products such as degreasers and cleaners, spray adhesives, spot removers, and lubricants.”
- Short-term exposure has the potential to cause adverse developmental and reproductive effects” in women of childbearing age. Chronic exposure risks include neurotoxicity, kidney, liver, reproductive toxicity, and lung cancer.

[\(EPA Fact Sheet\)](#)

[TERA report \(2004\)](#)

- Occupational exposure limit (OEL): 20 ppm
- Disclosure: “This work was funded by Albemarle Corporation and Ameribrom, Inc. The sponsors were given an opportunity to review this work for technical accuracy. However, the analysis as presented in this report represents the best scientific opinion of the authors. The analysis should not be construed as representing the opinion of the sponsors or other parties.”

[ACGIH \(2005\)](#)

- Threshold limit value (TLV): 10 ppm
- 2 times lower than TERA report value

[ACGIH \(2013\)](#)

- Threshold limit value (TLV): 0.1 ppm
- 200 times lower than TERA report value

[California OSHA \(2010\)](#)

- Permissible exposure limit (PEL): 5 ppm
- 4 times lower than TERA report value

[NIOSH \(2016\)](#)

- Proposed Recommended Exposure Limit (REL): 0.3 ppm
- 67 times lower than TERA report value

Ammonium Perfluorooctanoate (PFOA)

- Used as waterproofing or stain-removing agent in carpets, leathers, textiles, upholstering, paper packaging, and coating additives. Highly persistent in the environment and humans, and exhibits significant developmental toxicity, liver toxicity and potential adverse effects on the thyroid.

[\(US EPA 2016\)](#)

[West Virginia DEP Report \(2002\)](#)

- Health protective screening level for water: **150 ppb**
- Acknowledgements: “The West Virginia Department of Environmental Protection wishes to thank the following agencies and organizations that joined us as primary participants in this investigation: West Virginia Department of Health and Human Resources; U.S. Environmental Protection Agency (EPA) Region 3, Office of Research and Development (ORD) and Headquarters; E. I. Du Pont de Nemours, Inc. (as well as their employees, consultants - Potesta & Assoc., Inc., laboratory – Exygen Research, Inc., and attorneys); Marshall University; Toxicology Excellence for Risk Assessment (TERA); and Menzie Cura & Assoc., Inc.”

[DuPont \(1990s\)](#) (see p. 46)

- Drinking water guideline: **1 or 3 ppb**
- 50 to 150 times lower than WV DEP Report value

[EPA \(2016\)](#)

- Lifetime health advisory level: **0.07 ppb**
- 2,143 times lower than WV DEP Report value

[Vermont \(2016\)](#)

- Drinking water health advisory level: **0.02 ppb**
- 7,500 times lower than WV DEP Report value

Trichloroethylene

- A solvent and chemical intermediate known to cause cancer in humans, with many uses in industry and in a wide variety of commercial and consumer products.

[2016 paper by TERA](#) (Dourson et al.)

- Reference concentration (RfC): **3 to 30 µg/m³** (micrograms per cubic meter)
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: “The authors acknowledge a gift from the American Chemistry Council to prepare this manuscript from the previous work of the Alliance for Risk Assessment (ARA) coalition entitled ‘Practical Guidance for Contaminated Sites: Case Study: Trichloroethylene (TCE) Risk Assessment and Management’.”

[EPA \(2011\)](#)

- Reference Concentration (RfC): **2 µg/m³**
- 1.5 to 15 times lower than TERA’s value

Perchlorate

- Rocket fuel ingredient that has contaminated surface and groundwater in many states; interferes with normal thyroid hormone function.

[2004 paper by TERA](#) (Strawson et al.)

- Reference dose (RfD): **2 µg/kg/day**
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: “TERA wishes to thank the Perchlorate Study Group for its support over a number of years to study perchlorate’s toxicology and assess its risk. However, support for the development of this manuscript was provided only by internal developmental reserve funds of TERA, and not by any outside party.” Members of the Perchlorate Study Group are: Kerr-McGee Chemical Corporation; Goodrich Corp.; Aerojet; Lockheed Martin; American Pacific; Alliant; and Boeing.

[2012 paper by TERA](#) (Reichert and Dourson)

- Proposed eliminating the 3x uncertainty factor for intraspecies variability used by Strawson et al.
- Resulting reference dose (RfD): **6 µg/kg/day**

[EPA \(2005\)](#)

- Reference dose (RfD): **0.7 µg/kg/day**
- 3 to 8.6 times lower than TERA’s value

Chlorpyrifos

- Insecticide with agricultural uses including on corn, soybeans, fruit and nut trees, Brussels sprouts as well as non-agricultural uses including on golf courses, turf, utility poles and fence posts.

[2006 paper by TERA](#) (Zhao, Dourson, and Gadagbul)

- Reference dose: **10 ug/kg/day**
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: “The authors thank the Dow AgroSciences for support over a number of years to study chlorpyrifos’ toxicology and assess its risks. However, our deliberations shown in this paper have not been influenced by discussions with outside parties, including scientists at DOW AgroSciences.”
- Heavily relies on their own paper published a year prior ([Zhao et. al. 2005](#)) to support conclusions asserted in this paper.

[EPA Chlorpyrifos Human Health Risk Assessment \(2000\)](#)

- EPA reference dose: **0.3 ug/kg/day**
- 33 times lower than Dourson’s value

[EPA Chlorpyrifos Revised Human Health Risk Assessment \(2016\)](#)

- Based on new information since both the earlier EPA assessment and Dourson paper, EPA has revised the reference dose down to **0.0017 ug/kg/day**
- 5,882 times lower than Dourson’s value

Alachlor and acetochlor degradation products

- The parent chemicals are widely used herbicides, the degradation products of which are frequent contaminants of surface water and groundwater especially in the Midwest. In response, Minnesota and Wisconsin established limits on the degradates.

2010 paper by TERA (Gadagbui et al.)

- [DowAgroSciences and Monsanto hired TERA](#) to develop risk values for the substances and then convene and manage a workshop and designate an expert panel to review the risk values.
- [Dourson was then appointed by TERA to chair the expert panel](#).
- The resulting paper had 9 co-authors, 5 of whom (including Dourson) were TERA employees.
- Reference doses (RfD):
 - Alachlor degradates (ESA and OXA): 0.8 mg/kg-day, equivalent to **5,600 ppb** in drinking water¹
 - Acetochlor degradates (ESA and OXA): 0.2 mg/kg-day, equivalent to **1,400 ppb** in drinking water
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: “This work was performed under the auspices of the Steering Committee of the Alliance for Risk Assessment (ARA). Partial financial support came from Monsanto and Dow AgroSciences and in-kind support from US EPA, State of Maine, and TERA. Two panel members (L. Hicks and S. Ramasamy), however, did not accept the offered travel and per diem expense and/or honoraria.”

Wisconsin

- Drinking Water & Groundwater Quality Health Standards:
 - Alachlor degradate (ESA): **20 ppb** in drinking water, 280 times lower than TERA’s value
 - Acetochlor degradates (ESA and OXA): **230 ppb** in drinking water, 6 times lower than TERA’s value

Minnesota Department of Health (MDH) guidance

- [Alachlor degradates \(ESA and OXA\)](#):
 - 2009: **70 ppb** in drinking water, 80 times lower than TERA’s value
 - 2016: **50 ppb** in drinking water, 112 times lower than TERA’s value
- Acetochlor degradates:
 - [ESA](#): **300 ppb** in drinking water, 4.7 times lower than TERA’s value
 - [OXA](#):
 - 2011: **100 ppb** in drinking water, 14 times lower than TERA’s value
 - 2017: **90 ppb** in drinking water, 15.6 times lower than TERA’s value

1 To convert reference dose to water concentration limit: [EPA standard assumptions](#) are that the average adult weighs 70 kg and drinks 2 liters of water a day, and that drinking water accounts for 20 percent of an individual’s exposure: 0.8 mg/kg-day x 70 kg = 56 mg/day; 56 mg/day ÷ 2 liters/day = 28mg/liter; 28 mg/liter x 20% = 5.6 mg/liter or 5,600 ppb.

Diacetyl

- Artificial popcorn butter flavoring linked to severe lung damage in popcorn plant workers and some consumers.

[2010 paper by TERA](#) (Maier et al.)

- Occupational exposure limit (OEL): **200 parts per billion (ppb)**, 8-hour time weight average (TWA)
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: “We wish to acknowledge the funding of Cargill Inc., The Coca-Cola Co., ConAgra Foods Inc., Frito-Lay North America, Inc., General Mills Inc., The J.M. Smucker Co., Land O’Lakes Inc., Procter & Gamble, and Unilever. The sponsor companies were asked to review the material and provide technical comment. However, the results and conclusions presented represent those of the authors and not necessarily those of the sponsors.”

[NIOSH \(2016\)](#)

- Recommended exposure limit (REL): **5 ppb**, 8-hour time weight average (TWA)
- 40 times lower than TERA’s value

[ACGIH \(2012\)](#)

- Recommended exposure limit (REL): **10 ppb**, 8-hour time weight average (TWA)
- 20 times lower than TERA’s value

Acrylamide

- Used as an intermediate in manufacturing chemicals used in water purification and sewage treatment, paper production, and some cosmetics and soap preparations.
- Formed when carbohydrate-rich foods are prepared at high temperatures, notably in the production of fried, baked, and deep-fried foods

([US EPA Toxicological Review](#) and [CDC National Biomonitoring Program fact sheet](#))

[2008 paper by TERA](#) (Dourson et al.)

- Cancer slope factor: **0.030 mg/kg/day**
- Reference dose (RfD) range: **0.05-0.02 mg/kg/day**
- Published in *Regulatory Toxicology and Pharmacology*
- Disclosure: “We thank the reviewers of this article for additional insights into the toxicity of this chemical, including the receipt of in press information, and wish to acknowledge the funding of Burger King Corporation, Frito-Lay, Inc., H.J. Heinz Company, KFC Corporation, McDonald’s Corporation, The Proctor & Gamble Manufacturing Company, The Proctor & Gamble Distributing Company, and Wendy’s International, Inc. for the investigation of issues related to the development of this article. The opinions of the authors do not necessarily reflect the opinions of the reviewers or sponsors.”

[EPA \(2010\)](#)

- Cancer slope factor: **0.5 mg/kg/day**
- 16.6 times steeper than TERA value
- Reference dose (RfD): **0.002 mg/kg/day**
- 10 to 25 times lower than TERA value