

# The Delay Game

## How the Chemical Industry Ducks Regulation of the Most Toxic Substances

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# EXECUTIVE SUMMARY

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**F**or decades, the Environmental Protection Agency's (EPA) efforts to protect the public from health risks of hazardous chemicals have been hindered by chemical companies and the Toxic Substances Control Act (TSCA), the main law used to regulate chemicals in the United States. This paper examines the role of the chemical industry, polluters, their paid consultants, and trade associations in preventing the EPA from reaching conclusions about the toxicity and human health risks of hazardous chemicals. Through the case studies of three common chemicals and widespread pollutants—trichloroethylene (TCE), formaldehyde, and styrene—this paper reveals how industry has manipulated the regulatory process to prevent science-based assessments of toxicity and human health risks from becoming policy.

The Toxic Substances Control Act (TSCA) is in desperate need of reform. Its weaknesses have allowed chemical companies to exploit the act by thwarting the EPA's attempts to finalize health assessments and delaying regulation of chemicals—sometimes for decades. The chemical industry's roadblocks often follow predictable patterns:

- Attack early drafts of health assessments
- Force new reviews
- Hold workshops populated with industry-funded panelists
- Introduce new industry-funded studies when assessments are close to final
- Force more reviews
- Enlist elected officials to assist with political interference
- Attack new assessment drafts

Using these tactics, the chemical industry has effectively prevented the EPA from achieving its mission to protect human health.

This report details how the U.S. legal system and TSCA itself have helped the chemical industry to be effective in its efforts to delay regulations. Congress needs to reform TSCA to make it a more effective regulatory tool. The chemical industry should not be able to endlessly postpone regulatory decisions while profiting from unregulated chemical sales until all scientific controversies and uncertainties, large and small, have been eliminated. With good public policy, the EPA should be empowered to make the best decisions it can on a timely basis using existing information, and apply new science to update its evaluations as it becomes available.

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# INTRODUCTION

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**T**he legal system has given the chemical industry “home field advantage” for 35 years by placing the burden of proof on the government to establish that chemicals are harmful. This approach has allowed the industry to win almost every fight over whether a chemical is harmful, simply by raising repeated questions about scientific studies, asking for assessments to be revisited, and otherwise playing what we call “the delay game.”

The Integrated Risk Information System (IRIS) is an EPA program in which staff scientifically assess the health effects of chemicals already in commercial use. In the IRIS program, the EPA risk assessors evaluate all the relevant science and determine the “acceptable” level of exposure to a chemical, in the air, water, food, or soil. IRIS assessments are not regulations themselves, but they are frequently used by regulators—at the EPA, in the 50 states, and around the world—to set health-based standards for chemicals.

To maintain profits, the chemical industry is motivated to prevent the EPA from updating assessments of a chemical’s hazard under the IRIS system, especially if the assessment is likely to provide a first-time evaluation that a chemical is hazardous, or to show that the chemical is more dangerous than previously thought. The industry has gone to great lengths to prevent many of these assessments—including the three detailed in this report—from being completed. The longer the EPA is prevented from updating its assessments of formaldehyde, styrene, TCE, and other chemicals, the less pressure is leveraged on the industry to stop making, selling, and using those chemicals, and to replace them with safer alternatives.

Unfortunately, under the current law there is no enforceable deadline for the EPA to complete its chemical assessments, no “harmful until proven safe” interim standards to limit chemical exposures until assessments can be completed, and no consequences for industry if the EPA fails to complete (or is prevented from completing)

an assessment. Combined with the “innocent until proven guilty” approach of the current law toward chemicals—where the EPA must consider a chemical safe until it can reach an official conclusion that it is harmful above certain levels—industry has every incentive to resist data collection and data requests, and to argue with every study in order to delay the completion of those assessments.<sup>1</sup>

## THE FOUR DOG DEFENSE

The delay game involves what is by now a well-recognized series of tactics that started decades ago when industry challenged the hazards of lead, tobacco, and asbestos. These methods have earned a nickname—the Four Dog Defense. The basic steps of the defense are:

- 1. My dog does not bite.**  
At first, the company denies that its product is harmful. This may include attempts to discredit scientific studies, or authors of studies, that show harm and generate its own studies designed to show no harm.
- 2. My dog bites, but it didn’t bite you.**  
Industry concedes that the chemical is potentially harmful, but insists that no one is exposed to it. This argument works best if industry doesn’t test or monitor for the chemical—absence of data is often used as a reason to argue that there is no exposure.

**3. My dog bit you, but it didn't hurt you.**

Industry admits that people or wildlife are exposed to the chemical, but denies that the exposure caused harm. Industry concedes that the chemical is harmful at very high doses or under unrealistic test conditions, but not at the lower levels or real-world scenarios to which people or wildlife are actually exposed. Or the argument may focus on differences between humans and laboratory animals, alleging that harm such as cancer observed in animal experiments is not relevant to people.

**4. My dog bit you, and hurt you, but it wasn't my fault.**

Industry admits the chemical is making people sick, but tries to shift the blame to avoid regulation and liability. Possible culprits are improper use, use under past practices no longer followed (before we knew better), other chemicals, medications, smoking, or poor health.

Routinely, industry will ask the government to delay finalizing a health assessment while it conducts a new study, which it promises will settle any scientific controversies that the industry has itself generated along the way. These additional studies can add years if not decades to regulatory decision-making, leaving the exposed public with old and outdated information and inadequate protections in the meantime.

In fact, the new studies promised by industry to resolve controversies it has created rarely resolve the debate. More typically, new studies simply force additional analyses upon the EPA, adding to the delay. Sometimes, once the industry-sponsored studies are completed, companies will sponsor a workshop of scientists who are called independent but have financial ties to chemical firms, to reach their own conclusions about the “real” toxicity of a chemical. This new analysis can then be deployed to challenge the EPA's assessment. Other times, industry simply plunks all its new studies down for the EPA to sort through. In either case, by the time the EPA finally gets back on track with its assessment—possibly modified in light of the industry data, possibly not—industry will often ask for a new delay so it can sponsor more studies. The process is caught in a time loop, except time is only stopped for the regulations, while the use, manufacture, sale, and environmental exposure to chemicals continues unabated.

The recurring failure of the EPA to complete IRIS assessments and set new legal limits on chemicals is so extreme that it became the focus of an investigation and report in 2009 by the Government Accountability Office (GAO), an independent investigative arm of Congress, which concluded that the EPA's chemical assessment programs were some of the “highest risk of failure” programs in the entire federal government.<sup>2,3</sup> One of the most fundamental problems identified in the report was the lack of legal authority under TSCA for the EPA to obtain risk information from chemical companies.

TSCA is widely considered to be the largest failure of the major environmental laws enacted in the 1970s. The law “grandfathered” 62,000 chemicals, with no requirement for them to be tested or to meet a safety standard. The law also placed the burden of proof on the EPA to establish that a chemical was unsafe before it could take action, rather than requiring the chemical industry to prove that its products were safe before they could be marketed. What is worse, the law set impossibly high hurdles for the EPA to require testing of chemicals, or to take action against those chemicals already known to be unsafe. As a result, the EPA has only been able to require testing on approximately 300 of the 62,000 grandfathered chemicals, and taken limited regulatory action on only five chemicals.

As an example of the problem, despite a 10-year effort to ban asbestos and overwhelming evidence that it is deadly, the EPA lost an industry challenge in court and was not allowed to ban existing uses. As a result, although companies no longer mine asbestos in the United States, we continue to import products containing asbestos and ten thousand people die each year from past and on-going exposures to asbestos. These deaths represent the devastating failure of TSCA that continues today.

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### Marilyn's Story

“Asbestos has destroyed our family. Joe died when our kids were only 8 and 10 [2003]. They've had to go through critical parts of their lives without the wonderful father that they knew and loved. As a widow, I had to learn to care for myself and our young children without the comfort and love from [the] man I loved so much. Asbestos made me both a mother and a father. In 2009, all three of us are baffled that asbestos is still legal and that no real cure is available for mesothelioma victims.”<sup>4</sup> — Marilyn, Pennsylvania.

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In addition to TSCA's failure to regulate existing chemicals, the law strictly limits how much risk information the EPA can require from chemical manufacturers for new chemicals. As a result, most of the 22,000 new chemicals that have been added for use since 1976 were approved with little or no data on risks to health or the environment. The National Toxicology Program (NTP), a public chemical testing program housed within the National Institutes of Environmental Health Science (NIEHS) was created in 1978 partly to address this deficiency of risk information. However, the number of chemicals NTP can test is severely limited by its small budget, and it cannot hope to fill the gap created by the weak TSCA.

Although the chemical industry has claimed since August 2009 to be in support of reforming TSCA and achieving better regulation of chemicals to protect the public, it has challenged virtually every EPA action, assessment, or finding that might lead to such increased protection.

The three case studies presented in this report demonstrate the industry's effectiveness in blocking the EPA's attempts to finalize a health assessment. The roadblocks follow a pattern:

**Step 1:** Attack the EPA assessment

**Step 2:** Prevent the EPA from finalizing assessment by:

- Submitting volumes of data or public comments to challenge or discredit studies showing harm
- Calling for additional review by another scientific committee
- Using Congress to delay the assessment via letters or budget riders
- Getting the assessment delayed by the Office of Management and Budget

**Step 3:** Sponsor new studies to support one or more dogs from the Four Dog Defense

**Step 4:** Sponsor a meeting to review new studies

**Step 5:** Require the EPA to review new studies

**Step 6:** Require the EPA to redraft its assessment

**Step 7:** Attack the EPA reassessment (back to Step 1)

The three chemicals in our case studies are representative of a significant problem. According to a recent analysis of the IRIS Program by the Center for Progressive Reform (CPR), there are roughly 500 chemicals in the IRIS public database and about 300 to 400 that are more than 10 years old, awaiting either initial or updated assessments. This is a backlog that, at the current rate of nine assessments per year (up from two per year during the Bush administration), would take 55 years to complete.

## HEADLINES FROM THE DELAY GAME

To illustrate the attempts of the chemical industry to block risk assessments and regulations, below is a sample of headlines in the Washington beltway publication *Inside EPA*. Note that there were no headlines in 2009 of industry commending the EPA for any risk assessment and none announcing that industry was taking precautionary or proactive steps to remove an existing chemical from the market.

### Industry Fears New Formaldehyde Cancer Data May Guide EPA Risk Study

"Industry officials fear that new studies that are leading international and federal toxicology researchers to call for an upgrade in formaldehyde's listing as a human carcinogen may influence and tighten EPA's pending study of the chemical's risks, which the agency is under pressure to send to the National Academy of Sciences (NAS) for review." (*Inside EPA*, December 15, 2009)

### Industry Eyes Studies To Rebut Finding Of Formaldehyde-Leukemia Link

"Formaldehyde makers and users are striving to rebut a new study linking exposure to the chemical with myeloid leukemia by launching their own studies of hundreds of formaldehyde-exposed workers, as EPA works on an assessment of the chemical that industry fears will adopt several expert bodies' finding that it is a human carcinogen." (*Inside EPA*, February 23, 2010)

### Industry Urges EPA To Await New Formaldehyde Study For Air Toxics Rule

"Industry is criticizing EPA's reliance on what critics say is a flawed 1991 risk assessment of formaldehyde in setting a proposed air toxics standard for wood furniture manufacturing facilities, saying EPA should stall the rule until the National Academy of Sciences (NAS) completes its review of a new agency formaldehyde risk study." (*Inside EPA*, March 8, 2011)

### Court Blocks Industry Suit On Styrene Cancer Listing, Clearing EPA's Path

"A federal court has conditionally denied an industry motion seeking to remove styrene from the National Toxicology Program's (NTP) listing as a carcinogen, a decision which could pave the way for EPA to move forward on its own long-stalled risk assessment of the chemical that is expected to include a first-time estimate of its cancer risks." (*Inside EPA*, July 14, 2011)

### Industry Hopes NAS' Study Defense Bolsters Bid To Soften EPA's TCE Limits

"Chemical industry officials are pointing to a recently released National Academy of Sciences (NAS) letter defending its 2009 report on chemicals in drinking water at a North Carolina Marine Corps Base to bolster their efforts to soften EPA's draft risk assessment on the solvent trichloroethylene (TCE), one of the chemicals NAS studied." (*Inside EPA*, June 3, 2011)

## CASE #1: TRICHLOROETHYLENE



**Trichloroethylene (TCE), a chlorinated solvent used primarily for metal degreasing—most notably for jet parts—is a widespread drinking water contaminant that is leaching from military bases and industrial sites throughout the country. In addition to cancer, TCE has been linked with harmful effects to the central nervous system, kidney, liver, immune system, male reproductive system, and developing fetus. The EPA has been trying to finalize its assessment of TCE for 22 years. The EPA’s latest goal is to finalize it by the end of 2011.**

Although it is still used today, most TCE pollution comes from the improper disposal of waste from past uses. Approximately 2.9 million pounds of TCE waste is produced annually in the United States, with most of it emitted into air, according to the most recent data available.<sup>5</sup> TCE has been identified at approximately 760 Superfund sites, including many old military sites.<sup>6</sup> The public is exposed through drinking and washing with contaminated water, as well as breathing air contaminated with TCE vapor that can intrude into homes via contaminated soil.<sup>7</sup>

The EPA’s assessment of TCE last done through the IRIS program in 1987 is nearly 25 years old.<sup>8</sup> It had classified TCE as a “probable human carcinogen.” The Food and Drug Administration (FDA) had banned the use of TCE in food ten years earlier. In 1989, the EPA started to update its TCE cancer assessment, but didn’t issue a draft for public and peer review for a dozen years, until 2001.<sup>9</sup> The 2001 draft classified TCE as “highly likely” to cause cancer, consistent with the World Health Organization’s (WHO) classification of

“probably carcinogenic to humans” (IARC 1995, Group 2A), and the National Toxicology Program’s listing of “reasonably anticipated to cause cancer” through both inhaling contaminated air and through drinking contaminated water (9<sup>th</sup> Report on Carcinogens, 2002).<sup>10</sup>

Unlike other programs that only describe the qualitative hazards of chemicals, the EPA IRIS program calculates numerical risk estimates. The 2001 EPA draft for TCE calculated that the chemical was five to 65 times more toxic than previously estimated.<sup>11</sup> It also identified children as a susceptible population, and noted that co-exposure to some other chemicals may augment the toxicity of TCE, emphasizing that it is “important to consider the cumulative effects of TCE along with other environmental contaminants” when conducting a risk assessment.<sup>12,13</sup> This approach, ahead of its time, foreshadowed a number of the recommendations that would be made eight years later in a 2009 landmark report of the National Academies called *Science and Decisions: Advancing Risk Assessment*.<sup>14</sup>

## ATTACK AGENCY ASSESSMENTS

Because the TCE draft risk assessment laid the groundwork for much more stringent cleanup standards and exposure limits than the original 1987 assessment, it triggered a decade-long firestorm of criticism from the chemical industry, the Department of Defense (DOD) and the Department of Energy (DOE). The DOD and DOE together are responsible for about 1,400 TCE-contaminated dump sites in the nation,<sup>15</sup> giving them an incentive to avoid stringent cleanup requirements. The criticism paralyzed the EPA, and kept it from finalizing its analysis.

In a good-will effort to achieve a level of scientific consensus, the EPA hosted meetings in 1993 and 1995, and co-sponsored a series of workshops with the Pentagon and the Halogenated Solvents Industry Alliance, Inc. (HSIA) leading up to the draft.<sup>16, 17, 18</sup> Despite this early effort to consider broad viewpoints, the Pentagon, the biggest TCE polluter, protested that the EPA's 2001 draft was based on flawed science, and launched an aggressive campaign to have the assessment withdrawn.<sup>19</sup>

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### Debbie's Story

"We discovered in August 2005 that our home was contaminated with TCE. My husband passed in November 2010. Prior to his passing he had been diagnosed first with Parkinson's disease, reynolds phenomena and peripheral neuropathy, and later, lung cancer. I too had peripheral neuropathy and respiratory problems. I found two immediate neighbors who also passed from respiratory problems. One of my neighbors was diagnosed with cancer of the thymus, and has started a health study of our neighborhood."  
— Debbie, Ontario, Canada.

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Industry-sponsored scientists joined in the campaign, writing a letter objecting to the 2001 EPA draft assessment of TCE risks.<sup>20, 21</sup> The Air Force even went so far as to send an official letter opposing use of the 2001 risk estimates at its Lowry Air Force Base in Colorado, specifically in order to block better cleanup.<sup>22</sup> The letter argued that the EPA's remediation plans should be based on its previous cancer risk estimates, given that "the Department of Defense (DOD) officially disagrees with the conclusions and methodologies used by the EPA" and called the EPA assessment invalid, still in draft form, and subject to change.<sup>23</sup> Using circular logic, the DOD criticized the EPA assessment, which blocked it from being finalized—and then suggested that regulators reject the assessment because it was being criticized and still in draft form.

Despite tremendous pressure to delay, and in spite of the criticism from industry and the Pentagon, the EPA went ahead and sent its TCE draft assessment to its Scientific Advisory Board (SAB) in 2002 for peer review by independent scientific experts. The SAB issued a very favorable report, supporting the EPA's characterization of TCE's cancer risk and advising the agency to finalize the draft following minor

revisions.<sup>24</sup> Nonetheless, Bush Administration political appointees forced the EPA to pull back the assessment.<sup>25</sup> EPA scientist Vincent Cogliano, the main author of the 2001 assessment and now Acting Director of the EPA's IRIS chemical review program, identified both the Bush White House and the Pentagon as having created significant behind the scenes opposition to the assessment.<sup>26</sup>

## PREVENT THE AGENCY FROM FINALIZING ASSESSMENT

Some states, desperate for an updated TCE hazard number in order to begin cleanup at hazardous waste sites within their borders, adopted the more health-protective 2001 risk estimates despite their still-draft status, since they represented the best available science at the time. By early 2003, the Colorado Department of Public Health and Environment was one of these states, and it had begun to apply the 2001 risk estimates to clean up requirements.

Bush Administration political appointee Paul Gilman pressed regional Superfund directors to adopt weaker toxicity standards than those outlined in the draft assessment.<sup>27</sup> Colorado stood its ground. It was joined by New Jersey and eight other regional EPA offices in implementing the 2001 draft assessment recommendations.<sup>28</sup>

In early 2003 a Court of Appeals ruling allowed a class-action suit to proceed against an Illinois factory polluting nearby neighborhoods with TCE. The decision opened the way for future tort liability claims against industry for TCE contamination.<sup>29</sup>

In order to try and finalize its assessment, in 2004 the EPA hosted a symposium of new science. At the symposium, however, several DOD-sponsored scientists presented data arguing that TCE was not as toxic as the EPA had found.<sup>30</sup>

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### Joe's Story

"I worked as a mechanic for about six years. Day in and day out I used solvent cleaners [whose main ingredient was TCE]. Sometimes we would hand-fill small bottles of the chemicals, and it would spill all over our hands. I felt lightheaded and nauseous when using the cleaners, but mostly it irritated my lungs and my eyes burned. Several mechanics I worked with have since died from lymphoid cancers." — Joe, West Virginia

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## SPONSOR NEW STUDIES

The data introduced at the 2004 symposium focused on the third and fourth dogs in the Four Dog defense—my dog bit you but did not hurt you (TCE is not as harmful as the EPA supposes; rat cancers are not predictive of humans) and my dog bit you and hurt you but it was not my fault (past practices were at higher doses; the people who claim TCE gave them cancer also smoked).

## REQUIRE THE AGENCY TO REVIEW NEW STUDIES

The Pentagon forced the draft into a further delay by insisting on a consultation from the National Research Council of the National Academies (NRC, or Academies). This consultation took two more years and three quarters of a million dollars of taxpayer money. Nonetheless, when it was over, the 2006 NRC report defended the EPA's assessment, and urged the EPA to finalize it expeditiously.<sup>31</sup> The same year, the Los Angeles Times reported that TCE had "contaminated 23 sites in the Energy Department's nuclear weapons complex."<sup>32</sup>

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***"Hundreds of waste sites in the United States are contaminated with trichloroethylene, and it is well documented that individuals in many communities are exposed to the chemical, with associated health risks. Thus, the committee recommends that federal agencies finalize their risk assessment with currently available data so that risk management decisions can be made expeditiously."—National Academies report on TCE, 2006***<sup>33</sup>

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In the spring of 2007, six years after issuance of the 2001 draft, the Bush Administration side-stepped the science by issuing a rule exempting the military and certain industries from laws that would put a limit on air emissions of TCE and other halogenated solvents.<sup>34</sup> This exemption was challenged in court by environmental groups. In 2009, the Obama Administration agreed to reconsider the Bush-era air emission exemptions. The outcome of that process is still pending.<sup>35</sup>

## CHALLENGE THE AGENCY'S NEW DRAFT ASSESSMENT

In 2009, the EPA staff again updated its still-draft TCE assessment, this time classifying TCE as carcinogenic to humans by all routes of exposure, based mainly on its high

risk of causing kidney cancers, but also on Non-Hodgkin's lymphoma and liver cancer.<sup>36,37</sup> In addition to cancer, the 2009 draft links TCE exposure with elevated risks of harmful non-cancer effects on the human central nervous system, kidney, liver, immune system, male reproductive system, and the developing fetus.<sup>38</sup>

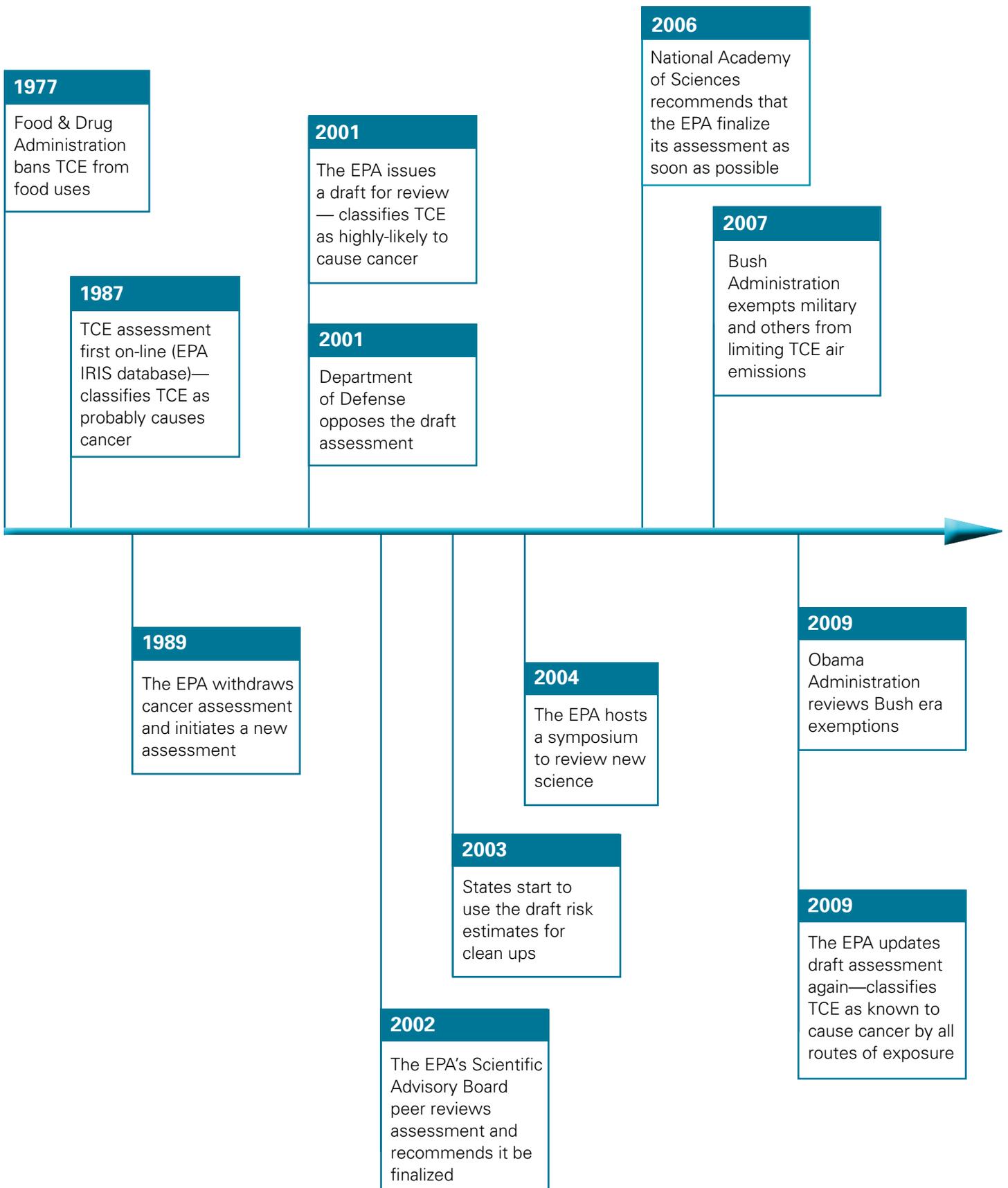
Not surprisingly, polluters lined up in opposition to the 2009 draft.<sup>39</sup> A new Scientific Advisory Board was convened to review the new draft, and once again it backed up the EPA's scientific assessment. The review process, though, took time and allowed continued exposure while stricter clean up and emissions standards were delayed. In the case of TCE, industry achieved two decades of delay, but ultimately the EPA's science won out.<sup>40</sup> In the end, industry was dealt a harsher blow because the scientific standards were raised as a result of new science:

1. The cancer data strengthened significantly, leading the EPA to classify TCE as carcinogenic rather than "likely" carcinogenic to humans.
2. Evidence of immune toxicity emerged.
3. Data on fetal cardiac effects associated with TCE strengthened.

Ironically, one of the key kidney cancer studies used in the stronger 2009 assessment was sponsored by the chemical industry (Charbotel et al, 2006) Funded by the European Chlorinated Solvents Association, the study showed a two-fold elevated risk of kidney cancer in TCE exposed workers. Currently, the industry is attempting to discredit this study by saying that it has methodological flaws.<sup>41,42</sup>

The 2009 assessment was rumored to be finalized and issued to the public in the last few work days before the September 5 Labor Day long weekend, 2011. However, in a surprise retreat it was held back on the Friday before the long weekend. On the same day IRIS draft assessments of two other chemicals—1,4 dioxane and n-butanol—that had already been made available for public comment on August 31 were pulled back without any explanation other than a website note that the two assessments were 'temporarily unavailable'.<sup>43</sup> Although it is not known whether this order originated with EPA Administrator Lisa Jackson or at a higher level, co-incidentally on the same day the White House ordered the EPA to withdraw proposed health-protective ozone air quality standards that were calculated to reduce risks of heart attacks, asthma attacks, and even deaths from smog-related diseases.<sup>44,45</sup> The TCE health assessment was finalized on September 28, as this report went to press.

## TCE Timeline 1987—2009



## CASE #2: FORMALDEHYDE



**Formaldehyde is a cancer-causing chemical used primarily to manufacture plywood, particleboard, resins, and glues. It off-gasses from these household products and contaminates indoor air. Formaldehyde also pollutes outdoor air as an ingredient in vehicle fuel emissions. In addition to causing cancer, formaldehyde is a powerful irritant, creating a burning sensation in the eyes, nose and throat and triggering respiratory difficulty in some asthmatics. The EPA has been working on an updated health assessment since 1998 and has just recently begun a new draft.**

Formaldehyde is a high volume industrial chemical; several million workers are occupationally exposed to it in the United States at any given time.<sup>46, 47</sup> Approximately 14.5 million pounds of formaldehyde waste is produced annually in the United States, with almost five million pounds emitted into air and most of the rest going to waste disposals, according to the most recent data available.<sup>48</sup>

The general public is commonly exposed when indoor air is contaminated with formaldehyde fumes emitted from the adhesives used to make the particleboard and plywood in our home furniture, and kitchen cupboards.<sup>49</sup> Although indoor air levels tend to be about 10 times higher than outdoor air levels, formaldehyde is also a contaminant of concern outdoors because it is emitted from vehicles and other sources of fuel combustion.<sup>50</sup>

### ATTACK AGENCY ASSESSMENTS

There is no longer any question that formaldehyde causes cancer in people. It causes cancer of the nose and nasal cavity in lab rats and, unfortunately, in people who are unlucky enough to be exposed to this chemical through workplace contaminated air. Formaldehyde was classified in 2009 as known to cause cancer in humans by the International Agency for Cancer (IARC), the science arm of the WHO, and also the National Toxicology Program (NTP), a part of the National Institutes of Health.<sup>51,52</sup> However, the EPA's job with formaldehyde, as with TCE, is more challenging than the jobs of IARC and NTP; it must conduct a quantitative analysis to develop a safe level of exposure. Thus these conclusions from other authoritative bodies do not allow the EPA to complete its task. Although the link between formaldehyde

inhalation and cancers of the nose and nasal cavity has been widely accepted, a long debate has raged over whether or not formaldehyde also causes leukemia, and over the cancer *potency* of formaldehyde (how much formaldehyde causes how much cancer).

## SPONSOR NEW STUDIES

For more than 12 years, the EPA has attempted to update its formaldehyde risk assessment. The formaldehyde industry has blocked the assessment from being finalized by using the first dog of the Four Dog Defense: my dog doesn't bite. Industry has objected to the EPA's classification of formaldehyde as a known human carcinogen (Group A), and has vehemently opposed the EPA's finding that formaldehyde may be linked with cancers other than in the nose and nasal cavity.

Part of the industry's concern may be its potential legal liability if formaldehyde is recognized as a more harmful chemical. If formaldehyde is officially linked to the more common leukemia and lymphoma cancers, that opens the possibility of litigation from exposed workers and members of the public (including all the people living in government-provided trailer housing after hurricanes Katrina and Rita).

The IRIS Program published its first formaldehyde risk assessment online in 1989, more than 20 years ago, identifying risks only from eating or drinking formaldehyde, but not from breathing it.<sup>53</sup> In 1991, the EPA added a risk estimate for breathing formaldehyde-contaminated air, and classified the chemical as a probable human carcinogen (Group B1) based on strong evidence of respiratory tract cancer in laboratory animal studies and some cancer data from exposed people.<sup>54</sup>

## CHALLENGE THE AGENCY'S NEW DRAFT ASSESSMENT

Several years later, in 1998, the EPA initiated a systematic update. In response, in 2001 the industry research group Chemical Industry Institute of Toxicology (CIIT) challenged the EPA exposure limit with a mathematical (theoretical) model and new risk estimates from research that it sponsored.<sup>55</sup> Significantly, the CIIT model only accounted for cancers of the nose and nasal cavity; other cancers such as leukemia of the blood were not included. Also, because of mechanistic assumptions in the model (e.g. excessive reliance on cytotoxic/irritant effects at high doses), low-dose risks due to this chemical's potential to damage a cell's genetic material may have been underestimated. The cancer risk estimates predicted by the CIIT model were thus thousands of times lower than the estimate from the EPA, suggesting it was a very weak carcinogen.<sup>56</sup>

In other words, industry called out the third dog of the Four Dog Defense: my dog bit you, but it did not hurt you.

## INDUSTRY GROUP FAILS TO REPORT FORMALDEHYDE FINDINGS

In 1981, the Chemical Industry Institute of Toxicology (CIIT), sponsored rodent studies that demonstrated formaldehyde inhalation over a lifetime was associated with death from bone marrow hyperplasia and leukemia.<sup>57</sup> However, CIIT failed to report on these findings in its 1983 publication of the study.<sup>58</sup> CIIT also failed at the time to report to the EPA its findings on blood and bone cancer, even though it is required by law for industry groups to provide toxicity information to the EPA. Moreover, in 2004 two CIIT researchers appear to have down-played their own findings, instead stating publicly: "The possibility that inhaled formaldehyde might induce various forms of distant-site toxicity has been proposed, but no convincing evidence for such toxicity has been obtained in experimental studies."<sup>59</sup>

Public health suffered a blow in 2003 when, in the absence of a finalized IRIS assessment, the EPA Air Office adopted the industry-modeled numbers in its proposed rule, exempting dozens of plywood facilities from adopting legally-required pollution controls for formaldehyde.<sup>60</sup> The rule was adopted a year later, despite significant public outrage. The rule was eventually overturned by an NRDC court challenge in 2007, after a federal court found that the EPA had created an illegal loophole and unlawfully extended the compliance deadline.<sup>61</sup>

## PREVENT THE AGENCY FROM FINALIZING ASSESSMENT

In order for the Air Office to use risk numbers from industry in its proposed rule, it needed to delay the IRIS program from finalizing its assessment. It did this with pressure from high level Bush Administration political managers at the EPA, who used the argument that IRIS should await an update of the epidemiology studies before completing its assessment.<sup>62</sup>

In the meantime, the science showing harm from formaldehyde, including leukemia, continued to strengthen. In 2003, the NCI reported evidence of an association between workplace formaldehyde and leukemia in a study of 26,000 workers.<sup>63</sup> This was followed by another large government study reporting similar results, this time in 11,000 garment workers studied by the National Institute of Occupational Safety and Health (NIOSH).<sup>64</sup>

## SPONSOR NEW STUDIES

In response to the new science, in 2004 industry formed a new coalition called the Formaldehyde Council, Inc. (FCI), self-described as representing the leading producers and users of formaldehyde in the United States.<sup>65</sup> Almost immediately after its formation, FCI-sponsored scientists published its own re-analysis of the government findings to specifically dispute the link between leukemia and formaldehyde.<sup>66</sup>

## REQUIRE THE AGENCY TO REVIEW NEW STUDIES

In 2004, at the behest of the FCI, Senator James Inhofe demanded that the EPA postpone the revisions of the formaldehyde risk assessment until the study could take into account industry data, a move that would delay new protective regulations.<sup>67, 68</sup> The EPA acquiesced to Senator Inhofe's demand, meaning that unsafe exposures would continue.

### TRAILER RESIDENTS SUFFER AFTER HURRICANES

In 2005, hurricanes Rita and Katrina devastated the Gulf Coast, triggering a need for temporary housing. The Federal Emergency Management Agency (FEMA) provided approximately 100,000 trailers to homeless residents in Louisiana and Mississippi. Soon after moving in, however, residents began complaining about respiratory symptoms that were subsequently linked to formaldehyde off-gassing inside the trailers. More than three years later, following various Congressional hearings and investigative reports, the Director of the Centers for Disease Control and Prevention (CDC), Dr. Julie Gerberding, finally announced publicly that levels of formaldehyde in the trailers were high enough to increase the risk of cancer and respiratory illness. She advised that people relocate.<sup>69</sup>

In 2006, the International Agency for Research on Cancer (IARC, 2006), the science arm of the WHO, reclassified formaldehyde as known to cause cancer in humans (Group 1) and specifically noted the compelling evidence of leukemia in the workplace studies.<sup>70</sup>

In spring 2008, the GAO released a report identifying interference by Senator Inhofe as contributing to the delay and complicating the EPA's attempts to complete its assessment of formaldehyde. The GAO also testified to this in Congress.<sup>71</sup>

## PREVENT THE AGENCY FROM FINALIZING ASSESSMENT

In June 2009, to prevent the EPA from finalizing its assessment, The Formaldehyde Council worked with Louisiana Senator David Vitter to block the confirmation of President Obama's nominee, Dr. Paul Anastas, to run the EPA's Office of Research and Development (location of the IRIS program). Senator Vitter held the nomination hostage until the EPA agreed to send its assessment to the National Academies for yet another review—ensuring a delay of at least two years before the EPA could update its formaldehyde assessment.<sup>72</sup> Ironically, Vitter's home state of Louisiana is a place where his constituents have reported health problems since being housed in formaldehyde-contaminated trailers after hurricane Katrina. The formaldehyde industry expressed its gratitude to Senator Vitter for his interference.<sup>73</sup>

In the fall of 2009 IARC and the NTP not only confirmed previous determinations that formaldehyde causes nose and nasal cavity cancer in humans, but went further and specified that there was sufficient evidence linking formaldehyde exposure to increased leukemia risk in people.<sup>74, 75, 76, 77</sup>

In June 2010, the EPA finally released its long-awaited draft assessment to the public.<sup>78</sup> The draft assessment identified formaldehyde as causing cancer in the nose and nasal cavity, and also elevating the risk of leukemia. Importantly, it estimated that the cancer risks posed by a full lifetime inhalation exposure to average indoor air formaldehyde levels could be as high as one in 1,000 cancers above background, approximately five-fold more carcinogenic than the old 1991 risk estimate still on IRIS.

## CHALLENGE THE AGENCY NEW DRAFT ASSESSMENT

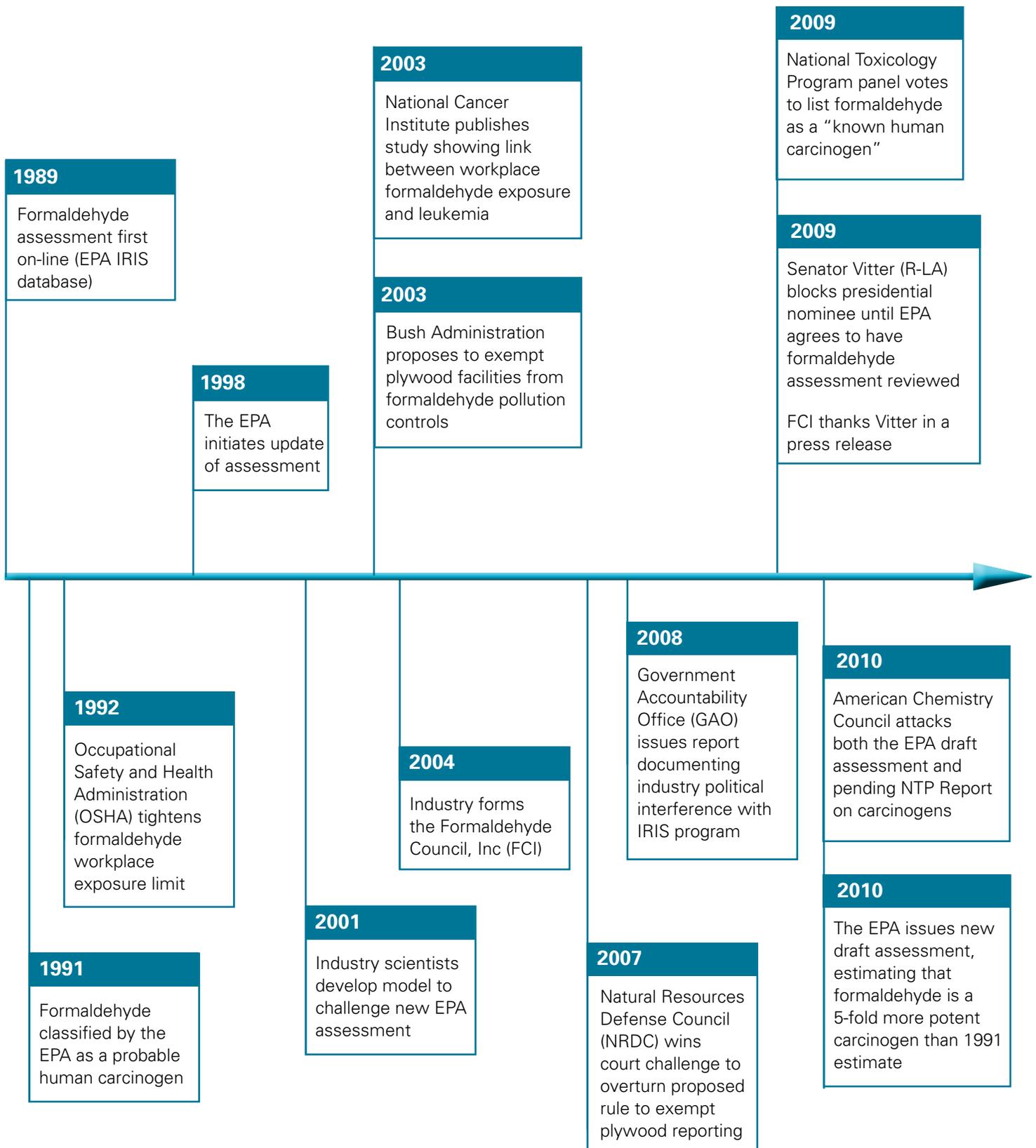
After a 14-month process, in April 2011 the Academies issued its review of the EPA draft assessment. The Academies confirmed the EPA's determination that formaldehyde causes cancer in humans, but recommended that the EPA rewrite its report to more clearly communicate the scientific reasoning underpinning its assessment. The Academies urged the EPA to finalize its rewritten report as soon as possible. While asking the EPA to state its reasoning more concisely, and to separate out leukemia risks from lymphoma risks, the Academies supported the EPA's determination to include leukemia in its calculation of cancer risks.<sup>79</sup>

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*“Joseph V. Rodricks, a consultant with Environ who briefed the American Chemistry Council about the [Academies’] report, acknowledged that the panel did not say “EPA got it wrong” by concluding formaldehyde causes leukemia and lymphoma,” the trade press reported. Instead, the panel told EPA to better support its conclusion. Rodricks said he interprets the evidence on leukemia risks as “virtually nonexistent.” The panel’s report, however, says EPA must address the topic and hence urges EPA to do so clearly and consistently, [Rodricks] said.”<sup>80</sup>*

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## Formaldehyde Timeline 1989—2010



## ATTACK THE REDRAFTED AGENCY ASSESSMENT

The American Chemistry Council (ACC, formerly called the Chemical Manufacturers Association), a chemical industry trade association, wasted no time in using the National Academies report to attack both the EPA draft assessment and the NTP's assessment of formaldehyde in its pending *Report on Carcinogens*. In both cases, the ACC referenced the Academies report as justification for its attacks.

A week after the National Academies report came out, ACC sent a letter to EPA Administrator Lisa Jackson, asking that all IRIS assessments currently in draft form, or expected to be issued as drafts in 2011 and 2012, be submitted for review by the National Academies.<sup>81</sup> This request would not only be cost-prohibitive, since each review by the Academies costs about three-quarters of a million dollars, but directly contradicts the actual recommendations of the Academies report, which specifically said, "The committee recognizes that revision of the approach will involve an extensive effort by EPA staff and others, and it is not recommending that EPA delay the revision of the formaldehyde assessment to implement the new approach."<sup>82</sup>

A week later, the ACC wrote another letter pressuring the Department of Health and Human Services (HHS) to revise its *Report on Carcinogens*, specifically challenging the link with leukemia.<sup>83</sup> The trade press, reporting on these delay tactics, said "Industry has already seized upon the [Academies'] report in their efforts to pressure EPA and HHS to alter their conclusions."<sup>84</sup>

The ACC's bid was ultimately unsuccessful in holding back the *Report on Carcinogens*. After a four year delay, the NTP issued the 12<sup>th</sup> *Report on Carcinogens* in June 2011, and listed formaldehyde as known to cause cancer in humans.<sup>85</sup> While the report acknowledged that the mechanism by which formaldehyde causes leukemia is not well understood, it relied upon existing evidence: "studies of workers exposed

to high levels of formaldehyde, such as industrial workers and embalmers, found that formaldehyde causes myeloid leukemia, and rare cancers including sinonasal and nasopharyngeal cancer."<sup>86</sup> The NTP included an addendum with its formaldehyde assessment that discussed the Academies review of the EPA's formaldehyde assessment under IRIS. The addendum made clear why the Academies critique did not undermine or conflict with the NTP's listing of formaldehyde as a human carcinogen. Ironically, the ACC was quoted in the New York Times as rejecting the report's conclusions and expressing concern that "politics may have hijacked the scientific process."<sup>87</sup>

In July 2011, the EPA announced a set of planned changes to the IRIS program in response to the recommendations of the National Academies panel.<sup>88</sup> However, since the release of the Academies report, it is the chemical industry that has been working actively to politicize the scientific process, including calling on the White House to assert greater control over both the IRIS program and the NTP, and pressing for the National Academies to be required to review *all* IRIS assessments.

In spite of all the politics and bureaucracy, the science on formaldehyde has remained steady: the EPA, the IARC, and an expert scientific advisory committee all concluded that the National Cancer Institute data show statistically significant increased incidences of leukemia or lymphoma in workers exposed to formaldehyde.<sup>89</sup>

The formaldehyde saga, with its years of delayed assessments and aggressive lobbying by the formaldehyde industry, demonstrates the need for clear statutory deadlines for chemical evaluations. If deadlines are missed, consequences need to be stipulated and enforced. The 13 years of delay caused by the chemical industry ploys on formaldehyde has likely brought them billions of dollars worth of sales, while costing the public more than a decade of exposures to a potent carcinogen, resulting in uncounted cases of cancer nationwide.

## CASE #3: STYRENE



**Styrene is used to manufacture many plastics, latex paints, synthetic rubbers, polyesters and coatings. It is also approved for use in food-contact materials, and is an FDA-approved synthetic flavoring in ice cream and candy.<sup>90</sup> Styrene, also found in tobacco smoke, is regulated as a Hazardous Air Pollutant by the EPA. The EPA has been trying to update its styrene assessment since 1998, with no end in sight.**

Approximately 4 to 5 billion pounds of styrene are produced annually in the United States, resulting in over 20 million pounds of waste styrene, with 17.8 million pounds emitted into air and 1.7 million pounds discharged into surface waters, according to the most recent data available.<sup>91,92</sup>

Styrene is listed under the Clean Air Act as a Hazardous Air Pollutant and is classified by the World Health Organization (WHO) chemical assessment program, the International Agency for Research on Cancer (IARC) as “possibly carcinogenic to humans.”<sup>93</sup> In addition, styrene oxide, a major metabolite of styrene, is listed by the National Toxicology Program’s Report on Carcinogens as “reasonably anticipated to be a human carcinogen.”<sup>94</sup> Nonetheless, the EPA’s old assessment of styrene, which was first on-line in 1987 and last revised in 1993, fails to account for styrene’s cancer risks; the outdated assessment provides risk estimates for only non-cancer effects.<sup>95</sup>

### SPONSOR NEW STUDIES

The EPA’s efforts to update the science on its styrene hazard assessments started in 1998. That year, the styrene industry itself volunteered to perform an updated risk assessment of the chemical, supposedly to relieve the EPA from having to undertake the task.<sup>96</sup> In a serious misstep that the EPA would eventually come to regret, the agency accepted the styrene industry’s offer. An industry trade association—the Styrene Information and Research Center (SIRC)—began drafting a toxicological review of styrene for the EPA.<sup>97,98</sup> With this review, the EPA essentially allowed industry to parse the evidence and reach its own conclusions in a literature review and scientific assessment of styrene’s cancer and non-cancer risks.

SIRC was not the only industry-based group working to influence the EPA’s styrene toxicity assessment. In 2000,

the International Institute of Synthetic Rubber Producers (IISRP), an industry trade association, submitted a study to the EPA that tried to shift the blame for an observed excess in leukemia deaths among a group of styrene-butadiene rubber workers from styrene to butadiene, another hazardous chemical that is also responsible for workplace cancers and deaths.<sup>99</sup> However, the fact that workers are often exposed to both deadly chemicals doesn't make either one any safer.

In 2002 the WHO undertook its own extensive scientific review with its IARC committee. This review concluded that styrene was possibly carcinogenic to humans (Group 2B), based on limited evidence in both humans and experimental animals.<sup>100</sup> The committee was comprised of 29 scientists, of whom three had financial ties to the styrene industry; two of the 29 were paid consultants for SIRC. This conflict was brought to light in a public letter from NRDC scientists and a letter from the former Director of IARC—an internationally-renowned cancer expert—signed by thirty prominent scientists and chemical experts.<sup>101,102</sup>

Following these public revelations of SIRC's participation in the IARC review and in drafting the EPA assessment, 16 members of the California Legislature asked Senator Barbara Boxer to launch an investigation into industry-sponsored groups being invited by the EPA to draft EPA chemical assessments. Styrene was mentioned specifically as an example of this outrageous practice.<sup>103</sup>

Later in 2002, a styrene industry consultant submitted to the EPA a study arguing that the cancers in lab rodents related to styrene are caused by a unique cellular process that is not likely to cause cancer in humans.<sup>104</sup> Industry was again calling out the Four Dog Defense, arguing the third dog: my dog bites, but it will not hurt you.

In 2003, SIRC submitted its draft styrene assessment to the EPA, having taken five years to complete it. However, the EPA found that SIRC's draft assessment was so poorly done that it could not be used; the agency subsequently announced its intentions to abandon the use of industry first drafts altogether. EPA management was even quoted in trade press expressing frustration with the failed program, saying it "did not save EPA staff time or effort" and created "substantial concerns about conflict of interest."<sup>105</sup>

In 2004, the American Composites Manufacturers Association (ACMA), an industry trade organization representing over 1000 companies that manufacture composite materials including fiberglass, plastics, and wood composites that are made with styrene resin, asked the EPA to avoid causing "unwarranted public concern and economic harm" when alerting the public about styrene's cancer risks.<sup>106</sup> ACMA, concerned that an EPA classification of a cancer risk will harm their industry, estimates that 80,000 workers are exposed to styrene as a result of work activities, and that "most Americans use products every day that may contain very small residual levels of styrene" including toys and even some foods.<sup>107</sup> They are concerned that an EPA classification

of a cancer risk will harm their industry.

In a continuing effort at damage control, later that year SIRC opposed the nomination of styrene for inclusion in the government's Report on Carcinogens.<sup>108</sup> The challenge was largely based on the conclusions of an expert panel sponsored by SIRC at the Harvard Center for Risk Analysis. The industry-funded panel concluded that "the balance of epidemiologic evidence does not suggest a causal association between styrene and any form of cancer in humans."<sup>109, 110, 111</sup>

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***SIRC also criticized the IARC cancer classification of styrene by pointing out weaknesses in the studies and noting that industry-sponsored reanalysis found no cancer risks.<sup>112</sup>***

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## **DELAY BY REQUIRING THE AGENCY TO REVIEW NEW STUDIES**

In the spring of 2011, consultants for the styrene industry presented the results of their new studies at a professional meeting of the Society of Toxicology. In an email to the EPA's scientists, they claimed to have demonstrated that styrene and styrene oxide are both "NOT toxic in mouse lungs"<sup>113</sup> [caps in original email] unless the chemicals are further metabolized. One consultant wrote, "I am not sure where you are in the draft development process, but I hope you will seriously consider these data and the impact on a cancer evaluation of styrene mouse lung tumors."<sup>114</sup> Note that this argument appears to be of questionable scientific relevance since styrene oxide, the metabolite of styrene, damages DNA directly, whereas the industry study addresses cellular damage, which doesn't pose any scientific challenge to the cancer risks. This is another example of the third dog in the Four Dog Defense—my dog bit you but did not hurt you.

As noted in our formaldehyde case study above, the chemical industry ran an aggressive but ultimately unsuccessful campaign to prevent the *12th Report on Carcinogens* from being published by the NTP. In addition to formaldehyde, another primary motivation for the campaign was the listing of styrene as "reasonably anticipated" to cause cancer in humans.<sup>115</sup> The final NTP report identified "limited evidence" for cancer from worker studies showing increased risk of cancers such as leukemia and lymphoma, "some evidence" of elevated cancer risks of the pancreas or esophagus among styrene workers; and evidence from mice studies of lung cancer.

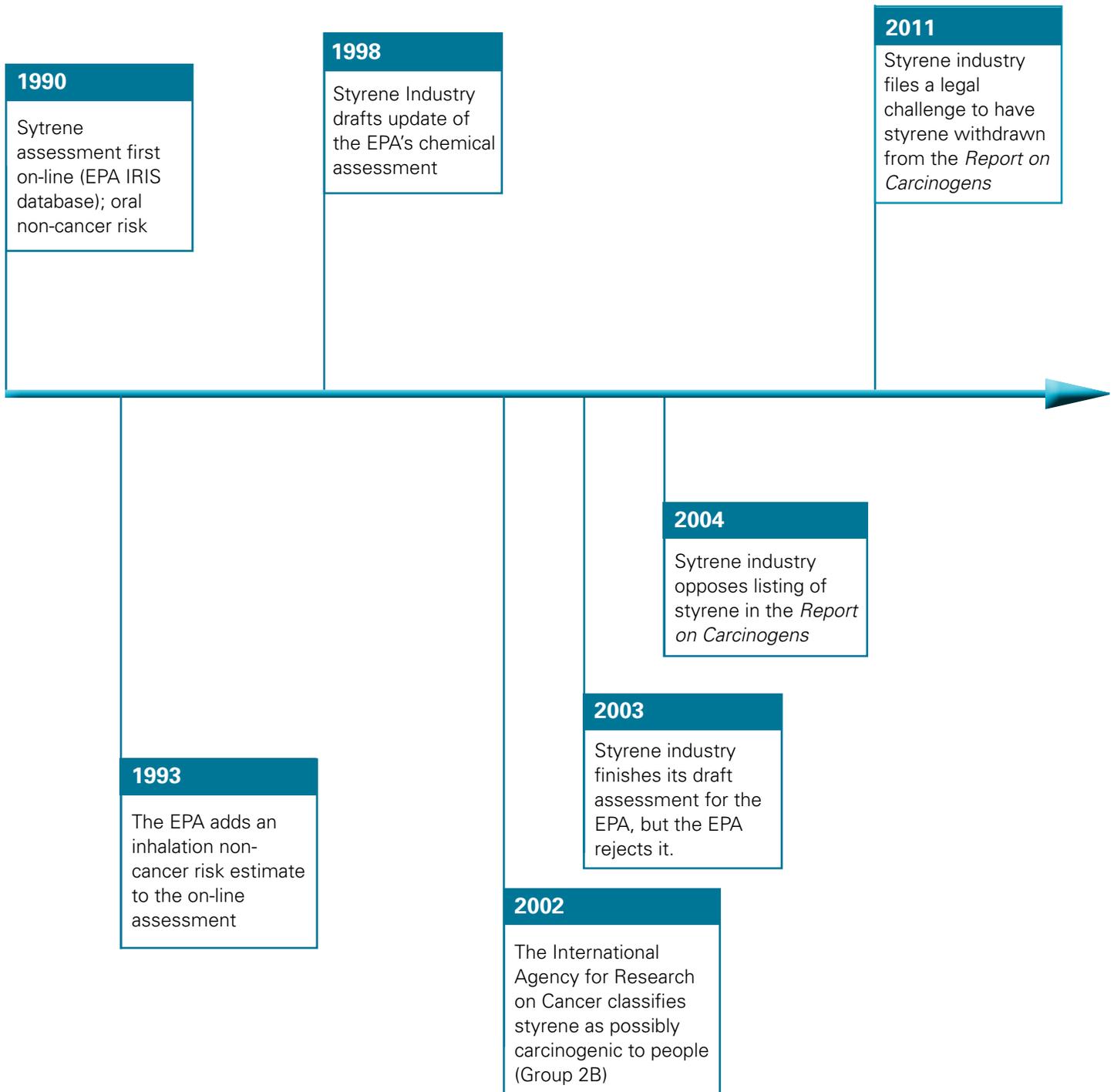
## ATTACK THE AGENCY'S ASSESSMENT

Immediately after the publication of the *Report on Carcinogens*, the styrene industry filed a lawsuit to have the listing withdrawn. That lawsuit continues to be litigated.<sup>116</sup>

Meanwhile, although the EPA assessment of styrene was launched in 1998, even now, 13 years later, no deadlines

or milestones have been completed. Even the very first step, writing the first draft of the assessment, has not been completed. Therefore, at this time the 1993 assessment, still lacking a cancer risk estimate, is the one that is posted on the EPA's IRIS database representing the EPA's most current scientific estimate of styrene's health risks—twenty years out of date.

### Styrene Timeline 1990—2011



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# CONCLUSIONS AND RECOMMENDATIONS

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***The EPA needs the authority to protect health. Meaningful TSCA reform must take away the incentive and rewards for the chemical industry to play the delay game while the public pays the price.***

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The Toxic Substances Control Act (TSCA) is in need of serious structural reform. Any effective system established for assessing chemicals under TSCA will need to include both enforceable deadlines for completing chemical assessments and meaningful consequences for the failure to complete an assessment within those deadlines. This should include setting default interim health-protective standards until the EPA can complete assessments, and restrictions on the expansion or new use of a chemical pending completion of the assessment. Such consequences will be necessary to eliminate the chemical industry's incentive to prevent assessments from being finalized, as is the current case with the IRIS program.

In this report, NRDC has documented the attempts to assess three high-volume “workhorse” chemicals commonly used in our country: TCE, formaldehyde, and styrene. Each of these chemicals has an extensive record of hazard data and has been the subject of study by government and non-governmental bodies for more than a decade. People are regularly made sick by these chemicals through household and industrial uses, and many have died as result. Nevertheless, health assessments that IRIS staff estimate should normally take two years have dragged on for a decade or more.<sup>117</sup>

There are scores of other chemicals that we know cause serious health effects (cancer, neurological problems, and reproductive harm) and for which exposure is widespread

and common. The nation urgently needs a law in place that enables the EPA to test, assess, and regulate chemicals in a timely manner in order to protect public health and environmental safety. TSCA as currently written is not that law. Meaningful reform must take away the incentive and rewards for the chemical industry to play the delay game while the public pays the price.

Congress needs to adopt several major reforms in order to make TSCA an effective regulatory tool:

- Shift the burden of proof from the EPA to the chemical industry to show that chemicals can be used without harming human health or the environment.
- Establish firm and enforceable deadlines for the EPA to complete its chemical assessments.
- Reverse the presumption of innocence, so that chemicals are presumed harmful in the absence of an assessment.
- Set default interim health-protective standards and restrictions on a chemical's use pending completion of a risk assessment.
- Give the EPA clear authority to obtain information on chemicals, require testing, and take action to protect the public when chemicals are known to be unsafe.

Chemicals can be designed to be non-toxic or less toxic. Many innovative businesses are already patenting and producing products that are safer for our families and the environment. But even these new, safer chemicals and materials will need to be tested and regulated. The public has the right to expect that the government will review the risks of chemicals and regulate them correctly. Congress and the Obama administration must act quickly to make the long-overdue reform of TSCA a reality.

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