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'Data Quality' Law Is Nemesis Of Regulation

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Second of three articles

Things were not looking good a few years ago for the makers of atrazine, America's second-leading weedkiller. The company was seeking approval from the Environmental Protection Agency to keep the highly profitable product on the market. But scientists were finding it was disrupting hormones in wildlife -- in some cases turning frogs into bizarre creatures bearing both male and female sex organs.

Last October, concerns about the herbicide led the European Union to ban atrazine, starting in 2005. Yet that same month, after 10 years of contentious scientific review, the EPA decided to permit ongoing use in the United States with no new restrictions.

Herbicide approvals are complicated, and there is no one reason that atrazine passed regulatory muster in this country. But close observers give significant credit to a single sentence that was added to the EPA's final scientific assessment last year.

Hormone disruption, it read, cannot be considered a "legitimate regulatory endpoint at this time" -- that is, it is not an acceptable reason to restrict a chemical's use -- because the government had not settled on an officially accepted test for measuring such disruption.

Those words, which effectively rendered moot hundreds of pages of scientific evidence, were adopted by the EPA as a result of a petition filed by a Washington consultant working with atrazine's primary manufacturer, Syngenta Crop Protection. The petition was filed under the Data Quality Act, a little-known piece of legislation that, under President Bush's Office of Management and Budget, has become a potent tool for companies seeking to beat back regulation.

The Data Quality Act -- written by an industry lobbyist and slipped into a giant appropriations bill in 2000 without congressional discussion or debate -- is just two sentences directing the OMB to ensure that all information disseminated by the federal government is reliable. But the Bush administration's interpretation of those two sentences could tip the balance in regulatory disputes that weigh the interests of consumers and businesses.

John D. Graham, administrator of the OMB Office of Information and Regulatory Affairs (OIRA), who has directed implementation of the Data Quality Act, said the law will keep the federal government hewing to "sound science." He said the act, which allows people and companies to challenge government information they believe is inaccurate, is equally accessible to "a wide diversity of interests, both in the business community and in the consumer, environmental and conservation communities."

But many consumers, conservationists and worker advocates say the act is inherently biased in favor of industry. By demanding that government use only data that have achieved a rare level of certainty, these critics maintain, the act dismisses scientific information that in the past would have triggered tighter regulation.

A Washington Post analysis of government records indicates that in the first 20 months since the act was fully implemented, it has been used predominantly by industry. Setting aside the many Data Quality Act petitions filed to correct narrow typographical or factual errors in government publications or Web sites, the analysis found 39 petitions with potentially broad economic, policy or regulatory impact. Of those, 32 were filed by regulated industries, business or trade organizations or their lobbyists. Seven were filed by environmental or citizen groups. Some environmental groups are boycotting the act, adding to the imbalance in its use.

Among the petitions:

• The American Chemistry Council and others challenged data used by the Consumer Product Safety Commission (CPSC) as it sought to ban wood treated with heavy metals and arsenic in playground equipment.

• Logging groups challenged Forest Service calculations used to justify restrictions on timber harvests.

• Sugar interests challenged the Agriculture Department and the Food and Drug Administration over dietary recommendations to limit sugar intake.

• The Salt Institute and the U.S. Chamber of Commerce challenged data that led the National Institutes of Health to recommend that people cut back on salt.

• The Nickel Development Institute and other nickel interests challenged a government report on the hazards of that metal.

• The Association of Home Appliance Manufacturers petitioned the CPSC to retract data that ranked the risk of lint fires in various clothes dryers.

Environmental and consumer groups say the Data Quality Act fits into a larger Bush administration agenda. In the past six months, more than 4,000 scientists, including dozens of Nobel laureates and 11 winners of the National Medal of Science, have signed statements accusing the administration of politicizing science.

The White House's heavy editing of a key global-warming report, its efforts to emphasize abstinence rather than condoms in the war against AIDS and its alleged stacking of scientific advisory committees have drawn particular ire. But many scientists and public advocates believe that far more is at stake with the Data Quality Act.

From their perspective, the act is shifting the authority over the nation's science into the politicized environment of the OMB -- a change, they say, that will favor big business.

"It's a tool to clobber every effort to regulate," said Rena Steinzor, a professor of law and director of the Environmental Law Clinic at the University of Maryland. "In my view, it amounts to censorship and harassment."

That's a view that Christopher C. Horner of the free-market Competitive Enterprise Institute -- which has used the act repeatedly to challenge scientific information -- brushed off as "whiny."

"Hey, you're making me be accurate," he mocked. "I have no sympathy for that."

Horner said the act, if anything, has proved less useful than anticipated to groups such as his that seek to minimize government regulation. And figures from the OMB confirm that agencies have in many cases resisted challenges to their scientific findings.

Of the 39 Data Quality Act petitions in The Post's analysis, five have resulted in at least some of the changes sought -- all of them filed by industry interests. Five were denied, five were diverted by the agencies to other bureaucratic avenues, and 24 are pending.

Yet there are signs, Graham acknowledged, that petitioners are becoming more innovative in their use of the act. And petitioners are homing in on agencies whose mission is to protect the environment and public health. The most heavily petitioned are the Environmental Protection Agency, the Fish and Wildlife Service, the National Institutes of Health, and the Consumer Product Safety Commission.

Studying Atrazine

Nearly 80 million pounds of atrazine are sprayed on tens of millions of U.S. acres every year, mostly on corn. It is, according to the EPA, the most prevalent herbicide in ground and surface water, remaining stable and toxic for decades in some environments.

It is also a major source of revenue for Syngenta, a Swiss company with U.S. headquarters in Greensboro, N.C., that sells hundreds of millions of dollars' worth of the chemical every year.

It has been nearly five decades since atrazine was first "registered" -- meaning it was approved for use under certain conditions. Over the years, as more was learned about the chemical's potential toxicity to wildlife and humans, it came under increasing federal scrutiny and regulatory restriction. The number of pounds that farmers can legally apply per acre has progressively been reduced, and users have been required to keep the chemical farther and farther away from wells, lakes and reservoirs.

For decades, the main concern was cancer. The chemical clearly causes cancer in rats, and male workers in Syngenta's production facility in Louisiana have experienced much higher rates of prostate cancer than other men statewide. But studies supported by Syngenta recently convinced the EPA that the mechanism by which atrazine causes cancer in rats probably does not occur in people. (The company said the only reason for the high rate of prostate cancer in its workers is that it has an aggressive screening program that finds cases that would otherwise go undetected.) Studies are ongoing, but the EPA has for now backed off atrazine's cancer threat.

Hermaphrodite frogs, however, have been more difficult to dismiss.

For years, evidence has accumulated suggesting that atrazine may scramble hormones in frogs and other animals. The European Union has officially declared the chemical an endocrine disrupter. Given those concerns, Syngenta's predecessor company -- Novartis Agribusiness -- decided early in the EPA's review not to leave the question up to government scientists. In 1998, it hired a private risk-assessment service, EcoRisk Inc. of Ferndale, Wash., to arrange experiments on atrazine's environmental impacts.

EcoRisk, whose past clients include the Chlorine Chemistry Council, Dow Chemical and Ciba-Geigy

Corp., in turn hired Tyrone B. Hayes, a professor of integrative biology and an expert in frog development at the University of California at Berkeley. Hayes holds a biology degree from Harvard and a doctorate in amphibian development from Berkeley, where he was tenured at age 30 and became the university's youngest full professor.

As part of a team of scientists assembled by EcoRisk, Hayes tested the effects of atrazine on tadpoles of African clawed frogs, a popular "lab rat" species for scientists. Male tadpoles raised with no atrazine in the water developed normally. But those exposed to atrazine were "demasculinized." They had smaller larynxes (voice boxes), their testosterone levels were one-tenth of normal levels, and many grew up as hermaphrodites, with a mix of male and female traits. Moreover, the effects appeared with very small exposures -- just 0.1 parts per billion, or the equivalent of one drop of atrazine in 5,000 40-gallon barrels of water. That's one-thirtieth the level currently allowed in U.S. drinking water.

When Hayes sought to publish his work and have the data considered by the EPA, the company told him to run the tests again, said Hayes and Tim Pastoor, a Syngenta vice president. When repeated studies confirmed the worrisome link, Hayes was reminded that his contract forbade him to publish without Syngenta's approval. He was told that his data ought to be passed to a company-selected statistician for double-checking.

Hayes quit EcoRisk and repeated his experiments on his own, expanding his work to include other frog species. In one follow-up study of 200 leopard frogs caught in the wild, he found that 100 percent of males in areas that had been treated with atrazine had abnormal sex organs. No such problems were seen in frogs from untreated regions. He published his results in two prestigious journals, Nature in 2002 and the Proceedings of the National Academy of Sciences in 2003. That ensured the EPA would consider his findings.

"We showed that these animals are chemically castrated," Hayes said.

Ernest Smith, a developmental biologist at Texas Tech University in Lubbock and a member of the EcoRisk team, denied that EcoRisk or Syngenta tried to bury Hayes's results.

"I think there were some communications breakdowns," he said.

Smith noted that studies conducted by the other team members had contradicted Hayes's data. Some showed health effects only at higher atrazine doses, while others found no effect at all.

A special EPA science panel would eventually level stinging criticisms at those studies for their poor design and sloppy implementation. Still, the conflicting results left the atrazine question at a standoff. That is when the company turned to the Data Quality Act -- and Jim J. Tozzi.

'Working the Regulatory Process'

Syngenta could not have found a better advocate. Tozzi wrote the Data Quality Act and arranged for its congressional passage after the 2000 elections.

Today he is a Washington lobbyist and head of the Center for Regulatory Effectiveness, a watchdog group that specializes in data quality. Tozzi does not reveal his center's contributors, and the atrazine petition he filed does not have Syngenta's name on it. The petition names only the Kansas Corn Growers Association and the Triazine Network, a coalition formed in 1995 to defend atrazine and related herbicides. But Pastoor, Syngenta's head of human safety, said the company helped finance the petition

process through contributions to another of Tozzi's businesses, a lobbying firm called Multinational Business Services.

Tozzi is "the master craftsman when it comes to working the regulatory process," said Ken Cook of the Washington-based Environmental Working Group. "He knows where the sensitive spots are and where to press and leave no fingerprints."

Once a self-described "bottom-tier" musician on the steamy New Orleans jazz circuit, Tozzi earned a degree in economics and rose to OMB deputy administrator under Ronald Reagan. Under his directorship, the OMB's Office of Information and Regulatory Affairs was the gatekeeper for virtually all proposed regulations dealing with public health and safety. It quickly became known as a bureaucratic "black hole," where proposed regulations went in for review and never came out, said Joan Claybrook, president of Public Citizen, a Washington-based consumer advocacy group.

Tozzi was at the OMB when evidence arose in the 1980s that giving aspirin to children with flu symptoms increased the risk of Reye's syndrome, a potentially fatal complication. A federal health agency recommended that aspirin containers bear warnings, but Tozzi said he was not satisfied the evidence was good enough. It took years for activists and Congress to force the labeling issue -- years in which almost 200 children died of Reye's. Today, with labeling, the syndrome is extremely rare.

After leaving the government, Tozzi helped Philip Morris fight mounting evidence of the dangers of secondhand cigarette smoke. That is when he pioneered the tactic of attacking the science behind proposed regulations.

"The argument that it costs too much to protect people does not sell," said Thomas O. McGarity, a professor at the University of Texas Law School in Austin and president of the Washington-based Center for Progressive Regulation, a network of academics that supports regulatory action to protect health, safety and the environment. "But what does sell is this idea that the science is not good."

Science is ever evolving and often hobbled by uncertainty, but policymakers have long recognized this and relied on weight-of-evidence arguments in making regulations, according to McGarity, other activists and Clinton administration officials. They point out that DDT was banned despite lingering doubts about its role in the decline of birds. Many other substances, including vinyl chloride and asbestos, also were regulated before their full effects were known.

Tozzi, believing that the regulatory bar was too low, tried repeatedly to get Congress to pass legislation that would make it easier to challenge the science used to underpin regulations. Then, unable to receive broad congressional support, he crafted legislative language himself and gave it to Rep. Jo Ann Emerson (R-Mo.), a former lobbyist and onetime deputy director of communications for the National Republican Congressional Committee. The wording -- two sentences of 32 short lines -- directed the OMB to issue guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies."

Emerson slipped the sentences into the 712-page Treasury and General Government Appropriations Act, which became the coming year's omnibus spending bill. Under pressure to wrap up the long-delayed budget, President Bill Clinton signed the huge bill on Dec. 21, 2000, nine days after the Supreme Court ruled that George W. Bush was to be the next president. It is not clear whether anyone in Congress other than Emerson and Sen. Richard C. Shelby (R-Ala.) knew about the buried language.

"We sandwiched this in between Jerry Ford's library and something else," Tozzi said. "Was it something

that did not have hearings? Yes. Is it something that keeps me awake at night? No. Is it something that I would do again, exactly? Yes, you bet your ass I would. I would not even think about it, okay? Sometimes you get the monkey, and sometimes the monkey gets you."

Tozzi found even more reason to rejoice as Bush made a pivotal appointment to head the OIRA, Tozzi's old domain within OMB that would now handle data quality: John Graham, a risk-assessment specialist with a history of close ties to regulated industries.

"John Graham came in, and he did an unbelievable job," Tozzi said. "Better than I could have done had I been there myself."

Politicizing the Process

Graham had been the head of Harvard's Center for Risk Analysis, an institution funded primarily by contributions from more than 100 industry and trade association donors. While there, he had amassed a reputation as a skilled critic of the cost of regulation.

In one analysis, conducted with funding from the auto industry, he concluded that it would be a mistake to require side air bags in cars because they would cost $400,000 for every year of life saved. Independent experts reviewing his work found that the figure was actually about $60,000, and Graham had to rewrite his article -- and change his conclusion -- before it could be published in a prestigious medical journal.

When Bush nominated Graham to head the OIRA, many citizen and environmental groups vehemently objected and more than one-third of the Senate voted no. In his first few months, Graham sent many near-final regulations back to the agencies that had proposed them, often saying he was not convinced they were worth the cost.

Then he turned to the job of implementing the Data Quality Act.

By the fall of 2001, Graham's office had published detailed guidelines for implementing the act. A year later, federal agencies started accepting petitions requesting that they withdraw information that allegedly did not meet OMB standards for "quality, objectivity, utility, and integrity."

Individual agencies are responsible for reviewing the challenged data and deciding whether they are indeed reliable. But the OMB, a part of the White House, oversees the process closely -- through involvement in the agencies' deliberations and by demanding annual reports describing how agencies dealt with each petition.

OMB staff members have been providing "extensive assistance to agencies in preparing responses to correction requests," Graham acknowledged. "OMB oversight is critical to make sure that agencies handle these requests in a diligent and consistent manner," he said.

Graham said the OMB's unprecedented foray into science is justified in part because the data in question often serve as a foundation for costly regulation, which the OMB oversees. To fulfill the new role, Graham hired the OMB's first nine career scientists, including six with PhDs.

The Data Quality Act, or at least something like it, "was absolutely needed," said Horner of the Competitive Enterprise Institute.

Yet Steinzor, the Maryland environmental lawyer, and other critics complain that the OMB's involvement politicizes the process. The expertise of the handful of scientists hired by Graham, they say, cannot match that of the thousands of experts on agency staffs.

And while Graham said the OMB still supports weight-of-the-evidence analyses, Steinzor and others contend that the Data Quality Act inherently focuses on individual snippets of data -- each of which is inevitably open to criticism -- instead of on overarching bodies of evidence.

"You can get lost in the minutiae, and that's exactly where they want you to go," Steinzor said. "They just pick, pick, pick, until you're so addled you can't protect people or the environment."

A Tool for Decreasing Regulation

A few environmental and public interest groups have tried to use the Data Quality Act. Public Employees for Environmental Responsibility, a Washington-based group that helps federal scientists who believe their data are being suppressed, has filed three petitions under the act.

One challenged the credibility of a Defense Department document supporting a proposed Army Corps of Engineers project; one contended that the Fish and Wildlife Service had made selective use of data to conclude that hunters should be allowed to shoot rare trumpeter swans; and one charged that Fish and Wildlife had used unsound science to develop "an inadequate recovery plan" for the Florida panther.

"I'm not sure it is the sharpest tool in the environmental toolbox, but at least it is a tool," said executive director Jeff Ruch, adding that the swan petition lost and the other two are still under review.

Many citizen groups and environmental activists believe the Data Quality Act will always be more useful to those seeking to decrease government regulation. Newly proposed regulations must be justified with evidence, they note, and the act is designed specifically to challenge such evidence.

"What it really can do best is slow the regulatory process," said Sean Moulton, a senior policy analyst with OMB Watch, a government watchdog group. "And even a simple delay of a rule can mean a huge financial windfall for an industry."

In the first 20 months, a handful of petitions -- all from industry -- have been at least partly successful. In one, the Competitive Enterprise Institute had wording added to a multi-agency federal climate change report stating that the report's findings did not meet Data Quality Act standards.

In another, a law firm with corporate clients in asbestos litigation got the EPA to agree to make changes in its booklet that offers warnings and safety advice to brake mechanics.

Yet another, filed by a group that receives funding from the conservative Scaife Foundation, succeeded in getting the National Institutes of Health to downgrade warnings about the effects of smokeless tobacco. And then there was the atrazine challenge.

'Manufacturing Uncertainty'

That petition, filed by Tozzi, made a two-pronged attack on the effort to regulate atrazine more stringently. The first was to claim that the evidence for atrazine's gender-bending effects in frogs was not fully reproduced by other Syngenta-funded EcoRisk scientists. The second was to claim that the EPA did not have the proper test to prove atrazine had ill effects.

Tozzi said reliance on irreproducible results would violate the Data Quality Act because information that is not reproducible is "not accurate, reliable or useful."

As evidence of irreproducibility, he pointed to the dozen or so studies sponsored by Syngenta in addition to Hayes's study. An independent panel of experts convened by the EPA had already expressed exasperation over the conflicting results and mistakes they found in the design and implementation of those studies.

In at least two of the studies the "control" frogs that were supposed to be atrazine-free were later found to have been in water contaminated with atrazine, an error the scientists said was unintentional. Another set of Syngenta studies was found to be unreliable because 80 to 90 percent of the animals died, apparently as a result of inadequate care.

Essentially what Syngenta-funded scientists did "was produce a number of studies that were purposefully flawed and misleading, and that changed the weight of the evidence," Hayes said.

While the EPA review also found some flaws in Hayes's studies, his conclusions have been echoed by at least four other independent research teams in three countries.

"What a coincidence that everybody can find an effect of atrazine on gonads," Hayes said, "except [those] funded by Syngenta."

David Michaels, a professor of occupational and environmental health at George Washington University School of Public Health and Health Services, said even a good study will appear "not reproducible" if enough bad studies are thrown into the mix.

"I call this 'manufacturing uncertainty,' and there is a whole industry to do this," said Michaels, who was the Energy Department's assistant secretary for environment, safety and health under Clinton. "They reanalyze the data to make [previously firm] conclusions disappear -- poof. Then they say one study says yes and the other says no, so we're nowhere."

Pastoor of Syngenta said there was no conspiracy to create conflicting data.

"I don't think it's extending things too far to say atrazine may be one of the best studied chemicals on the face of the earth," he said. "Unfortunately -- or fortunately, depending on how you look at it," other EcoRisk team members "could not replicate what Tyrone had done."

But Hayes was not the only team member who at least privately agreed that atrazine was having some effect on frogs. Team member James Carr of Texas Tech told Hayes in an e-mail in February 2003: "I agree with you that the important issue is for everyone involved to come to grips with (and stop minimizing) the fact that independent laboratories have demonstrated an effect of atrazine on gonadal differentiation in frogs. There is no denying this."

The second prong of Tozzi's attack was that the EPA had not designated tests that would serve as the gold standard of proof of hormone disruption in frogs.

The EPA does have certain "guideline tests" that can automatically trigger regulation, including some that measure certain health effects of chemicals on wildlife. But not for hormone disruption.

Jennifer Sass, a scientist with the Natural Resources Defense Council, said Tozzi's position flies in the

face of decades of regulatory science. She said the evidence on atrazine's effects was more than convincing by traditional standards. The act, she said, has "hamstrung EPA's ability to express anything that it couldn't back up with a mountain of data. It basically blocked EPA scientists from expressing an expert opinion."

Hayes said he supports efforts at the EPA to create a gold standard test. However, he said, "when we discover a pattern like this, we know we have a problem. Yes, we should work to validate it perfectly. But in the meantime, let's not keep using 80 million pounds of atrazine per year while we figure it out."

Avoiding Tighter Restrictions

The EPA ultimately agreed with Tozzi that the lack of such a test prevented it from regulating atrazine as a hormone disruptor -- a concession many environmentalists found surprising.

No one claims that Syngenta's Data Quality Act petition was single-handedly responsible for giving atrazine's renewed approval the green light. But coming at the end of an arduous 10-year review, the data quality challenge was "the final one-two-three punch," said Sass of the NRDC, which has sued the EPA repeatedly on atrazine.

She and others said that once the EPA conceded that it could not regulate atrazine as a hormone disrupter, Syngenta was free to reach the regulatory finish line.

In closed meetings -- details of which the EPA has declined to release -- company representatives and EPA officials worked out a plan to avoid tighter restrictions. Instead, the plan calls for Syngenta to track atrazine levels in 40 U.S. watersheds over the next three years to see how farmers are doing in their efforts to minimize contamination. If concentrations rise above a level that the company agrees is "of concern," then the company will work with the farmers to try to reduce the levels.

The company will also fund more studies on frogs and reanalyze its data on employee cancers.

The resolution, Sass said, was "basically negotiated instead of going with a scientific rationale."

Asked why other stakeholders, such as environmental groups or outside scientists, were not allowed to be part of the negotiations as they were in earlier stages of atrazine's review, James Jones, director of the EPA's office of pesticide programs, said opening the meetings "would be incredibly complicated and would create a disincentive for the company to come to the table."

Exempting Atrazine

In June, Tozzi filed his latest Data Quality Act petition.

This time it was directed at the National Toxicology Program. That is a part of the National Institutes of Health that reviews chemicals to see if they cause cancer.

The program had announced in the Federal Register that atrazine was among a long list of chemicals that it was considering for examination. In his petition, Tozzi seized on a few sentences from the program's description of its chemical review procedures. He claimed that those sentences contained discrepancies that violated the Data Quality Act.

Therefore, he wrote, the program should be barred from reviewing the cancer-causing potential of any

chemicals. In particular, the petition noted, atrazine.

Researchers Lucy Shackelford and Julie Tate contributed to this report.