

The VCCEP: Big Issues, High Stakes

by

Lynn L. Bergeson*

It's almost here, and it's big. The Voluntary Children's Chemical Evaluation Program (VCCEP) is EPA's newest "voluntary" initiative designed to obtain hazard and exposure information to characterize adequately risks of chemical exposure to children. EPA is poised to roll it out imminently.

The VCCEP is controversial, precedent setting, and breathtakingly significant for chemical producers and certain product manufacturers alike. As of this post-election writing, EPA makes no commitments as to when the Program will be issued in final, only that it expects to do so soon, perhaps this calendar year. While presidential election uncertainty casts some doubt on the political viability of the VCCEP, given how far down the road EPA is with the Program and broad stakeholder buy-in (at least in some quarters), it may be too late to pull it back regardless of who wins the election. This article describes the major features of the VCCEP as described by EPA in stakeholders meetings conducted this Fall, and outlines the issues fueling the debate around why this Program is so significant.

EPA' Commitment to Children's Health

The VCCEP is a perfect illustration of three Clinton Administration goals: improve and protect children's health, expand chemical right-to-know, and pursue innovative strategies under Toxic Substances Control Act (TSCA) authorities to obtain chemical hazard data. The merging of these

goals is perhaps best reflected in Executive Order 13045—*Protection of Children from Environmental Health Risks and Safety Risks*, signed on April 21, 1997. The Executive Order requires federal agencies to assign a "high priority" to addressing health and safety risks to children, to coordinate research priorities on children's health issues, and to ensure that regulatory standards reflect special risks to children. Implicit in the Order's issuance is an Administration view that children are susceptible to special risks posed by chemical exposure, presumably risks to which adults are not subject (or at least not as subject), and that neither such risks nor means to abate them are adequately understood.¹

EPA responded immediately, by creating the Office of Children's Health Protection (OCHP) to facilitate EPA's efforts to protect children from environmental health threats.² The Office's stated mission is "to coordinate children's health issues across EPA."³

VCCEP Beginnings

Vice President Gore gave further expression to the Administration's commitment to children's health issues in 1998, announcing on Earth Day a new testing initiative focusing on chemicals children are most likely to encounter. The testing initiative was initially outlined as a TSCA Section 4 test rule. The planned rule announced in April 1998 would have required the testing of an initial set of almost 100 chemicals to which children are believed to have a high likelihood of exposure, and for which EPA believes it lacks sufficient toxicity data to assess the risk of exposure to children.

* Lynn L. Bergeson is a founding shareholder of Bergeson & Campbell, P.C., a Washington, D.C. law firm concentrating on chemical, medical device, and diagnostic product approval and regulation, and associated business issues.

Under a draft of a TSCA Section 4 test rule that EPA casually mentioned it had already drafted, 12 toxicity tests⁴ would have been required to be conducted. The tests were the same being required under the Food Quality Protection Act (FQPA) for tolerance reassessment and application of the 10x safety factor that EPA may apply as an additional level of protection for children in considering tolerance reassessments for pesticides. EPA's game plan was to use the same set of test methods for evaluating threats to children that are believed to arise from chemical exposures. Testing costs would have cost between \$3 to \$6 million per chemical.

Industry advocacy, conducted chiefly through the American Chemistry Council's (formerly Chemical Manufacturers Association) Public Health Team, and other considerations resulted in EPA's subsequent decision to reconsider the wisdom of issuing a TSCA Section 4 test rule and instead to convene a series of multi-stakeholder dialogues to obtain comment on virtually all aspects of the Program. Issues to be considered included chemical selection criteria, testing battery, and whether a Section 4 test rule was the first, best, or only way to obtain the exposure and hazard data EPA believed necessary to characterize risks to children. Thus, in August 1999, EPA announced the scheduling of three stakeholder meetings to assist in the design and development of a voluntary program to test commercial chemicals to which children have a high likelihood of exposure.⁵

EPA convened stakeholder meetings on September 22, 1999, November 30-December 1, 1999, and April 26-27, 2000. In advance of the third and final stakeholder meeting in April 2000, EPA released its "Straw Proposal," entitled *Framework for a Voluntary Children's Chemical Evaluation Program*.⁶ The April version of the Straw Proposal⁷ included a revised chemical testing tiering scheme that includes exposure data in each tier of the chemical evaluation process and a narrower proposed list of 45 test chemicals, down from almost 100.⁸ EPA selected these chemicals based upon biomonitoring data said to demonstrate that the selected chemicals are contained in human tissue or blood and believed to be in food children eat or drink, or in the air children breathe, supplemented with environmental monitoring data.

The biomonitoring data came from three databases: (1) the National Health and Nutrition Study (NHANES III); (2) the National Human Tissue Survey (NHATS); and (3) the Total Exposure Assessment Methodology (TEAM). The environmental monitoring data were collected from various EPA databases, including: the National Contaminants Occurrence Database, National Human Exposure Assessment Survey (NHEXAS), and the Food and Drug Administration (FDA) list of direct and indirect food additives.

The American Chemistry Council retained an independent contractor, Novigen Sciences, Inc. (Novigen), to review the databases EPA used. Novigen concluded that NHANES III does not represent the U.S. population as a whole, and that the biomonitoring data do not include children. Novigen further concluded that NHATS was discontinued in 1990 and contains only a small number of children's tissue samples. Novigen also concluded that although TEAM has some relevant data, the majority of the data pertain to occupational exposures, not children. Novigen expressed its views that NHEXAS should not be used because it is in the design phase and only certain portions of it have been completed. Industry stakeholders urge EPA to conduct a more detailed examination of the available biomonitoring data to determine if there are data specific to children.

In the Straw Proposal, EPA divided hazard data and exposure information needs under the VCCEP into three tiers. Tier I included a review of preliminary exposure assessment information, a review of the hazard data obtained from the HPV Challenge Program, and the preparation of overall hazard assessments and robust summaries for available information. HPV Challenge Program data provide general human health toxicological information, which would be combined with exposure data to assess potential effects of chemicals on children's health and to assess whether more extensive testing is needed. Tier II studies consisted of a 90-day subchronic in rodents, 2-generation reproduction and fertility effects study, developmental toxicity studies in two species, and additional triggered genotoxicity, immunotoxicity, metabolism, and pharmacokinetics studies, including a mouse lymphoma assay. Tier III studies include

carcinogenicity or chronic toxicity/carcinogenicity, adult neurotoxicity screening battery, and a developmental neurotoxicity (DNT) study. There was no triggering from tier to tier. Instead, EPA proposed a peer consultation process to review the data and determine the need for any additional testing.

Stakeholders responded with varying concerns. Because each of the candidate chemicals is presumed to be present in human tissue and/or blood, environmental groups and children's health advocates urged EPA to require a complete data set for each. Industry and animal welfare advocates generally approved of the tiered system approach, but raised concerns regarding EPA's statement in the Straw Proposal that it believes "a full toxicity and exposure evaluation will be needed for each chemical."

Environmental groups and children's health advocates argued that once a chemical is found in human tissue, no additional exposure data are necessary for purposes of determining whether testing is needed. Industry representatives stressed that routes of exposure should have equal weight in the evaluation.

Animal welfare and industry stakeholders voiced strong concern regarding the validation of the DNT. Critics claimed that the DNT study protocol had not been sufficiently validated and that the DNT study had little or no impact on regulatory risk assessment. The American Chemistry Council claimed that the mouse lymphoma assay has an unacceptable high incidence of false positives, and questioned its utility for regulatory purposes.

Public interest stakeholders expressed concern that moving from tier to tier does not involve a scientific decision-making process. Industry representatives, not surprisingly, approved of, and environmental representatives disapproved of, EPA's inclusion of a requirement for renewed commitments after Tier I, for Tier II and for Tier III testing.

The Straw Proposal included a "peer consultation" process between Tiers I and II and between Tiers II and III. EPA envisioned the peer consultation process as a forum for stakeholder

nominated scientists and other outside experts to examine the chemical data summaries, including the data needs section. According to EPA, the peer consultation process should be conducted by a "scientifically recognized third party," who would be responsible for organizing the meetings and collecting and distributing the documents submitted by sponsors. EPA proposed that the meetings be open to the public and that public comments—written and/or oral—be accepted. The documentation from these meetings would be placed in a public record.

The peer consultation process evoked concern from most stakeholders. Public interest group representatives expressed concern that the peer consultation was too resource intensive for them to participate in the manner they would like. They further stated that due to the extensive time commitment required, it may prove difficult to recruit experts to serve on the panel. EPA estimated the peer consultation group would meet two to three times per year for two or three days to evaluate three or four chemicals. Some stakeholders expressed concern that EPA underestimated the time necessary to conduct a peer consultation.

Much concern was expressed regarding the lack of guidance for the peer consultation. The American Chemistry Council strongly urged that the group be guided by well-established core principles enhancing transparency, objectivity, and scientifically defensible testing recommendations.

In response to these concerns, EPA suggested at the last stakeholder meeting a "demonstration" period, whereby 20 or so chemicals would proceed through Tier I and into the first peer consultation. Information gathered from this demonstration period would be used to evaluate how the process is working and how best to proceed with other chemicals. There was no decision regarding which chemicals would be included in the demonstration or how they would be selected. Little was offered outlining the membership of the peer consultant group, how it would be funded or administered, whether it would conduct its reviews based on "core principles," and, if so, what they might be, and how transparency would be ensured.

Key Elements in the Draft Final Program

The draft final VCCEP contains several key elements, and important changes to the Straw Proposal issued in April. Each element is discussed below.

The Commitment—Under the draft final VCCEP, volunteers apparently commit only to Tier I testing. As under the Straw Proposal, Tier I testing consists of the OECD SIDS and HPV endpoints. It is important to note that sponsors, who will be given 180 days from Program issuance to “volunteer,” commit only to the Tier I testing, and not to proceed necessarily to Tier II testing requirements. This is a significant change from the Straw Proposal and a condition industry stakeholders characterized as “must have.” In addition, and importantly, the mouse lymphoma assay was dropped from the Tier II test, and from the testing battery altogether.

Pilot Chemicals—EPA’s Straw Proposal listed 45 chemicals that EPA believes are found in human tissues and have high exposure potential for children. In the final VCCEP, EPA is expected to remove 23 chemicals that it believes do not warrant consideration under the VCCEP. EPA reportedly has agreed to proceed with the remaining initial list of 22 pilot chemicals. The *Federal Register* notice will reference a document that describes in more detail the selection process, but apparently nonetheless lists all 157 chemicals in EPA’s biomonitoring data sets, as well as the original set of VCCEP candidate chemicals. The significance of this should not be overlooked. Industry advocates believe that the mere “listing” of a chemical in this context will have a stigmatizing and profoundly adverse effect on the marketing of any listed chemical or of products in which the chemical is included.

Peer Consultation—The draft final VCCEP contains no significant changes from the Straw Proposal. The peer consultation concept introduced under the Straw Proposal was not intended to be a consensus-based process and was designed only to identify areas of agreement, disagreement, and supporting scientific rationale. Details as to its formation and governance were

sketchy, and would appear to remain so under the draft final VCCEP.

Unresolved Issues

Without question, the framework for obtaining test data and exposure information on chemicals to which children are believed to be exposed has changed radically from Earth Day 1998 to the VCCEP roll-out, expected in late 2000. The contrast could not be more dramatic: a mandated TSCA Section 4 test rule has morphed into a “voluntary” chemical testing program; a worst-case \$6 million testing package per chemical has shrunk to step-wise, tiered testing; and test chemicals have downsized from a total of approximately 100 to a pilot program of 22 chemicals. These and other changes are improvements of EPA’s original concept. Nonetheless, despite the stakeholders meetings, comments, and seemingly endless discussion, problems remain. Key among them are the following.

Flawed Chemical Selection—While EPA’s decision to initiate a pilot program of 22 chemicals is prudent, VCCEP-lite was driven more by resource constraints than by an attempt to correct fundamentally the inherent flaws in the chemical selection process. There are two core problems with the selection process.

First, and most fundamentally, the initial chemical candidates were selected based on data demonstrating that they are contained in human tissue or blood and reported in at least one of several databases, and believed to be in food and drink consumed by children or in the air they breathe. The biomonitoring databases, however, are severely flawed and cannot properly be used for this purpose. The fact that the pilot chemicals are a subset of these chemicals necessarily means that the same problems remain. Only the proportion of the problem has diminished. Novigen’s extensive review of the biomonitoring data confirmed that these data have not been carefully or thoroughly verified by EPA using appropriate quality assurance and quality control methods. The data were found to be either outdated, from non-representative examples of the U.S. population, not to include children, or generated from limited pilot

studies. None of the biomonitoring data for the chemicals identified by EPA could be reliably used to extrapolate to a subpopulation of U.S. children. Additionally, none of the actual biomonitoring data used by EPA are publicly available. Novigen relied upon the several reports that were obtainable for purposes of its review, not the actual data. These limitations raise serious questions as to the integrity of the very data on which the pilot chemicals were selected.

Second, presumably the selection of the 22 pilot chemicals is intended to bear some relation to the risks each is believed to pose to children's health. Given that the pilot chemicals are a subset of the original VCCEP chemicals, however, their selection is instead based on the biomonitoring data that were simply not intended to demonstrate children's exposure. The pilot chemicals cannot, therefore, reasonably be claimed to represent those that are likely to pose a greatest risk to children. Indeed, based on the selection criteria, there is no credible reason to believe any pose any particular risk to children at all. Despite this, however, each could well be stigmatized, perhaps irreparably, merely because they are the first group to be served up under the VCCEP.

One commenter, the Chemical Specialties Manufacturers Association (CSMA), urged EPA to defer rolling out the VCCEP until the results of NHANES 99+ are available and incorporated into the data mix.⁹ The NHANES 99+ project started in March 1999 and is examining 5,000 Americans annually in 15 locations nationwide. Unlike the VCCEP biomonitoring data, NHANES 99+ is measuring chemicals in the blood, serums, and urine of children. Most of the chemicals for which screening is underway were nominated by EPA. Despite industry's urging to defer the VCCEP until these data are made available, EPA apparently has decided to push forward. Political expedience would seem to carry more weight in EPA's decision-making process than scientific integrity.

Tiered Testing—A major sticking point between EPA and industry stakeholders was the concept of tiered testing. Initially, EPA rejected the notion of tiered testing as scientifically unjustified. Eventually, EPA proposed a three tiered testing

program, similar to the program recommended by the American Chemistry Council. The issue, however, of how a chemical progresses from one tier to the next remained unresolved. The American Chemistry Council argued that a "positive" result in one test should not necessarily trigger a general advance to the next tier. Rather, a positive result in one test in a given tier should trigger only specific endpoint testing in a subsequent testing tier.

Another issue was whether multiple exposure testing or only testing in the expected primary exposure route would be required. Industry stakeholders argued that multiple route testing was wasteful of animals, resources, and time. Careful review of the final VCCEP is necessary to determine if these issues have been adequately resolved.

Peer Consultation—This component of the VCCEP was the least developed under the Straw Proposal and remains ill-defined under the draft final VCCEP. The peer review process is one plainly embraced by all stakeholders. As is always the case, however, the devil is in the details. The process envisioned under the draft final VCCEP contemplates the formation of a separate group of peer reviewers at the end of each testing tier to review the data and determine whether the chemical should progress to the next testing stage. The outcome of the period process is agreement or disagreement with the chemical sponsors' recommendations regarding toxicity and/or exposure information.

That said, all the unanswered questions inspired by the Straw Proposal would appear to remain. Exactly who staffs the peer review group? What are the mechanics of peer selection? What process should be employed in assessing the evidence, reviewing the documents and data, and deriving a scientifically credible assessment of the test sponsors' recommendations? What are the "guiding principles" for the peer consultation process? Will a core group of scientists serve as a core group to ensure consistency throughout the process? If not, how will consistency be ensured? A careful review of the final VCCEP is necessary to assess whether these questions have been adequately addressed.

Paucity of Exposure Information—Another critical issue that remains unresolved is how the final VCCEP will ensure that all necessary exposure information essential to ensure a scientifically defensible risk characterization will be forthcoming. EPA correctly noted at the beginning of the stakeholders meetings that the VCCEP is relevant to a diverse universe of chemical producers and users. The reality is, however, that the lion's share of the testing costs will likely be borne by the chemical producer community. There are many reasons for this, not the least of which is that any program that seeks to obtain toxicity data voluntarily or, alternatively, through a TSCA Section 4 test rule if volunteers are not forthcoming, is understandably going to be perceived as a chemical producer initiative. After all, EPA's reach under TSCA Section 4 historically has extended to chemical manufacturers and processors of targeted chemicals, and not to those entities that might pose the greatest exposure risk.¹⁰ Even under a TSCA Section 4 test rule, EPA cannot compel the development or submission of exposure information. EPA could obtain these data under its TSCA Section 8(a) authority, but the exercise of this authority was never seriously considered by EPA for these purposes.

An essential element of any risk characterization, however, is the availability of relevant exposure data. For some—perhaps most—of the pilot VCCEP chemicals, however, major sources of potential exposure to the chemical are not in any meaningful way related to the manufacturing or processing of the chemical, and thus fall outside the scope of TSCA Section 4's traditional reach.

Ethylbenzene is illustrative of this point. According to the American Chemistry Council's Ethylbenzene Panel,¹¹ a coalition of ethylbenzene producers, the most recent Toxics Release Inventory (TRI) data, 1998, demonstrate that the chemical industry represents approximately 14% of total TRI ethylbenzene air emissions. Other major sources of ethylbenzene predominantly make up the emissions reported in the other industry sectors and, hence, are more likely sources of exposure. According to the Panel, ethylbenzene produced by ethylbenzene manufacturers is essentially consumed in the production of styrene. The majority of ethylbenzene found in both urban and

rural air does not result from ethylbenzene manufacturing and processing, but rather from non-industrial combustion processes.¹² The concern expressed by this consortium of chemical producers is a fundamental problem with the VCCEP that extends to other chemicals. Other examples include alpha-pinene and (R)-(+)-p-mentha-1,8-diene (d-limonene), both common natural compounds found in plants, including fruits and vegetables. Acetone is a natural metabolite. Isophorone occurs naturally in cranberries.¹³

If it is to be successful and scientifically defensible, the VCCEP must structurally take into account the fact that manufactured chemicals subject to traditional TSCA jurisdiction do not in all, or even most, cases represent the primary sources of chemical exposures to children. The draft final VCCEP, however, would appear expressly not to factor this simple fact into the Program.

Structurally, therefore, the draft final VCCEP would appear to be fundamentally flawed and thus destined to fail to achieve EPA's stated goal of protecting children's health. The implications of this flaw are great. For example, once a chemical producer or consortium of producers decides to sponsor a chemical, how can it interest other non-chemical producers to volunteer their time, resources, and data to the cause? Recognizing that EPA cannot compel the development or submission of exposure information under TSCA Section 4, the threat of issuing such a rule if volunteers are not forthcoming rings hollow to entities other than affected chemical producers. Moreover, without essential exposure information, how can EPA assure a scientifically defensible risk characterization will be forthcoming from the Program? A real concern is absent exposure information, risk characterizations will necessarily rely on default values and assumptions that could compromise the objectivity of the VCCEP, and could well lead to inaccurate estimates and false portrayals of potential risks from chemicals. Finally, the free rider effect is very much at play in the VCCEP. If a few producers banded together to volunteer for a pilot chemical, there is little incentive for others to participate aside from the "bragging" rights that accompany such volunteering. The incentive to join the cause among those beyond TSCA Section 4's traditional reach is even more

EPA Administrative Law Reporter

1601 Connecticut Avenue, N.W., Suite 602, Washington, DC 20009 • 202-462-5755 • Fax 202-328-2430

attenuated under these circumstances. Fundamental questions of fairness, due process, and equity arise as a result. There are no easy answers to these questions.

Implications

Chemical producers of the pilot chemicals and the makers of products containing these chemicals must soon decide whether they will sponsor a pilot chemical or not. The implications of the VCCEP will be felt by entities far beyond the chemical producers who will likely bear the lion's share of the cost of engaging in chemical testing. What test results will show, how these test results will be communicated to the public, and the impact these

results may have on the marketing of certain and other consumer products will be felt for years to come in a wide variety of business sectors.

With the many problems fundamentally plaguing the integrity of the VCCEP, one questions why the rush to judgment. EPA is insistent upon rolling out the VCCEP sooner rather than later even though compelling reasons urge caution and much more Program fine tuning. If the goal of the Program is to characterize health risks to children, EPA should resolve the core problems identified above and defer issuing the Program until then. In the interim, pilot chemical stakeholders will need to think long and hard about volunteering for the VCCEP.

Notes

¹ The Order states there is “[a] growing body of scientific knowledge [that] demonstrates that children may suffer disproportionately from environmental health risks and safety risks.” Executive Order 13045 (Apr. 21, 1997), at 1-101. No support is offered for this statement.

² Other federal agencies have risen to the call. Last year, for example, the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS) created the Center for the Evaluation of Risks to Human Reproduction (CERHR). The Center was created to provide assessment of reproductive health risks associated with human exposure to naturally occurring and “man-made” industrial chemicals.

³ Letter from Carol M. Browner to “Readers” transmitting *The EPA's Children's Environmental Health Yearbook* (June 1998).

⁴ The 12 toxicity tests are: *in vitro* and *in vivo* mutagenicity studies; metabolism study in rodents; acute toxicity study; subchronic (90-day) toxicity studies in two species (mice and rats); prenatal developmental toxicity studies in rodents and nonrodents (rats and rabbits preferred); 2-generation reproduction study in rodents (usually rats); developmental neurotoxicity study in rodents

(usually rats); neurotoxicity screening battery in rodents (usually rats); immunotoxicity study in rodents; and carcinogenicity or combined chronic and carcinogenicity studies in two species (mice and rats). The Office of Pollution Prevention and Toxics' Proposed Test Battery for the Children's Health Testing Program, www.epa.gov/scipoly/sap/1999/may/oppt_test.htm#proposed.

⁵ 64 Fed. Reg. 46673 (Aug. 26, 1999).

⁶ EPA, “*Straw Proposal*” for Discussion Purposes: *Framework for a Voluntary Children's Chemical Evaluation Program* (Apr. 10, 2000), <http://www.epa.gov/opptintr/chemrtk/kdsfr410.htm>.

⁷ EPA circulated an earlier version of the Straw Proposal on November 16, 1999, at the second stakeholders meeting. A copy is available on the Internet at www.epa.gov/opptintr/chemrtk/framtest.htm.

⁸ The chemicals include: dichlorvos; acetone; benzene; tribromomethane; vinylidenechloride; isophorone; methyl ethyl ketone; trichloroethylene; 1,1,2,2-tetrachloroethane; alpha-pinene; diethylphthalate; dibutyl phthalate; butyl benzyl phthalate; o-phenylphenol; naphthalene; quinoline; o-xylene; o-dichlorobenzene; 1,2,4-trimethylbenzene; isopropylbenzene; ethylbenzene;

styrene; diethyl hexyl adipate; p-xylene; p-dichlorobenzene; ethylene dibromide; ethylene dichloride; m-xylene; toluene; chlorobenzene; n-dodecane; di(2-ethylhexyl)phthalate; di-n-octyl phthalate; p-dioxane; decane; tetrachloroethylene; 2,6-di-tert-butyl-p-cresol; m-diethylbenzene; hexyl acetate; m-dichlorobenzene; octamethylcyclotetra-siloxane; 1,1,1,2-tetrachloroethane; undecane; mixed xylenes; and (R)-(+)- p-mentha-1,8-diene.

⁹ CSMA is a trade association representing companies engaged in the formulation and packaging of household chemicals and institutional chemical specialty products.

¹⁰ EPA has toyed with the idea of expanding the scope of the term “manufacturer” in prior TSCA rulemaking efforts, but thus far has not yet responded dispositively to the matter. For a detailed review of this, see Lynn L. Bergeson and Lisa M. Campbell, *Chemical Testing Under TSCA —Who Is On the Hook?*, *EPA Administrative Law Reporter*, Vol. 16, Numbers 1 & 2 (July and August 2000).

¹¹ The author is outside legal counsel to this consortium. The opinions expressed here are solely those of the author’s.

¹² Additionally, the Panel noted that in EPA’s Notice of Proposed Rulemaking on Control of Emissions and Hazardous Air Pollutants from Mobile Sources, mobile sources make up approximately 84% of the national emissions of ethylbenzene. Letter from Courtney M. Price to James Aidala and Susan Wayland, regarding voluntary Children Chemical Evaluation Program (Docket Number OPPTS-00274) (October 23, 2000) at 2. “By extrapolation, the Chemical Industry (SIC 28) contribution to the national emissions is only .36%.”

¹³ Letter from D. Douglas Fratz, CSMA, to Document Control Office, EPA, regarding Docket Control Number OPPTS-00274B (May 30, 2000) at 8.