



**BERGESON & CAMPBELL, P.C.**

1203 Nineteenth Street, NW | Suite 300 | Washington, DC | 20036-2401 | tel 202.557.3800 | fax 202.557.3836 | web www.lawbc.com

**MEMORANDUM**

Via E-Mail

DATE: December 26, 2006  
TO: Firm Clients and Friends  
FROM: Bergeson & Campbell, P.C.  
RE: 2007 Outlook for Chemicals and Pesticides

This memorandum is intended to provide a summary outlook on possible key directional trends and developments in the U.S. Environmental Protection Agency's (EPA) regulation of chemicals and pesticides in 2007. We would be pleased to expand upon any thought noted below, which is intended only to survey the coming year's key activities in these areas.

**New Leadership**

The leadership vacuum in EPA that existed this time last year has been filled by the nomination and approval of former EPA Region 7 Administrator Jim Gulliford as Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances (OPPTS). The post of Deputy Assistant Administrator for OPPTS (the political deputy position) continues to be vacant, however. Mr. Gulliford has now been in the job for about six months, but the next six will be nothing like his first.

**Capitol Hill**

Given the election results, which leave both houses of Congress in the control of the Democrats, it is expected that EPA will find itself inundated by Congressional "investigations," oversight hearings, and information requests, and generally sharp partisan inquiry. This is a fundamental shift from the past twelve years of relatively benign neglect on the part of Congress -- and a shift that is widely expected to consume very large amounts of time and resources (especially on the part of senior managers and program officials), regardless of the outcome of any hearings or reports which result from the effort. In addition, should these efforts uncover any real or alleged program deficiencies, further time and attention will have to be devoted to those issues. The overall theme of much of this work will be to examine EPA's



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 2

overall implementation and management of environmental protection programs, reaching all program media (air, water, waste, pesticides, and toxics).

Among the Committees of jurisdiction which will experience a sea of change in their efforts to conduct EPA oversight are: (1) Senator Barbara Boxer (D-CA), now Chair of the Senate Environment and Public Works Committee, who has been active on the issue of EPA's allowance of and reliance on pesticide studies conducted with human subjects, and who has previously indicated that the Toxic Substances Control Act (TSCA) is high on her list of environmental statutes needing overhaul; (2) Senator Joseph Lieberman ("I"-CT), now Chair of the Senate Homeland Security and Governmental Affairs Committee, who in the past has conducted hearings on pesticide matters (*e.g.*, the review and use of lawn chemicals, the now infamous Alar episode, and special review chemicals such as the EBDCs); (3) Representative John Dingell (D-MI), now Chair of the House Energy and Commerce Committee, who in the past has been perhaps the most blistering critic of EPA program management and its toughest oversight Chair; and (4) Representative Henry Waxman (D-CA), now Chair of the House Government Reform Committee, who has been interested in wide areas of food safety and pesticide use, risks to children (especially from exposure to lead), and numerous other issues related to the work of EPA's pesticide and chemical management programs.

Each of these Members will have dozens of new staff all assigned to, among other things, examining EPA program management and implementation of the respective statutes. This does not include the many other Members who will have direct jurisdiction over OPPTS programs (*e.g.*, Senator Tom Harkin (D-IA), Chair of the Agriculture Committee, who is an ardent supporter of sustainable agriculture, or Senator Byron Dorgan (D-ND), who as Chair of EPA's appropriation Subcommittee will continue his push for pesticide price harmonization between Canada and the United States). This list will also include the Chairs of the legislative Subcommittees with direct jurisdiction over the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and TSCA, all now controlled by Democrats.

It will take a significant amount of time for these Committees and Subcommittees to get organized, hire staff, and begin oversight work in earnest. Agendas and areas of interest will have to be identified and developed. This will also take time. Nonetheless, the life of an EPA program official (especially Administrator Steve Johnson or Assistant Administrator Jim Gulliford) will not be the same as of January 2007. The new Congress will have to "show results" in short order, and some amount of EPA oversight will likely be on that list.

Predicting in what area exactly Congress will "investigate" or develop an interest at this time is uncertain at best, but at a minimum, climate change and a number of other air program rules have been the most prominent issues in the past few years, along with drinking



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 3

water standards for arsenic and perchlorate. At the same time, EPA jurisdiction is claimed to be had by literally dozens of different Committees and Subcommittees. This means not only redundant or duplicative inquiries, but also represents a likelihood that some hearings will be held on those issues that have not been of much widespread interest in order for various Committees and Members to distinguish themselves from the other efforts (an example of this might be the attempt by EPA to clarify whether a pesticide registration obviates the need for a National Pollutant Discharge Elimination System permit under the Clean Water Act under certain conditions, or, the need for much enhanced chemical testing requirements under TSCA).

For the pesticides and toxics program, notwithstanding the relatively successful meeting of the Food Quality Protection Act (FQPA) deadline by the Office of Pesticide Programs (OPP), some inquiries will examine whether the risk assessments have been adequately prepared, grounded in “good science,” and truly represent completion of FQPA’s requirements. We expect the issue of “risks to children” to be especially talked about -- which could prompt inquiries into EPA’s application of the FQPA 10x safety factor or children’s exposure to chemical substances in general. The registration review program will likely come under scrutiny, as well as FQPA endocrine disruptor testing requirements. Under the guise of homeland security, the chemical industry will likely face renewed interest and pressure concerning “inherently safer technologies,” which is a continuation of past debates concerning toxics use reduction and green chemistry. Particularly with the European Union’s (EU) recent enactment of the Registration, Evaluation and Authorization of CHEMicals (REACH) regulation, TSCA and its utility and effectiveness in managing chemicals and chemical risks likely will garner some, perhaps considerable, attention. Notwithstanding that REACH implementation is still quite a ways off -- the new European Chemicals Agency will not become operational until June 2008 -- comparisons between the TSCA and REACH frameworks undoubtedly will be drawn.

As in the past for a number of reasons, in the typical course of business, the appropriations process continues to be the most likely vehicle for any actual legislation. This year the pesticide industry is supporting the extension and renewal of the Pesticide Registration Improvement Act (PRIA), which is expected to raise industry registration fees by approximately 5%, but in return would continue to provide some measure of budget (baseline) protection to ensure that EPA’s pesticide program can still provide timely assessments and reviews of registration submissions. Any riders concerning the list of issues already mentioned, human studies, price harmonization, and lead abatement program, among others, would most likely emerge as part of an EPA appropriations bill, since with the Congress so evenly divided direct floor action is still not an easy or likely course. The one exception remains the long-pending legislation to implement the international agreements to comply with Prior Informed Consent (PIC)/Persistent Organic Pollutants (POP) international agreements that would require



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 4

amendments to both FIFRA and TSCA. At the same time, once even non-controversial amendments are agreed upon, that legislation readily becomes a target for more divisive measures which often doom the entire bill.

The current Farm Bill expires in 2007 and the Agriculture Committees are expected to begin the process designed to extend or amend the current programs. Budget considerations will be the dominant factor by far, but the legislation itself, even if non-controversial *per se*, will provide another opportunity for environmentally-related amendments (*e.g.*, the 1990 Farm Bill became the vehicle for attaching “Circle of Poison” legislation in both the House and Senate).

There is also one item of unfinished legislative business from the past Congress which now seems destined for oblivion: the proposed amendments to the Endangered Species Act (ESA) which hoped to address the backlog of ecological reviews that continues to accumulate between EPA and the Department of the Interior. With the new Congress, no one expects any such legislation to move, and if anything, hearings may be held with the aim of revealing whether the issued counterpart regulations themselves comply with the requirements or goals of the ESA. This implies that continued judicial intervention will drive this issue set, and outcomes concerning particular pesticides will be unpredictable and often ad-hoc.

### **Activist Agendas, Litigation, and Chemical Testing**

Even though Congress is expected to be much more receptive to the issues and agendas of the environmental community, activists will continue to face a difficult time since they still must overcome Republican control of the White House. Oversight can push an agenda only so far, and much effort over the next two years will be devoted to creating opportunities for raising the profile of environmental issues in preparation for the 2008 elections. As a result, litigation will continue to be a ready tool, as will publicity splashes intended to induce change by force of public opinion. For example, for the pesticides program, litigation over the ESA likely will continue.

There remains the possibility if not likelihood of a lawsuit over the arguable failure of EPA to review all existing tolerances within ten years of FQPA’s enactment. EPA admits that not all tolerances have been reevaluated (EPA claims 99%), and, certain programs have been lagging (*e.g.*, endocrine disruptor testing, registration review). Some of the remaining tolerances and pesticide products to be reviewed, however small in number, concern some of the more controversial (and therefore difficult) pesticide products.



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 5

Activists will continue to press EPA's toxics programs for enhanced testing regimens in general, particularly in light of the EU's REACH program. EPA is also expected to be under renewed pressure to launch the Nanoscale Materials Stewardship Program. EPA is expected to convene a second peer consultation in the first quarter of 2007 to address materials characterization issues and to issue the final White Paper on Nanotechnology. EPA is reportedly anxious, as are many in industry, to get on with the voluntary program as at least two other countries (the U.K. and Australia) have already launched their voluntary programs.

Public pressure may also be brought to bear on EPA over its recent extension until March 23, 2007, of the 2006 Inventory Update Reporting (IUR) deadline, especially in view of the view maintained by some that the High Production Volume (HPV) Challenge Program, based as it was on the 1990 IUR, and is limping towards the finish line. EPA has acknowledged that its public database containing the data submitted under the HPV Program, the HPV Information System, could be more useful, and the longer it takes to make improvements and post additional data to the website, the more likely public discord. By the same token, although EPA has now issued a test rule for a handful of the HPV "orphan" chemicals and information-gathering rules for most of the others, until it issues TSCA Section 4 test rules for the remaining HPV orphans, EPA may continue to hear criticism.

Activities on endocrine disruptors are also expected to continue in 2007. EPA has been implementing its Endocrine Disruptor Screening Program (EDSP) since 1998, and some speculate that there will be renewed pressure to produce something soon, or at the least demonstrate that progress is being made as the FQPA deadline has passed. EPA is planning to require 50 to 100 chemicals to undergo screening for their potential to disrupt the endocrine system, and EPA reportedly is planning to initiate testing in early 2008. As reported by EPA, the list of chemicals initially subject to this requirement will include both active and inert ingredients in pesticide products. EPA intends to publish in 2007 a notice announcing the proposed list of chemicals selected using the methodology set forth in its September 27, 2005, notice announcing its exposure-based approach that considers human exposure using four different pathways. Following public comment, EPA will decide on a final list of chemicals. Given the controversy endocrine disruptors have inspired for years, this rulemaking is expected to be as controversial as it is significant.

The Department of Homeland Security (DHS) will also generate substantial interest in rulemaking activity in 2007. In late December 2006, DHS signed off on an Advance Notice of Rulemaking (ANR), which discusses "a range of regulatory and implementation issues" implementing Section 550 of the Homeland Security Appropriations Act of 2007. Section 550 provides DHS with authority to issue interim final regulations for the security of certain domestic chemical facilities. Under the ANR, chemical facilities fitting a certain risk



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 6

profile would complete a “Top-screen” risk assessment methodology, assessable through a secure Department website. If a chemical facility qualifies as “high risk,” the Department would require the facility to prepare and submit a Vulnerability Assessment and Site Security Plan, among other measures. Comments on the ANR are requested by February 7, 2007, and interim final regulations must be issued by law by April 4, 2007. The scope and implementation of the Section 550 rule is expected to generate significant comment and interest, as are other DHS chemical facility initiatives in 2007.

### **Budget/Resources**

The push to control the federal budget deficit will continue to bode badly for EPA and the pesticide and chemical regulatory programs in general. The proposed Fiscal Year (FY) 2008 budget will likely see similarly severely squeezed revenues as in recent past years, which will diminish the funds available for travel, training, grants, and contractor support. Contractor support cutbacks will directly and adversely affect the program’s ability to conduct scientific assessments, since primary science review is usually outsourced to outside contractors.

Another continuing related issue for the pesticides program is the meager resources that agencies outside of EPA are providing towards completion of ESA reviews. This will mean there is the same significant choke point in the ESA assessment process separate from any implications of the assessments themselves. As mentioned, in the past legislative amendments proposed to the ESA statute might have addressed this bottleneck, but it is unlikely that Congress will even consider any ESA changes.

Also with regard to the pesticides program, PRIA resources will continue to make a positive difference, but principally in avoiding even more serious cuts to the program. This is why the pesticide industry has cooperated in attempting to reach a consensus with EPA and environmental advocates on a PRIA extension, which would continue at least some measure of budget protection for the next few years.

### **TSCA Chemical Testing**

EPA devoted considerable energy to engineered nanoscale materials in 2006, and will likely continue to do so in 2007. Assistant Administrator Gulliford has made clear that nanotechnology is among his top priorities, so the pace of the launch of the Nanoscale Materials Stewardship Program (NMSP) should be much faster than it was in 2006. As these engineered nanomaterials continue to find their way into ever more diverse products and applications, EPA will continue to adapt its new chemicals review program to new engineered nanomaterials



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 7

consisting of chemical substances so that such nanomaterials can be reviewed appropriately under the TSCA new chemicals program.

EPA is expected to continue negotiating Enforceable Consent Agreements (ECA) for the remaining hazardous air pollutants (HAPs) under the TSCA Section 4 test rule proposed over a decade ago, and to continue work on its Section 4 test rule for certain chemicals on the Agency for Toxic Substances Disease Registry (ATSDR) Priority List of Hazardous Substances proposed in October 2006.

EPA is also expected to take final action on its proposed Significant New Use Rule (SNUR) for certain perfluoroalkyl sulfonates (PFAS) under TSCA Section 5(a)(2) not addressed under the March 2002 PFAS SNUR. EPA proposed revisions to the SNUR in March 2006 and final action is expected in mid-2007.

### **Conclusion**

The arrival of Steve Johnson as Administrator did not come with a clear agenda for fundamental change, and internally most EPA programs have seen little change in the general patterns of behavior or underlying policies. This might prove disappointing to those who, of whatever political stripe, feel that EPA policies or the institution itself is due for more fundamental change, particularly, in the area of science assessments, accommodating the explosion of issues presented by emerging technologies, its approach to decision-making, “attitude” towards regulated entities, allocation of time or resources, and agenda and priority setting, among other key issues. Given the expected intense scrutiny from the new Congress, any shifts in EPA behavior or attitude will be towards more “defensive,” perhaps more “pro-environment,” than the last few years.

As a Democratic Congress attempts to present their case to the public, the role of the media will be enhanced to publicize whatever findings are announced, and generally add to the pressure and scrutiny of all but the most routine decisions. This might induce EPA to proceed more slowly and cautiously across the board, to rely even more so on additional layers of science review and public process announced as transparency initiatives, and general reluctance to take on difficult or controversial issues.

This could affect even initiatives where EPA would seem to have fairly autonomous control over the selection of priorities, agenda items, and policy determinations. For example, until now many in the pesticide industry have suggested that EPA issue some sort of mislabeling regulation to clarify the pre-emption issue as it now stands after the Supreme Court’s decision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). It has not been forthcoming



Memorandum to Firm Clients and Friends  
December 26, 2006  
Page 8

for any number of reasons, but now with the renewed oversight by Congress any presumptive time frame can only be slowed down. This will occur across many policy initiatives almost regardless of program area or significance.

In addition, certain issues of more intense Congressional pursuit, whatever course they may take, will likely push themselves to a greater degree onto the EPA agenda. Absent Congressional pressures, EPA would otherwise be expected to do its job with minimal notoriety and ever-reduced resources. The renewed attention by Congress, as well as the already begun jockeying among prospective Presidential candidates of both political parties, will drive EPA agenda and attention in ways not seen for many years. Climate change may well capture the airwaves and public mood, as may energy efficiency as a response to rising energy prices, or “chemical trespass” as indicated by biomonitoring results, or chemical testing coordinated with REACH, or generally “kids’ risk” since “it takes a village,” whatever this expression means. As a result, EPA’s course over the next year is much less predictable than in the past, and EPA itself will have to wait and see what the future holds in store.

\* \* \* \* \*

We hope this information is helpful. As always, please call if you have any questions.