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MEMORANDUM

Via E-Mail

DATE: January 6, 2009

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: 2009 Outlook for Chemicals and Pesticides

This memorandum provides a summary outlook on possible directional trends and developments in the U.S. Environmental Protection Agency's (EPA) regulation of chemicals and pesticides in 2009. The new Administration and Congress promise an eventful New Year.

Overview

Climate change legislation and regulatory measures will be the dominant issue, and if attained, the signature environmental achievement of the Obama Administration. The issue will dominate all EPA operations, including those primarily focused on chemicals and pesticides, consume the time and attention of senior EPA leadership, and eclipse virtually all other issues for at least the first year. Mr. Obama's appointment of Carol Browner as Assistant to the President for Energy and Climate Change, Heather Zichal as Deputy Assistant to the President for Energy and Climate Change, and Lisa Jackson as EPA Administrator demonstrates unequivocally that climate change will be the overarching priority for the Administration. Energy policy will be a key second priority. This may be in play soon in the Administration, as energy legislation is expected to be addressed early in the new term.

The broad implications for climate change and energy policy invited by Representative Waxman's (D-CA) selection as the Chair of the House Energy and Commerce Committee remain uncertain. Certainly Mr. Waxman is expected to press for a much more aggressive position on emission caps and timing of emission reductions.

Other significant priorities likely to consume the new EPA Administration's time are expected to include chemical control legislation, including amending, possibly significantly, the Toxic Substances Control Act (TSCA), reinstatement of the Superfund tax, and reauthorization of the Chemical Facility Anti-Terrorism Standards, which are set to expire in 2009. While pesticide regulation *per se* may not be among the top priorities of the Obama



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Administration, virtually every one of the priorities that the Administration has will affect EPA's regulation of these products.

As discussed below, the mandate for "change" will affect all program areas.

Personnel

Carol Browner has been named the Assistant to the President for Energy and Climate Change, a new position that emphasizes the Obama Administration's commitment to addressing climate change issues as a top priority. Browner's deputy, Heather Zichal, previously served as Senator John Kerry's (D-MA) Legislative Director where she coordinated domestic and foreign policy issues. In 2004, Zichal was responsible for the Kerry campaign's energy and environmental policies. Reportedly, Zichal is well versed in climate change and other key environmental issues, and skillful in legislative negotiations.

Nancy Sutley has been named Chair of the White House Council on Environmental Quality (CEQ). Currently, Sutley is Deputy Mayor for Energy and Environment, City of Los Angeles, and served as a Special Assistant to Browner during her tenure as EPA Administrator. Lisa Jackson, head of New Jersey's Department of Environmental Protection, is President-Elect Obama's pick to head EPA. Jackson also held positions at EPA during Browner's tenure as EPA Administrator. Given the number of former Browner staff assistants sprinkled throughout EPA and CEQ, some believe that Browner may direct to a significant extent again EPA's priorities.

Dr. John P. Holdren has been appointed head of the White House Office of Science and Technology Policy. In this post, Holdren will serve as Obama's Chief Science Adviser and co-chair the President's Council of Advisers on Science and Technology. Holdren is director of the Science, Technology, and Public Policy program in the Belfer Center for Science and International Affairs at Harvard's John F. Kennedy School of Government. Holdren is a physicist well-known for his contributions on climate and energy policy.

Key EPA appointments will be the sub-cabinet positions, including Deputy Administrator and the Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances (OPPTS). None to date has been named to these positions.

For OPPTS, there is no obvious list of likely candidates that has been vetted publicly. The OPPTS job is among the least sought position, and considered to be less prestigious (or at least career-enhancing) than similar positions in the other media programs (*e.g.*, air, water, General Counsel). Virtually no names have circulated concerning the OPPTS



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position. Carolyn Brickey, now of the Center for Responsible Lending and former Executive Director of the National Campaign for Pesticide Policy Reform and former Senior Counsel for the Senate Agriculture Committee, has occasionally been discussed in the past, but in past election cycles has expressed disinterest in the position.

It will be one of the selections considered after the new Administrator's core team is in place, with a goal of meeting certain criteria sometimes associated with the job of regulating pesticides and chemicals -- a science or medical background, for example.

Heads of other agencies will also influence EPA policy and direction. Browner will influence to a significant extent CEQ priorities as she does EPA priorities. Steven Chu, who has been heavily involved in many clean energy initiatives, has been named to head the Department of Energy. Also of interest is Mr. Obama's selection of Ken Salazar to head the Interior Department, given the importance of Endangered Species Act (ESA) issues to pesticide regulation in particular and chemical regulation in general. Mr. Salazar is considered by some to be a centrist and has taken positions on ESA issues that some environmentalists have opposed. Iowa Governor Tom Vilsack has been named Department of Agriculture head. He is expected to promote the use of biotechnologies and biofuels. Coming from Iowa, Vilsack is expected to continue to support the bulk of the farm programs as currently enacted. Often, if the Secretary is from the Midwest, there is a strong push to name a Deputy Secretary from California. As yet, no nominee has been named.

Congress

Congress will continue to have a significant impact on shaping EPA programs and priorities. In the Senate, it is expected that Senator Barbara Boxer (D-CA) will remain Chair of the Environment and Public Works Committee, and continue to press EPA for strong environmental protection policies, interpretations, and initiatives across EPA's entire regulatory universe. For the Senate Agriculture Committee, with jurisdiction over the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Senator Tom Harkin (D-IA) is expected to continue as Chair.

In the House, the unexpected ascent by Representative Waxman to Chair of the House Energy and Commerce Committee will significantly affect EPA's operating environment. Representative Waxman's success signals a significant shift toward more aggressive proposals on health care, energy, and environmental protection across the board.

There are many other Committees and Subcommittees that have some jurisdiction over EPA matters, and the members and leaders of those Committees will be decided shortly.



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The assignment of these positions may be critical in obtaining an early sense of how future environmental legislation or hearings on environmental issues might take shape over the next session of Congress.

Advocacy Group Strategies

Given the advent of a Democratic Administration and stronger Democratic majorities in Congress, advocacy groups will have a different menu of choices with which to pursue their goals and expanded horizons for developing new initiatives.

Under the Bush Administration, judicial activism was the option of choice, borne in large part by the lack of alternatives. Now, non-governmental organizations (NGO) are in the position of bringing litigation that would challenge positions proffered by the Democratic Administration expected to be allies. In some cases, fundamental differences will still drive a litigation strategy. In others, there will be a kind of cooperative approach in fostering either litigation and/or favorable settlements.

NGO advocates can be expected to use “investigations” and “exposes” to identify and promote issues of concern. There will also be an even more cooperative context for critical General Accountability Office reports to help move along issue sets.

One irony here is that Congressional oversight hearings during the last two years have been critical of EPA and encouraging to the advocacy community. With Democratic control of both the Congress and the White House, they will now likely be less intense in terms of being critical of current EPA programs and practices. Partly this will be a kind of “honeymoon” period, and partly this will be to wait and see if the new leadership of agencies delivers on meeting the needs of the Congressional overseers.

Priorities

The new EPA and related federal agencies will have a full agenda with the overarching priorities of climate change and energy. At the same time, other EPA offices less involved with climate and energy issues will also have new leadership, and will be busy with ensuring environmental constituencies are addressed and agendas identified and implemented.

It is simplistic, but relevant for a starting point, to assume that the new Administration will believe that since the Bush Administration was anti-environment, the new Administration should consider almost all initiatives and decisions of the past eight years to be very suspect. This may be contrary to reality, but it will be an explicit consideration in



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evaluating continuing current initiatives or approaches. Although the implementation of the Food Quality Protection Act (FQPA), for example, is generally considered successfully completed, there will be some initial bias that “more needs to be done.” New leadership will be prodded to make significant changes to address the presumed errors of omission and commission which have occurred under the Bush Administration. For example, there are reports that transition team members have inquired about the current status of the Office of Pesticide Programs’ (OPP) worker protection issues.

Office of Pollution Prevention and Toxics (OPPT) Chemical Control Issues

Legislative Priorities

Chemical control legislation will likely be the most visible early priority directly pertinent to Bergeson & Campbell, P.C.’s clients. There will be a renewed emphasis on chemical testing and control. Indeed, this has already begun with EPA’s vigorous launch of the Chemical Assessment and Management Program (ChAMP) and its two key component parts, the Inventory Reset Program and the Inorganic High Production Volume (IHPV) Challenge Program, discussed below.

The existing legislative template is the Kid Safe Chemical Act re-introduced by Senator Frank Lautenberg (D-NJ) and others last May. Most generously stated, it is an attempt to meld FQPA assessment standards (mandatory safety factors for children’s exposures) with the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program (testing and control). The bill as introduced in 2008, however, includes numerous provisions that are either contradictory or unlikely to be in any enacted final legislation. For example, it would legislate a firm risk assessment standard of one in a million risk for B2 carcinogens -- risk assessment terminology not relied on by EPA even during the Clinton Administration. The expectation is that this will represent significant changes to all elements of the current law to require vastly more testing and use-specific evaluations, and be imposed on the entire universe of industrial chemicals regulated by TSCA, including new and existing chemical substances. Designing an approach that balances the goal of more thorough testing and evaluation of chemicals with the need to prioritize among a vast universe of potentially covered substances will not be easily done in a legislative forum. Even assuming the adoption of some kind of “FIFRA-like” approach, which has over time mostly proven successful, the question will remain as to how to triage tens of thousands of chemical substances, whether by volume, hazard indicator, or other identifier.

National Nanotechnology Initiative (NNI) Reauthorization legislation is also likely to be revisited, probably very early in the 111th Congress. The NNI Reauthorization bill



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that passed the House in the 110th Congress is expected to be reintroduced with perhaps an even greater emphasis on environmental, health, and safety research funding in light of the negative response by the National Research Council to the federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research, released last February by the Nanoscale Science, Engineering, and Technology Subcommittee.

Regulatory Priorities

Given the emphasis on climate change, there will be less attention paid to chemical issues, at least in the earliest days of the Administration. As the full set of new appointees roll in, with Regional Administrators appointed, and new Assistant Administrators for the Office of Research and Development (ORD) and OPPTS appointed (historically these have been among the last positions confirmed), there will be more pressure to have an impact or announce new initiatives. This would likely come towards the last quarter of 2009 as the new team settles into place. At the same time, to make an impression of change, the new leadership team likely will seek actions or announcements starting in mid-year (or earlier) to exhibit strong environmental leadership. This could take many forms: new initiatives concerning “tougher enforcement,” investments in environmental research (climate change, risks to children), or specific regulatory initiatives (tolerance revocations concerning certain pesticides). To some degree, this is the most likely time for public communications errors -- since the new officials have to learn exactly what their programs do and the extent of their jurisdiction. As they learn, after some initial period of adjustment, they likely will become more circumspect and realize that if they help create a food or chemical panic, they will have to deal with it.

There is a similar galvanizing process that will occur within the Congress, as members identify issues of concern and attempt to make decisions about what issues to pursue. One difference from the Executive branch is that members of Congress are less responsible for having to resolve any problems they identify as they press the agencies for action.

One important player for EPA in this arena will be the leadership of ORD. ORD will play a pivotal role in setting the tone and direction of how EPA navigates any on-going or newly identified “chemicals of the week.”

OPPT is committed to fulfilling U.S. commitments made under the Security and Prosperity Partnership of North America through the ChAMP. The U.S. committed to complete screening-level hazard and risk characterizations and initiate action on more than 6,750 chemicals produced above 25,000 pounds by 2012. EPA’s commitment to ChAMP and the more recently announced ChAMP enhancements, the TSCA Inventory Reset Program and the IHPV Challenge Program, are expected to command significant time and resources in 2009 and



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beyond. Not only are senior OPPT staff plainly enthusiastic about the program, ChAMP's output will provide a much needed response to anticipated Congressional and environmental advocates' renewed concern with the state of domestic chemical regulatory measures, particularly in light of REACH's growing momentum in the EU. While these administrative initiatives are unlikely to prevent legislative action, they may well soften the hit OPPT might otherwise take without them.

OPPT is also expected to focus extensively on all things nano. 2008 saw an unprecedented number of regulatory/policy developments pertinent to nanoscale materials. Earlier in 2008, OPPT launched its Nanoscale Materials Stewardship Program. OPPT recently announced that it will issue an interim evaluation of the program in March 2009, and a final evaluation to be issued in April 2010. The results of these assessments could well inspire additional regulatory action, or accelerate the pace of initiatives in the pipeline.

In October, OPPT noted publicly that carbon nanotubes are presumed to be new chemicals requiring TSCA Section 5 premanufacture notification. Manufacturers and importers have until March 2009 to get their regulatory house in order, raising at least the possibility that manufacturers and importers that neglect to do so may be on the receiving end of EPA's enforcement discretion. EPA also has taken regulatory action on alumina and silica nanoparticles in issuing a Significant New Use Rule in November. EPA's request for comment on a citizen petition filed last May requesting regulation of nanosilver and products containing nanosilver also telegraphs cross-program interest in the petition and EPA's interest in addressing the petition in a thoughtful, deliberate way. Many believe that these initial regulatory initiatives are merely the start of more comprehensive regulatory measures EPA will pursue in 2009 and thereafter with respect to nanoscale materials.

In the other areas mostly affecting OPPTS, the agenda for change likely will also include:

- Greater emphasis on children's risks and special caution when regulating exposure to chemicals or products children might be exposed to;
- Renewed emphasis on environmental justice issues, which could affect decisions in both the pesticides and toxics programs;
- Increased scrutiny to the effectiveness of OPP's Worker Protection Standards program and consideration of tougher standards and requirements. This will also be incorporated as an environmental justice issue;



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- Results of biomonitoring studies that show exposure to chemicals from uncertain pathways and with limited data about potential risks that result;
- “Right to know” initiatives to require disclosure of chemical use and release information, product labeling disclosures, pressure to disclose more information currently allowed to be claimed as confidential business information, such as wider and earlier release of production data or toxicological studies;
- More peer review of all proposed decisions to ensure “good science,” with more emphasis on conflict of interest screening criteria;
- Renewed emphasis on the potential for risk assessment modeling to incorporate potential effects of low-dose exposures;
- Possible effects of chemicals and pesticides on the endocrine system of humans and animals -- this will be especially driven by the FQPA requirements for endocrine effects testing;
- More cross media initiatives that might continue to blur the autonomy of FIFRA authority over regulated products (*e.g.*, should certain pesticide uses be required to have water permits);
- Toxics use reduction, perhaps wrapped in the cloak of chemical plant security and hazardous material transportation restrictions;
- Initiatives to inform consumers and foster market adoption of greener products, recycling of packaging, reducing the carbon footprints, and the like;
- Proposed trade agreements to include greater assurance of compliance with environmental standards to help “level the playing field” for U.S. entities; and
- Greater belief in international approaches and agreements to attain environmental objectives (*e.g.*, not only to approve the Persistent Organic Pollutant treaty, but use it).



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OPP Pesticide Chemical Control Priorities

ESA issues will continue to garner considerable attention with potentially greater significant effects on pesticide registration decisions and pesticide use. NGOs have focused sizeable resources in challenging ESA compliance in the courts, with some major successes, and this has caused the need for much attention from industry in defending litigation, ensuring that appropriate information is before the courts, as well as in implementing court decisions and in making efforts to ensure that the regulatory process is improved. The Bush Administration's attempts to resolve the issues that plague the consultation process between EPA and the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (the Services) has had limited success and will likely remain a key issue for the Obama Administration.

Recent headlines have focused on the final rule published by the Services on December 16, 2008, which is intended to allow federal agencies to decide for themselves whether federal actions threaten protected species. Even if they make that determination, federal agencies could nevertheless consult with the Services informally, but that process would be limited to 60 days, which would be a significant change from current requirements. The rule also is intended to minimize the ability to consider the impacts of climate change on protected species. Several NGOs are challenging the rule in the U.S. District Court of the Northern District of California. The Obama Administration will also be expected to support efforts to propose changes to the rule to address NGO concerns.

Another recent action that has garnered much attention and will likely be the focus of Obama Administration attention is the Interior Department's December 16 final special rule amending regulations at 50 C.F.R. Part 17 to adopt for the polar bear the protections contained in the Marine Mammal Protection Act and the Convention on International Trade in Endangered Species of Wild Fauna and Flora. The polar bear was listed as threatened based on climate change concerns, though Bush Administration officials were reportedly reluctant to do so. The December 16, 2008, rule, which was issued under ESA Section 4(d), has been criticized by NGOs as not doing enough. The final rule helps streamline determinations of which activities are allowed in the bears' habitat, but it does not impose any new requirements. The rule is noteworthy given that climate change issues have driven the issue, and the Obama Administrations' focus on those issues may well have wide reaching impacts

EPA "made a great deal of progress" towards implementing several related endocrine initiatives in 2008: developing a battery of validated assays to screen chemicals for their potential to interact with the endocrine system; identifying the initial group of chemicals for testing; and describing procedures for issuing test orders. Industry pointed out to EPA that



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pesticide chemicals are rich with data and should not be required to do screening level studies when more substantial studies are already available for these chemicals. There was also considerable comment provided on EPA's proposed policies and procedures. According to EPA, it expects to begin issuing test orders for Tier 1 screening of the initial list of chemicals under the Endocrine Disruptor Screening Program in early 2009. Testing for potential endocrine effects was a priority for the Clinton Administration and could be the subject of more aggressive activity by the Obama Administration. FQPA-mandated endocrine testing requirements have been a continued focus of the advocacy community, so the new EPA leadership team can be expected to make this issue an early priority.

Fortunately, FQPA implementation during the Bush Administration is generally considered to have been a success. There are a few pesticide reviews that are still not completed, and even fewer are expected to remain past January 20, but on those that remain, there may be significant battles over EPA positions on restricting or eliminating certain pesticide products. There will be questions about underlying policies used so far during FQPA, especially the 10X children's safety factor. Mostly this is a debate about agricultural pesticides. Reports have also been heard that the transition team has inquired about end-use product reregistration, that is, have the requirements and timelines for end-use product changes outlined in the Reregistration Eligibility Decision (RED) of an active ingredient actually been captured in end-use product labels. This may cause a renewed emphasis on the legal significance of REDs and the basis for the EPA decisions they contain.

The new Administration will likely renew calls for "pesticide use reduction," along with a call for less prophylactic use of pesticides. Pesticide use in schools will again become an issue, and school districts might be encouraged to use no or less pesticides.

Calls for allowing, if not encouraging, states to develop their own (and differing) approaches to these issues may also lead to conflicting or inconsistent standards for using pesticides in the home, schools, or public parks and highways.

Most discussions of pesticide use in homes, schools, and public facilities do not consider that antimicrobial cleaning products would possibly be included in requirements concerning "pesticides." This distinction would be problematical, for example, if a city or school district proposed not to use any pesticides in its facilities, not realizing that antimicrobial cleaning products could be affected (not just insecticides and herbicides).

Calls for mandatory minimum training for all commercial applications of general use pesticides will likely be proposed and will have to wrestle with the question of what training



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requirements, if any, are appropriate for pest control operators, landscape technicians, and institutional custodial staff.

As it remains controversial, the issue of testing which involves human research subjects can be expected to face further scrutiny and as a result, at a minimum, will be slowed down as the new team is briefed, made to understand the options and tradeoffs, and slowly acknowledges the need for some kind of tests that involve human test participants. There is a small chance that some kind of blanket prohibition could be proposed, but the reach of any such ban would have to be relatively narrow so as to not adversely affect the ability of the program to do its job (*e.g.*, have reliable information about potential occupational risks). Some believe that Senator Boxer plans to seek some sort of human studies restrictions as part of any TSCA reform package, and any TSCA provision might be made applicable to FIFRA studies if Senator Boxer believes that the current rule is not sufficiently protective. The direction these policies may take could in some measure depend on the impetus they are given by challenges to the rule currently pending in the courts, most notably in the Second Circuit Court of Appeals, where a decision could be issued at any time.

Predictions

At this early stage, most “predictions” are heavily laced speculation. The key points to keep in mind include:

- President Obama and his Administration will have many more significant issues on his plate than environmental issues; the same can be said for Congress;
- The highest priority for any new EPA Administrator will be climate change, which has little direct connection to OPPTS issues (except that any increased resources to design or implement climate programs will siphon resources from the other parts of EPA);
- The new leadership team will initially have a bias that the Bush Administration decisions and initiatives were strictly anti-environment across the board; this bias will gradually subside, but actions taken in the first months of the new Administration will be strongly influenced by this belief;
- FQPA implementation is generally regarded as a success, although some clamor will be heard about children’s exposures and endocrine disruptors;



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- The new OPPTS appointee will likely need to spend more time, at least initially, on chemical testing and control issues than on pesticides (TSCA amendments, ChAMP, nanotechnology); and
- There always remains a risk that some new “chemical of the month” will somehow appear, and with a new team in charge trying to establish a reputation, past models of interaction may not be the path most followed.

At this early stage, the best advice is, by definition, of a generic nature: entities regulated by OPPTS, both in OPPT and OPP, will benefit from good corporate stewardship -- complying with all applicable requirements, maintaining good working relationships with all levels of EPA and the Congress, and engaging constructively with the regulatory authorities even if there are disagreements over particular matters or policies.

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