



®

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

MEMORANDUMVia E-Mail

DATE: January 7, 2008

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: 2008 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 2008. We would be pleased to expand upon any thoughts noted below, which are intended only to survey the coming year's key activities in these areas.

2008 Congressional Activity/Presidential Election and Possible Effect on EPA

Given that both houses of Congress are in the control of the Democrats and the election that is months away, EPA will continue to find itself inundated by Congressional "investigations," oversight hearings, and information requests, and generally sharp partisan inquiry. Jurisdiction over EPA programs 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.

Hearings and Investigations

In particular, 2008 will see a rash of "investigations" and reports by various non-governmental organizations (NGO) and/or unfriendly Congressional Committees as part of Presidential politics. It will focus on EPA's record, its alleged lack of accomplishments, and general "Bush is bad" rhetoric. Such hearings, reports, and inquiries will generally mirror the larger environmental themes that have already permeated the Presidential campaigns -- specifically climate change, fuel efficiency, and sustainable energy policies. These hearings and

{0501.078 / 17 / 00024715.DOC}



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 2

inquiries consume very large amounts of time and resources (especially on the part of senior EPA managers and program officials), regardless of the outcome of any hearings or reports resulting from the effort.

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 could examine whether the risk assessments have been adequately prepared, are grounded in “good science,” and truly represent completion of FQPA’s requirements. Given renewed public interest in the safety of food and toys imported from other countries, the issue of “risks to children” could be of special focus. This 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. Concern with toys has already prompted legislation that cleared the Senate Commerce Committee intended to increase funding for the Consumer Product Safety Commission (CPSC). Additionally, Senator Frank Lautenberg (D-NJ) announced late last year that he intends to re-introduce the Kids Safe Chemicals Act, which would require testing of chemicals and impose limits on the use of certain chemicals that cannot be proved safe.

Particularly with the European Union’s (EU) enactment of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, the Toxic Substances Control Act (TSCA) and its utility and effectiveness in managing chemicals and chemical risks likely will garner some, perhaps considerable, attention in hearings and inquiries. Notwithstanding that REACH implementation has not quite arrived -- the new European Chemicals Agency will not become operational until June 2008 -- comparisons between the TSCA and REACH frameworks will continue to be drawn. A recent Governmental Accountability Office (GAO) report, prepared at the request of Senator Lautenberg, comparing TSCA with REACH, helps to highlight some of the more prominent differences between the EU and domestic chemical regulatory programs.

Some patterns have emerged with hearings convened by the current Congress: often a hearing is held to review a report by GAO which is argued as critical of the Administration, or a hearing is held to inquire of EPA why a petition for a certain action or policy was denied by EPA (usually a petition filed by an advocacy group). EPA’s denial of the petition then provides a ready record from which Congressional critics can probe the basis in law or policy. GAO reports also typically provide fodder for those seeking to criticize current Agency policies. As a result, to some degree, future oversight hearings can be anticipated where citizens petitions, GAO reports, or positions taken in government briefs seem to differ from the stated goals and objectives of the majority members of Congressional Committees of



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 3

jurisdiction. One example: GAO is working on a biomonitoring report due to be released in Spring 2008 -- which will almost certainly be the basis of some kind of Congressional hearing to critique EPA inactivity in the area.

Even though a Democrat-majority Congress is expected to be 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 year will be devoted to creating opportunities for raising the profile of environmental issues in preparation for the 2008 elections. As a result, as discussed below, 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 Endangered Species Act (ESA) likely will continue, not only to influence election politics, but to prepare for the inevitable transition to a new Administration, of whichever stripe.

Legislation

Little legislation is expected to be seriously considered during the 2008 election year. Presidential election politics are expected to dominate very early in 2008, which will leave little room for legislative initiatives to see the light of day. These include mostly straightforward and long-standing initiatives such as legislation to implement the international agreements to comply with Prior Informed Consent (PIC)/Persistent Organic Pollutants (POP) international agreements that would require amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and TSCA, as well as inherently controversial proposals concerning FIFRA preemption of state laws or any amendments to the ESA.

A coalition of environmental groups has already formed and is urging the federal government to reform TSCA. The relentless beat of REACH will continue to be heard on the Hill and in state legislatures nationally in 2008 and beyond. While chemical companies and others will point to the Montebello Agreement forged during the August 2007 Security and Prosperity Partnership (SPP) meeting in August, others will claim Montebello is inadequate and/or too little, too late.

The current Farm Bill could be used to try to enact pesticide amendments, controversial or otherwise; this type of bill in the past has been a vehicle for some pesticide-related amendments. Budget considerations will be the dominant factor by far, however, and Congress appears to have little desire to use the Farm Bill for controversial pesticide-related legislation. Relatively non-controversial amendments may be included. For example, the pesticide industry seeks to have provisions requiring mandatory pesticide container recycling



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 4

included as part of the Farm Bill, to level the playing field among registrants, some of whom have created such recycling programs.

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. Key House Democrats are already drafting legislation to revise the final chemical plant security rule issued by the Department of Homeland Security (DHS) to give DHS permanent authority to implement chemical security regulations while authorizing states to set stricter limits. The legislation, prepared by Representative Bernie Thompson (D-MS), Chair of the House Homeland Security Committee, is set to take effect in October 2009, when authority for the current federal regulations expires. The bill also includes a mandate for facilities to adopt inherently safer technologies.

Possible Transition under a Democratic Administration

Although conventional wisdom of a likely Democratic victory could certainly prove incorrect, it is interesting to muse at least briefly about some possible tendencies of a new Democratic Administration.

During the first months of the new term, Congress would be pressed to reform and reverse the “bad” record of the Bush EPA, and would likely seek more intense scrutiny of particular pending decisions, as well as general demand for more protective policies (renewed emphasis on risks to children, rejuvenation of the role of the Children’s Health Office, more rhetoric about pesticide use reduction as pollution prevention). Senator Boxer has already announced, for example, that the Senate Environment and Public Works Committee will hold hearings soon on bills aimed at “clarifying” the scope of EPA’s authority under the Clean Water Act (CWA). While intended to address the 2006 *Rapanos* decision (holding that a hydrological connection alone is insufficient to establish CWA jurisdiction), other issues, including pesticide drift and the National Pollutant Discharge Elimination System (NPDES) program, could be implicated.

Other issues dormant during the Bush years but likely renewed as part of a Democratic Administration include: school Integrated Pest Management (IPM), worker protection standards for occupational risk, tacit or explicit support for local ordinances, and possibly additional pronouncements (*e.g.*, judicial amicus briefs) pushing tort opportunities under the Supreme Court’s *Bates* decision on FIFRA preemption, though there is some hope that the *Riegel v. Medtronic* case currently before the Supreme Court may result in a decision that



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 5

puts some bounds on the *Bates* decision; that case addresses a statutory provision in the Federal Food, Drug, and Cosmetic Act (FFDCA) that is analogous to FIFRA preemption provisions.

Of particular concern to the pesticide industry under a less friendly Administration would be policies further eroding the autonomy of FIFRA and the Agricultural Committees of Congress to control pesticide approvals. In particular, the current Administration has strongly supported the position that pesticide uses, when label directions are followed, are not subject to the CWA's NPDES requirements. Should a new Administration reverse this point of view, an entirely new set of issues would confront the pesticide registrant and user communities.

Pesticide Regulatory Activity in 2008 -- A Year of Unfinished Business, Posturing, and Positioning

2008 will be a "lame duck" year for the present Administration and most focus will be on Presidential politics. There remain, however, some important deadlines, milestones, and hoped for achievements that can reasonably be anticipated to dominate the Office of Prevention, Pesticides and Toxic Substances' (OPPTS) agenda for the coming year. Various interests will seek to complete certain actions hoping to insulate the outcome against possible changes that will come with a new President (the devil you know is more predictable than the devil that may be inaugurated). At the same time, other interests will attempt to slow down certain decisions, hoping for the same changes might bring a more friendly perspective on certain agendas or policies.

Completing Reregistration of Pesticides

Although EPA was perceived to be relatively successful in completing FQPA requirements to review all tolerances before August 2006, there are a handful of difficult food use active ingredients remaining in the reregistration process. Some are still under review (*e.g.*, the soil fumigant cluster), and some are currently under consideration for formal cancellation proceedings (*e.g.*, carbofuran). These cases are complex and represent almost invariably controversial conclusions. As a result, these issues are mostly unpredictable as to the amount of time or programmatic resources that will have to be expended during 2008.

In addition, as part of the initiative to authorize industry registration fees (Pesticide Registration Improvement Act (PRIA)), amendments were added to require all pesticides (*i.e.*, including non-food use pesticides) to be reviewed by August 2008. This leaves a number of these non-food use active ingredients (mostly antimicrobial products) to be reviewed over the next nine months. Meeting this deadline will consume a significant amount of



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 6

management time and attention, and already has resulted in a shift in program resources to attempt to meet this goal.

In meeting the 2006 FQPA tolerance reassessment deadlines, EPA was eager to see many (but not all) outstanding issues resolved that otherwise might have delayed issuance of Reregistration Eligibility Decision (RED) documents. This is likely to be repeated in the run-up to the 2008 deadline for non-food REDs, although the issues may be less potentially controversial since by definition they are not related to food use pesticides.

***EPA's Announced Pesticide Agenda:
Endocrine Disruptors, Worker Protection, Drift Policy, RED Compliance***

Another element of FQPA not yet completed is implementation of the statutory requirement concerning endocrine disruptors. This will not only be part of the general menu of criticism about perceived past EPA inaction, but also will come into its own special focus as EPA seeks to impose the initial screening test requirements on a number of pesticides before the end of 2008. Any test results will then be considered by the next Administration, but even before that, the selection or removal from the list of pesticides to be tested may itself become controversial. Although required to be started years ago under FPQA, EPA is only now articulating the process planned to be used to issue testing orders for the first proposed list of chemicals, all pesticides, and the comment period remains open on the first list, which will undoubtedly include criticism of the methods EPA used to select particular pesticides. There remains an obvious fear that any on this first list, however parsed and described as simply a list of testing requirements, could lead to misrepresentation that the list is one of *per se* harmful substances. To date, EPA has carefully crafted its messages to avoid such an outcome, but the issuance of the final list will be another opportunity for mangled media coverage.

Also long in development has been revisions to EPA's Worker Protection Standards (WPS). EPA now plans to issue a proposed rule to update and revise the current standards in late 2008. Some expected changes are not seen as controversial (*e.g.*, more tailored training modules for different kinds of workers), but it is not clear how ambitious EPA might be in attempting to revise or extend the current program (*e.g.*, should the new rules require Occupational Safety and Health Administration (OSHA)-like hazard communication requirements). Lastly, as a proposed rule, the final determination (*i.e.*, the final rule) will by definition be left to a new Administration, which will drive some part of the concern about any package of proposed changes.

EPA has also publicly announced its intentions to issue a proposed Pesticide Registration (PR) Notice concerning "drift" -- the deposition of some amount of pesticide



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 7

product off the intended target application site. This issue has historically been controversial, and remains difficult to resolve among strongly held views concerning what constitutes harm, compliance with label application requirements, and how best to avoid or mitigate off-target deposition of even small amounts of “properly” applied pesticide formulations.

EPA also has announced its intention in 2008 to issue a rule proposing separate data requirements for plant-incorporated protectants (PIP). To date, EPA has relied on the microbial pesticide data requirements tailored for PIPs on a case-by-case basis. EPA states that establishing separate PIP data requirements is appropriate as information needed to support the registration of a PIP has evolved along with the expanding knowledge base of pesticide chemical technology.

Finally, EPA reportedly is reviewing compliance with the apparent mandates of RED decisions issued over the past years. For example, if a RED states that certain label revisions are needed to be eligible for reregistration, EPA will now examine if all such continued registrations actually contain such revisions. This review is partly driven by common sense and management of the review process, and partly driven by a fear of possible litigation over FQPA “unfinished business,” as discussed below.

TSCA-Related and Other Chemical Regulatory Activity

Nano and Related Issues

EPA is expected to roll out the Nanoscale Materials Stewardship Program (NMSP) in early 2008, and regardless of what the final voluntary program actually entails, it is likely to draw criticism from some stakeholders. Many will wait to see what kind of response the voluntary program draws before declaring the program a success, or alternatively, concluding that the NMSP met with the same dismal response as the U.K. Department for Environment, Food and Rural Affairs (DEFRA) voluntary program, ensuring its fate as a failed voluntary program. EPA will, under those circumstances, be urged to exercise its broad authority under TSCA Section 8 to issue requests for data and take other actions in the event the NMSP is declared a failure. As EPA has alluded to its authority in this regard in various *Federal Register* notices over the past few years, stakeholders should not be too surprised to see nano TSCA Section 8(a) and/or (d) rules in their future.

EPA continued to devote considerable energy to engineered nanoscale materials in 2007, and will likely do even more in 2008. As engineered nanomaterials continue to find their way into ever more diverse products and applications, EPA will continue to adapt its new



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 8

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

Another issue of note includes implementation of Global Harmonization of Classification and Labeling of Chemicals (GHS), but it is unclear how global commitment to achieve GHS by 2008 will impact EPA in practice. As noted above, endocrine issues will be important in 2008 as chemical manufacturers whose substances are slated for testing urge a different result, and seek both to fine tune the testing, and argue over the relevance of test results.

In addition to the legislative issue noted above, DHS will generate interest in 2008. DHS plans to propose standards for the use of third-party auditors to conduct audits and inspections under its Chemical Facility Anti-Terrorism Standards found in 6 C.F.R. Part 27. DHS intends to provide details about its proposed use of third-party auditors, and will identify those tiers of facilities for which it will use third-party auditors. DHS plans also to propose standards and requirements for third-party auditors, and plans to consider issues such as the certification, qualifications, independence, objectivity, training, confidentiality, ethical obligations, and conflicts of interest issues of third-party auditors. In addition, DHS will consider the issue of who will pay for third-party auditors. DHS will also likely continue its efforts with regard to chemical facilities fitting a certain risk profile to ensure their security.

TSCA Chemical Testing

EPA is expected to continue negotiating Enforceable Consent Agreements (ECA) for the remaining hazardous air pollutants (HAP) under the TSCA Section 4 test rule proposed over a decade ago. EPA plans final action on the rule addressing chemicals that were not the subject of voluntary agreements in late 2008. EPA will continue work on its October 2006 proposed Section 4 test rule for certain chemicals on the Agency for Toxic Substances Disease Registry (ATSDR) Priority List of Hazardous Substances. According to EPA, this test rule is intended to address health effects data needs identified by ATSDR and EPA for certain substances that are commonly found at sites listed on the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) National Priorities List (NPL) and are also HAPs under Section 112 of the Clean Air Act (CAA). Final action is expected in late 2008.

OPPTS also expects to propose a second Section 4 test rule under TSCA in early 2008 that will require testing for a number of High Production Volume (HPV) chemicals that were not sponsored as part of the voluntary HPV Challenge Program. The first test rule for orphan HPV chemicals, proposed in December 2000 and issued in final in March 2006, focused on HPV chemicals with substantial worker exposure. The proposed rule scheduled to be published in 2008 is expected to require similar screening level testing for additional



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 9

unsponsored HPV Challenge Program chemicals. EPA also will continue in 2008 to evaluate data submitted on chemicals through the HPV Challenge Program and develop HPV Chemical Hazard Characterizations on selected HPV chemicals. EPA expects to post completed Chemical Hazard Characterizations to its High Production Volume Information System (HPVIS) website/database.

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 Spring or Summer of 2008.

EPA plans to issue its final rule on enzyme and protein nomenclature in May 2008.

Litigation

Litigation by environmental groups will continue to be a ready tool, as will publicity splashes intended to induce change by force of public opinion.

With regard to FIFRA, there remains the possibility 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 over 99%), and certain 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. To generate publicity, and/or to prepare for a possible new Administration, a generic challenge to many RED determinations might be made on the basis of allegedly deficient determinations about the FQPA 10x safety factor (that the 10x factor should not have been reduced or removed).

The mother lode of pesticide litigation, however, remains to be the ESA. Put simply, litigation is expected to continue unabated. Relief in any sense is nowhere in sight, since the key roadblock continues to be the inability and reluctance of the appropriate federal agencies outside of EPA, such as the Fish and Wildlife Service of the Department of Interior, to process the analyses forwarded by the pesticide program. This continues to be a frustrating situation to pesticide registrants, and the eventual resolution of the situation is uncertain at best. Separate from any speculation about the motivations or capabilities of the staff or offices outside of EPA, there is a large roadblock in the lack of budgetary resources in these other agencies.



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 10

Budget/Resources

The push to control the federal budget deficit will continue to bode poorly for EPA and other domestic agencies in general. The proposed Fiscal Year (FY) 2009 budget will likely see similarly squeezed revenues as in recent past years that will diminish the funds available for travel, training, grants, and contractor support. With regard to the pesticides program, PRIA resources will continue to make a positive difference, principally in avoiding even more serious cuts to the program. This is why the pesticide industry helped to reach a consensus with EPA and environmental advocates on a PRIA extension (signed into law on October 9, 2007, which would continue at least some measure of budget protection for the next few years.

As mentioned, another continuing related issue for the pesticides program is the meager resources that agencies outside of EPA are able to provide 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. Eventually, many expect that only some kind of legislative amendments will resolve this bottleneck, but it is unlikely that Congress will consider seriously any kind of changes to either FIFRA or ESA to address the situation during this election year.

2009 Transition Year for a New Administration

Regardless of election results, 2009 will see a new President and almost certainly a new leadership team at EPA. As a result, for OPPTS, most of 2009 will see Jim Jones in charge as Acting Assistant Administrator -- partly because OPPTS leadership is typically one of the last senior positions to be decided during a Presidential transition. Even assuming little controversy or few nomination battles for EPA positions, new leadership for OPPTS might not be in place until Labor Day (September) 2009. During this transition time, then, few new initiatives would be expected to be generated, except for any overall initiatives of any new Administration (most likely regarding broad, Administration-wide policies, and not OPPTS-specific ones).

Conclusion

As a Democratic Congress and Presidential candidates attempt to present their case to the public that a change in Administration is needed to better protect the environment, 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 issued by EPA. This might induce EPA to proceed more slowly and cautiously across the board, to rely even more so on



®

BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
January 7, 2008
Page 11

additional layers of science review and public process announced as transparency initiatives, and general reluctance to take on difficult or controversial issues.

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, especially in the last year of a lame duck Administration. The renewed attention by Congress to issues such as climate change, oil prices and fuel efficiency, sustainability, and the effectiveness of Bush Administration policies, as well as the continued jockeying among prospective Presidential candidates of both political parties, will drive EPA agenda and attention in ways not seen for many years. 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.