CHEMICAL PRODUCT DEVELOPMENT AND DEFENSE

MEMORANDUM

Via E-Mail

DATE: December 31, 2009

TO: Clients and Friends

FROM: The Acta Group, L.L.C.

RE: EPA Announces Action Plans For Existing Chemicals

True to her word, yesterday U.S. Environmental Protection Agency (EPA) Administrator Lisa P. Jackson announced action plans on phthalates, long-chain perfluorinated chemicals (PFC), polybrominated diphenyl ethers (PBDE) in products, and short-chain chlorinated paraffins (SCCP). This EPA initiative announces actions that are almost breathtaking in scope, and its development and implementation of the action plan items will set a number of new precedents -- and possibly shape future legislative proposals -- that industry will need to participate in and monitor closely. EPA has never previously announced so many actions under the Toxic Substances Control Act (TSCA), nor has it ever cited use of Section 6 so widely. Moreover, that it was issued in this form after being reviewed by the Office of Management and Budget (OMB) is significant and portends potentially great and largely unfettered EPA activity in the months to come. A final point is to recognize EPA's decision to rely on the Office of Pollution Prevention and Toxics' (OPPT) Design for the Environment (DfE) program to assist in conducting alternatives assessments for two of the chemical classes (phthalates and PBDEs). The DfE program's previous alternatives assessments have been open to participation by industry as well as other stakeholders in a forum that allows for complex issues and difficulties to be explained and addressed.

The action plans, discussed in more detail below, summarize available hazard, exposure, and use information; outline the risks that each chemical may present; and identify specific steps EPA is taking to address those concerns. According to EPA, "[a]s those actions begin, there will be opportunities for public and stakeholder comment and involvement." EPA states that its actions "represent its determination to use its authority under the existing Toxic

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Substances Control Act (TSCA) to the fullest extent possible, recognizing EPA's strong belief that the 1976 law is both outdated and in need of reform."

Jackson also announced that EPA intends to establish a "Chemicals of Concern" list and commence a process that may result in regulations requiring "significant risk reduction measures" to protect human health and safety. The Chemicals of Concern list will rely on EPA's authority under TSCA Section 5(b)(4)(A)(i), which authorizes EPA by rule to "compile and keep current [a] list of chemical substances with respect to which the Administrator finds that the manufacturer, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment." This section of TSCA, previously described as the "Risk List," has not otherwise been used by EPA. The listing requires a rulemaking and a finding that a chemical "presents or may present an unreasonable risk," and EPA's announcement emphasizes the "may present" arm of the findings. When the Bush Administration raised the possibility of using the Section 5(b)(4) listing under the Chemical Assessment and Management Program (ChAMP), industry raised a number of "black list" concerns in its comments. Thus, any such list is likely to be targeted as a presumptive "hit" list not unlike the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) authorization candidate list. More information is available on the action plans and the Chemicals of Concern list at http://www.epa.gov/oppt/existingchemicals.

Background

On September 29, 2009, Jackson announced the Obama Administration's core principles for TSCA legislative reform. In parallel with the legislative initiative, Jackson also announced EPA's plans to strengthen its current chemical management program and increase the pace of its efforts to address chemicals that pose a risk to the public. While the Obama Administration believes that legislative reform is necessary for an effective chemicals management program, Jackson stated that EPA is committed to strengthening the performance of the current program in the meantime. Enhancements include the development of chemical action plans that outline EPA's risk management efforts on those chemicals of greatest concern. EPA's initial list of chemicals being considered for action plan development included benzidine dyes and pigments; bisphenol A (BPA); PBDEs in products; PFCs; phthalates; and SCCPs. According to EPA, prioritizing chemicals for future risk management action is the final component of this effort, and EPA stated that it "intends to formally engage stakeholders and the public in this discussion in the coming months."

Action Plans for Existing Chemicals

EPA states that it chose the initial chemicals selected for action plan development on the basis of multiple factors, including chemicals identified as persistent, bioaccumulative, and toxic; high production volume (HPV) chemicals; chemicals in consumer products; chemicals of particular potential concern for children's health because of reproductive or developmental toxicity; chemicals subject to review and potential action in international forums; chemicals found in human blood in biomonitoring programs; and chemicals in categories generally identified as being of potential concern in the New Chemicals Program.

Phthalates Action Plan Summary

EPA's phthalates action plan addresses dibutyl phthalate; diisobutyl phthalate; butyl benzyl phthalate; di-n-pentyl phthalate (DnPP); di (2-ethylhexyl) phthalate; di-n-octyl phthalate; diisononyl phthalate; and diisodecyl phthalate. EPA states that it is concerned about phthalates because of their toxicity and the evidence of pervasive human and environmental exposure to these chemicals. EPA notes that phthalates are used in "many industrial and consumer products, many of which pose potentially high exposure. Phthalates have been detected in food and also measured in humans." According to EPA, adverse effects on the development of the reproductive system in male laboratory animals are the most sensitive health outcomes from phthalate exposure. EPA states: "Several studies have shown associations between phthalate exposures and human health, although no causal link has been established. Recent scientific attention has focused on whether the cumulative effect of several phthalates may increase the potential reproductive effects in the organism exposed." The document goes on to state that "EPA believes that the *cumulative* health risks of phthalates should be assessed to determine what actions are warranted to insure protection of children's health from this group of chemicals" (emphasis added). While this approach is consistent with the recommendations made by the National Academy of Sciences (NAS) in its 2008 review, *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*, available at http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12528, it appears to be the first time that OPPT has stated its intention to undertake a cumulative risk assessment approach on a class of chemicals.

The action plan in its "Environmental Exposure" section also states that phthalates have a "propensity for global transport" although no evidence for this statement is provided.

On the basis of existing information, according to EPA, "the following regulatory actions would be warranted to manage the risk that may be presented by the eight phthalates":

- EPA intends to initiate rulemaking in autumn **2010** to add these eight phthalates to the Concern List under TSCA Section 5(b)(4) as chemicals that present or may present an unreasonable risk of injury to health or the environment. EPA also intends to initiate rulemaking in late **2010** to add the six phthalates not already on the Toxics Release Inventory (TRI).

- EPA will consider initiating rulemaking in **2012** under TSCA Section 6(a). In preparation for potential rulemaking, EPA intends to cooperate with the Consumer Product Safety Commission (CPSC) and the U.S. Food and Drug Administration (FDA) to assess the use, exposure, and substitutes for these chemicals. EPA plans to consider the results of the cumulative assessment due to be completed by CPSC in **2012** pursuant to the Consumer Product Safety Improvement Act of 2008 (CPSIA), as well as the ongoing review of phthalates at FDA and the assessment for EPA's Integrated Risk Information System (IRIS) Program, due to be completed in **2011**. These assessments will inform EPA's decision on future action to address these chemicals. EPA states that potential control measures, which would be based on the finding that these chemicals "present or will present an unreasonable risk of injury to health or the environment," may include a ban of all or several of these chemicals, as appropriate.

- EPA may consider pursuing additional rulemaking under TSCA Section 5(a)(2) in late **2010** or early **2011** to require manufacturers and processors of DnPP to notify EPA before manufacturing or processing DnPP for a significant new use. The most recent Inventory Update Reporting (IUR) data contain no reports of this phthalate being produced or imported into the United States, and thus it is possible that any use of DnPP may be a significant new use.

- EPA intends to conduct a DfE and Green Chemistry alternatives assessment by **2012**. The information developed could be used to encourage industry to move away from phthalates in a non-regulatory setting to expand risk management efforts beyond whatever regulatory action might be taken under TSCA, or it could be used as input to a regulatory action. The alternatives assessment would build upon existing

knowledge and would consider exposures to all human sub-populations, including children, as well as environmental exposure.

More information regarding EPA's phthalates action plan is available on the Internet at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates.html. EPA's recognition of the many ongoing assessments elsewhere in EPA and in other agencies is an important point to note, as the task of untangling potential exposure sources depending on the applicable regulatory authority is likely to be quite complex and could draw attention to a need for clearer statutory authorities for dealing with such complex exposures.

PFCs Action Plan Summary

EPA notes that the long-chain PFCs comprise two sub-categories: perfluoroalkyl sulfonates (PFAS) and perfluoroalkyl carboxylates (PFAC). The PFAS sub-category includes perfluorohexane sulfonic acid, perfluorooctane sulfonic acid, other higher homologues, and their salts and precursors. The PFAC sub-category includes perfluorooctanoic acid, other higher homologues, and their salts and precursors. EPA states that some of the potential PFAC precursors "include chemicals known commercially as fluorotelomers." It is important to note that, as described in EPA's communication, the "long chain PFCs" do NOT differ from the chemicals that EPA focused on under the 2010/2015 PFOA Stewardship Program (thus EPA has not signaled concern with the C6 PFAC).

According to EPA, long-chain PFCs are found world-wide in the environment, wildlife, and humans; are bioaccumulative in wildlife and humans, and are persistent in the environment; and are toxic to laboratory animals and wildlife, producing reproductive, developmental, and systemic effects in laboratory tests. EPA states: "To date, significant adverse effects have not been found in the general human population. However, given the long half-life of these chemicals in humans (years), it can reasonably be anticipated that continued exposure could increase body burdens to levels that would result in adverse outcomes."

EPA lists the following actions concerning PFCs:

- EPA intends to consider initiating rulemaking under TSCA Section 6 to manage long-chain PFCs. If EPA can make certain findings with respect to these chemicals (further analysis of the information will be performed as part of TSCA Section 6 rulemaking), TSCA Section 6 provides authority for EPA to ban or restrict the manufacture, processing, and use of these chemicals. A rule addressing the PFAS sub-category could

expand the reach of three Significant New Use Rules (SNUR) that EPA has promulgated over the past decade. EPA notes as an example that this could involve PFAS-containing articles. Whether the action goes beyond the current scope, such as regulating ongoing uses of PFAS chemicals (*i.e.*, those recognized and, accordingly, not regulated by the SNUR) or phasing out existing stocks of, *e.g.*, fire-fighting fluids, remains to be seen. A rule addressing the PFAC sub-category could expand the reach of the 2010/2015 PFOA Stewardship Program beyond the eight participating companies and further address the concerns for potential PFAC exposure through the use of PFAC-containing articles. EPA will develop more detailed assessments to support the TSCA Section 6(a) "presents or will present an unreasonable risk" findings. If these more detailed assessments indicate that a different approach to risk management is appropriate, EPA will consider additional approaches.

- As part of EPA's efforts to manage PFCs, EPA also intends to evaluate the potential for disproportionate impact on children and other sub-populations. EPA states that, "[g]iven that human biomonitoring data have demonstrated that humans are exposed to PFCs in the womb, during infancy, and during puberty, and that animal studies have shown that the fetus and neonate are sensitive life stages to PFC exposures, EPA will consider effects to the developing fetus and children."

- EPA will continue with the 2010/2015 PFOA Stewardship Program to work with companies toward the elimination of long-chain PFCs from emissions and products. Of unknown significance is the statement in the action plan (p. 19) to the effect that the "PFOA Stewardship Program is expected to eliminate the *production* of C-8 based fluorotelomers by the eight participating companies by 2015" (emphasis added), a statement which uses language different from that used previously. EPA will also continue to evaluate alternatives under EPA's New Chemicals Program and collaborate with other countries on managing PFCs.

More information regarding EPA's long-chain PFCs action plan is available on the Internet at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pfcs.html.

PBDEs Action Plan Summary

EPA notes that PBDEs include the commercial versions of pentabromodiphenyl ether (c-pentaBDE), octabromodiphenyl ether (c-octaBDE), and decabromodiphenyl ether (c-decaBDE). EPA states that each of these commercial products is a mixture composed of several PBDE congeners. According to EPA, it is concerned that certain PBDE congeners are persistent, bioaccumulative, and toxic to both humans and the environment. The critical endpoint of concern for human health is neurobehavioral effects. EPA states that various PBDEs have also been studied for ecotoxicity in mammals, birds, fish, and invertebrates and that, in some cases, current levels of exposure for wildlife may be at or near adverse effect levels.

According to EPA, on the basis of existing information, it believes that the following actions would be warranted:

- EPA intends to initiate rulemaking in autumn **2010** to add these commercial PDBE mixtures and/or the congeners they contain to the Concern List under TSCA Section 5(b)(4) as chemicals that present or may present an unreasonable risk of injury to health or the environment.

- EPA intends to initiate rulemaking to propose a TSCA Section 5(a)(2) SNUR requiring notice to EPA prior to the manufacture or import of articles to which c-pentaBDE or c-octaBDE have been added. A notice of proposed rulemaking is intended to be published in **2010**.

- EPA also intends to support and encourage the voluntary phase-out of manufacture and import of c-decaBDE. EPA has received commitments from the principal manufacturers and importers of c-decaBDE to initiate reductions in the manufacture, import, and sales of c-decaBDE starting in **2010**, with all sales to cease by **December 31, 2013**. EPA intends to encourage other importers of c-decaBDE to join this initiative. As part of this encouragement, EPA intends to develop DfE and Green Chemistry alternatives analysis for c-decaBDE to aid users in selecting suitable alternatives. The alternatives analysis is intended to begin in spring **2010**.

- EPA also intends to initiate rulemaking to propose a simultaneous SNUR and the previously announced test rule for c-decaBDE. The significant new use would be manufacture of c-decaBDE or articles to which c-decaBDE has been added. The TSCA Section 4 test rule would require

> development of information necessary to determine the effects of manufacturing, use, or other activities involving c-decaBDE on human health or the environment. If the EPA determines that manufacture of c-decaBDE or of articles to which c-decaBDE has been added has not ceased, EPA intends to promulgate the test rule. EPA intends to publish notices of proposed rulemaking for the SNUR and the test rule in **2010**. The combination of the two proposals (the SNUR and the test rule) could present importers with a dilemma: do they defeat the SNUR by acknowledging ongoing importation when doing so could provide the information EPA needs regarding ongoing production to proceed with the test rule, or do they cease importation. One tricky issue for EPA will be how, possibly in both these proposals, it deals with recycled plastics and the subsequent use (processing) of recycled materials containing decaBDE to make new articles.

More information regarding EPA's PBDEs action plan is available on the Internet at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pbde.html.

SCCPs Action Plan Summary

EPA states that, for purposes of the action plan, SCCPs include all individual chemicals or mixtures that contain: $C_xH_{(2x-y+2)}Cl_y$ where x = 10-13; y = 3-12; and the average chlorine content ranges from approximately 40 to 70 percent with the limiting molecular formulas set at $C_{10}H_{19}Cl_3$ and $C_{13}H_{16}Cl_{12}$. According to EPA, it intends to evaluate further whether medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs) also should be addressed. These chemicals appear to present similar concerns, although data on them are not as comprehensive as data on SCCPs.

According to EPA, SCCPs are persistent, bioaccumulative, and toxic to aquatic organisms at low concentrations. SCCPs have been measured in a variety of environmental media, including air, sediment, surface waters, and wastewater. SCCPs have also been measured in a variety of biota, including freshwater aquatic species, marine mammals, and avian and terrestrial wildlife. In addition, SCCPs have been detected in samples of human breast milk from Canada and the United Kingdom, as well as in a variety of food items from Japan and various regions of Europe. SCCPs have also been teed up for possible action under the Stockholm Convention.

EPA lists the following actions it is taking concerning SCCPs:

- EPA states that, in conducting its review, it determined that some of the specific SCCPs, MCCPs, and LCCPs currently being manufactured and/or used in the U.S. are not on the TSCA Inventory. Any substance that is not on the TSCA Inventory is classified as a new chemical. Prior to manufacture or import of a new chemical for general commercial use, a notice must be filed with EPA under TSCA Section 5. EPA intends to address the discrepancy between the specific chlorinated paraffins companies are actually manufacturing or importing and those listed on the TSCA Inventory. EPA intends to require companies to submit pre-manufacture notices for the SCCP, MCCP, and LCCP fractions that are not on the TSCA Inventory, and, if appropriate, will initiate action under TSCA Section 5 to address their potential risks. According to EPA, it plans to explore this question "in the near future." Although EPA can be expected to take the position that evidence that a chemical not listed on the Inventory is being made and used in the U.S. provides the basis for enforcement action, no mention is made of this point in the action plan.

- Concurrently, EPA intends to consider initiating action under TSCA Section 6(a) to ban or restrict the manufacture, import, processing, or distribution in commerce, export, and use of SCCPs based on the persistence, bioaccumulation, and toxicity of SCCPs and their presence in the environment. Regulation of SCCPs under TSCA Section 6(a) will be based on the finding that SCCPs "present or will present an unreasonable risk of injury to health or the environment."

- EPA intends to evaluate further whether the manufacturing, processing, distribution in commerce, use, and/or disposal of MCCPs and LCCPs should also be addressed under TSCA Section 6(a).

- As part of EPA's efforts to address SCCPs, EPA also intends to evaluate the potential for disproportionate impact on children and other sub-populations.

More information regarding EPA's SCCPs action plan is available at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/sccps.html.

Conclusion

These action plans are bold, and telegraph EPA's intent to use current law notwithstanding any legislative attempts to modify TSCA. These action plans may inform at least two aspects of any future TSCA legislative debate: (1) EPA's thinking about how to evaluate and possibly control chemical risks are belied by elements of these plans that may serve as a template for how to structure future Administration proposals for reform; and (2) EPA's rhetoric is not as shrill as some may have feared, although this may further develop as EPA continues to implement these plans and roll-out future ones, as Administrator Jackson pledged to do.

Even if critics of the current law and program lament the ambitions and time-frames laid out here, the obvious possible "fix" is to accelerate a review and control process, while EPA has laid out a standard risk assessment approach. If these plans, or something like them, are eventually seen as a reasonable method of assessment and control, albeit with accelerated processes or time-frames, they would be less radical than other proposed schemes. They also indicate that however crippled some may view past TSCA implementation, reform, not revolution, may be sufficient to meet the needs of a modern chemical control law. Lastly, in selecting these action plans, EPA has both explicit and implicit risk criteria that may help inform the debate about how many of the existing universe of 80,000 chemicals are of possible concern. The spectre of "80,000 unregulated chemicals" provides a different political momentum than "100-1000 suspect chemicals" -- which may help move any eventual discussion of amendments towards the political center and facilitate something resembling a dialogue process as proposed by various players in the current debate.

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