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MEMORANDUM

Via E-Mail

DATE: September 16, 2009

TO: Clients and Friends

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

RE: ECHA Press Releases Concerning Good Practice and Clarification to Avoid Unnecessary Animal Tests

Yesterday the European Chemicals Agency (ECHA) issued two press releases, one announcing that over 500 companies met to share best practice, and another regarding a clarification to avoid unnecessary animal tests. This memorandum briefly summarizes the press releases, which are available on the Internet at http://echa.europa.eu/doc/press/pr_09_14_lead_registrants_workshop_final_20090915.pdf, and http://echa.europa.eu/doc/press/pr_09_13_animal_testing_carification_20090915.pdf.

The European Commission and ECHA organized a meeting for lead registrants and candidate lead registrants to share their experience on taking the lead in developing joint registration dossiers for chemical substances. Under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, companies intending to register the same substance must work together in a Substance Information Exchange Forum (SIEF) to share data on the hazards and safe use of the substance, and prepare a single registration dossier. At the meeting, described in the press release entitled "Over 500 REACH Lead Registrants Share Good Practice," speakers urged lead registrants to "dare to share" and to "be early, be early -- at least two months" before the official deadline in submitting their dossiers. Speakers also informed companies about further support to enable them to fulfill their roles, including a series of targeted webinars run by experts from within ECHA. The webinars are addressed to lead registrants who have notified themselves to ECHA.

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In the second press release, entitled "Clarification Will Avoid Unnecessary Animal Tests," ECHA announces a new clarification of the information requirements for manufacturers and importers of chemical substances under the REACH regulation. According to the press release, the clarification applies to companies manufacturing or importing substances at quantities greater than or equal to 100 tonnes (and 1,000 tonnes) per year who need to provide information in their registration dossiers on the repeated dose toxicity or reproductive toxicity of their substance. Under the clarification, companies who need to provide information based on long-term toxicity studies do not also need to submit the results of screening or short-term studies for their submission to be considered "complete" by ECHA. ECHA encourages companies to consult its fact sheet for the complete clarification to enable them to decide which information they need to provide for their dossiers to pass the technical completeness check. The fact sheet is available on the Internet at http://echa.europa.eu/doc/reach/reach_factsheet_testing.pdf.

ECHA states in the press release that when a dossier has passed the completeness check, ECHA will provide a registration number to the company, who can then continue to manufacture, import, and market the substance. ECHA emphasizes "the information requirements constitute the minimum information required for a technical dossier to pass the completeness check for the two particular hazard endpoints -- repeated dose toxicity and reproductive toxicity -- and that additional information may be necessary to comply with the REACH legislation and to ensure safe use." According to ECHA, registrants who decide to submit testing proposals for the longer term studies without having completed the shorter ones must take that into account by including in the Chemical Safety Report and in the exposure scenario the interim risk management measures that they put in place and those they recommend to downstream users to manage the risks yet to be explored. ECHA states: "The responsibility for the safe use of the chemical lies with the manufacturers, importers and downstream users."

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