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ENVIRONMENTAL, SAFETY AND HEALTH REVIEW – UNITED STATES

Spring 2011

Welcome to the Spring edition of the Squire Sanders *Environmental, Safety and Health Review – United States,* our quarterly update on developments in the fast moving area of environment, health and safety and other regulatory issues. This is our first edition following the combination of Hammonds and Squire Sanders on 1 January 2011 and we are delighted to include a contribution from Dave Gordon a partner based in our Birmingham, UK office on changes to The European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation.

For further information on any of the articles included in this review, please feel free to contact the individuals named after each article.

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Wind Energy Projects: US Fish and Wildlife Service's Draft Eagle Conservation Plan Guidance and Land-Based Wind Energy Guidelines

Ronda L. Sandquist – Phoenix
Gina Guy – Phoenix

On February 18, 2011 the United States Fish and Wildlife Service published its "Draft Eagle Plan Conservation Guidance" [1] for public review and comment. The Draft Eagle Plan outlines a process for authorizing permits for a programmatic take of bald and golden eagles in connection with wind energy projects subject to an approved "Eagle Conservation Plan." The Draft Eagle Plan defines a "take" as injuring an eagle, interfering with normal eagle breeding or feeding, or taking an action leading to nest abandonment. The Draft Eagle Plan describes issues

[1] 76 Fed. Reg. 9529.

that need to be addressed in the siting and design of wind energy projects to reduce or minimize risks to eagles. Accordingly, owners and operators as well as developers of wind energy projects need to consider several issues related to the Draft Eagle Plan.

Background

The management of both bald and golden eagle species is governed by the Bald and Golden Eagle Protection Act.[2] The Fish and Wildlife Service recently published regulations that provided for permits authorizing a "take" of eagles. [3] The subsequently issued Draft Eagle Plan is intended to provide a framework to support Fish and Wildlife Service "take permits" for eagles as a result of ongoing activity that is otherwise lawful. However, no programmatic take permit will be issued without an approved Eagle Conservation Plan. Under the Draft Eagle Plan, the Fish and Wildlife Service will work with the applicants to develop an Eagle Conservation Plan, to show "how the applicant will comply with regulatory requirements" to avoid and minimize the risk of take, as well as "formally evaluat[e] possible alternatives in siting, configuration and operation of wind projects." [4] The Fish and Wildlife Service will determine the nature and extent of future National Environmental Policy Act (NEPA) documentation for programmatic take permits for eagles and the adoption of Eagle Conservation Plans. Developers should explore the NEPA aspect as early as practicable to integrate the Fish and Wildlife permitting action with any other NEPA documentation that may be needed for their project.

Potential Issues With Guidance: Permit Term

If the Fish and Wildlife Service determines the project can be permitted, the permit is limited to five years and will be renewed if all the necessary conditions are met. Given the cost and complexity of wind energy projects, the duration of the permit seems extremely short and could impact the ability of a project to secure financing. The Draft Eagle Plan should be revised to allow a longer permit time and a presumption that the permit will be renewed absent a change in circumstances

Quantifying Eagle Takes

When it issued its rules, the Fish and Wildlife Service stated that the number of permits to be issued would be "limited." [5] Based upon the Fish and Wildlife Service's estimated total population for each species, it is authorizing annual takes of 60 golden eagles (from a total population estimated at 32,593) and 1,103 bald eagles (from a total population estimated at 155,473).

However, the Draft Eagle Plan considers that eagle takes resulting from project operations might exceed the predicted recurring eagle take.[6] If exceedances of predicted eagle takes occur, Fish and Wildlife Service will either:

- Collect a compensatory mitigation payment from the applicant for the pooled mitigation fund; or
- Approve a compensatory mitigation payment from the applicant.

Relationship Among Endangered Species Act, Bald and Golden Eagle Protection Act and Migratory Bird Treaty Act

The Draft Eagle Plan does not propose to authorize take of any bird species subject to the protections of the Migratory Bird Treaty Act,[7] enacted in 1918 to implement the 1916 Convention between the United States and Great Britain (for the Dominion of Canada) to protect migratory birds. The Convention was significantly amended in 1995. While both species of eagles are "migratory" for purposes of the Migratory Bird Treaty Act, the Fish and Wildlife Service has not applied its general migratory bird regulations to the two eagle species because of the applicability of the Bald and Golden Eagle Protection Act. Issues relating to migratory birds not listed under the Endangered Species Act (ESA) must be addressed separately from eagles and ESA-listed species.

Unlike the ESA, neither the Bald and Golden Eagle Protection Act nor the Migratory Bird Treaty Act specifically authorizes the issuance of permits for incidental take. However, both acts authorize the Fish and Wildlife Service to implement necessary regulations and to exercise

[2] 16 U.S.C. § 668, (1940).
[3] 50 C.F.R. § 22.26 (2009).
[4] 76 Fed. Reg. 9529, 27.
[5] 74 FR 46836 (Sept. 11, 2009).
[6] 76 Fed. Reg. 9529, 28.
[7] 16 U.S.C. §§ 703-712 (1918).

discretion with respect to enforcement of these acts. The proposed Draft Eagle Plan is based upon the regulations and policies regarding enforcement of these statutes by the Fish and Wildlife Service, not express statutory authorization of incidental take. The Draft Eagle Plan permits should provide authorization for eagle take under both statutes and should also clarify language regarding other laws that cover takes of bald and golden eagles.

Comments on the Guidance are due May 19, 2011. Impacted owners, operators and developers of wind energy projects should consider submitting comments.

Draft Land-Based Wind Energy Guidelines

In addition to the Draft Eagle Plan, the Draft Land-Based Wind Energy Guidelines were also published on February 18, with comments due by May 19, 2011. The Wind Energy Guidelines are intended to be used for all utility-scale and community-scale land-based wind energy projects. The Wind Energy Guidelines will apply to all projects, whether built on public or private land, and are intended to address the potential negative effects on species and their habitats from wind energy development.

The effect of the Wind Energy Guidelines, if finalized, is likely to vary depending on the size and location of particular projects. Experts retained by project developers will need to become familiar with these guidelines to deal effectively with the Fish and Wildlife Service and state regulators.

Potential Issue With Wind Energy Guidelines:

Commentors need to ensure that the guideline's provisions are realistic in the context of on-the-ground application to projects. The actions required should be economically reasonable and technically feasible, and utilize recognized methodologies and protocols.

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Circuit Courts Weigh in on the Timing and Ripeness of Appeals of Determinations Regarding Project Effects on Endangered Species

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Agency reviews of major projects often trigger compliance with the NEPA so referrals and permits are coordinated amongst several agencies. The determination of whether the project will jeopardize endangered or threatened species or their critical habitat will be made either by the US Fish and Wildlife Service or the National Marine Fisheries Service by means of a Biological Opinion. The issuance of the Biological Opinion concludes the consultation between the Fish and Wildlife Service or National Marine Fisheries Service and the other federal agencies and must be reflected in the Environmental Impact Statement or Environmental Assessment for the project. The Fourth Circuit Court of Appeals recently held that a Biological Opinion issued during the NEPA process was a final agency action and ripe for judicial review even before the lead agency had made its final decision on the NEPA analysis and project permits – a determination that could assist in challenging Biological Opinions before they are implemented as part of an Environmental Impact Statement or Assessment. *See Dow Agrosciences LLC et al. v. National Marine Fisheries Service,* 2011 U.S. App. LEXIS 3907 (4th Cir. 2011).

Dow Agrosciences LLC concerned a Biological Opinion from the National Marine Fisheries Service, directed to US EPA for Dow's proposed re-registration of the insecticides chlorpyrifos, diazinon and malathion. The Biological Opinion had "concluded that the insecticides will destroy or harm Pacific salmonids and their habitat."[8] Dow and other plaintiffs holding the registrations for these insecticides challenged the Biological Opinion before US EPA's final decision on the re-registration.

Known as "jeopardy opinions" because the consulting wildlife agency has found that the proposed action will cause jeopardy to the species or its critical habitat, the

[8] 638 F. Supp. 2d 508, (D. Md. 2009).

obligation to enforce the conditions prescribed in the Biological Opinion are implemented by US EPA, as the action or lead agency, not the National Marine Fisheries Service. The district court in *Dow Agrosciences LLC* held that the Biological Opinion was itself not reviewable until and unless it was implemented in a final decision by US EPA concerning the re-registrations.

On appeal, the Fourth Circuit reversed, holding that the Biological Opinion was itself independently reviewable because it was a final agency action by the National Marine Fisheries Service. The court ruled that no other adequate remedy for judicial review of the Biological Opinion was available; and that its provisions had "immediate and independent legal consequences that could not be changed on later review of EPA's action on the registration" (*Id.* at 12). Moreover, actions by private persons taken in violation of the "safe harbor" provisions of the Biological Opinion could give rise to independent civil and criminal enforcement for violations of the ESA by the Fish and Wildlife Service or National Marine Fisheries Service, as well as exposure to the citizen suit provision in the ESA.[9] The ruling on appeal was consistent with the Supreme Court's holding in *Bennett v. Spear,* 520 U.S. 154 (1997). The case was remanded to the district court.

Similarly, in *San Luis Delta Mendota Water Authority v. Salazar,* 2011 U.S. App. LEXIS 6203 (9th Cir. 2011), the court considered whether a Biological Opinion stating that the reasonable and prudent alternative to insulate projects from an incidental take of the Delta smelt during critical times of the year was appealable even though no actions had yet been taken to enforce the actual opinion. The Ninth Circuit ruled that the growers, who received water through canals, had a sufficient injury because the Biological Opinion for the Delta smelt resulted in reduced water deliveries to the growers. Despite the plaintiff's allegations, the court found that the growers did not have to demonstrate threat of imminent enforcement under the ESA before bringing their appeal. Although it was a pre-enforcement challenge, the growers would suffer hardship if the court withheld consideration because of the Department of Interior's power to enforce the ESA "imposes a significant practicable harm upon" the growers.

Both cases indicate that the courts are willing to review and hear appeals of Biological Opinions for endangered species that may restrict activities before permit issuance, commencement of activities or enforcement pursuant to the ESA.

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Legal Issues Responding to the Marcellus Shale Gas Drilling Boom

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Shale gas exploration and development techniques have existed for decades.[10] However, shale gas has been a largely untapped fuel reserve due to the expense and operation necessary to retrieve the gas from the deep sedimentary rock thousands of feet under the earth's surface.[11] Its production is more expensive than coal and generally considered not as clean as nuclear or renewable fuels. However, concerns regarding limited oil reserves, skyrocketing prices and dependency on foreign oil along with the expense and pace for renewable energy development (not to mention the recent attention to nuclear issues), created the "perfect storm" for significantly increased consideration of shale gas as a viable fuel source – in fact, fervor and excitement are certainly

[9] 16 U.S.C. Sec. 1540(g).

[10] Shale gas is developed by horizontal well drilling and hydraulic fracturing techniques. Typically, this is performed where a rig drills a vertical hole several thousand feet deep to the layer of shale. Pressurized water, combined with sand and fracking chemicals, are blasted down the well creating shale fractures. Shale gas is then produced from the fractures where the liquids are forced back up the well.

[11] Shale gas formations exist throughout the world. In the United States, larger formations exist in Louisiana, Texas, Oklahoma and the "Marcellus shale" formation that spans from Pennsylvania and New York to West Virginia.

developing. In 2000, shale gas constituted only 1 percent of the natural gas supply in the United States. By contrast, based upon what some have referred to as the Marcellus Shale gas drilling "boom" in just the last few years, shale gas now constitutes approximately 25 percent of the natural gas supply in this country.

Legal Issues That Arise in Shale Gas Drilling and Development

With this boom of activity, a myriad of new legal issues have arisen in response. Landowners (lessors) and gas companies (lessees) are seeking counsel in lease negotiations where issues range from geographic scope and time period for drilling, to royalty payments and pooling clauses. Drilling permits, zoning, land use and local government approvals, water withdrawal registrations, wetlands and jurisdictional waters permits, pipeline and right-of-way acquisitions, sediment control plans, endangered species issues, wastewater management and disposal plans, and many other permitting, approvals and authorizations also arise in shale gas development activities.

In addition, recent disputes have arisen with respect to road damage and noise attributed to the rigs and machinery used on the country roads in the gas development areas, triggering litigation and claims filed against municipalities, state transportation departments and others. Thus, heavy hauling maintenance agreements, weight restricted roads and other transportation issues arise in connection with shale gas transportation as well.

Environmental activism and attention have increased, too. Environmental groups are concerned about possible well explosions, air emissions, underground and cement casing failures, surface spills, groundwater contamination and water withdrawal impacts. Environmental groups argue that the volume of water and chemicals that must be used to extract oil and gas from deep wells in the Marcellus and Utica shale formations without more regulatory oversight is a concern. These groups have recently lobbied state legislatures for moratoriums to withhold approval of well permits involving high volume, horizontal hydraulic fracturing, exploration, or extraction until such time as drilling practices are more regulated from an environmental standpoint.

Indeed, some states in the Marcellus shale formation have responded with legislative and regulatory initiatives. New York, for example, issued a moratorium on the issuance of new drilling permits while regulations are being drafted for high-volume hydraulic fracking. Lawmakers in West Virginia and Ohio have called for the same, although a moratorium is not yet in place. In 2010, with the passage of Senate Bill 165, the Ohio General Assembly passed the first update of Ohio's oil and gas drilling laws in more than 40 years, amending several provisions in Ohio Revised Code Chapter 1509. In both West Virginia and Ohio, discussions are underway regarding new regulations, and both states are investigating the processes used to extract gas in Marcellus shale while still allowing wells to be drilled. As of March 2011, the West Virginia Legislature had not agreed on bills regulating Marcellus shale drilling.

Pennsylvania has also been very busy in its legislative and regulatory efforts. Several new shale gas bills were introduced in the Pennsylvania Legislature this year. One bill, "The Fracturing Responsibility and Awareness of Chemicals Act," would mandate disclosure of chemicals being used by drilling companies. Another bill is titled "The Marcellus Shale on the Job Training Act of 2010," and a third bill calls for new regulations that would require drilling companies to fund programs dealing with any drilling accidents that might occur. Other bills introduced in the Pennsylvania House of Representatives propose to impose a tax on natural gas extraction, with some exemptions for wells with low production rates. Pennsylvania also adopted regulations in June 2010 to limit pollutants in drilling wastewater.

Legal issues will continue as the rapid pace of Marcellus shale gas drilling moves forward. As legislative and regulatory initiatives continue to develop and environmental activism and litigation increase in the shale gas arena, it is clear that legal questions will not go away any time soon.

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FY 2011 Budget Results in Significant Cuts to US EPA's Funding but Not Its Ability to Regulate GHGs

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The Democrat-controlled Senate and the Republican majority in the House reached an eleventh hour agreement on the fiscal year (FY) 2011 federal budget on April 8, narrowly avoiding a government shutdown. The budget deal, which was finalized as Public Law 112-10 on April 15, cuts overall federal spending by US$38.5 billion. These cuts include a nearly US$1.6 billion budget reduction for US EPA compared to FY 2010 levels. The cut is US$900 million more than Senate Democrats proposed in their spending measure, but far less than the US$3 billion called for in the funding bill passed by House Republicans in mid-February.

US$997 million of the spending cuts are slated to come at the expense of US EPA's clean water and drinking water state revolving funds (SRFs), which provide grant and loan assistance for water infrastructure projects carried out by states. The budget agreement will also add to previously imposed cuts to state and tribal assistance grant (STAG) accounts, dropping the aid for implementation of state and tribal compliance and enforcement programs from US$4.97 billion to US$3.76 billion. In addition, funds for US EPA's Programs & Management Account will be cut by US$232 million while US EPA's Science & Technology Account will be reduced by US$31 million.

The final agreement does not include any of the House Republicans' proposed riders to limit US EPA's greenhouse gas (GHG) permitting authority. Efforts to delay or strip US EPA of authority to regulate GHG emissions suffered a setback in a series of Senate votes on pending small business legislation during the lead-up to the budget agreement. Senate Minority Leader Mitch McConnell's (R-KY) proposal to permanently block US EPA from regulating GHG emissions was able to garner only 50 votes in the Senate, well short of the 60 votes needed for approval. By a much wider margin, the more moderate proposals of several Senate Democrats to delay or curtail US EPA's GHG permitting authority also failed to gain Senate approval. Nevertheless, House Republicans were able to include an appropriation rider that eliminates White House czar positions, including the climate change advisor's position previously held by Carol Browner.

Republicans plan to revisit these appropriation riders to limit US EPA's authority to regulate GHG emissions when Congress begins crafting the FY 2012 budget bill. Indeed, House Budget Committee Chairman Paul Ryan (R-WI) initiated this process with the introduction of House Republicans' proposed FY 2012 budget plan, entitled "The Path to Prosperity," on April 5, 2011. Ryan's plan seeks to pare back nondefense discretionary funding to FY 2008 levels and is sure to include additional slashes to US EPA's budget once the House Budget Committee markup of the bill is complete. Congress must pass another spending measure before the expiration of the FY 2011 budget deal, which runs through September.

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Supreme Court Wary of Federal Common Law Remedy for Global Climate Change

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Oral argument was held on April 19, 2011 in *American Electric Power Co., Inc. v. Connecticut*, Case No. 10-174, a case that has the potential to define the judiciary's role in the regulation of climate change.

In *American Electric Power*, the plaintiffs sought to enjoin greenhouse gas emissions from six electric power corporations on the grounds that their emissions were contributing to global climate change and, as a result, causing a public nuisance. The plaintiffs' claims were dismissed by the Southern District of New York on political question grounds but reinstated by the Second Circuit. The court of appeals, which not only rejected the political question doctrine as a bar to suit, but also addressed two other potential grounds for dismissal, finding the plaintiffs

had standing and that the Clean Air Act did not preempt the plaintiffs' claims.

Now on *certiorari*, the Supreme Court has the opportunity to resolve several key issues that will determine whether public nuisance law is a viable basis for regulating greenhouse gas emissions, including whether there is a federal common law of public nuisance to address greenhouse gas emissions in light of the Clean Air Act, whether the effects of global climate change can be "fairly traced" to any individual emitter of greenhouse gases to satisfy Constitutional standing, and whether judicial action capping a defendant's greenhouse gas specific emissions is capable of redressing the effects of global climate change.

While several justices, including Justice Alito and Justice Roberts, questioned whether adequate standards are available for judges to adjudicate nuisance claims alleging global climate change, the issue that drew the most attention from the Court was whether US EPA's regulatory efforts have displaced the federal common law of public nuisance for greenhouse gas emissions. Justice Ginsburg noted that the relief requested would set a district judge up as "a kind of super EPA," while Justice Kagan questioned whether the balancing of benefits and harms requested was "the paradigmatic thing that agencies do rather than courts." Justices Breyer and Scalia also questioned the implications of allowing a federal common law suit to continue, both in terms of the power of the judiciary to regulate greenhouse gas emissions and the reasonableness of doing so in light of pending US EPA regulation.

Since the Second Circuit's decision in September 2009, US EPA has taken several steps to implement greenhouse gas regulations, including issuance of its tailoring rule last June and entry of two settlement agreements this past December requiring US EPA to promulgate greenhouse gas regulations for electric generating units and refineries by 2012. While the defendants contend that these steps show that US EPA has occupied the field of greenhouse gas regulation, the plaintiffs contend only that they indicate that US EPA may do so in the future. In either case, however, the Supreme Court is faced with a very different legal landscape than that which was before the Second Circuit. In the end, this may provide the Court with a basis for resolving the current appeal without wading into broader standing and political question issues.

Another case involving whether plaintiffs have standing to sue for injuries caused by global climate change, *Native Village of Kivalina v. ExxonMobil Corporation et al.*, No. 09-17490 (9th Cir. November 6, 2009) is now before the Ninth Circuit but has been stayed until at least June 15, 2011 and in light of the Supreme Court's pending decision in *American Electric Power.*

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President Obama's Executive Order Regarding Improving Regulation and Regulatory Review

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On January 18, 2011 President Obama announced the issuance of Executive Order 13563, "Improving Regulation and Regulatory Review," which outlines the Administration's principles to improve regulation and requires all federal agencies to conduct a "retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome and to modify, streamline, expand, or repeal them in accordance with what has been learned."[12] Executive Order 13563 is essentially a restatement of Executive Order 12866 issued by President Clinton in 1993 and includes requirements that were part of the 1980 Regulatory Flexibility Act but were never fully implemented in earnest.

Executive Order 12866 requires that each agency:

1. Propose or adopt a regulation only upon a reasoned determination that its benefits justify its

[12] Regulation and Regulatory Review; Improvement (EO 13563), 76 Fed. Reg. 3821 (January 21, 2011).

costs (recognizing that some benefits and costs are difficult to quantify);

2. Tailor its regulations to impost the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations;

3. Select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

4. To the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and

5. Identify and assess incentives to encourage the desired behavior, such as use fees or marketable permits, or provide information upon which choices can be made by the public.

Executive Order 13563 reaffirms these principles and further requires that regulations be adopted through a process that involves public participation, that will require:

- Greater coordination across agencies to reduce redundant, inconsistent or overlapping requirements;
- Agencies to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and
- Agencies to ensure the objectivity of any scientific and technological information and processes used to support the agencies' regulatory actions.

Finally, Executive Order 13563 requires all federal agencies to develop and submit a preliminary plan documenting that agency's plan to periodically review its existing significant regulations within 120 days of the order to eliminate the objectives outlined above.

In response to Executive Order 13563, US EPA issued a request for public input on its plan for periodic review of its significant regulations.[13] US EPA held a series of listening sessions and town hall meetings and accepted written comments through April 4, 2011.[14] Shortly after Executive Order 13563 was issued, the National Association of Manufacturers and other trade groups began calling for US EPA's recent GHG-related rulemakings to be included in the agency's review. US EPA responded in a press release, however, that it was confident its GHG regulations would "pass muster under the sensible standards the President has laid out." US EPA is currently reviewing comments received and expects to submit a draft preliminary plan to the Office of Management and Budget's Office of Information and Regulatory Affairs shortly.

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REACH Update

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The European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals[15] (REACH) regulation took effect on June 1, 2007. REACH regulates the chemical substances used in products throughout the EU. Under REACH, producers and importers of goods must comply with its communication and registration requirements for the chemicals contained in their products and with any restrictions on the use of specific chemicals. The year 2010 has been vital in achieving REACH's aims of protecting health and the environment. Industries have met REACH's challenges by submitting nearly 2,500 dossiers by the first registration deadline of November 2010.

To ensure the safe use of products, companies affected by REACH must now provide consumers with updated safety

[13] Improving EPA Regulation; Request for Comment; Notice of Public Meeting, 76 Fed. Reg. 9988 (February 23, 2011).
[14] Extension of Comment Period: EPA's Plan for Retrospective Review Under Executive Order 13563, 76 Fed. Reg. 14840 (March 18, 2011).
[15] Regulation (EC) No. 907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, OJ 2006, L 396, pp. 1-849.

data sheets and inform them of exposure scenarios. Failure to register products under REACH may lead to companies receiving the ultimate sanction – loss of the EU market. REACH impacts all sectors and not just chemical importers/manufacturer. It affects all products containing the chemicals REACH regulates.

Beginning on January 3, 2011, industries must identify substances for the classification and labeling (C&L) inventory. The European Chemicals Agency (ECHA) has already received 3.1 million C&L notifications covering more than 100,000 substances that are hazardous or subject to REACH registration. This is a legal obligation, and companies must comply or face action from the national enforcement authorities.

REACH and C&L are well under way, but there are some additional areas to watch in the coming months.

Intermediates

The revised REACH guidance on intermediates is likely to have a significant impact on small and medium-sized enterprises (SMEs) and the fine chemicals sector. Intermediates handled under strictly controlled conditions have reduced information requirements under REACH. Last year, the regulators decided both to revisit the definition of intermediates under REACH and to clarify what constitutes strict control. The updated REACH guidance on intermediates was published in December 2010.

However, many trade organizations believe that the costs for either updating an intermediate dossier or investing in modifications to the installation in line with the new guidance will not be a viable option for many companies, especially SMEs.

Additionally, under the updated REACH guidance, hazard data cannot be used as part of a containment strategy and the use of local exhaust ventilation is considerably restricted. The removal of these two approaches significantly reduces the implementation flexibility of "strictly controlled conditions." As a result, both non-hazardous and hazardous substances will often be treated in the same way when they are used as intermediates under strictly controlled conditions.

The sector is also concerned that the updated guidance will mean additional data will be needed to update REACH registration dossiers. This additional information, combined with a requirement for a detailed description of the applied strictly controlled conditions, appears beyond the requirements of the original REACH legal text.

Downstream users will also have to re-examine if their intermediates still fall under strictly controlled conditions as defined in the updated REACH guidance.

Extended Safety Data Sheets

Additionally, many of the substances registered in 2010 were classified as substances of very high concern (SVHCs), so companies in the supply chain must also now provide their customers with updated safety data sheets (SDSs). For hazardous substances produced in volumes of 10 tons a year or more, exposure scenarios must also now be attached to the SDS. Exposure scenarios should include the uses and activities covered, and the operating conditions and risk management measures required to ensure safe use in a particular scenario. Unfortunately, the sector has dealt with exposure scenarios using a variety of formats, so downstream users can expect to see a range of documents, which adds to the complexity.

Dossier Updates

Although the deadline for 2010 registration has passed, REACH registrants still need to update and manage their dossiers. Article 22 of REACH specifies that registrants are expected to update:

- New uses;
- New hazard/exposure information;
- Changes in classification and labeling;
- Chemical safety report changes, such as exposure scenarios;
- The legal entity status following a merger or acquisition or following the appointments or change of representatives; or
- The composition of the substance if it changes significantly.

There is no time limit identified for incorporating these updates; however, prompt updating is expected so the lead registrant should put procedures in place to monitor the areas that may change and budget accordingly.

Downstream User/Intermediates

Hundreds of substances registered in 2010 as intermediates are actually used as non-intermediates by downstream users. Using substances registered as intermediates in non-intermediate applications will still be lawful provided volumes do not exceed the 1,000 ton per year threshold. However, downstream users should re-check the registration status of all their substances and check tonnage use where appropriate. This issue is likely to impact most chemical formulators such as detergent makers, paint manufacturers, construction chemicals manufacturers and adhesive companies.

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Environmental, Safety & Health

In today's global economy, environmental issues know no boundaries – forcing companies across the globe to pay close attention to ongoing compliance issues and be prepared when a crisis or regulatory action surfaces. Whether it is the need of counsel pertaining to a compliance matter, an industrial accident, a proposed regulation or allegations of environmental violations, Squire Sanders is ready to assist companies in a range of industries including aerospace, automotive, biotechnology, mining, iron and steel, pulp and paper, chemical and waste management in navigating the maze of complex regulations that affect multinational business operations. We offer the full range of services to corporations with business operations and investment interests in the European Union, Russia, Asia, the Middle East and the Americas.

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