

About This Issue

This issue of the *International Law Report* highlights the European Union's proposed new chemicals legislation and its impact on U.S. companies, recent developments in the U.S. Government's immigration policies, and export control issues relating to Libya and Syria.

In This Issue:

- **European Update:**
 - The Proposed EU REACH Legislation
- **Immigration Update:**
 - Update on Visas and Green Cards
- **Export Update:**
 - Developments in Export Controls

■ Editorial Contact

If you have questions, comments or ideas about articles in the *ILR*, please contact the editor:

William T. O'Brien
202.496.7107

EUROPEAN UPDATE

▶ How Far Does the Proposed EU REACH Legislation "Reach"?

The most important piece of chemicals legislation in the European Union since 1981, the EU's recent [REACH proposal](#) will impact numerous industries across a geographic area that stretches beyond the borders of the EU. REACH (**R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals) directly addresses EU chemical manufacturers and importers, EU users of chemical substances, and EU manufacturers and importers of finished articles. In terms of geographic coverage, although only applicable in the EU, REACH must be taken into account by any industry whose production or marketing strategy involves EU territory, even if temporarily or partially.

In terms of actual direct obligations, the proposed Regulation can be divided into three main "streams": First, data gathering and data reporting are addressed by its Registration and Evaluation stages. Second, the imposition of actual manufacturing, marketing and use restrictions takes place under its Authorisation and Restrictions stages. Third, the Regulation also addresses the relationship between the different levels in the supply chain, and sets up a system of responsibility for downstream or upstream uses.

Registration

The "Registration" stage requires each EU manufacturer or EU importer of chemical substances in yearly quantities of 1 tonne or more to submit a technical dossier to

the newly created European Chemicals Agency. A Chemical Safety Report, containing the risk assessment for the intended uses, must accompany the technical dossier for substances produced or imported in yearly quantities of 10 tonnes or more. Manufacturing or importation may commence three weeks after the registration date if there is no request for further information or there is no rejection decision.

Certain substances covered by more specific legislation are exempted from registration, such as substances used in pharmaceuticals, food and feed additives or pesticide active substances. Notably absent are substances used in food contact materials, which must be registered just like any other chemical substance. Polymers are also exempted from registration.

The registration obligation is also imposed on companies marketing or importing finished articles. Mainly, dangerous substances contained in articles must be registered if, among other conditions, they are intended to be released from the articles under normal and reasonably foreseeable conditions of use, and such release presents a risk to human health or the environment.

Evaluation

The "Evaluation" stage is built into the system to allow a substantial review of the information that becomes available through registration, or to impose data requirements on an ad hoc basis. The "dossier evaluation" allows the competent authority of the Member State of manufacturing or importation to assess the registration dossier. The "substance" evaluation allows the Member State's Competent Authority (CA) to require industry to provide any relevant information in case it believes there is a risk to human health or the environment.

Authorisation

"Authorisation" is the third substantial stage of REACH. Unlike registration, which is directed at manufacturing and import, authorisation is necessary prior to the use and marketing of a substance. Authorisation covers all substances, whether or not they have been registered or evaluated. The groups of substances eligible for authorisation are those meeting the criteria for classification as category 1 and 2 CMRs, PBTs, vPvBs or other substances that are identified as causing serious and irreversible effects to humans or the environment (such as those having endocrine disrupting properties). The actual substances that will require authorisation will be decided upon by the European Commission.

The authorisation must be granted if the applicant proves that the risks posed by the substance in question are adequately controlled. Alternatively, it may be granted (but is not mandatory) if the applicant proves that the socio-economic benefits outweigh the risk to human health and/or the environment arising from the use of the substance, and if there are no suitable alternative substances or technologies. Therefore, suitable alternative substances or technologies pre-empt the granting of an authorisation on socio-economic grounds, but they are not relevant if the authorisation is granted on the basis of adequate control of risks.

Specific substances whose uses are strictly regulated under other EU legislation are exempted from authorisation, meaning that they can be used without the need to obtain an authorisation. This is the case, for example, of R&D substances, pesticides, pharmaceuticals, or food and feed additives.

Restrictions

“Restrictions” can be imposed on the manufacturing, marketing, or use of chemicals, when there is an unacceptable risk to human health or the environment which needs to be addressed on a Community-wide basis. These provisions do not address companies directly, but rather impose obligations on the CAs and Community institutions. Companies, of course, must comply with the prescribed restrictions, but they are not required to submit information or participate in the process.

Regulating the Supply Chain

Finally, the proposed REACH legislation also seeks to regulate the relationship in the supply chain. So-called “downstream users” (a novel concept in EU chemicals legislation) have specific obligations that center around performing and providing a risk assessment for their specific uses if such risk assessment is not provided by their upstream supplier. They must also ensure that relevant information is transmitted up and down the supply chain. Although the Material Safety Data Sheet remains the main tool for the transmission of information through the supply chain, it must be accompanied by the results of the Chemical Safety Report for substances above 10 tonnes.

Impact on U.S. Companies

U.S. companies are directly affected by REACH in several ways. U.S. companies exporting chemical substances into the EU must communicate with their importers, who will be responsible for the registration of such substances with the European Chemicals Agency. They may choose an “only representative” who would cover several importers and would communicate all confidential substance information directly to the Agency. In addition to data reporting, such companies must also meet their responsibility towards downstream users in the supply chain and comply with any restrictions on manufacturing or use.

U.S. companies exporting finished articles into the EU must provide information on the possible releases of substances. If releases of dangerous substances that present a risk to human health or the environment occur, such substances must be registered with the European Chemicals Agency. They must also comply with any restrictions on manufacturing or use of substances.

U.S. companies importing substances or finished articles from the EU will be indirectly affected, since the costs of REACH will be mirrored by the cost of the resulting products.

Finally, any EU-based affiliate or subsidiary of a U.S. company will be directly affected, since it will be considered an EU manufacturer, user, or importer and the obligations described above will apply directly.

The proposal for the REACH Regulation was put forward by the European Commission in October 2003. It is currently being considered by the European Parliament and the Council of the European Union. Because adoption is not expected before 2006, there are still ample opportunities for changes to the current text and for interested companies to make their voices heard.

The REACH proposal can be found at http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html.

Ruxandra Cana
Brussels

[↗ Back to top](#)

IMMIGRATION UPDATE

▶ Visa Revalidation

The State Department will cease to process visa revalidation applications after July 16, 2004, but will continue to process applications filed before that date, even where they have requested additional evidence. The State Department has taken this action because it does not have the capacity to acquire the biometric identifiers that visas will be required to contain.

This is likely to pose an inconvenience to many employees who are accustomed to being able to revalidate extensions of visas. Presumably, this development will also cause delays at the consulates since individuals who would have applied for revalidation through the State Department will now be forced to apply at consulates for renewal visas. The State Department has indicated that, "in order to mitigate the inconvenience to applicants, we will direct all visa adjudicating posts to accommodate on a priority basis applicants who would have benefited from our visa reissuance services." Consulates in Mexico and Canada will also have some capacity to process visa applications. However, it remains to be seen how this will be implemented.

Please note that this change does not affect an employee's ability to work in the U.S., but it definitely makes travel - both for pleasure and work reasons - more difficult.

▶ PERM

In 2002, the Department of Labor proposed a regulation, the Program Electronic Review Management System (PERM), that will make it much more difficult, if not impossible, for many foreign nationals to obtain permanent residency ("green cards"). While it was recently reported that PERM would be published in September 2004, all indications are that it may be slightly delayed. It will become effective 120 days after it is published. Businesses that wish to retain foreign national employees on their payroll should consider moving forward to sponsor their employees for green cards now, under the current rules, before the new regulation goes into effect.

▶ H-1B Cap Relief

Congress established a cap on the number of H-1B visas that CIS (U.S. Citizen and Immigration Services, formerly the Immigration and Naturalization Service) can approve each fiscal year. While the cap was raised, temporarily, for several years, that increased number expired on October 1, 2003, leaving only 65,000 new H-1Bs available for FY2004. As of April 1, 2004, CIS has accepted petitions for new H-1Bs, but will not provide start dates before October 1, 2004 (the beginning of the new

fiscal year). Legislation has now been introduced that would exempt foreign nationals who have obtained a Master's Degree, or higher, from the current H-1B cap. The degree must be from a U.S. university and the exemption would be capped at 20,000 annually. This legislation also incorporates limitations on L-1B status to prevent these employees from being placed at third-party worksites where they would not be supervised and controlled by the petitioning employer. Finally, the legislation would re-instate, and make permanent, the \$1,000 training fee and non-displacement and recruitment attestations for H-1B dependent employers, as well as impose a new \$500 "fraud detection and prevention fee" on H-1B and L-1B petitions. We caution that this legislation is preliminary and, even if enacted, would likely be modified from the original version.

Employers who are contemplating hiring H-1B employees should do so sooner rather than later, since it remains to be seen how many of the 65,000 H-1Bs for fiscal year 2005 will be taken before the fiscal year actually starts.

James D. Levine
Atlanta

[↗ Back to top](#)

EXPORT UPDATE

▶ Developments in Export Controls

Libya

Libya's new approach to the world community has prompted dramatic changes in U.S. Export Control policy regarding Libya. As a result of Libya's renunciation of terrorism and its efforts to dismantle its weapons of mass destruction and missile programs, on April 23, 2004 President Bush announced that the Iran and Libya Sanctions Act would no longer apply to Libya. Until now, Libya has been a part of the Anti-Terrorism Club - those countries which had been singled out for their support of terrorism - and thus effectively off-limits to U.S. exporters. The Treasury Department has also modified sanctions imposed on U.S. firms and individuals under the International Emergency Economic Powers Act to allow most commercial activities, financial transactions, and investments with Libya to resume. The U.S. has maintained sanctions against Libya since January 1986 through the Libyan Sanctions Regulations (31 CFR Part 550) and the Export Administration Regulations (15 CFR Part 730 et. seq.), with joint licensing responsibility shared between the Department of Commerce and the Department of the Treasury. The new policy established by this rule will require licenses issued by the Bureau of Industry and Security for the export or reexport of most items on the Commerce Control List.

Syria

The Syria Accountability and Lebanese Sovereignty Restoration Act of 2003 requires the President to impose sanctions against Syria if it continues to support terrorism and fails to take other required steps, such as the withdrawal of its troops from Lebanon. Having made a determination under the Act that such conditions exist, President Bush issued an Executive Order on May 11 banning most U.S. exports to Syria except food and medicine, and prohibiting the export to Syria of any items that appear on the United States Munitions List (arms and defense weapons, ammunition, etc.) or Commerce Control List (dual-use items such as chemicals, nuclear

technology, propulsion equipment, lasers, etc.). Additionally, the Executive Order restricts U.S. banking activity with Syria and freezes assets of certain Syrian citizens and entities.

John Liebman
Los Angeles

Michele Miranda
Washington, DC

[↗ Back to top](#)

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