The past year has been a period of important change and anticipation for the European Union and its Member States. Attempts to reach agreement on a new EU Constitution ended abruptly, raising significant concerns about the long-term viability of many of the proposed legal and political changes that were to occur in order to continue progress on the notion of a unified Europe. As of May 1, 2004, the pre-existing infrastructure of the EU was challenged with the accession of ten new states in the European Union as provided in the Accession Treaty signed on April 16, 2003. With the addition of Cyprus, the Czech Republic, Estonia, Hungary, Malta, Latvia, Lithuania, Poland, Slovakia and Slovenia, the EU now has twenty-five Member States and a total population in excess of 450 million.

This survey of recent developments in the EU touches on a number of areas important to professional legal advisors with clients or employers active in the EU, including corporate governance, regulation of competition and mergers, technology transfers, capital raising and industry-specific regulations. Not covered herein, yet no less important, are specific legal developments in each of the Member States.  

I. EU Constitution

One of the major events of 2003 was the attempt by leaders of the fifteen current members of the EU and the ten states acceding to the EU in May 2004 to negotiate and finalize a

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1. Information included herein has not been updated since December 31, 2003.
The draft constitution considered in meetings that began in early October 2003 in Rome was prepared by a 105-member Convention chaired by former French President Valéry Giscard d'Estaing. While the work of the Convention, which extended over sixteen months, resulted in a draft that was acceptable in many areas to all parties involved in the process, a number of contentious points remained unresolved as the Inter-Governmental Conference convened, including each of the following:

- The proposal that decisions outside of key policy areas such as taxation, foreign policy and defense must receive approval from at least fifty percent of the Member States that represented at least sixty percent of the total population of all Member States. This proposal was not popular with many smaller states that favored retaining the historical “weighted” system that allocated voting rights based on population size.
- The proposal that the number of full voting members of the European Commission be reduced to fifteen, which would mean that not all Member States would have their own voting commissioner at all times. This change raised concerns among many of the smaller states that are joining the EU in 2004.
- The creation of a new EU foreign minister, with responsibility for coordinating the common foreign and defense policies of the EU, raised questions about accountability to the Member States and allocation of foreign aid.
- The proposal that the European Council elect a president to serve for a period of two and one-half years, with the possibility of extension to five years, raised concerns from many of the smaller Member States that preferred the current system of rotating the presidency among all Member States every six months.

In addition, some Member States were disappointed that the draft constitution only made reference to the cultural and spiritual heritage of the EU and did not include any mention of God or Christianity. However, any changes in this area would certainly draw opposition from those Member States, such as France, that are strictly secular and would also raise issues in the future in the context of accession discussions with other states, such as Turkey, with substantial Muslim populations. In the defense area, certain Member States were concerned about the adoption of mutual assistance clauses.

After a month of extensive debate and negotiation, discussions fell apart in December 2003, and EU leaders departed Rome without an agreement on the new constitution or any definitive plans to resume talks. The main conflict remained the proposal for modifying the voting rights of the Member States. In particular, Poland and Spain were unwilling to agree to what they saw as a significant reduction in the voting rights that they would have enjoyed under an agreement reached in Nice several years ago. Their position was criticized by Germany and France, evidencing the deep divisions that between the larger and smaller members of the EU.

II. EU Takeover Directive

After over a decade of debate and negotiations, substantial progress was made in 2003 with respect to the proposed EU Takeover Directive. The Takeover Directive is an attempt to implement a comprehensive and consistent framework for takeovers that would apply...
throughout the EU. The Takeover Directive would establish general principles and requirements for the conduct of takeover bids that are intended to streamline the acquisition process within the EU and recognize the rights of shareholders with respect to approval of the offer terms and participation in such offers.

Earlier versions of the Takeover Directive included the following requirements:

- Persons that acquired control of a target company are required to make an offer to purchase the shares of all shareholders of the target company at an equitable price.
- Bidders that failed to offer liquid securities (i.e., securities that had been registered for trading in a regulated market) as consideration to shareholders of a target company must offer a cash alternative.
- The board of directors is prohibited from taking defensive measures (e.g., adoption of poison pills) upon receipt of a takeover bid unless such actions were authorized in advance by the shareholders of the target company in a general meeting that was called for that specific purpose.
- Any actions taken by the board of directors of a target company intended to frustrate a takeover bid would be unenforceable. Examples of prohibited actions, sometimes referred to as “breakthrough provisions,” include restrictions on voting rights and the authorization of securities with multiple voting rights at shareholders’ meetings to approve defensive measures as described above.

The last two restrictions created substantial controversy, and many felt these rules would increase the vulnerability of European companies to unwanted takeovers by companies based outside of the EU. Some of the Member States, as well as lobbying groups for a number of industries, argued that the Commission’s proposals were contrary to accepted business practices and historical legal precedents.

In an effort to break the impasse and move the Takeover Directive forward, the Member States reached a compromise in late 2003 that significantly dilutes the original proposals and reduces the chances for achieving a uniform set of rules and guidelines for takeovers within the EU. Under the agreement, which was not supported by the Commission, each Member State could elect not to impose the restrictions on unapproved defensive measures and/or breakthrough provisions on companies with registered offices in the Member State, although individual companies could still adopt the restrictions on their own. Also, even if a Member State does adopt the restrictions, it can grant relief from such restrictions to companies that are confronted with a bid from a company not subject to the same restrictions (i.e., a bidder from another Member State that has opted out). It is expected that this will place foreign bidders at a decided disadvantage when competing with offers from a bidder from the same Member State in which the target is registered.

The compromise was approved by the European Parliament in December 2003, and final approval from the Council of Ministers was expected to come in January 2004. According to this agreement, each of the Member States must implement the Directive by January 2006.

III. Reform of EU Merger Control Policies and Procedures

One of the most important recent developments in the EU is the extensive reform of the Commission's merger control policies and procedures. The stated goals and objectives of the changes include improving the transparency of the review decision process with respect
to mergers in the EU and enhancing the role that economic analysis plays in the assessment of the competitive effect of such transactions. The cornerstone of these reforms is a new Merger Control Regulation that will enter into force on May 1, 2004. In addition, substantial revisions to the Horizontal Merger Guidelines will go into effect as of that same date along with a comprehensive set of new procedural rules that will govern enforcement of competition law in the EU and, in particular, the conduct of investigations of proposed mergers.

A. NEW MERGER CONTROL REGULATION

One of the most important provisions in the new Merger Control Regulation is the introduction of revised substantive standards for evaluating the competitive effects of a proposed merger. Specifically, the Commission will assess whether a merger "would significantly impede effective competition." In making this assessment, the Commission would be required to take particular note of whether the merger would create or strengthen a dominant position; however, it will also be able to intervene in cases where the merger does not create a dominant player but the potential anti-competitive effects are nonetheless substantial. Of particular interest would be cases where the transaction led to or is to occur within a market that already is, a "non-collusive oligopoly," since one or more of the firms in that situation may hold the economic power to appreciably influence one or more important parameters of competition (such as prices, production, quality of output, distribution or innovation). In turn, the new standard would provide the Commission a clearer opportunity to consider factors such as any efficiencies brought about by the merger in the course of its assessment, even in cases where a dominant position is created or strengthened.

Another important objective of the new Merger Control Regulation was to clarify jurisdictional issues and ease the burden previously imposed on merging parties to make multiple national filings with respect to a proposed transaction. Under the prior version of the Merger Control Regulation, jurisdiction of the Commission was determined by whether or not the concentration had a "Community dimension," which was based on the application of several tests based on the turnover of the parties to the transaction. As to concentrations that had a Community dimension, the Commission had the exclusive jurisdiction with respect to review. On the other hand, concentrations that did not have a Community dimension were not subject to filing with the Commission; however, the parties would nonetheless be required to spend substantial time and resources complying with the pre-merger notification requirements of one or more of the Member States.

In order to reduce the notice requirements that might be imposed on concentrations that did not otherwise qualify for the exclusive jurisdiction of the Commission, it was originally proposed that the Commission have exclusive jurisdiction over a transaction without Community dimension when a referral request had been accepted by at least three Member States. However, under the version of the new Merger Control Regulation that is to go into effect, any Member State can prevent the Commission from assuming exclusive jurisdiction by opposing a referral request. While this will certainly reduce the anticipated benefits of the new system and increase the likelihood that parties to a transaction will remain subject to review in several Member States, the rules do allow the parties to request the use of the referral system at the pre-notification stage and impose shorter deadlines on the Commission and each Member State to decide as to requesting, granting or accepting a referral.
Among the other provisions of practical interest in the new Merger Control Regulation are the following:

- The "standstill obligation," which prohibits the parties from implementing a merger without approval from the Commission, remains in effect; however, parties can apply for an individual exemption from this obligation. It is hoped that the Commission will, through publication of a notice, ease the exemption process for transactions that would be reviewed under the simplified procedures (e.g., no affected markets).
- Parties will be permitted to notify mergers before a binding agreement is executed, provided that they can demonstrate (e.g., through a letter of intent or an agreement in principle) a good faith intent to conclude an agreement. Early notification allows the parties to reduce or eliminate concerns about the impact of the merger controls before further time and effort are spent on finalizing an agreement.
- The merger investigation deadlines for complex cases (e.g., cases where remedies are being considered or an in-depth (Phase II) investigation is launched) have been extended in order to reduce some of the pressures that existed under the old system. In particular, if remedies are proposed, the Phase I and Phase II deadlines will each be automatically extended by ten and fifteen working days, respectively. In addition, if agreed by each of the Commission and the merging parties, a further extension of twenty working dates will be available in Phase II cases.
- The potential fines imposed by the Commission with respect to any failure to provide sufficient or correct information in the course of its fact finding efforts have been substantially increased and the investigatory powers of the Commission have been broadened.

B. Best Practice Guidelines

The procedural changes described above with respect to investigations will be supplemented by the Commission's newly-promulgated Best Practice Guidelines. In particular, these Guidelines, which formalize a number of the recent changes made by the Commission to improve the due process for parties during each of the stages of review for a proposed transaction, include the following:

- Formal guidance regarding the timing and scope of the disclosures that parties should make when taking advantage of pre-notification procedures.
- Allowing the parties regular access to the main third-party submissions throughout the course of any investigation, as well as providing that the information in the Commission's files must be made available soon after the commencement of a Phase II investigation rather than when the statement of objections is issued.
- Providing for "clear-the-air" meetings during the investigation process that would allow the parties to interact directly with third parties regarding concerns raised about the proposed merger.
- Implementing a regular process for convening "state-of-play" meetings between the parties and senior officials from the Commission during the course of an investigation to update the parties on the progress of the investigation and provide an opportunity for the parties to discuss the case directly with the investigating team.

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C. Revision of Horizontal Merger Guidelines

Another important development relating to the assessment of proposed merger transactions is the substantial revision of the Horizontal Merger Guidelines by the Commission set to take effect as of May 1, 2004, the same date as the new Merger Control Regulation. These Guidelines were developed by the Commission to provide guidance as to how the Commission evaluates concentrations between firms that are active sellers in the same relevant market or concentrations between firms that may be potential competitors in such a market. The revised Guidelines provide an explanation of the circumstances under which a proposed horizontal merger may create or strengthen a dominant position and then describes certain key factors that the Commission intends to take into account in determining if the proposed transfer will actually be a significant impediment to effective competition in the relevant market.

The new Horizontal Merger Guidelines identify three main types of transactions that are likely to create or strengthen a dominant position:

- A proposed merger that will create a combined firm that will have a very large market share (i.e., more than 50 percent) and a significant market share advantage over rival firms. This is the classic dominant position situation and would appear in situations in which there is a monopoly or near monopoly.
- A proposed merger will lead to a “non-collusive oligopoly,” which is explained above in the context of the new EU Merger Control Regulations. In this case, the analysis proposed under the Guidelines will vary based on the type of market. For example, if the products are relatively homogeneous, regulators will evaluate the possibility that the merger entity will reduce its output in order to drive up the price level and look to assess the likelihood that rival firms will expand their output to stabilize prices.
- A proposed merger would lead to a “collusive oligopoly,” which would require the analysis that has traditionally been followed in the “collective dominance” cases such as in the Airtrous judgment by the Court of First Instance.

If it is determined that a proposed transaction may result in the creation or strengthening of a dominant position, the Commission must take into account the following potentially mitigating factors in evaluating whether the merger will significantly impede effective competition in the relevant market:

- A merger is less likely to significantly impede effective competition in situations where customers have the power to fend off price increases based on reductions in output by tapping alternative supply sources. For example, buyers may be able to purchase comparable goods through imports from outside the relevant market or may opt to meet their requirements through vertical integration.
- The absence of significant barriers to entry will also reduce the likelihood that a merger will significantly impede effective competition. With respect to this factor, consideration will be given to whether new entrants are likely to be able to achieve sufficient profitability in the post-merger situation to make it likely that they will opt to enter the market.
- Efficiencies, which must be demonstrated by the merging parties, may also be taken into account provided that they benefit consumers, are merger-specific, timely, and can be readily verified. Efficiencies are most important in the case of non-collusive oligopolies and likely will not be persuasive if the merger creates a monopoly case.
• A merger that creates or strengthens a dominant firm may be allowed in situations where the target company is a “failing firm,” a situation that is likely to exist when: (1) the target would otherwise be forced to exit the market in the near future; (2) there is no less anti-competitive alternative acquisition opportunity available to the target; and (3) the assets of the target would inevitably exit the market unless the transaction is allowed to go forward.

D. Administrative Reforms

The formal procedures and guidelines described above have been accompanied by various structural changes within the DG Competition. For example, commencing on May 1, 2004, the Merger Task Force will dissolve and all mergers will be handled by sectoral directorates of the DG Competition organized by industry. In fact, this process began in 2003 with the establishment of fully functioning merger review units to handle mergers in the information, communication and multimedia areas and in the services area. In addition, the DG Competition has supplemented its resources by recruiting additional economists who will participate in the assessment of cases.

IV. EU Competition Law Modernization Package

Another important development in the competition law area that will go into effect as of May 1, 2004 is the new rules relating to the enforcement of articles 81 and 82 of the EC Treaty. These rules, in the form of Regulation 1/2003, were actually approved by the Council at the end of 2002. In October 2003, the Commission promulgated the initial drafts of an implementing regulation and various notices in what is referred to generally as the “Modernization Package.”

In general, Regulation 1/2003 provides that parties seeking clearance or an individual exemption under article 81(3) of the EC Treaty will no longer be required to notify the agreement to the Commission. In addition, the National Competition Authorities (NCA) and national courts would be empowered and required to apply the competition rules of the Community in full, an initiative known as the “decentralization of competition law enforcement.” The overriding objective of these changes is to free the Commission to focus on cases that have a broader European dimension. For companies, the elimination of the notification procedures means that a greater premium will be placed on private legal analysis of the effect of the proposed transaction in light of the competition rules of the EU.

The Modernization Package establishes the rules that will apply to any remaining procedures that the Commission may conduct under articles 81 and 82 of the EC Treaty. The regulation addresses a wide range of matters, including the procedures for taking statements from witnesses, changes in the investigative powers of the Commission, access to files for the parties, the right to be heard, and the confidentiality of certain information developed and exchanged during the investigation process. In addition, the Package includes several notices dealing with the following issues:

• The procedures for lodging a complaint, including the requirement that processing of a complaint will only occur if the complainant has a legitimate interest in the alleged infringement and there is sufficient information in order to allow the Commission to launch an investigation.
• The procedures for requesting and obtaining non-formal guidance from the Commission; however, the Commission has made it clear that guidance letters will only be
issued in cases where the agreement or practice raises novel legal issues and the economic importance of the case is sufficiently material to warrant assessment by the Commission.

- The rules for allocation of cases within the NCAs, which will include the Commission and the NCAs, which will generally follow the principle that a case should be handled by the NCA that is most impacted by the facts of that case.

- The procedures to be followed by the national courts of each Member State to request guidance or information from the Commission, as well as the rights of the Commission and the NCAs to intervene in cases to make sure that the competition rules are being applied consistently by the national courts throughout the EU.

- The rules for determining when trade between the Member States is appreciably effected, in which case the competition rules of the EU will take precedence over any national rules. The notice provides that the determination of whether the effect is "appreciable" will depend on market shares, revenues, and the effect of other similar types of agreements.

- Further guidance on the application of article 81(3) of the EC Treaty which describes the burden of proof imposed on companies seeking to take advantage of the automatic exemption afforded by article 81(3). The guidance is to be read in conjunction with existing case law, block exemptions, and the guidelines relating to Vertical Restraints and on Horizontal Cooperation.

V. Proposed New Technology Transfer Block Exemption Regulation

The Commission published its initial proposal for a new EU Technology Transfer Block Exemption Regulation on October 1, 2003. The new Regulation will update and replace current Regulation 240/96 that sets out the competition rules with respect to the licensing of patents, know-how and copyrighted software. The proposal follows several changes that the Commission has embraced when developing the recently adopted changes to the guidelines relating to vertical and horizontal agreements. Specifically, going forward, the exemption would be based on market share thresholds and whether or not the parties have included certain restrictive provisions in the agreement.

The new safe harbor that was proposed in the initial draft of the proposed new Regulation would provide an exemption for license agreement between competitors with less than 20 percent combined market share or between non-competitors with each less than 30 percent market share. The Regulation would also include guidance on how the Commission will handle situations that fall outside of the specified safe harbor.

The availability of the safe harbor would be further conditioned upon the absence of certain provisions in the agreement. For example, when the agreement will be between competitors, the parties may not include restrictions relating to price fixing, market and customer allocation, output or the ability of the licensee to exploit its own technology or engage in research and development activities. A similar, albeit shorter list, would apply to agreements between non-competitors. These lists of per se restrictions are similar in effect to the "black lists" included in prior guidelines. The proposal also includes a "grey list" of various provisions which, if included, would not destroy the availability of the exemption but which would require a fuller assessment of the competitive effects of such provisions. Examples of these provisions include such things as "grantbank" and "no challenge" clauses and restrictions on innovative activities and output.
The new Regulation also includes guidelines for certain other technology transfer arrangements apart from licensing agreements. Notably, the Regulation includes guidelines for structuring multi-party technology pools, including the principles that will be used by the Commission to assess the competitive effect of such arrangements. However, the initial proposal has been criticized for its failure to deal with a number of issues that commonly arise in such situations, including sharing of information regarding patent positions, pricing, and other licensing terms that would normally be required in order to ensure compliance with standards.

VI. Commission Action Plan for Modernization of Company Law and Enhancement of Corporate Governance

Responding to recent events in the United States, including the corporate governance crisis created by Enron and other cases and the adoption of the Sarbanes-Oxley Act, the Commission presented a proposed Action Plan for "Modernising Company Law and Enhancing Corporate Governance in the EU" in May 2003. The Action Plan, issued in the form of a Commission Communication, is intended to serve as an outline of the approach that the Commission proposes to follow with respect to reforms in the areas of company law and corporate governance. The Communication is one of several recent initiatives by the Commission and was accompanied by the publication of a separate communication setting forth a proposed EU policy approach aimed at ensuring audit quality and public confidence in the audit profession.

In publishing the Communication, the Commission emphasized its belief that future actions at EU level in the area of company law should seek to enhance shareholder rights, clarify management responsibilities, and modernize the provisions related to the protection of creditors and foster efficiency and competitiveness of business. The Commission also noted that it is appropriate to make distinctions between categories of companies, with more stringent rules being applied to listed companies and companies that have publicly raised capital and a more flexible framework for SMEs.

In preparing the overall action plan, the Commission distinguished actions in three phases (short term, medium term, long term), based on priorities described in further detail in the Communication. For purposes of the Communication, "short-term" initiatives are to be completed in the 2003-2005 period, "medium-term" projects are to take place in the 2006-2008 period, and "long-term" activities would occur in 2009 and beyond.

One of the most important short-term objectives, which would be implemented by a Directive amending existing legislation, is the enhancement of corporate governance disclosures. Specifically, listed companies would be required to include in their annual report and accounts a coherent and descriptive statement covering the key elements of their corporate governance structure and practices, which should at least include the following items:

1. The operation of the shareholder meeting and its key powers, and the description of shareholder rights and how they can be exercised;
2. The composition and operation of the board and its committees;
3. The shareholders holding major holdings, and their voting and control rights as well as key agreements;
4. The other direct and indirect relationships between these major shareholders and the company;
5. Any material transactions with other related parties;
(6) The existence and nature of a risk management system; and
(7) A reference to a code on corporate governance, designated for use at national level, with which the company complies or in relation to which it explains deviations.

Another Directive to be proposed in the short-term would seek to create an integrated legal framework to facilitate efficient shareholder communication and decision-making (participation in meetings, exercise of voting rights, cross-border voting). For example, shareholders of listed companies would be provided with electronic facilities to access the relevant information in advance of General Meetings and shareholders of listed companies would be provided with enhanced rights to ask questions, table resolutions, vote in absentia, and participate in General Meetings via electronic means.

The Commission also intends to take action with regard to the board of directors. First, it is intended that a new Directive amending existing legislation be promulgated that would confirm the collective responsibility of board members for financial statements and key non-financial statements, including the annual corporate governance statement mentioned above. Second, in key areas where executive directors clearly have conflicts of interests (i.e., remuneration of directors, and supervision of the audit of the company's accounts), the Commission intends to recommend that such decisions in listed companies be made exclusively by non-executive or supervisory directors who are in the majority independent. In so doing, the Commission will define minimum standards applicable to the creation, composition and role of the nomination, remuneration and audit committees. The audit committee, in particular, will be given an essential role in supervising the audit function, both in its external aspects (external auditor selection and monitoring of the relationship between the company and the external auditor) and its internal aspects (review of accounting policies and monitoring the company's internal audit procedures and risk management system). Finally, the Commission will recommend what it considers to be an appropriate regime for directors remuneration, including disclosure of remuneration policy in the annual accounts, disclosure of details of remuneration of individual directors in the annual accounts, prior approval by the shareholder meeting of share and share option schemes in which directors participate, and proper recognition in the annual accounts of the costs of such schemes for the company.

Other short-term goals and objectives announced by the Commission include:

- Convening a European Corporate Governance Forum to co-ordinate corporate governance efforts of Member States;
- Simplification of the capital maintenance regime originally included in the Second Company Law Directive;
- Increased disclosure of group structure and relations, both financial and non-financial;
- Proposals for a Tenth Directive on cross-border mergers and a Fourteenth Directive on cross-border transfer of the seat; and
- A feasibility study on the practical needs for—and problems of—a European Private Company.

The medium-term objectives include additional corporate governance initiatives. For example, the Commission proposes a new Directive that would require institutional investors to disclose their investment policy and the voting rights policy of those companies in which they invest and to disclose to their beneficial holders at their request how these rights have been used in a particular case. In addition, the Commission is looking at promulgating a new Directive or a Directive amending existing legislation that would enhance the re-
sponsibilities of members of the board of directors, including shareholders' rights to ask a court or administrative authority to authorize a special investigation into the affairs of the company, wrongful trading rules that would impose personal accountability on directors of failed companies in certain instances, and directors' disqualification across the EU as a sanction for misleading financial and non-financial statements and other director misconduct.

Other medium-term objectives include the following:

- Examination of the consequences of an approach aiming at achieving a full shareholder democracy (one share/one vote), at least for listed companies;
- Review of the feasibility of an alternative to the capital maintenance regime not based on the concept of legal capital;
- Framework rule for groups, allowing the adoption at subsidiary level of a coordinated group policy;
- Prohibition of stock exchange listing for abusive pyramids, if appropriate, following further examination and expert input;
- Simplification of the Third Directive (mergers of public limited liability companies) and Sixth Directive (division of such companies) and creation of squeeze-out rights (for majority shareholders) and sell-out rights (for minority shareholders) for listed companies that meet or exceed certain thresholds;
- Possible proposal of a Statute for a European Private Company (depending on the outcome of the short term feasibility study);
- Assessment of the need for the creation of other EU legal forms (e.g. European Foundation); and
- Introduction of basic disclosure rules for all legal entities with limited liability, subject to further examination.

At this point, the sole long term action item is the possible introduction in the Second Company Law Directive of an alternative regime, depending on the outcome of the medium term feasibility study.

Initial comments on the Communication were due by August 31, 2003, and the Commission announced on November 21, 2003, that it had received indications of widespread support for a very large majority of the proposals from national administrations, industry representatives, institution investors and professional and financial service providers. Accordingly, the Commission indicated that it intended to move forward quickly with implementation of the Action Plan beginning with adoption of a proposal for a Directive on cross-border mergers. Other areas of immediate concern include simplification and modernization of current rules relating to capital maintenance and alteration, promotion of the role of non-executive or supervisory directors and reform of directors' remuneration schemes.

VII. EU Prospectus Directive

On December 31, 2003, the EU Prospectus Directive\(^2\) entered into force, which signifies an important step in creating a single, EU-wide regime for public offerings and listings of securities. The Prospectus Directive will require EU Member States to implement its pro-

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visions through regulation at the national level by July 1, 2005. It is anticipated that the Prospectus Directive will have significant consequences for issuers from outside the EU (non-EU issuers) and raise potential areas of concern for participants in European capital markets.

A. Financial Services Action Plan

The Prospectus Directive is a key component of the Commission's Financial Services Action Plan (FSAP), which aims to create a single market in financial services for the EU by 2005. The Prospectus Directive follows the so-called "Lamfalussy process," a four-level approach to harmonization of financial services regulation throughout the EU, that includes: (1) broad framework principles, and Commission implementing powers, set out in directives (Level 1); (2) measures implementing the directives adopted by the Commission with the prior approval of the European Securities Committee (comprised of high-ranking officials of Member State governments) or in certain cases by the Council of Ministers and based on the advice of the Committee of European Securities Regulators (CESR) (an advisory committee comprised of representatives of Member States' national regulators) (Level 2); (3) strengthened co-operation between the competent authorities of the Member States under the auspices of CESR to achieve a uniform application of EU regulation across the EU (Level 3); and (4) strengthened enforcement by the Commission to ensure Member State compliance with EU legislation (Level 4).

B. Overview of the Prospectus Directive

The Prospectus Directive will apply to offers to the public in the EU and admissions to trading on an EU regulated market of securities, and will introduce a single, enhanced regime within the EU to govern the content, format, approval and publication of prospectuses. It will provide for a "single-passport" regime under which prospectuses, once approved by the competent authority in the relevant Member State (Home Member State), can be used across all of the EU upon mere notification to the competent authorities in other Member States (Host Member States) in which the offer is extended or an admission to trading is made. Such authorities are not permitted to require inclusion of additional information in the prospectus relating to their domestic market.

The Prospectus Directive will not apply to non-equity securities of Member States, their local authorities and central banks, public international bodies of which they are members and the European Central Bank. It will, however, apply to non-EU sovereign and quasi-sovereign issuers, but it is expected that a reduced-disclosure regime will apply for such issuers.

In addition to the prospectus approval and publication requirements, the Prospectus Directive will require issuers to provide annually to the competent authority in their Home Member State a document that contains or refers to all information that the issuer has published or made available to the public over the preceding twelve months in Member States and in non-EU countries in compliance with its obligations under EU or third-country securities laws.

C. Offerings and Listings Subject to the Prospectus Directive

The Prospectus Directive imposes the obligation to publish a prospectus when making an "offer of securities to the public" or "seeking admission to trading on a regulated mar-
"Offer of securities to the public" is defined broadly in the Prospectus Directive as "a communication to persons in any form and by any means, presenting sufficient information on the terms of the offer and the securities to be offered, so as to enable an investor to decide to purchase or subscribe to these securities." "Regulated markets" will include the major EU stock exchanges, but also other markets where securities currently are yet not regarded as "admitted to official listing." Member States will each provide a list of regulated markets within their jurisdiction.

The Prospectus Directive contains exemptions from the obligation to publish a prospectus upon an offer of securities (but note that these exemptions are irrelevant in determining whether a prospectus needs to be published to obtain the admission to trading on an EU regulated market of the offered securities): (1) offers made to "qualified investors"; (2) private placements made to fewer than 100 persons (other than "qualified investors") in each Member State; (3) offers with a minimum total consideration per investor or specified denomination per unit of €50,000; and/or (4) offers of securities with a total consideration of less than €100,000 in any twelve-month period.

Any resale of securities offered in an exempt offer will be regarded as a separate offer that must itself be exempt or be made pursuant to a prospectus. Unlike in the United States, where "restricted" securities (that is, securities acquired from an issuer or an affiliate in a transaction other than a public offering) generally season after two years, the Prospectus Directive does not contemplate that these securities will ever "season" and become freely re-saleable in the secondary markets until and unless a prospectus covering these securities is approved and published. These restrictions, if confirmed by official guidance at a later stage, would be particularly important in a situation where the securities subject to an exempt offer are of a class of securities already admitted to trading on a regulated market, and benefit from an exemption from the obligation to publish a prospectus for their admission to trading (for instance, where they represent less than ten percent of the number of shares of the same class already admitted to trading on the relevant EU regulated market). As a result, it is currently unclear how the purchaser would be able to resell these securities on-exchange where the exchange operates as an anonymous dealers' market, which is generally the case in the European Union, where it is not possible to determine if the ultimate purchasers are qualified purchasers or if there are less than 100 of them in any Member State.

In addition to the exemptions described above, the Prospectus Directive contains a list of exemptions from the obligation to publish a prospectus upon a public offer or an admission to trading for conversion offers, takeovers, mergers, bonus issues, and employee and director stock ownership programs, subject in certain cases to alternative disclosure requirements, as well as for the admission to trading of less than ten percent of the number of shares of the same class already admitted to trading on the relevant EU regulated market.

D. Applicable Regulator for Non-EU Issuers

Under the Prospectus Directive, a single national regulator in the EU will have authority to approve all public offers and admissions to trading of Equity and Low-denomination Debt Securities (as defined below) of a given issuer following the implementation of the Prospectus Directive. For non-EU issuers, that regulator will be the competent authority of the Home Member State in which the issuer first makes (or made) an offer of such
securities to the public\(^3\) or applies (or applied) for the admission of such securities to trading after December 31, 2003.\(^4\)

"Equity and Low-denomination Debt Securities" includes: (1) equity securities; (2) convertible bonds (that is, debt securities convertible into equity securities of the same issuer); (3) exchangeable bonds (that is, debt securities convertible into equity securities of another issuer), but only where the issuer of the overlying debt security and the issuer of the underlying equity security are members of the same group; and (4) non-convertible or exchangeable debt securities issued in minimum denominations of less than €1,000 or its near-equivalent in another currency.

By contrast, for public offers and admissions to trading of securities of non-EU issuers other than Equity and Low-denomination Debt Securities, the non-EU issuer will remain free to select as their Home Member State, on an issue-by-issue basis, the Member State where the securities are to be admitted to trading on an EU regulated market or where the securities are offered to the public.

The Prospectus Directive confers upon non-EU issuers whose Equity and Low-denomination Debt Securities have already been admitted to trading on an EU regulated market the right to elect their Home Member State by notifying the competent authority of such Member State of their election by December 31, 2005. Officials of the Commission have shared with us, on a non-binding basis, their view that a non-EU issuer whose Equity and Low-denomination Debt Securities have already been admitted to trading on a EU regulated market should be able to notify the competent authority of any Member State in which it has, before December 31, 2003, made a public offer or an application for admission to trading. In the absence of textual support for this interpretation or formal, binding guidance, a non-EU issuer should, in our opinion, preferably, as soon as possible and if not yet done so after December 31, 2003, apply for a listing in the preferred Member State in combination with a notification to the competent authority of such Member State.

The "election" of a Home Member State will not become effective until the Prospectus Directive's implementation date; until then, a non-EU issuer can continue to file documents and obtain approvals for listings and offers of securities on an issue-by-issue basis and rely on current mutual recognition procedures in accordance with current practice.

\(^3\) What the term "offer to the public" means for this purpose is still unclear. Officials of the Commission have confirmed to us, on a non-binding basis, that before the implementation of the Directive the concept of public offer as defined in the existing securities laws of the relevant Member State should be applied for this purpose; accordingly, an offer that does not constitute an offer to the public under the securities laws currently existing in the Member State in which it is made should not constitute an offer to the public for purposes of "locking in" a non-EU issuer's Home Member State. However, given the significant uncertainty and the non-binding nature of the Commission's advice, non-EU issuers should consider selecting a Home Member State through more secure methods (e.g., by ensuring that its first listed issue of Equity or Low-denomination Debt Securities after December 31, 2003 is listed only in the Member State that it wishes to choose as its permanent Home Member State for such securities). Factors an issuer may wish to consider, in selecting a Home Member State, include the relevant competent authority's language (as discussed below), familiarity with the issuer's affairs and/or the type of financial products issued by the issuer and type of review process. We would expect the United Kingdom, and Luxembourg for debt issuers, to constitute natural candidates for non-EU issuers.

\(^4\) Whether the admission to trading of additional securities of a class of securities that is already listed on an EU regulated market, as opposed to the admission to trading of a new class of securities, would "lock in" the Home Member State, is still unclear.
E. INFORMATIONAL REQUIREMENTS

Disclosure requirements under the Prospectus Directive will be set through the Level 2 measures. It is expected that substantive disclosure standards will be broadly based on the International Organization of Securities Commission’s disclosure standards and require the inclusion of audited financial information for two of three years depending on the type of security covered by the prospectus. These financial statements must be prepared and presented in accordance with International Financial Reporting Standards (IFRS), or if not applicable, Member State national accounting standards. Non-EU issuers would be permitted to provide financial statements prepared in accordance with accounting standards other than IFRS only if these standards are “equivalent” to IFRS.

It is expected that non-EU issuers that have been or will have been admitted to listing after December 31, 2003 (first-time non-EU issuers) should be allowed to continue to apply “internationally accepted standards” until their financial year starting on or after January 1, 2007. Currently only U.S. GAAP is considered to be an “internationally accepted standard.”

First-time non-EU issuers will probably be required to include financial statements prepared in accordance with IFRS unless other accounting standards applied by such issuers are considered “equivalent” to IFRS. First-time non-EU issuers will be required to include three years of historical financial information prepared in accordance with IFRS (or equivalent standards) in their prospectuses, irrespective of the date of the offering or listing. For example, a first-time non-EU issuer offering or listing securities in the European Union in the second half of 2005 will be required to include historical financial information prepared in accordance with IFRS (or equivalent standards) for 2004, 2003 and 2002.

Non-EU issuers that have been admitted to listing before December 31, 2003 (seasoned non-EU issuers) will probably not be required to include financial statements prepared in accordance with IFRS in their offering or listing prospectuses until the implementation of the European Union Transparency Directive (which will probably be at the end of 2005 or beginning of 2006, and will require non-EU issuers, unless they are found to be subject to equivalent requirements in their home country, to publish periodic financial reports in accordance with certain specific requirements as to timing and content and report certain information regarding major shareholders and shareholders’ meetings). Following the implementation of the Transparency Directive, seasoned non-EU issuers will be required to include financial statements prepared in accordance with IFRS or equivalent standards in their offering or listing prospectuses.

Non-EU issuers of “wholesale debt” (that is, debt issued in minimum denominations of €50,000 (or its equivalent in another currency) or more) will probably be allowed to include financial statements prepared in accordance with accounting standards other than IFRS provided that a narrative description of the material differences between the standards applied by the issuer and IFRS is inserted in the prospectus.

F. LANGUAGES

When an issuer is making a public offer or seeking admission to trading in one or more Host Member States, but not its Home Member State, the issuer has an option to produce the prospectus in a “language that is customary in the sphere of international finance,” which will include, at least, English. However, where an issuer is making a public offer or seeking admission to trading on a regulated market in both its Home Member State and a
Host Member State or in its Home Member State only, a prospectus must be prepared in a language accepted by the competent authority of the Home Member State for use in that Member State. Accordingly, it is likely that the current practice of using separate home country- and English-language prospectuses in EU-wide offerings will continue. Where an English-language prospectus is prepared for use in one or several Host Member States, the competent authority of such Member States may only require that the summary be translated into its official language(s).

G. Conclusion

The new regime created by the Prospectus Directive is in certain respects far from perfect, suffers from a lack of clarity and consistency, and may, therefore, fall short of its goal of creating a strong and efficient EU-wide framework for capital raising activities. It is to be seen whether the Commission, through Level 2 implementing measures, succeeds in taking away certain of these uncertainties and inconsistencies.

VIII. Illegal Agreements/Unilateral Decisions: Adalat and Volkswagen Cases

Article 81 of the EC Treaty contains a general prohibition against agreements between undertakings, decisions by associations of undertakings and concerted practices between undertakings which may affect trade between Member states and which have as their object or effect the prevention, restriction or distortion of competition within the common market. Where the effects of such practices do not extend beyond the borders of a single Member State of the EU they can be caught by national prohibitions equivalent to the one contained in article 81.

This prohibition applies only to anticompetitive conduct that is coordinated bilaterally or multilaterally, but not to independent decision-making. The latter could only be considered within the scope of another provision, article 82 of the EC Treaty (abuse of dominant position), if it could be established that the concerned undertaking holds a “dominant position” in the market where the effects of the anticompetitive conduct are felt. Such an exercise might prove difficult since only after the market has been properly defined, both in product and geographical terms, is it possible to establish the existence of a dominant position.

The above leads one to consider that even large companies, such as Bayer and Volkswagen, which have been the “victims” of the Commission Decisions annulled by the judgments of the European Courts that will be analyzed in the following paragraphs, may engage in practices that unilaterally restrict competition without breaching European competition law, provided that its effects are felt only in product and geographic markets where they are not dominant.

However, things are not that simple because from a competition law perspective, the term “agreement” is not interpreted so narrowly as under contract law. For an agreement to be sanctioned under competition law it does not need to be legally binding or have the outer appearance or the specificity of a contract. Thus, measures that appear unilateral may in fact be the result of an agreement or concerted action likely to infringe article 81 of the EC Treaty.
After the issue of two Commission Decisions (Decisions in cases IV/34.279/F3-Adalat and COMP/F-2/36.693-Volkswagen) that to a certain extent have been calling into question the delimitation between the scope of articles 81 and 82 of the EC Treaty, the European Courts have now shed some light on the distinction between illegal agreements and lawful unilateral decisions by means of its rulings in joined cases C-2/01 P and C-3/01 P, BAI v. Bayer AG and Commission v. Bayer AG of 6 January 2004, and T-208/01 Volkswagen AG v. Commission of the European Communities of 3 December 2003.

A. THE ADALAT CASE

In most Member States, the competent authorities fix the price of pharmaceutical products. From 1989 to 1993, the prices in France and Spain of a product produced by the Bayer Group, Adalat, were 40 percent lower than those charged in the United Kingdom. This price differential led Spanish and French wholesalers to export large quantities to the United Kingdom, causing significant losses to the British subsidiary of Bayer.

The pharmaceutical group reacted by changing its delivery policy and began not to fill all the increasingly large orders placed by wholesalers in Spain and France with its Spanish and French subsidiaries. The wholesalers reacted by lodging complaints against Bayer before the European Commission.

According to the Commission's analysis, delivery of the volumes which Bayer France and Bayer Spain had agreed to supply was subject to compliance with an export ban. Bayer monitored Adalat supplies and adjusted the volumes to be supplied in the future by reference to the wholesalers' conduct in response to the alleged export ban. If they infringed the ban (which was detected by Bayer when orders increased), wholesalers faced an automatic reduction in supplies.

The Commission considered that such an export ban had been agreed to by Bayer and the wholesalers, as part of their ongoing commercial relations, because the wholesalers' conduct showed an implicit acquiescence to the export ban. The wholesalers began to place their orders in such a way as to suggest that the orders were intended to cover only domestic requirements. As a result, Bayer's policy was declared contrary to article 81 of the EC Treaty and the pharmaceutical group was fined.

By application lodged at the Registry of the European Court of First Instance (CFI) on March 22, 1996, Bayer sought the annulment of the Commission Decision and, by judgment of October 26, the CFI upheld Bayer's pleas in law. However, the Bundesverband der Arzneimittel-Importeure eV (BAI) and the European Commission requested the European Court of Justice (ECJ) to quash the judgment of the CFI.

The ECJ has now definitively settled the Adalat case by stating an "agreement between undertakings" requires the existence of a meeting of minds between at least two economic operators. The form of the agreement is not important, insofar as it faithfully reflects such a meeting of the minds.

The ECJ recognizes that such an agreement may be derived from the behavior of the parties at stake but confirmed the understanding of the CFI. It rejected the position assumed by the Commission that, without more, a measure adopted by a manufacturer, which has

the object or effect of restricting competition, and that falls within the context of continuous business relations between the manufacturer and its wholesalers, is not sufficient for a finding that such an agreement exists.

In fact, for an agreement within the meaning of article 81 of the EC Treaty to be capable of being regarded as having been concluded by tacit acceptance, it is necessary that the manifestation of the wish of one of the contracting parties constitutes an invitation to the other party, whether express or implied, to achieve a declared joint anti-competitive goal. Accordingly, it is not enough that the manufacturer requires from the wholesalers a particular line of conduct or seeks to obtain their adherence to its policy particularly, if as in this case, it is not at first sight in the interests of the wholesalers.

B. The Volkswagen Case

The German car manufacturer, Volkswagen, sells its motor vehicles in the EU within the framework of a system of selective and exclusive distribution through authorized dealers with whom it has concluded dealership agreements. In 1996 and 1997, Volkswagen called upon its German dealers not to sell the new Volkswagen Passat model below a recommended price and to limit, or even not to grant, discounts to customers. As a result of a consumer's complaint, the Commission issued a Decision stating that Volkswagen and its German dealers had entered into an agreement preventing competition through discounts among dealers, which was contrary to article 81 of the EC Treaty.

Volkswagen challenged the decision before the CFI. In the CFI's view, the Commission was wrong in asserting that the signature by Volkswagen's dealers of the dealership agreement implied the acceptance of subsequent modifications of its terms. It cannot be claimed that a dealer who has signed a dealership agreement, which complies with competition law, is deemed, upon and by such signature, to accept in advance later unlawful modifications. For the call made by Volkswagen to its dealers to be considered as part of the pre-existing contract, it should both be intended to influence the dealers in the performance of the contract and, above all, be in some way or another, accepted by the dealers. Such an acceptance was not in this case sufficiently proved in the Commission's Decision.

C. Conclusion

These rulings confirm that European competition law cannot sanction genuine unilateral acts even where such acts have anti-competitive effects, insofar as the concerned undertakings do not hold a dominant position. They also contribute to the still-difficult task of drawing the line between truly unilateral acts and those that are only unilateral in appearance.

IX. The REACH Proposal for Chemical Regulation

On October 29, 2003, the Commission approved a controversial final proposal to replace existing EU chemical regulation with a comprehensive new chemical control system known as “REACH” (the REACH Proposal). The REACH Proposal would establish sweeping new requirements for registration, evaluation, authorization and potential restriction of new and existing chemicals. The REACH Proposal would create a new European Chemicals Agency (the Agency) and impose significant burdens on a broad range of chemicals, chemical preparations, and chemical-containing products manufactured in or imported to the EU.
As currently structured, the REACH Proposal poses serious challenges to manufacturers and importers, and to a lesser extent, downstream users of chemicals. The REACH system effectively places the burden on such entities to demonstrate that use of covered substances is safe over their entire life cycles. Given its breadth, the REACH Proposal would impose wide-ranging new requirements that have no international precedent. Many sectors have questioned the feasibility, cost, and effectiveness of the program. The potential economic dislocation, both inside and outside the EU, is a significant concern.

A. Fundamental Approach Underlying the REACH Proposal

The REACH Proposal is an outgrowth of the Commission's February 2001 White Paper entitled "Strategy for a Future Chemicals Policy." The White Paper generally focused on: (1) the lack of publicly available information on the properties and uses of the majority of chemical substances on the market; (2) the burden placed on regulators, rather than industry, to identify the risks associated with the use of various chemicals; and (3) the slow pace of the current chemical risk assessment process.

The REACH Proposal would take a fundamentally different approach to establish broad obligations to assess and evaluate a wide range of chemical substances:

* REACH is based on the Precautionary Principle—that it is up to manufacturers, importers, and downstream users to ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment.
* REACH is a hazard-based, rather than a risk-based, system. The fundamental premise that all chemicals must be affirmatively demonstrated to be safe is at the core of the registration and evaluation system. While some modifications have been made to exempt substances and volumes not expected to pose significant risks, there is only limited integration of risk-based assessments into the base registration and evaluation steps of the program. For the majority of substances, there is no mechanism for consideration of whether, under normal management and use, there is actually any potential for exposure or harm to human health or the environment.

While traditional regulatory schemes wholly or partially exempt existing chemicals, REACH would impose the same onerous requirements on chemicals with years of safe use in the marketplace.

Manufacturers and importers would be required individually to register their substances, with no chemical inventory-based system to avoid duplicate registrations. In other words, even where a manufacturer already has registered a chemical, a second manufacturer with the same chemical, using it in the same way, would have to undergo the same registration process.

Not surprisingly, the Commission expects submission of tens of thousands of registrations. Because of the broad implications, preliminary cost estimates for REACH range in the tens of billions of Euros.

B. Basic Thresholds for Applicability

In general, the REACH Proposal would apply to a chemical substance produced or extracted in the EU by an individual manufacturer entity, or imported as an individual substance or as part of a preparation into the customs territory of the EU by an individual
importer entity, in each case in an amount of one metric ton or more per year. Certain REACH requirements also apply to intermediates and to articles containing subject chemicals. Polymers, R&D substances, and certain other narrowly crafted categories of substances benefit from whole or partial exemptions. The limited scope of the exemptions and the expansive applicability of REACH to articles and intermediates—effectively moving REACH far beyond the traditional ambit of chemical manufacturers—have been particularly controversial.

C. INITIAL REGISTRATION OF CHEMICALS AND DATA REQUIRED

Generally, each manufacturer or importer of a substance which, either on its own or in a preparation, is manufactured or imported at a volume of one metric ton or more per year would be required to submit a “registration” for that substance to the Agency. The registration requirements would apply to all existing and new substances whether or not another manufacturer or importer has already submitted a registration for the substance. The registration consists of a detailed dossier of a broad range of chemical-specific information supported by toxicity studies and data. Various categories of substances and preparations are excluded from this general registration requirement.

Registration would be phased in over a period of years. Registration requirements would apply in three years for specified substances of very high concern (e.g., those subject to authorization requirements) and other substances manufactured or imported at volumes greater than 1,000 metric tons per year, in six years for substances in excess of 100 metric tons per year, and in eleven years for substances in excess of one metric ton per year.

The amount of toxicological and ecotoxicological information required to support the registration is determined by which of four volume-based tiers (1–10, 10–100, 100–1,000, and >1,000 metric tons per year) apply to the specific substance. The lower tier requires a basic battery of short-term test data, whereas the higher tiers require extensive data including results of sub-chronic or chronic toxicity and reproductive effects studies and a series of environmental effects tests.

In response to the concerns of animal rights groups, the REACH Proposal explicitly states that testing on vertebrate animals “shall only be undertaken as a last resort.” Yet, the Proposal only contains limited provisions for sharing of data and testing costs among manufacturers of the same chemical. While some of the data requirements may be addressed by use of data from specified models (i.e., qualitative or quantitative structure activity relationship models) and information from structurally-related substances, there is considerable concern that the REACH Proposal would require a significant amount of unnecessary testing.

Downstream users are also affected by the registration requirements and provisions in several different ways, including communication of information to upstream suppliers and assuring use of appropriate risk management measures based primarily on information from their suppliers.

D. THE CHEMICAL EVALUATION PROCESS

Under the new regulatory system, the next step—the evaluation process—would consist of two separate types of reviews:
COMPARATIVE LAW

- A review of the testing dossier for an individual registration by the competent authority of the Member State in which the manufacture takes place or the importer is established; and
- The evaluation of a substance to determine whether industry should obtain and submit additional data, which also would be primarily implemented by the competent authorities.

Even though the draft evaluation decisions by Member States are submitted to the Agency and circulated to the other Member States for review and approval, the process by which substance evaluations are allocated to and conducted by individual Member States raises concerns about the potential for inconsistent approaches to evaluation and decision-making.

E. AUTHORIZATION MUST BE OBTAINED FOR SPECIFIC COVERED SUBSTANCES

Use or placement on the market of certain specified substances of very high concern must be the subject of a specific authorization granted by the Commission. Generally, authorization requires a demonstration that the risk to human health and the environment is adequately controlled, or that the socio-economic benefits arising from the use of the substance outweigh the risk to human health and the environment and there are no suitable alternative substances or technologies. Applications for authorization are submitted to the Agency, whose opinion is to be considered in the Commission's final determination. If authorization is denied, that use of the subject substance would be "sunset."

Covered substances would include (with certain narrow exemptions) those meeting specified criteria for classification as carcinogens, mutagens or reproductive toxins (CMR), persistent, bioaccumulative and toxic substances (PBT), or very persistent and very bioaccumulative substances (vPvB), and those identified as having endocrine disrupting properties.

F. POTENTIAL RESTRICTIONS AND BANS ON USE

Under the REACH Proposal, the Commission would also have the authority to issue a restriction, which may range from a use limitation to an absolute ban of the substance. Either the Commission or the Member States may propose such restrictions, based on a determination that the manufacture, use or placement on the market of a substance poses an unacceptable risk to human health or the environment and a risk assessment that identifies why Community-wide action is necessary. The Agency's committees on risk assessment and socio-economic analysis would then evaluate the proposal, and the opinions of the two committees would be provided to the Commission for a final determination.

G. THE NEW EUROPEAN CHEMICALS AGENCY

Under the REACH Proposal, the new European Chemicals Agency would play a key role in decision making and in coordinating input and activities of the Member States:

- The Agency will maintain the central information database and coordinate and disseminate guidance to Member State competent authorities. In particular, the Agency will develop guidance on prioritization of substances for evaluation.
- The Agency will receive all registrations and conduct an initial review for completeness.
- Although the Member States will play the primary role in the performing the evaluations and identifying any actions required, the Agency is tasked with assuring the consistency of these decisions at the draft stage.

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The Agency will receive and evaluate all authorization applications. Specific Agency committees on risk assessment and socio-economic analysis will issue recommendations and opinions on authorization applications and will also develop opinions on substances nominated for restrictions by the Commission or a Member State.

H. PROSPECTS FOR PROGRESS ON THE REACH PROPOSAL

The REACH Proposal is controversial in many respects. Industry and a number of Member States have expressed deep reservations about its economic impact and feasibility, questioned its failure to incorporate fundamental principles of risk assessment, and cast doubt on the legitimacy of the associated cost-benefit analysis. NGOs and others seek to expand the REACH Proposal to establish a novel "duty of care" from manufacturers through downstream users and set up a new system that would mandate production substitution and achieve widespread chemical bans.

At present, perhaps the only point of consensus is the expectation that REACH will be intensely reviewed and debated in the coming years. Some of the significant remaining issues that should be addressed in this ongoing debate include:

- Whether the program should rely on basic risk assessment concepts to avoid the inclusion of low risk substances for which the program produces no health or environmental benefits.
- Whether the registration process should be streamlined to eliminate duplicative filings and incorporate an inventory system that promotes broad reliance on and access to existing data.
- Absent change, whether the undue reliance in the authorization provisions on hazard criteria rather than risk-based criteria, along with the stigma resulting from products classified as intrinsically hazardous, may have the effect of unnecessarily diminishing demand for products and forcing substitutions even in the absence of any real risk or net gain in protection of human health or the environment.
- Whether the current provisions on data sharing and consortia formation are inefficient and inequitable, likely leading to wasted resources on duplicative testing.
- Whether downstream users who typically do not have experience and technical expertise with chemical control regulation should not be subject to requirements to prepare and submit chemical safety reports, identify appropriate risk reduction measures, and apply for and implement authorizations.
- Whether greater protection needs to be provided for certain critical confidential information, particularly relating to substances and additives.
- Whether allocation of authority between the Member States and the European Chemical Agency should be reviewed to assure efficient and consistent decision-making, based on sound science.

I. CONCLUSION

While the current REACH Proposal has already been the subject of considerable debate, including extensive debate in the Environment and Enterprise Directorates and a round of public comment and revision, the upcoming review by the European Council of Ministers and the European Parliament will determine whether, and to what extent, this REACH approach will form the basis for future EU chemical regulation. Notwithstanding the Commission's approval, many aspects of REACH remain in flux. The proceedings on the
REACH Proposal are not expected to conclude before 2005. The contentiousness of so many issues will certainly delay the proceedings, and developments will be complicated by the elections to the European Parliament in 2004 and by the appointment of a new Commission, also in 2004.

X. Control of Cartels

The determination of the Commission to clamp down on cartel operations is frequently expressed in the ardent statements of Mario Monti, the Commissioner responsible for EU competition policy. The regulatory regime is rapidly evolving to eradicate what he terms as “cancers” of the modern market economy—the hard core cartels which impair competition. Mr. Monti has been quoted as saying: “The competitive struggle without effective antitrust enforcement is like a fight without a referee.” Presently, competition rules and “referees” abound.

A. What is driving change?

Radical reforms of existing EU competition law enforcement procedures (laid down in Regulation 17/1962) are on the horizon. Described by Monti as “the most important legislative initiative in the competition field” in some ten years, the reforms will overhaul forty year old procedures and make available resources that have up to now been tied up in dealing with voluminous notifications to the Commission of agreements between various entities, the majority of which do not present any real risk to competition. When the reforms become applicable via Regulation 1/2003 in May 2004, the energies of the Commission’s 200 or so antitrust officials will be smartly focused on proactively investigating agreements which seriously damage competition in the common market. Cartels will be particularly susceptible. The reforms will also decentralize some of the Commission’s current enforcement responsibilities and enable national regulators and courts to engage in local enforcement. A European Competition Network has been set up to facilitate cooperation, allocate cases and ensure that the law is applied consistently across the board. While a great deal of flexibility will be applied to the allocation of cases it is understood that, in general, the Commission will reserve to itself responsibility for investigations involving more than three member states. Regulation 1/2003 will also give the Commission wider reaching powers of investigation and increased powers to impose fines.

There has been a dramatic increase in the levels of cooperation amongst international competition authorities to coordinate enforcement efforts and root out cartels. In January 2003, officials from the Commission carried out dawn raids on fourteen chemicals companies suspected of participating in cartels. The raids involved significant coordination between the Commission and regulators in the UK, the Netherlands, Germany, Italy and Belgium. Japanese, American and Canadian authorities carried out inspections in tandem. In May 2003, some of the world’s largest mining concerns including Rio Tinto and BHP Billiton were raided in London in connection with an investigation into price fixing of copper concentrates. A simultaneous raid took place at the premises of a major producer of copper concentrates in Portugal. Similar investigations were also conducted by the U.S. Department of Justice and the Canadian Competition Bureau. In October 2003, the Commission hosted the fifth International Cartel Workshop which brought together cartelbusters from thirty-five different countries.

The Commission’s officials will receive greater powers of investigation under Regulation 1/2003. Officials will have the power to seal premises and documents under investi-
igation for the period and to the extent necessary for the inspection. Their interrogation powers will extend to enable them to ask questions during investigations relating not only to the documents under inspection, but to the wider investigation as a whole. Perhaps the most intrusive power added to their armory is that they will be able to enter the homes of company executives when they hold a reasonable suspicion that books and other documents relevant to the investigation might be found there.

Greater and better resourcing—the organization chart of the Directorate General of Competition (DG Comp) gives a glimpse of the great potential. Last year, DG Comp underwent a major reorganization aimed at enhancing sectoral knowledge of markets, improving internal decision making procedures, and increasing the efficiency of enforcement in readiness for the coming into force of Regulation 1/2003. The recent appointment of Professor Röller, a leading economist and competition expert, to the position of Chief Competition Economist at DG Comp demonstrates the continuing commitment of the Commission to achieving its goals.

In an increasing number of jurisdictions, leniency programs are offered by regulators as a highly effective incentive for companies and employees to blow the whistle on other cartel participants. These programs have brought about a significant increase in self reporting and contributed to the success of a number of high profile cartel prosecutions including Lysine (2000), Vitamins (2001) and Plasterboard (2002) to name but a few. In the EU, revisions to the leniency policy have not only made it easier for cartel participants to get full immunity but also afford more certainty as to the extent of fines they face. In general, an absolute immunity is afforded to the first party to come forward, whether or not an investigation has begun. Subsequent parties who come forward may qualify for a reduction in fines where they provide evidence which adds significant value.

Last, but by no means least, fines in cartel cases are consistently increasing and have now reached unprecedented levels. In 2001/2002, the fines imposed in nineteen cases earned the EU budget €2.8 billion, equating to an average fine of approximately €150 million per case. The ten largest cartel fines in the EU (see inset box) were deliberately set so as to be cartel prohibitive and correct the perceptions of any companies still laboring under the 

<table>
<thead>
<tr>
<th>Year</th>
<th>Case</th>
<th>Total amount per case (€ million)</th>
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<tbody>
<tr>
<td>2001</td>
<td>Vitamins</td>
<td>855</td>
</tr>
<tr>
<td>2002</td>
<td>Plasterboard</td>
<td>478</td>
</tr>
<tr>
<td>2001</td>
<td>Carbonless Paper</td>
<td>313</td>
</tr>
<tr>
<td>1998</td>
<td>TACA¹</td>
<td>272</td>
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<tr>
<td>2001</td>
<td>Graphite Electrodes</td>
<td>218</td>
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<tr>
<td>2003</td>
<td>Sorbates</td>
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<td>2002</td>
<td>Citric Acid</td>
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<tr>
<td>2002</td>
<td>Methionine</td>
<td>127</td>
</tr>
<tr>
<td>1994</td>
<td>Lombard Club/Austrian banks</td>
<td>124</td>
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<td></td>
<td>Cartonboard²</td>
<td>119</td>
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</tbody>
</table>

² Figures taken from statistics available on the European Commission Web site.
¹ Fine including other aspects of antitrust infringements.
² Fines reduced by Court judgments.
misguided belief that price fixing pays. Of particular note is the record fine imposed on the
vitamins cartels in 2001 of €855 million, with Hoffman-LaRoche bearing the brunt of
€426 million. In the EU, the maximum punishment for breaching cartel laws is a fine of
up to 10 percent of each cartel participating company's worldwide turnover in the preceding
business year. Fines imposed reflect factors such as the size of the company and its market
share, the duration of the cartel, the impact of the illicit agreement on the consumer and
whether there is a history of infringements. They also take into account any aggravating
circumstances (such as lack of cooperation) and mitigating circumstances (such as active
and consistent cooperation).

B. **Dawn Raids**

Given the major economic impact of cartels and the will of the regulators to strenuously
enforce regulations, the investigative techniques employed are becoming increasingly prob-
ing and intrusive. Dawn raids are a highly effective investigative technique which are de-
signed to catch out companies when they least expect it.

Under Regulation 17/62, dawn raids may only be authorized by a formal Commission
decision. It is necessary for companies to recognize the distinction between the two. If the
investigation is carried out pursuant to a decision, the company will be liable to a fine if it
refuses to allow the investigation to take place. On the other hand, there is no obligation
on a company to submit to an investigation by authorization, although refusing to do so
will buy only a short respite because an authorization will be speedily converted into a
formal decision if necessary. Companies should seek the advice of their external competition
lawyers before they refuse to submit to an investigation by authorization as doing so can
seriously damage relationships with regulators.

The Commission's legal powers during raids are extensive. Not only can they enter a
company's property and examine and copy all relevant documents, but they also have the
power to ask employees on the spot questions in relation to any documents examined. There
are, of course, limits on these powers and it is essential for those managing dawn raids to
ensure that the investigation is properly executed. For instance, the company will not be
obliged to disclose documents and information outside the scope of the investigation or
that is subject to legal privilege.

C. **Managing Dawn Raids**

When managing a raid, there is a delicate line to be drawn between confining the in-
vestigation to what is set out in the authorization or decision and committing an offence
of obstruction. Educating employees on how to cooperate without volunteering informa-
tion which is outside the scope of the investigation is vital. Training is required on every
aspect of a dawn raid and should be focused on the various levels of staff as appropriate—
from receptionist and security personnel—to more senior managers and in-house coun-
sel—to company executives.

All companies should have systems in place to ensure that raids are managed smoothly
and effectively and that negative publicity is kept to a minimum. They should also be well
advised as to the availability of leniency programs in relevant jurisdictions and understand
whether and the timing of when it is appropriate to apply. Dire consequences can follow
from being caught up in a cartel investigation. The fact that there are no time limits on
their completion means they can go on for years depending on the complexities of each
case, the extent of cooperation afforded to the regulators and whether or not allegations are contested. It is not unusual for companies and consumers to boycott the products and/or services of cartel participating companies. There is also a growing trend towards third parties bringing claims against cartels for loss of business. Damages claimed in these can be more punitive than the fines themselves. Raids are invariably of great interest to the press and one need only look at the leniency applications and decisions posted on the Commission website to see that a name and shame policy is in operation. If business interruption, sanctions, and civil claims do not seriously affect the bottom line for companies, then reputation damage almost certainly will.