



**COUNCIL OF
THE EUROPEAN UNION**



Brussels, 21 June 2006
10783/06 (Presse 189)

EU-US Summit - Vienna, 21 June 2006

TABLE OF CONTENTS

VIENNA SUMMIT DECLARATION	2
2006 EU-U.S. Summit Progress Report on Political and Security Issues	15
2006 EU-U.S. Summit Progress Report on the Economic Initiative	21
Joint Report on the Roadmap for EU-US Regulatory Cooperation.....	25
EU – US Action Strategy for the Enforcement of Intellectual Property Rights.....	41

P R E S S

VIENNA SUMMIT DECLARATION

We, the leaders of the European Union (EU) and the United States of America (U.S.), met today in Vienna to respond to the concerns of our citizens for peace, security, stability and prosperity in an increasingly globalised world.

We welcome that over the past year our Transatlantic Partnership has delivered real results as shown by the political and economic Progress Reports we issued today. We remain committed to finding common or complementary lines of action in many areas. Over the last year there have been many examples of how productive our relationship is, in the Middle East, Iran, the Western Balkans, Belarus, on the frozen conflicts, and Sudan, as well as in our efforts to promote transatlantic trade and investment under last Summit's Economic Initiative.

We have decided to further strengthen our strategic Partnership by adopting a number of priority actions to support our cooperation in the following four areas:

- Promoting peace, human rights and democracy worldwide;
- Confronting global challenges, including security;
- Fostering prosperity and opportunity;
- Promoting strategic cooperation on energy and energy security, climate change and sustainable development.

Promoting Peace, Human Rights and Democracy Worldwide

We recognise that the advance of democracy is a strategic priority of our age. We will intensify our efforts to promote peace, democracy, freedom, the rule of law and respect for human rights in the world to make it more secure, safe, and prosperous for all mankind. Noting the need for tolerance of diverse cultures, beliefs and religions and the importance of dialogue while emphasising respect for universal human rights, we will sustain our efforts to advance democracy.

We will work with the United Nations and international and regional organisations, civil society, non-governmental organisations and dedicated individuals committed to human rights, democracy and the rule of law. We will work to ensure that the newly created **Human Rights Council** becomes an effective and efficient body committed to the promotion and protection of human rights and fundamental freedoms for all. We underline our shared commitment to UN-Reform and we welcome the establishment of and give our backing to the **Peacebuilding Commission** and the **UN Democracy Fund**.

We will continue to support reform in the **Mediterranean region** and the **Middle East** and will promote greater participation of civil society in the reform process through our respective efforts, including the Barcelona Process, the European Neighbourhood Policy, the Middle East Partnership Initiative, and our joint actions through the Broader Middle East and North Africa Initiative and the Foundation and Fund for the Future.

We will continue to closely cooperate in the **Middle East**, notably through the **Quartet**. We welcome the temporary international mechanism to deliver assistance directly to the Palestinian people. We will continue to deliver humanitarian assistance and promote Palestinian democracy and civil society. Whilst recalling President Abbas' commitment to a platform of peace, we will continue to urge the new Palestinian government to commit to non-violence, recognise Israel's right to exist and accept existing agreements and obligations. We will continue to call on Israel to ease restrictions on access and movement and to take additional steps including with respect to the Palestinian tax and customs revenues, to improve the humanitarian situation of the Palestinian people. We remind both sides of their obligations under the 15 November 2005 Agreement. We will continue to promote a negotiated solution to the Israeli-Palestinian conflict on the basis of the Roadmap in order to advance a just, viable and lasting two-state solution and we call on both parties to avoid unilateral measures that prejudice final status issues. We call on the Palestinian Authority government to implement policies that will permit the international community to provide greater support to and review its policies on contact with the Palestinian Authority.

We will strongly urge **Syria** to implement United Nations Security Council Resolutions (UNSCR) 1559, 1595, 1636, 1680 and 1686 and to prevent its territory from being used to support violence in Iraq, and end cross-border transit and support for terrorist groups.

Similarly, Syria must end its support for Lebanese and non-Lebanese militias, and prevent the smuggling of arms and other support to these groups. We will work together to increase support for human rights and democracy, and secure the release of political prisoners in Syria. We will strongly urge Syria to refrain from any attempt at destabilising Lebanon.

We will jointly support political, economic and institutional reforms in **Lebanon**, as well as its sovereignty, democracy, territorial integrity, unity and political independence. We will strengthen efforts to coordinate assistance to Lebanon, and we support the reform plan of the Lebanese government and seek to work towards an international Core Group conference. We support the efforts of the Lebanese government to disarm and disband Lebanese and non-Lebanese militias, as called for in UNSCR 1559 and 1680, and we will support the call expressed by the UN Security Council to halt the flow of arms and funds to terrorist groups and militias. We support UNSCR 1686 and the continuation of the investigation of the assassination of former Lebanese Prime Minister Rafiq Hariri.

We support progress by the Government of **Egypt** towards ensuring fundamental freedoms and building multi-party democracy. We will continue to encourage the Egyptian government to proceed with the fundamental political and constitutional reforms it announced, particularly by replacing the emergency law with a counterterrorism law in conformity with international human rights standards.

We will support the newly constitutionally elected government of **Iraq** and call upon it to continue the policies of inclusiveness as a means to overcome divisions within Iraq. We will continue to assist in building an independent, stable, secure, democratic, prosperous and united Iraq at peace with its neighbours and the international community. We call on the international community to show its support for the new government in particular by increasing development, rule of law, and security assistance, offering capacity building support, providing generous debt relief on terms equivalent to the Paris Club Agreement and extending its local presence keeping in mind the security situation.

Over the past year our cooperation on **Iran** has reached a new level. We have worked closely together at every stage of the ongoing attempts to address the question of Iran's nuclear programme. We have agreed on a set of far-reaching proposals as a basis for discussion with Iran. We believe that they offer Iran the chance to reach a negotiated agreement based on cooperation, if Iran is willing to make that choice. The United States has made clear that it is prepared to join the negotiations should Iran resume full and verifiable suspension of all enrichment related and reprocessing activities as required by the International Atomic Energy Agency (IAEA). We have agreed that if Iran decides not to engage in negotiations, further steps would be taken in the Security Council. We urge Iran to take the positive path.

Building on the success of the London January 2006 conference on **Afghanistan**, we will support Afghan efforts to build a democratic, accountable and sustainable state. We will pay particular importance to governance, human rights, reform of the public administration, the judiciary and security sector, counter-narcotics as well as an Afghan-led process of reconciliation and justice.

Recognising the next year to be a crucial period for the **Western Balkans**, we will build on the experience of our successful transatlantic cooperation by cooperating to stabilise the countries in the region, support their European and Euro-Atlantic perspectives and to combat organised crime and corruption. We will continue to work with the North Atlantic Treaty Organisation (NATO) as well as the Organisation for Security and Cooperation in Europe (OSCE) to ensure the security and prosperity of the region. On Kosovo in particular, we will continue to ensure the convergence of our positions on the ongoing talks in order to promote a lasting status that respects the Contact Group principles. We will develop our relations with Montenegro as a sovereign, independent State and call on both Serbia and Montenegro to pursue a direct and constructive dialogue on their future relations.

Ukraine has made remarkable progress in democratic and economic reforms. Building on the March 2006 elections, we will support Ukraine's development as a democratic, prosperous and secure country. We will help Ukraine pursue economic reforms, combat corruption and reform the energy sector.

We will continue to support the democratic aspirations of the people of **Belarus** and work together to strengthen democratic institutions, assist civil society, and promote independent media. We condemn the use of violence in Belarus and the repression of the democratic opposition and we urge the authorities of Belarus to release all political detainees. The travel ban imposed on President Lukashenko and others, as well as the freezing of assets of individuals responsible for violations of international election standards and human rights abuses, are good examples of our broad cooperation and coordination. We remain resolved to help the people of Belarus achieve their aspirations for a better future.

We will contribute to finding a solution to the Transnistrian conflict that assures **Moldova's** territorial integrity. We will work with all relevant parties to resolve through peaceful, negotiated settlements the frozen conflicts in the **Southern Caucasus** and encourage the democratic processes in Armenia, Azerbaijan and Georgia.

We will work together to promote democratic and economic reforms, human rights, freedom of expression and the press, the rule of law in **Central Asia** to promote international security and stability. We continue to call upon the government of Uzbekistan to facilitate an independent international investigation into the tragic events of Andijan.

We attach great importance to our relationship with **Russia** and are pursuing deeper cooperation on a range of issues of common interest, including some important foreign policy issues, non-proliferation and counterterrorism. We are concerned about some recent developments in Russia and the region and will work with Russia to promote energy security, the application of the rule of law, an independent judiciary and full respect for human rights, including free and independent media and a vibrant civil society, and a resolution of frozen conflicts in the region. We will make constructive use of the OSCE as an important forum for cooperative and comprehensive security and call on Russia to fulfil all Istanbul and OSCE commitments.

Regarding our respective relations with **Latin America and the Caribbean**, we recognise the need for greater collaboration to promote stable and effective democracies, as well as market economies that contribute to greater social cohesion. We will actively engage NGOs and civil society, and we will support access to information, establishment of rule of law and independent media where this is not provided. Where necessary, we call on countries in the region to provide coherent and effective support and protection to individuals, organisations or institutions working for the promotion and protection of human rights and democracy. We express our deep concern about the human rights situation in Cuba, and urge the Cuban government to take rapid steps to improve the situation. We welcome the reestablishment of the constitutional order in Haiti, support the renewal of the UN Stabilisation Mission's mandate, and welcome police and troop contributions to the mission.

We will jointly work towards rapid implementation of the **Darfur** Peace Agreement. We will work with the United Nations and other international and regional partners and organisations, including NATO, to strengthen the African Union Mission in Sudan (AMIS) with the assistance required, and UN authorisation to "bluehat" the AMIS force by September. We will continue to support the Comprehensive Peace Agreement in Sudan and will continue to mobilise resources for humanitarian needs.

We will seek to ensure successful elections on 30 July 2006 in the **Democratic Republic of Congo**, and will continue our support for the building of government institutions, training programmes, and security sector reform. In the post-transition the European Union and the United States will prioritise support for improved governance, the rule of law and security sector reform.

In **Somalia**, we reiterate our support to the efforts of the Transitional Federal Institutions (TFI) in pursuing dialogue, reconciliation and stable governance. We will assist the transition and the establishment of viable and inclusive institutions in order to promote stability in Somalia and the region.

We will further coordinate our respective efforts on humanitarian and democracy assistance to address the worsening plight of the population in **Zimbabwe**. We call on the Government of Zimbabwe to restore democratic freedoms and the rule of law, and to respect human rights. We are ready, as soon as significant action in this direction is taken, to reconsider the restrictive measures now in place against Zimbabwe. We also call for measures by the Government of Zimbabwe needed to reverse the economic collapse.

We will enhance our joint efforts in **conflict prevention and crisis management** by increasing consultations on current and potential crises, identifying ways to strengthen cooperation in crisis management and post-conflict reconstruction and coordinating efforts to improve international crisis management capacities.

Confronting Global Challenges, including Security

Since no single nation can efficiently and effectively deal with global challenges such as climate change, counter-terrorism, non-proliferation, pandemics and natural disasters on its own, we commit ourselves to strengthening our cooperation to address these challenges.

Consistent with our common values, we will ensure that measures taken to combat terrorism comply fully with our international obligations, including human rights law, refugee law and **international humanitarian law**. We attach great importance to our ongoing in-depth dialogue on our common fight against terrorism and our respective domestic and international legal obligations.

We will step up our cooperation against **terrorism**, including through denying resources (financing, travel, and other material support) and shelter to terrorists, and we will coordinate efforts to prevent a new generation of recruits from emerging by countering radicalisation and recruitment, and promoting tolerance, including by cooperating on developing regional strategies and by implementing – and encouraging others to implement – steps required by UNSCR 1624. In particular, we will work to enhance our border security cooperation by improving lost and stolen passport data sharing with Interpol, coordinating the implementation of biometric standards based on International Civil Aviation Organisation (ICAO) recommendations. We will cooperate to block terrorism financing, in particular in the informal financial sector, by developing improved procedures for information sharing and a more pro-active use of financial investigations implementing Financial Action Task Force (FATF) Special Recommendations, among others by enforcing cash declaration regulations for travellers, optimising the use of financial intelligence and controls, and engaging the private sector to develop partnerships to enhance protection of financial institutions.

We will strengthen our cooperation by completing negotiations on a Eurojust-U.S. cooperative agreement and we will step up our coordination to improve counterterrorism capacity building in third countries. We welcome the signature of bilateral agreements by EU Member States and the United States to accompany the EU-U.S. Mutual Legal Assistance Treaty and Extradition Agreements, and will aim to bring them into force as soon as possible. We intend to agree without delay on a Comprehensive UN Convention on International Terrorism and on a universally accepted definition of terrorism, and we will work with others towards a targeted UN strategy on combating terrorism. We take note of the "Vienna Initiative", initialled on 4 May, on possible future tripartite cooperation in the field of justice and home affairs between the European Union, the Russian Federation and the United States.

We will strengthen our efforts to prevent access by terrorists to weapons of mass destruction (WMD) and their means of delivery. We will work together to further implement our Programme of Work on the **Non-Proliferation** of WMD, in particular by reinforcing our support for the Nuclear Non-Proliferation Treaty and we will continue to work together to strengthen it, stressing the importance of compliance and promoting its universality.

Our cooperation will include the full implementation of UNSCR 1540, including by conducting joint demarches, where appropriate, to urge all countries to fully implement their obligations under UNSCR 1540, and by assisting States to meet their obligations. In implementing UNSCR 1540, we will also address the issue of financing of proliferation-related activities and develop our cooperation in that regard by seeking to identify, track, seize or freeze assets associated with the proliferation trade, in accordance with national legislation and consistent with international law, and consider further actions against proliferation finance.

We will support the rapid opening and conclusion of negotiations on a Fissile Material Cut-Off Treaty at the Conference on Disarmament and emphasise that, pending the conclusion of the Treaty and the Treaty's entry into force, all states should declare publicly and observe a moratorium on the production of fissile material for use in nuclear weapons. We will continue to work together in the Nuclear Suppliers Group framework on proposals to develop transfer restrictions on enrichment and reprocessing (ENR) technology and to support multilateral mechanisms for reliable fuel supply assurances for States that have chosen not to pursue ENR.

We will coordinate efforts in preparing for the Biological Toxins and Weapons Convention Review Conference with a view to promote a productive outcome, the universality of the convention and the implementation by all States Parties through national laws and regulations in order to put these obligations into practice. We reaffirm our commitment to the Chemical Weapons Convention and its full implementation.

We reiterate our support for multilateral efforts to improve prevention and combat global health threats such as the spread of **pandemics**, including HIV/AIDS, Malaria and Tuberculosis, and other communicable diseases like SARS and Hepatitis. We agree that priority should be given to promoting effective control measures in animal health as a means to reduce outbreaks of H5N1 in birds. We will further increase regional and global cooperation between states, international organisations and civil society in mitigating and preparing for a pandemic, to which input by the International Partnership on Avian and Pandemic Influenza is welcome. We will further improve coordination of our response to **natural disasters** that have cost the lives of hundreds of thousands of people.

Fostering Prosperity and Opportunity

We reiterate our strong commitment to reaching an ambitious conclusion to the Doha Development Agenda by the end of 2006. These negotiations are at a critical phase and we call on all World Trade Organisation (WTO) members to demonstrate the political will and courage necessary to achieve an ambitious and balanced agreement that will help strengthen global economic growth, improve living standards, and alleviate poverty. We recognise the need for trade ministers to make substantial progress on core negotiating areas over the next few weeks in order to ensure that this historic opportunity to liberalise trade is not missed. As responsible leaders, we will continue to work in cooperation with other WTO members towards an agreement that is worthy of the objectives identified in launching the Doha Development Agenda in 2001.

We will increase our partnership with developing countries to promote growth globally for the benefit of all. This will help us to realise the internationally agreed development goals and objectives, including the Millennium Development Goals and the objectives and commitments of the Monterrey Consensus, which have helped to galvanise efforts towards poverty eradication through development cooperation and economic growth.

We will redouble our efforts to promote economic growth and innovation and reduce the barriers to transatlantic trade and investment by implementing all aspects of the Transatlantic Economic Initiative, in line with the Work Programme agreed at the EU-U.S. Economic Ministerial Meeting in November 2005, and to be updated and reviewed at a second EU-U.S. Economic Ministerial meeting later this year.

We endorse the new Action Strategy for the Enforcement of Intellectual Property Rights against piracy and counterfeiting. Implementation has already started with concrete actions aimed at promoting strong and effective enforcement in third countries, strengthening cooperation to reduce global piracy and counterfeiting, and offering public-private partnerships to protect intellectual property. We will enhance our dialogue to promote a more efficient international patent system.

We will build on the progress of the High Level Regulatory Cooperation Forum and associated dialogues, and expand implementation of our Regulatory Cooperation Roadmap to address new topics and sectors and initiate targeted exchanges of regulatory experts. As part of our Innovation Initiative, we will work to measure innovation performance, its impact on the economy, and to understand better each other's innovation policies. We will implement the EU-U.S. plan on e-accessibility with the goal of reaching a coherent approach on our policies in this area. We will work on an implementing arrangement on environment research and eco-informatics under our Agreement on Scientific and Technological Cooperation. We will continue to work together through the EU-U.S. Financial Markets Regulatory Dialogue and the Policy Dialogue on Border and Transportation Security.

We pledge to keep our investment regimes open and to build on existing investment flows to boost growth and create jobs in the transatlantic economy. We will address obstacles to transatlantic investment with a view to promoting closer economic integration.

We will redouble our efforts to conclude a first stage **Air Transport Agreement** in 2006. The European Union and the United States will cooperate closely on the legal framework governing the transfer of air passenger data following the European Court of Justice ruling of 30 May 2006.

We will work together to ensure implementation of phase I of the **Wine Agreement**, and, as mutually agreed, pursue negotiations on phase II in September.

We have signed today a new Agreement on **Higher Education and Vocational Training** under which our respective educational institutions will inaugurate innovative joint study programmes, and which will promote exchanges of students, teachers, and other professionals, strengthen the Fulbright-Schuman Programme and encourage greater institutional collaboration in tertiary education.

We recognise the need for tangible progress to be made towards the establishment of reciprocal **visa-free travel** for all EU citizens to the United States, as part of our efforts to promote the economic and social benefits of increased travel while keeping borders secure.

Promoting Strategic Cooperation on Energy and Energy Security, Climate Change and Sustainable Development

We recognise the strategic role of security of supply, competitiveness and sustainability in the energy sector. In this connection, we strongly reaffirm our commitment to the energy security principles enunciated by the International Energy Agency. We have agreed to reinforce our **strategic energy cooperation** to:

- support diversification of energy sources and supplies;
- secure our energy infrastructure;
- promote market-based energy security policies that ensure competition, transparency, respect for contracts, and non-discriminatory trade, transit, and access;
- speed development of new lower-pollution and lower carbon technologies;
- accelerate investment in cleaner, more efficient use of fossil sources and renewable sources in order to cut air pollution harmful to human health and natural resources, and reducing greenhouse gases associated with the serious long-term challenge of global climate change.

We will cooperate to ensure sufficient, reliable and environmentally responsible supplies of energy at prices reflecting market fundamentals, facilitating sustained global economic growth as well as expanding access to energy in developing countries. Thus, we agree to:

- Improve **energy security** by enhancing the dialogue with the main transit, producer and consumer countries and by promoting diversification of energy sources and supply routes worldwide and notably in the Caspian sea region, Middle East, continental Africa and Latin America;
- Analyse **geopolitical implications** of the worldwide energy situation as it develops, its impact on our external policies and to develop mutually reinforcing policies where appropriate;
- Promote **energy security policies in key third countries** by encouraging a gradual transition to market pricing and behaviour, and coordinate capacity-building assistance to emerging economies, including to increase energy efficiency, adopt clean technologies and build strategic stocks;

- Support maintenance and improvement of **pipeline infrastructure** to ensure uninterrupted deliveries and facilitate diversification investments in large transnational projects by ensuring convergence of legal and regulatory frameworks and supporting collaboration among energy regulatory authorities, notably with Ukraine;
- Coordinate where appropriate **technical assistance** to improve energy legal and regulatory frameworks and investment climates in third countries;
- Improve the security of **global energy networks** and develop standards for physical security of critical energy infrastructure;
- Facilitate development of **Liquefied Natural Gas (LNG)**;
- Increase our **coordination within international fora**, notably the G8, the International Energy Agency (IEA) and the International Energy Forum (IEF);
- Use energy in a **more efficient and environmentally responsible** manner, and in particular cooperate on improving the efficiency of world-wide traded products. In this context we have just initialled a new Energy Star Agreement;
- Make more and better use of **renewable energy sources** and reinforce technological cooperation and partnerships, notably on environmentally-friendly low emission power generation technologies, hydrogen energy, carbon sequestration, cutting gas flaring and biofuels;
- Promote **diversification of fuel sources** in the transportation sector, including through increased use of biofuels;
- Continue cooperation through the International Partnership for a **Hydrogen Economy** and increase collaboration over **regulatory, standards and trade issues** affecting alternative fuels and emerging technologies, especially hydrogen;
- Cooperate on developing efficient, **transitional transport technologies**, and fuel standards, such as plug-in hybrids or efficient diesel engines;
- Continue **scientific exchanges** among EU and U.S. research and development organisations focused on energy efficiency in buildings;

- Promote, consistent with national energy policies, **safety standards** in the production of nuclear energy.

To monitor and guide this process, we will conduct an **annual strategic review** of EU-U.S. energy cooperation.

We also agreed to **promote energy security worldwide** by applying the following Energy Security Principles:

- (a) Contractual commitments should be upheld and market-based principles should prevail at all stages of the energy supply chain.
- (b) Diversifying sources of energy and modes/routes of transit and ensuring non-discriminatory third-party access to transit infrastructure will improve the functioning of energy markets worldwide.
- (c) Open, transparent, non discriminatory and stable legal conditions that ensure fair and equitable treatment for energy investment and trade are essential to helping producing and transit countries meet market demands.
- (d) Further development of production and export capacities in producer countries in a safe and secure environment, and the upgrading of existing and development of new energy transportation infrastructures by producer and transit countries as well as further development of refinery capacity in all countries are critical.
- (e) Bolstering and ensuring the highest levels of physical and environmental security and safety of energy infrastructures, as well as the highest level of nuclear safety, is crucial to the durability and sustainability of the global energy system.
- (f) We should encourage the most economic and efficient use of energy worldwide notably through the use of market-based instruments to minimise negative environmental consequences, and should promote in particular the use of cleaner and more efficient use of fossil fuels and the development of economically competitive non-fossil energy sources based on appropriate policies and market-based instruments.
- (g) We should promote continued research, development and deployment of alternative energy sources and the facilitation of technological and industrial cooperation.

- (h) Supporting effective implementation of transparency and data sharing initiatives, such as the Joint Oil Data Initiative (JODI), including on the evaluation of oil reserves, and the Extractive Industries Transparency Initiative (EITI) will improve transparency and predictability of the market for all stakeholders.
- (i) Addressing energy poverty endured by many of the world's poorest people who will still lack access to modern energy services is a priority.

We will work more closely to address the serious and long-term challenge of **climate change, biodiversity loss and air pollution** and will act with resolve and urgency to reduce greenhouse gas emissions. We will continue our dialogue and efforts under the UN Framework Convention on Climate Change (UNFCCC), including work on long-term cooperative action in the process established in Montreal in December 2005. To this end, we have agreed to establish an **EU-U.S. High Level Dialogue on Climate Change, Clean Energy and Sustainable Development** to build on existing bilateral and multilateral initiatives and further advance implementation of the G-8 Gleneagles Plan of Action for Climate Change, Clean Energy and Sustainable Development. This dialogue will be guided by the ultimate objective of the UNFCCC and will initially meet in fall 2006 in Helsinki. Among topics of importance for this dialogue will be experience with different market-based mechanisms to promote cost-effective reductions in greenhouse gas emissions, advancing the development and deployment of existing and transformational technologies that are cleaner and more efficient, producing energy with significantly lower emissions, efficiency and conservation, renewable fuels, clean diesel, capture of methane, lower emitting agricultural operations and energy production and distribution systems, as well as other environmental issues.

2006 EU-U.S. SUMMIT PROGRESS REPORT ON POLITICAL AND SECURITY ISSUES

Introduction

Overall, our relationship has continued to develop in a very positive way in the follow up to the 2005 Summit. We have “put the relationship to work” by concentrating on specific issues. More effective dialogue, often in advance of policy formulation, has led to convergence on some key issues.

We can identify genuine progress in several areas, including those targeted by the joint declarations adopted at the 2005 Summit.

Key Accomplishments

Democracy and Human Rights

Beginning with Ukraine in late 2004, we have seen the development of cooperation in our dialogue on **democracy promotion**, both in the long-term and with a more immediate focus. Intense exchanges took place on countries like **Lebanon, Belarus, Burma, Ukraine, Georgia, Kyrgyzstan, Ethiopia, Zimbabwe, Egypt and Yemen**. In each case the nature and level of our dialogue has varied, from high-level political exchanges to working level desk-to-desk contacts and co-operation on the ground in ensuring coherence in assistance programmes. We are convinced of the importance and strength of delivering the same political messages and coordinating possible actions in certain countries.

We have pursued dialogue on country resolution strategies in the **UN Commission of Human Rights** and the **United Nations General Assembly (UNGA) Third Committee**, where we succeeded in having a number of country resolutions adopted. We have had intensive consultations during the UN negotiations on the establishment of the **Human Rights Council**, and held regular consultations on human rights. We worked together to help establish a **UN Democracy Fund** to promote and consolidate new and restored democracies and a **Peacebuilding Commission** to work in an advisory capacity on specific post-conflict situations. We have moved forward on the **management reform agenda** outlined in the World Summit Outcome Document. We have supported election monitoring missions by the **Organisation for Security and Cooperation in Europe**, and collaborated on initiatives to stem trafficking in persons.

Regional issues

We have seen a period of profound and rapid change in the **Middle East** with the Gaza disengagement followed by elections in the occupied Palestinian territories and in Israel. The European Union and the United States have held regular consultations, in particular within the Quartet, on the evolving situation. Hamas' election victory in the Palestinian elections means we are faced with an entirely new situation, reinforcing the need for close EU-U.S. co-operation. This was in evidence in the successful conclusion of negotiations to open the Rafah border crossing between the Gaza Strip and Egypt, an agreement overseen by EU monitors and reinforced by assistance to Palestinian customs. On **Syria/Lebanon**, we have developed a joint policy within the UN aimed at ending Syria's interference in Lebanon, and we have maintained parallel pressure on Damascus to comply with the requests by the UNSC in connection with the murder of former Prime Minister Rafiq Hariri. We have worked together to prepare the international conference in support of the Lebanese reform programme. On the **Broader Middle East and North Africa initiative**, launched by the G8, we have worked together to produce concrete results in the Forum for the Future meetings, launching or supporting a number of initiatives such as the Foundation for the Future and the Fund for the Future, and initiatives supporting civil society organisations and educational reforms.

On the **Western Balkans**, we have coordinated our messages very closely to support and accompany the status process in **Kosovo**, cooperating closely with UN Special Envoy Martti Ahtisaari and with the United Nations Mission in Kosovo (UNMIK). We have pursued the promotion of constitutional and police reforms, and, in coordination with NATO, defence reforms in **Bosnia and Herzegovina**, as well as consolidation of democracy in **Serbia and Montenegro** and preparations for a Montenegrin independence referendum that ensured the outcome was accepted as legitimate. We have underlined that full cooperation with International Criminal Tribunal for former Yugoslavia (ICTY) is an essential element for integration into European and Euro-Atlantic structures.

We have sought to engage with **Russia** on internal and neighbourhood matters, notably democratic freedoms, respect for human rights, civil society and transparency and a responsible approach to energy security matters. We welcomed **Ukraine's** free and fair parliamentary elections held in March. We both have concluded agreements toward Ukraine's WTO accession bid. We have worked closely on **Belarus** in order to develop complementary long-term strategies to support democratisation, civil society, opposition and democratic forces, to increase access to independent media and to improve the human rights situation. We delivered strong joint messages both before and after the March elections. We have taken joint steps to expand travel restrictions and to impose targeted financial sanctions against those responsible for the violations of international electoral standards, human rights and the crackdown on civil society and the democratic opposition.

Afghanistan has reached a critical point in its stabilisation. We both have provided financial assistance for Afghani parliamentary elections. At the London Conference on Afghanistan in February 2006, we renewed our commitments to Afghan reconstruction and support for the Afghanistan Compact, which provides a blueprint for building greater security, further progress on rule of law, governance and human rights, and economic and social development. We cooperate in a number of sectors vital to Afghanistan's development, such as counter-narcotics, security sector and judicial reform, civil society development, human rights, education and culture. Twenty-three EU member states participate in International Security Assistance Force (ISAF), and the European Union has contributed over €3.3 billion to Afghan reconstruction and development since 2002. The United States has requested over \$1.1 billion for Afghanistan in its 2007 budget request. Since 2001, the United States has committed over \$10.3 billion to Afghanistan.

On **Iraq**, we hosted the EU-U.S. Conference on Iraq in Brussels in June 2005 to build a renewed international partnership with Iraq, to support Iraq's political transition process, to encourage its economic recovery and reconstruction and to help establish the rule of law and public order. This conference was attended by over 80 ministerial-level delegations and demonstrated support for the Iraqi Transitional government and people in the period leading up to the elections in the latter half of 2005. The EU-Iraq Joint Political Declaration committed the European Union to holding a senior-level dialogue with Iraq. The European Union agreed to open a Baghdad office, and broadened the scope of its assistance beyond already substantial aid and reconstruction programmes by supporting the electoral and constitutional process and opening negotiations on a trade and co-operation agreement. The European Commission, which provided € 518 million in assistance from the end of 2003 to 2005, plans to provide an additional € 200 million in 2006 for a total of € 718 million. The European Union provided electoral experts for the December 2005 elections and trained approximately 300 international experts. Through the EU Integrated Rule of Law Mission for Iraq, EUJUST LEX, the European Union provides a significant number of Iraqi criminal justice officials with professional learning opportunities. The mission is a crucial complement to other international efforts in the area of rule of law in Iraq. The United States provided substantial support for the December 2005 elections through NGOs, which trained approximately fifteen thousand election monitors. In conjunction with the UN, the United States provided the Independent Electoral Commission of Iraq (IECI) \$41 million to support a variety of election programmes, including training of election administrators, logistics, voter education, public outreach and conflict mitigation. As of early June, the United States had provided \$14.5 billion of the \$20.9 billion it had committed to support the reconstruction of Iraq, and expects to complete the large infrastructure projects it had undertaken by the end of 2006. U.S. assistance programmes are increasingly focused on building Iraqi government capacity, both at the ministerial and local levels.

On **Iran**, joint efforts achieved a strong international consensus that Iran must not be allowed to develop a nuclear weapons capability and must comply with its international obligations, including a full and sustained suspension of enrichment-related and reprocessing activities and a return to negotiations. We coordinated closely our political messages, where the EU has taken the leading role and the U.S. has supported EU diplomacy.

We have strengthened our cooperation on **Africa**, in order to promote peace, democracy and human development, in particular by enhancing **AU capacity** for peace support operations, backing the implementation of the comprehensive peace agreement in **Sudan**, supporting AU leadership in the **Darfur** crisis through the UN and other international and regional partners and organisations, including NATO, pursuing a resolution of the border stalemate between **Ethiopia and Eritrea**, and supporting the **Somalia** reconciliation process. We have also worked together on a regional approach to peace and security in West Africa, by enhancing conflict management in Economic Community of West African States (ECOWAS) and supporting the peace process on the **Democratic Republic of Congo**, namely through the assistance to the organisation of the coming elections.

In **Latin America and the Caribbean**, we have worked very closely to promote stability and security in Haiti through the deployment of a UN mission including troops and police officers, to advance democracy by supporting the organisation of successful presidential and parliamentary elections in February and April 2006, and to address critical humanitarian needs, strengthen governance, and foster broad-based economic recovery by providing humanitarian and development assistance to the population and local authorities.

On **East Asia**, we have continued our strategic dialogue on East Asia that includes security and military issues as well as economic and other issues. We have also advocated regional integration and an inclusive East Asian Community process that complements existing fora.

Security Issues

Our cooperation in the **fight against terrorism** has continued unabated. Well-established working relations at all levels have enabled us to deepen our mutual understanding and information sharing. We have continued to grapple together with important issues related to the fight against terrorism and the role of the UN, terrorist financing, radicalisation and recruitment into terrorism. Our continued contacts have helped to create new avenues for strengthening coordination on provision of technical assistance to third countries. In particular, we welcome our in-depth dialogue on international and domestic legal frameworks that govern individual and collective responses to terrorism and on the need for states to ensure that any measures taken to combat terrorism comply with their obligations under international law, including human rights law, refugee law and International Humanitarian Law.

In the area of Justice and Home Affairs cooperation, all EU member states and the United States have signed bilateral instruments accompanying the EU-U.S. Extradition and Mutual Legal Assistance Agreements, setting the stage for prompt ratification and entry into force of these important new law enforcement agreements. Negotiations between Eurojust and the United States started on a cooperation agreement. Jointly we have recognised the importance of effective border management and the need for effective exchanges of information to combat trans-national threats while protecting personal privacy. We are working to ensure the Interpol Stolen and Lost Travel Document database is populated with pertinent data from all EU Member States and the United States. We have had extensive discussions regarding the extension of visa free travel to EU Member States not in the Visa Waiver Program.

In our critical efforts to stop the **proliferation of weapons of mass destruction (WMD)**, we continued to make individual and collective efforts on implementation of key multilateral arms control, disarmament, and non-proliferation treaties, core regimes and initiatives including the G8's Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, the Proliferation Security Initiative, and the Global Threat Reduction Initiative. Through our action to promote full implementation of UNSCR 1540, we worked to make it an effective tool to prevent proliferation of dangerous materials and WMD to both state and non-state actors. The European Union and the United States worked together to obtain the Security Council's unanimous adoption of UNSCR 1673, which extends for two years the mandate of the Committee established pursuant to UNSCR 1540. We took actions to put in place the legal and regulatory infrastructure to prevent the proliferation of WMD and their means of delivery, particularly to terrorists. We launched a dialogue on compliance and verification issues where we undertook to examine a number of concrete challenges to some specific disarmament and non-proliferation regimes, and have agreed to continue this exchange focusing on individual countries of concern and specific Treaty regimes. We have begun discussions in the run-up to the 2006 Biological and Toxin Weapons Convention Review Conference. We also worked together to strengthen the Non-Proliferation Treaty (NPT) and the International Atomic Energy Agency (IAEA), including through the Committee on Safeguards and Verification and by promoting adherence to safeguard agreements and the Additional Protocol and to promote the negotiation in the Conference of Disarmament of a treaty banning the production of fissile material for nuclear weapons or other nuclear explosive devices. We reaffirmed the value of continuing consultations on arms control, non-proliferation, and disarmament issues and will seek ways of strengthening coordination.

On **crisis management**, we have begun a positive and mutually beneficial dialogue. Working contacts between EU institutions and their U.S. counterparts have multiplied, both in Brussels and in crisis areas, contributing to an efficient cooperation on specific issues such as the Democratic Republic of Congo (DRC) and Sudan, where the European Union and NATO have helped support the African Union Mission in Sudan (AMIS). Informal consultation and cooperation mechanisms have been established between EU representatives and the U.S. Coordinator for Stabilisation and Reconstruction. For the first time the European Union has hosted a series of briefings for the yearly U.S. politico-military conference in Brussels. We look forward to closer cooperation in early warning in order to identify potential crises at an early stage and respond effectively to resolve conflict and prevent instability.

2006 EU-U.S. SUMMIT PROGRESS REPORT ON THE ECONOMIC INITIATIVE

Introduction

Following the commitment at the 2004 Dromoland Summit to further transatlantic economic integration, the June 2005 EU-U.S. Summit launched the “Initiative to Enhance Transatlantic Economic Integration and Growth”. This covers regulatory and standards cooperation, open and competitive capital markets, innovation and the development of technology, trade, travel and security, energy efficiency, protection of intellectual property rights, investment, competition policy and enforcement, procurement and services. A joint EU-U.S. Work Programme to implement the Initiative was welcomed at the informal EU-U.S. Economic Ministerial in November 2005. This report notes areas of progress made in the past seven months to implement this multi-annual programme under the Economic Initiative and in other areas of transatlantic cooperation.

Key Accomplishments

The joint **Action Strategy for the Enforcement of Intellectual Property Rights** in third countries is ready for endorsement at the Summit. Implementation has already started with concrete actions aimed at promoting strong and effective enforcement in third countries, strengthening cooperation to reduce global piracy and counterfeiting, and fostering public-private partnerships to protect intellectual property.

The renewal of the **Agreement on Higher Education and Vocational Training** will be signed in the margins of the Summit.

We look forward to concluding a first-stage **Air Transport Agreement** before the end of this year.

We also hope to conclude an **Agreement on Cooperation in the Regulation of Civil Aviation Safety** within the next twelve months, which will ensure safer transatlantic air travel.

The renewal of the “**Energy Star Agreement**” for the promotion of energy efficient office equipment has been initialled and will be signed by the end of the year.

A first phase Agreement was signed on **Trade in Wine**, which establishes mutual acceptance of existing wine-making practices on both sides and recognises each other’s names of origin. Negotiations on the second phase are now starting.

Regulatory Cooperation

Regulatory cooperation was enhanced in three ways. First, a dialogue was initiated between the **European Commission and the U.S. Office of Management and Budget** on issues of a "horizontal" nature, such as transparency and methodologies for impact and risk assessment, in order to improve our understanding of each other's regulatory systems and practices. Second, a **High-level Regulatory Cooperation Forum** was established. It held its initial meeting in Brussels on "good regulatory practices" in January, followed by a meeting in Washington D.C. in May on "best cooperative practices and regulatory work plans". As a result, a set of best cooperative practices was established to guide regulators and complement our Guidelines for Regulatory Cooperation and Transparency. Views were also exchanged on the way our respective regulatory work plans are created, and new topics for cooperation were identified. Building on the success of the first two meetings, the European Union and the United States will continue their exchanges in future Forum events. Third, regulators on both sides continued to work on sector-specific areas covered by the **Roadmap for Regulatory Cooperation**. There was notable progress in a number of dialogues, including those on pharmaceuticals, consumer product safety and energy efficiency. A detailed account of progress can be found in the Joint Report on the Roadmap for EU-U.S. Regulatory Cooperation.

Transatlantic Capital Market Integration

In the context of the EU-U.S. **Financial Markets Regulatory Dialogue**, progress has been made. On accounting standards, both sides confirmed their strong commitment to achieving the goal of eliminating reconciliation requirements and promoting convergence, clarifying the steps required to get there and enhancing cooperation among regulators to ensure optimal outcomes. Some other recent positive developments involve the supervision of financial institutions, notably the implementation of Basel II on international capital adequacy standards, and the supervision of financial conglomerates, reinsurance of collateral requirements; and proposed rules to facilitate deregistration of foreign firms that no longer want to trade in the U.S. stock markets.

Investment

The European Union and the United States recognise the importance of maintaining open investment regimes that can create new opportunities and build prosperity. We have agreed to continue our discussions on investment issues including to address any remaining significant obstacles to investment between us.

Energy Security

Joint cooperation on **energy security** has started with the aim of improving reliability of energy supplies by increasing diversification, making better use of renewable energy sources, using energy more efficiently and cooperating to encourage improved energy security policies in third countries. The European Union and the United States have held four joint workshops on energy technologies, efficiency and alternative fuels. An agreement on the International Thermonuclear Energy Reactor (ITER) was initialled in May 2006 and will be signed at the Fall ITER Ministerial. The European Commission is joining the **Methane-to-Markets Partnership**.

Innovation

In the field of spurring **innovation** and the development of technology, the European Union and the United States are cooperating to improve their common knowledge on how to measure their innovation performance and to understand better each other's **innovation policies**. A rolling work plan on **e-accessibility** has been agreed and has started, with a goal of reaching a coherent approach on our policies in this area. A new EU-U.S. **civil space dialogue** has been launched and will be continued next year. Transatlantic conferences have been held on the medical and health aspects of **nanotechnology**. A possible coordinated call for research proposals in the field of nano(eco)toxicology is being examined. The Commission has launched a wide public debate on **Radio Frequency Identification** technology that will include a series of workshops with invited U.S. speakers. Discussions on **cyber security** policy are being planned. Ongoing EU-U.S. cooperation to tackle **spam** led to the organisation of a joint workshop on spam enforcement and contributed to the adoption by the Organisation for Economic Cooperation and Development (OECD) of a number of recent initiatives. We have started discussions on **e-health** initiatives, and will hold a first EU-U.S. workshop on patient safety, meet on joint research on biomedical informatics, and establish working groups on interoperability and certification of electronic health record systems. The renewal of the administrative arrangement for the **EU-U.S. Task Force on Biotechnology Research** has been signed in June 2006.

Trade, Travel and Security

Negotiations are being pursued on **visa exempt travel** and on comparable results aiming at equivalence between the EU **Authorised Economic Operator** provisions and the U.S. **Customs-Trade Partnership Against Terrorism**. The European Union and the United States are coordinating capacity building assistance for the implementation of the World Customs Organisation Framework of **Standards to Secure and Facilitate Global Trade**. EU and U.S. customs authorities are working on simultaneous **risk analyses** on identical data to facilitate exchange of information between customs administrations on the results of risk analysis, and to promote cooperation on enforcement and prevention of incidents. As part of **container security cooperation**, minimum requirements and control standards for feeder ports have been agreed and are currently being implemented. Discussions are taking place on ways of improving cooperation on **air transport security and cargo traffic**. There have been joint air cargo security training visits and joint air cargo inspection missions. Work on **security related technologies** is continuing with the aim of creating a better understanding of each others' security research programmes, sharing experiences on the potential use of sensor-network technologies in addressing security concerns, and discussing new rules for advanced notification of documentation prior to arrival at the port of entry.

Government Procurement

The European Union and the United States have worked extensively in order to advance the negotiations on the **revision of the WTO Government Procurement Agreement (GPA)** to reach the mutual goal of completing the review by the end of 2006, including through joint submissions to the GPA Committee. The European Union and the United States will take steps to ensure that negotiations on all pending **accessions to the GPA** are accelerated and that all countries that took commitments to start negotiations for accession to the GPA respect them.

Services

European and American architectural professional organisations signed a joint recommendation for a **Mutual Recognition Agreement for Architects** in **November 2005**. The European Commission and the U.S. government, in close cooperation with relevant regulators and professional associations, will consider options to promote progress towards such an agreement in accordance with each side's legal systems.

JOINT REPORT ON THE ROADMAP FOR EU-US REGULATORY COOPERATION

At the June 2005 EU-US Summit, the United States and European Commission issued the Roadmap for EU-US Regulatory Cooperation to provide a framework for cooperation on a broad range of important horizontal and sectoral areas. Under this ongoing multi-year initiative, US and European authorities aim to build effective mechanisms to promote better quality regulation, minimize unnecessary regulatory divergences to facilitate transatlantic trade and investment and increase consumer confidence in the transatlantic market.

This joint report highlights key Roadmap achievements over the past year and highlights some future work that the United States and the European Commission intend to advance in the coming year – both specific sectoral activities as well as horizontal initiatives. This work will evolve as each side continuously examines areas of mutual interest for regulatory cooperation, and considers input from interested transatlantic stakeholders.

Since the 2005 EU-US Summit, we have advanced EU-US regulatory cooperation in three principal ways:

- 1) We established the EU-US High-Level Regulatory Cooperation Forum and held its initial meeting in Brussels on "good regulatory practices" in January, followed by a meeting in Washington D.C in May on "best cooperative practices and regulatory workplans." As a result, we have developed a set of Best Cooperative Practices to guide regulators and complement our Guidelines on Regulatory Cooperation and Transparency.
- 2) We initiated a dialogue between the US Office of Management and Budget and relevant experts in the European Commission to address horizontal regulatory management issues (e.g., transparency, risk assessment, impact assessment, public consultation) in order to improve our understanding of each others' regulatory systems and practices.
- 3) US, European Commission, and, where relevant, European Community regulators are pursuing a broad range of sector-specific activities covered by the Roadmap for EU-US Regulatory Cooperation. We achieved notable progress in a number of areas, including pharmaceuticals, consumer product safety, and energy efficiency. We are building on this successful work by pursuing cooperation on new topics (see report annex).

Further information about cooperative activities under this initiative is available at:

http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/Section_Index.html

http://europa.eu.int/comm/enterprise/enterprise_policy/gov_relations/internatl_regul_coop_eu_us/index.htm

I. EU-US High-level Regulatory Cooperation Forum

- We established the High-level Regulatory Cooperation Forum as a platform for activities related to promoting cooperation on cross-cutting regulatory cooperation topics and developing a future cooperative agenda.
- We conducted two High-level Regulatory Cooperation Forum events: 1) Conference on Good Regulatory Practices in January 2006, hosted by the European Commission in Brussels; 2) Conference on Best Cooperative Practices and US and EC Regulatory Workplans in May 2006, hosted by the US Government in Washington D.C.
- Based on Forum discussions and the experiences gained through a wide range of EU-US regulatory cooperation activities, we developed an agreed set of Best Cooperative Practices (link) to guide regulators and complement the EU-US Guidelines on Regulatory Cooperation and Transparency.
- Through our exchanges, we identified a range of new topics for regulatory cooperation to pursue under selected sectoral dialogues (see report annex).
- Building on the success of the first two meetings, we will continue this exchange at future Forum events and other conferences.

II. Horizontal Initiatives

A. OMB-EC Dialogue:

- We established an informal dialogue led jointly by the US Office of Management and Budget (OMB) and the relevant services of the European Commission to discuss general regulatory policies and practices of mutual interest, and promote a better understanding of our respective regulatory systems.

- The OMB-EC Dialogue met in September 2005 (Washington) and January 2006 (Brussels) to discuss good regulatory practices, with a focus on transparency provisions and public consultation, and our respective impact assessment methodologies.
- Building on extensive exchanges, we are comparing our respective guidelines for conducting impact assessments.
- In the coming year, the Dialogue is considering to conduct a comparison of our respective risk assessment methodologies.
- We will explore how our horizontal dialogue on good regulatory practices (e.g., transparency, impact assessments) can feed more effectively into ongoing sectoral dialogues.

B. EU-US Experts Exchange Program:

- Our horizontal and sectoral dialogues in the past year have underscored the importance of promoting more extensive exchanges of US and EC regulatory experts.
- We intend to enhance mechanisms to promote exchanges of US and European regulatory experts in specific areas/projects of mutual interest that otherwise cannot be funded through existing regulatory agency budgets.
- We are working to target such exchanges to specific priority areas of regulatory cooperation, such as discrete topics identified in the Roadmap for Regulatory Cooperation.

III. Sectoral Activities

1. Pharmaceuticals

1.1 Human medicinal products

Objective: Cooperation between the US Food and Drug Administration (FDA), DG Enterprise and Industry/Pharmaceuticals Unit and the European Medicines Agency (EMA) on matters related to ensuring the safety, quality, and efficacy of pharmaceutical products.

In the past year, FDA, DG Enterprise and Industry and the EMEA substantially enhanced their regulatory dialogue and expanded their exchange of information and data on pharmaceuticals.

- FDA, DG Enterprise and Industry and EMEA pursued a broad range of robust cooperative work outlined in the Implementation Plan for Medicinal Products for Human Use, including sharing of regulatory and inspectional information, scientific exchanges, and parallel scientific advice.
- FDA and EMEA pursued a pilot program to support parallel scientific advice on pharmaceuticals. After successful work on five drugs in the past year, this pilot program was renewed in 2006.
- FDA and EMEA initiated cooperation in a new area in the past year – pharmacogenomics. In May 2006, FDA, EMEA and the EC issued agreed principles for processing joint FDA-EMEA voluntary genomic data submissions, including joint briefings for sponsors. This process helps ensure that regulatory authorities are familiar with issues arising from the integration of pharmacogenomics in drug development and that industry has an opportunity to hear scientific perspectives from FDA and EMEA.
- FDA, DG Enterprise and Industry and EMEA are collaborating effectively on the harmonization of technical requirements for registering pharmaceuticals through the International Conference on Harmonization (ICH). Over 50 harmonized guidelines have been issued to date on various issues of pharmaceutical quality, safety, efficacy and electronic exchange of information. At the Steering Committee meeting in November 2005, discussion began on strategies to make the process more efficient. Discussions on the “Future of ICH” will continue at the next meeting in Yokohama in June 2006.
- FDA and EC experts plan to intensify cooperation in the next year, with particular focus on vaccines (including preparedness for influenza pandemic), medicines for children; medicines for rare diseases (‘orphans’), oncology, pharmacogenomics and counterfeit medicines.
- FDA and EC experts plan to hold a workshop in 2007 on better regulation of medicinal products through transatlantic dialogue.

1.2. Veterinary medicinal products

Objective: Enhance the existing regulatory dialogue between the FDA and the **European Commission** and the European Medicines Agency (EMA), building upon ongoing cooperative activities in the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH).

- FDA, the European Commission, and EMA are pursuing cooperation on: 1) harmonized guidelines for regulatory requirements where significant differences exist among VICH members; 2) the global response to significant emerging issues and science that impact on regulatory requirements within VICH regions and/or adopted VICH guidelines; and 3) promotion of consultation and communication mechanisms that result in wider international awareness and acceptance of VICH guidelines.
- Through a nine step process, VICH has finalized 41 guidance documents since its start. Expert Working Groups meet throughout the year and report their progress to the VICH Steering Committee.
- The 17th VICH Steering Committee met to oversee and manage harmonization activities in Japan, October 31-November 1, 2005. The 18th VICH Steering Committee meeting, first meeting of the Phase II of the VICH process, was held in London at EMA, May 31 – June 1, 2006. The 19th VICH Steering Committee will be held in Washington in January 2007.

2. Automobile Safety

Objective: Cooperation between the US National Highway Traffic Safety **Administration** (NHTSA) and DG Enterprise and Industry/Automobile Unit in areas of automobile safety regulations.

- NHTSA-DG Enterprise and Industry are pursuing regulatory cooperation on safety of hydrogen fuel cell vehicles and vehicle compatibility.
- We are exploring cooperation on the regulatory approaches for electronic stability control systems and collision avoidance systems.

- We are discussing ways to promote a science-based approach to global technical regulations under the United Nations 1998 Agreement.

3. *Information and Communications Technology Standards in Regulations*

Objective: Cooperation between the US Department of Commerce and DG **Enterprise** and Industry and DG Information Society and Media on the use of information and communication technology (ICT) standards in accordance with the Terms of Reference established in March 2004.

US and EC experts agreed on a rolling work plan and work is well underway on many of the tasks envisioned. Key accomplishments include:

- Conducted two successful international workshops within the framework of the ICT dialogue on e-accessibility: one on public procurement and one on conformity issues related to the accessibility of ICT products and services.
- The US Access Board will review the standards for electronic and information technology covered by section 508 of the Rehabilitation Act and by section 255 of the Telecommunications Act. The US Access Board will issue an invitation to the European Commission to participate in the relevant Federal Advisory Committee to ensure coherence in requirements to the greatest extent possible.
- The EC has launched a mandate to the European Standards Organizations for developing a standard for accessibility of ICT products to be used in public procurement. This mandate specifically calls for coordination with US developments.
- In the second half of 2006, an exchange of information is planned, and a study tour is being considered, focusing on how US government agencies determine/demonstrate that ICT products conform to requirements. The EC is interested in learning from US government and industry experience on conformity assessment.
- Both sides are working to identify better methods to assess and quantify progress made in providing greater access to ICT products and are interested in exchanging experiences.

4. *Cosmetics*

Objective: Cooperation between the US Food and Drug Administration (FDA) and DG Enterprise and Industry/Cosmetics Unit regarding: (a) alternative (i.e., non-animal) testing methods; (b) respective regulatory approaches applied in the areas of hair dyes and sunscreen ingredients (UV filters); and (c) other projects of mutual interest.

- FDA and the EC are pursuing cooperation in cosmetics and certain over-the-counter drugs harmonization activities under the Cosmetics Harmonization and International Cooperation (CHIC) process.
- In the framework of CHIC, FDA and DG Enterprise and Industry are exchanging extensive information on the respective regulatory systems, safety concerns, and alternative test methods, including the discussion on the establishment of a rapid alert system to exchange data on adverse reactions.
- The US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the European Centre for the Validation of Alternative Methods (ECVAM) are collaborating closely on the development and validation of alternative test methods to animal testing for cosmetic ingredients.

5. *Consumer Product Safety*

Objective: Cooperation between the US Consumer Product Safety Commission (CPSC) and DG Health and Consumer Protection in association with DG Enterprise and Industry regarding the safety of consumer products.

CPSC and DG Health and Consumer Protection launched a senior-level dialogue and **signed** an exchange of letters in February 2005 to implement mutually agreed Guidelines for Information Exchange and Cooperation intended to strengthen bilateral communication and to improve U.S and EU consumer health and safety protection. In the past year, CPSC and DG Health and Consumer Protection have built upon these Guidelines through pursuit of a range of specific cooperative projects in the area of consumer product safety, including:

- Joint support for the International Consumer Product Health and Safety Organization (ICPHSO) and creation of the International Consumer Product Safety Caucus (ICPSC) for government regulators to discuss international consumer product safety issues of common concern.
- Collaboration on strategies to increase regulatory compliance of products manufactured in China, including training opportunities.
- Cooperation on standards for child-resistance mechanisms for cigarette lighters.
- Sharing of product recall information involving magnetic toys and lead in jewelry.
- Enhanced cooperation and understanding in the area of science-based risk assessment. Joint investigation into the respective risk assessment analyses concluded in certain cases.

6. *Consumer Protection Enforcement Cooperation*

Objective: Develop mutual assistance mechanisms in the field of cross-border **consumer** protection enforcement cooperation. Build on the existing informal dialogue between the European Commission/DG Health and Consumer Protection and the US Federal Trade Commission (FTC) in the ways foreseen by article 18 of Regulation 2006/2004 on consumer protection cooperation (CPC), including through the possible establishment of a EU/US mutual assistance agreement.

- Congress has considered, and the Senate has passed, legislation mirroring the CPC provisions on cross-border consumer protection enforcement. FTC and DG Health and Consumer Protection are laying the groundwork for enhanced effective cooperation.

7. *Unfair Commercial Practices*

Objective: Establish regulatory dialogue between the FTC and DG Health and Consumer Protection on unfair commercial practices. This dialogue will aim at increasing convergence in this area.

- In October 2005, DG Health and Consumer Protection studied extensively how the FTC has implemented its laws against unfairness and deception. Since then, DG Health and Consumer Protection has shared with FTC updates on its process for transposing the Unfair Commercial Practices Directive.

8. *Nutritional Labeling*

Objective: Cooperation between FDA and DG Health and Consumer Protection on issues of mutual interest in the field of nutritional labelling.

- Experts from FDA and DG Health and Consumer Protection are engaged in discussions on regulatory issues relating to health claims, nutrition labeling, fortification, supplements, and infant formula. Specific areas under discussion include: 1) possible collaboration on the EU's Estimated Average Requirement (EAR) and the US Recommended Daily Allowances (RDA) for nutrients; and 2) cooperation on food labels.
- FDA and DG Health and Consumer Protection concluded a confidentiality arrangement in 2005 to facilitate the sharing of non-public information in this subject area.

9. *Food Safety*

a.1. Objective: Cooperation between the US Food and Drug Administration (FDA), DG Health and Consumer Protection and DG Enterprise and Industry on broad range of food safety issues of mutual interest.

- FDA and Health and Consumer Protection experts are pursuing specific regulatory cooperation projects in the areas of seafood and dairy.
- FDA and DG Health and Consumer Protection concluded an exchange of letters in June 2005 to facilitate the sharing of non-public data/information.
- FDA and DG Health and Consumer Protection concluded an implementation plan in September 2005 on the sharing of confidential information related to food safety, including guidance documents, documentation relating to controls, and information relating to notification system relevant to food safety.

- FDA and DG Health and Consumer Protection initiated in June 2006 an informal exchange on food nanotechnology cooperation.

a.2. Objective: Cooperation between DG Health and Consumer Protection and the US **Department** of Agriculture (USDA) Food Safety Inspection Service (FSIS) on legislation concerning meat and meat products.

- FSIS, FDA and DG Health and Consumer Protection held a seminar focused on Hazard Analysis and Critical Control Point (HACCP). The meeting was successful and the main goal was reached. However it appeared evident that the two systems, although based on the same principles, are still different for important points.
- FSIS and DG Health and Consumer Protection are exploring how to concretely pursue equivalence between the respective Hazard Analysis and Critical Control Point (HACCP) based control systems for meat and meat products.
- FSIS and DG Health and Consumer Protection are exploring a new equivalence determination exercise between the relevant US and EU legislation.

b. Objective: Cooperation between FDA and the European Food Safety Authority (EFSA) on food safety issues, including information sharing on risk assessments.

- FDA and EFSA have initiated a cooperative dialogue.
- FDA and EFSA concluded a confidentiality arrangement to facilitate the sharing of non-public data/information relating to food issues.
- FDA is assisting EFSA in the development of a strategy for the conduct of microbial risk assessments.

c. Objective: Establish new regulatory dialogue between the USDA, EFSA and DG **Health** and Consumer Protection in order to provide greater transparency regarding each side's development of risk assessments for animal, plant, and consumer safety.

- USDA and EFSA are discussing approaches to risk assessments and future plans based on our common interest in promoting sound science.

- USDA and EFSA are exploring an exchange of staff to facilitate mutual understanding of each other's approach to the risk assessment process. In particular, this would include EFSA hosting an APHIS expert in risk analysis. In return APHIS offered to host an EFSA expert at one of APHIS' risk assessment centers in the United States.

10 *Marine Equipment*

Objective: Consistent with the objectives of the US-EC Marine Equipment MRA, enhance the regulatory dialogue between the US Coast Guard (USCG) and DG Energy and Transport and DG Trade¹ assisted by the European Maritime Safety Agency (EMSA) aimed at increased convergence of US and EU technical regulations for marine equipment.

- USCG and DG Energy and Transport are in the process of developing a two-way Alert System for the notification of urgent safety issues associated with marine equipment approved under the MRA.
- The MRA has enhanced communication and cooperation concerning the testing methods and proper certification of equipment safety to ensure their compliance with IMO standards.
- USCG and EC to explore achieving equivalent US and EU technical regulations for specific marine equipment and expanding the product scope of the US-EC Marine Equipment MRA.

11. *Eco-Design*

Objective: Cooperation between the US Environmental Protection Agency (EPA) and DGs Energy and Transport, Environment and Enterprise and Industry in the area of eco-design of energy-using products at the appropriate technical level.

¹ In this context, reference to DG Energy and Transport/DG Trade must be understood to include the necessary consultations with Member States within the EU.

- EPA and the EC to explore possibilities to share experience on respective approaches relative to: the eco-design of energy-using products (EuP), Integrated Product Policy (IPP), restrictions on hazardous substances (RoHS) and waste from electrical and electronic equipment (WEEE) and to exchange information informally on standards and other topics of mutual interest.
- EPA to share information informally on approaches and activities at EPA including the new IEEE standard 1680 Electronic Product Environmental Assessment Tool (EPEAT) and Design for Environment (DfE) program.

12. *Chemicals*

Objective: Pursue informal cooperative dialogue, in the spirit of the EU-US **Guidelines** on Regulatory Cooperation, between the US Environmental Protection Agency (EPA), DG Environment, DG Enterprise and Industry and DG Health and Consumer Protection and relevant agencies on chemicals related issues of mutual interest.

- The US EPA and the European Commission are together leading and will continue to collaborate in the OECD Chemicals Committee's work on the development of the Global Chemicals Portal, among other pertinent and emerging issues. The US High Production Volume Information System (HPVIS) recently came online and will be one of the national databases contributing to the Portal.

13. *Energy Efficiency*

Objective: Building upon the existing cooperative dialogue between the US Environmental Protection Agency (EPA), US Department of Energy and the European Commission's DG Energy and Transport, engage on a broad range of energy efficiency issues of mutual interest.

- We have finalised the negotiations on a new EU-US agreement on Energy Star for office equipment. The new agreement will contain more ambitious energy efficiency criteria. We plan to sign this Agreement by fall 2006.

- The US and the EC have revised the energy efficiency criteria for imaging equipment (printers, copiers, scanners, fax machines, mailing machines, and multifunction devices) and computer monitors. These revisions make the specifications more stringent, such that ENERGY STAR qualified models represent the top performers in the market without a sacrifice in features or performance. The revision of the energy efficiency criteria for computers will be finalized soon. We will continue our efforts to keep the criteria up to date in order to further foster energy efficiency in office equipment.
- We intend to pursue further cooperation on energy efficiency on the basis of the renewed EU-US Energy Star Agreement.

14. *Telecommunications and Radiocommunications Equipment, Electromagnetic Compatibility*

Objective: Building on existing regulatory dialogues between the US Federal **Communications** Commission (FCC) and the European Commission, and the US-EC Mutual Recognition Agreement (MRA), pursue enhanced cooperation on regulatory approaches in the areas of telecommunications, radiocommunications equipment and electro-magnetic compatibility.

- The FCC and the EC are consulting on regulatory developments in our respective markets and will consider cooperative approaches for achieving consistent regulatory treatment of telecommunications and radiocommunications products.
- FCC and EC will pursue a dialogue on regulatory approaches relating to software-defined radio and cognitive radio and on radio spectrum policy.

15. *Medical Devices*

Objective: Enhance the existing regulatory dialogue between the FDA and DG **Enterprise** and Industry and DG Trade on medical devices, building upon ongoing cooperative activities in the Global Harmonization Task Force (GHTF) and consistent with the objectives of the US-EC MRA annex on medical devices.

- Our regulatory authorities are promoting cooperative activities in the Global Harmonization Task Force (GHTF), including the preparation of guidance documents and compatible regulatory approaches for medical devices.

- We have agreed to expand the FDA-DG ENTR-EMEA confidentiality arrangement to include exchanges of information relating to medical devices.
- We are pursuing implementation of the US-EC MRA annex on medical devices and an agreed approach for bringing the MRA annex into operation.
- We are exploring the possible expansion of the product scope of the EU-US MRA annex of medical devices to include in-vitro diagnostic devices.

Annex: New Topics for EU-US regulatory cooperation in 2006/2007

1. Horizontal OMB-EC dialogue:

- Finalise joint comparison of our respective practices on impact assessments
- Compare notes and approaches on how to carry out risk assessments
- Consider potential training schemes on better regulation topics
- Compare respective rule-making procedures – linkages with other studies
- Conduct exchange and discussion of our respective regulatory workplans
- Explore how horizontal dialogue on good regulatory practices (e.g., transparency, impact assessments) can feed more effectively into ongoing sectoral dialogues

2. Sector-specific dialogues:

Pharmaceuticals:

- Intensify cooperation, with particular focus on vaccines (including preparedness for influenza pandemic), medicines for children; medicines for rare diseases ('orphans'), oncology, pharmacogenomics and counterfeit medicines
- Hold workshop in 2007 on better regulation of medicinal products through transatlantic dialogue

Telecommunications and Radiocommunications equipment

- Promote dialogue/cooperation on regulatory approaches relating to software-defined radio and cognitive radio and on radio spectrum policy

Energy Efficiency

- Pursue cooperation on the basis of the renewed EU-US Energy Star Agreement

Medical Devices

- Expand the FDA-DG ENTR-EMEA confidentiality arrangement to include exchanges of information relating to medical devices
- Expand the scope of the US-EC MRA annex to include in-vitro diagnostic devices

Marine Equipment

- Establish a two-way alert system for sub-standard marine equipment
- Expand the product scope under the EU-US MRA

Automobile Safety

- Explore cooperation on the regulatory approaches for electronic stability control systems and collision avoidance systems

EU – US ACTION STRATEGY FOR THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

At the 2005 EU–US Summit, our Leaders agreed that:

“Growing global piracy and counterfeiting threatens the competitiveness of innovative industries, the livelihoods of creative artists and workers, and the health and safety of consumers in the European Union, the United States and beyond. We are committed to effectively combating piracy and counterfeiting at home and abroad” (2005 EU-US Economic Initiative)

In order to implement this objective, the EU and the US have issued this Action Strategy for the Enforcement of Intellectual Property Rights with concrete actions aimed at:

- Promoting strong and effective enforcement internally and at our borders;
- Strengthening cooperation to reduce global piracy and counterfeiting; and
- Fostering public-private partnerships to protect intellectual property.

Following the informal EU-US Economic Ministerial in November 2005, a working group composed of officials representing lead agencies and services from both administrations was constituted to identify the areas and modalities for joint action. The working group has operated in close consultation with industry and other interested parties and will ensure their active participation in the strategy’s implementation.

The EU and the US now agree to the following action points:

I. Improving Enforcement

a) On Customs and border control

1. Increase cooperation to strengthen border enforcement of IP rights, taking fully into account the five-point plan agreed in the framework of the Joint Customs Cooperation Committee (JCCC):

- Exchange IPR border enforcement practices and experiences: Risk analysis and management, statistical seizure data, working with right holders and right holder use of customs resources to enforce their rights, enforcement techniques, and legislation.
- Exchange of operational staff: Jointly target and examine shipments to obtain additional insight into IPR enforcement practices and experiences.
- Exchange of enforcement information on IPR seizures and trends Enhancing targeting and controls for counterfeit goods posing health and safety or security risks is a priority for cooperation in this area. A mechanism for making exchanges is under development.
- Identification of specific areas for cooperation. Issuance of joint guidelines to assist the private sector to take advantage of the border enforcement tools that are available to protect IP. Closer cooperation with customs authorities, for example by creating IP toolkits, to assist customs officers has been identified as an area for cooperation. Development of guidelines underway.
- Engagement in a joint IPR border enforcement action, in areas of particular concern to be jointly agreed (for instance involving security/safety and public health issues).

b) *Bilaterally*

2. Step up our actions to encourage third countries to enforce IPR and to combat counterfeiting and piracy. This should be done *inter alia* through coordinated efforts that draw upon information from industry; coordinated messages on key enforcement issues and active complementing of each others' bilateral efforts working with third countries; and exchange of information about significant IP-related meetings and other events that provide opportunities to advance these objectives.
- Our initial efforts will focus on China and Russia as well as other infringing and trans-shipment areas of key concern in Asia, Latin America and the Middle East.

3. Create bilateral IP networks in our Embassies/Delegations in relevant third country capitals to facilitate information sharing, delivery of complementary and/or joint messages as appropriate, cooperation on training and technical assistance programmes, and assisting industry enforcement efforts.
- Expand cooperative action in Beijing and Moscow with future consideration of extension to other third country capitals.

c) Multilaterally

4. Facilitate the ongoing OECD IP study by providing data and any other necessary and available resources, recognizing that current, independent and reliable information on the scope and effects of IP theft will shape a more compelling pro-IP enforcement message for consumers and governments worldwide.
5. Support implementation of the 2005 G8 Leaders Statement on Reducing IPR Piracy and Counterfeiting through More Effective Enforcement, in particular in the area of the fight against criminal infringements of IP rights to reduce substantially global trade in pirated and counterfeit goods.
6. Enhance collaboration against counterfeiting and piracy in relevant multilateral venues, including the WTO (TRIPS-Council). In particular, we will ensure cooperation and effective European Community participation in WIPO activities relating to intellectual property rights enforcement.
7. Encourage and assist third countries to implement the WTO Agreement on Trade Related Aspects of Intellectual Property Rights.

d) On technical assistance

8. Strengthen IPR enforcement internationally through coordinated and/or complementary technical assistance cooperation and capacity building programmes, including addressing the issue of public awareness. Share information with each other and with industry on training opportunities and programmes. Launch joint activity in capacity building programmes in select key countries. Identify ways to increase private sector participation/support.

- Reference US: USG Training Coordination Group site - www.training.ipr.gov.
- Reference EU: DG Trade Website.
- Initial programmes for cross-participation to include ECAP II and Paraguay.

II. Promoting public-private partnerships

9. Involve industry by providing information on IPR related meetings and activities in third countries to facilitate industry input and providing feedback on meetings and results.
10. Launch joint public-private roundtable discussions in third countries, with the support of our interested parties, to prioritise key IPR enforcement challenges.
11. Assist SMEs with IPR protection and enforcement challenges in third countries.
 - Share information on SME challenges and existing programmes and efforts to educate and cooperate with SMEs on IP protection and enforcement in third countries.
12. Increase public awareness of the need to address IPR infringements such as at trade fairs and share ideas on ways to improve enforcement against such infringements, in cooperation with the interested parties.

Invite industry to:

13. Assume an expanded role in the public-private enforcement partnership by working closely with and supporting law enforcement agencies' efforts:
 - Share more information and intelligence with the relevant authorities, lodge well-developed and defined requests for assistance, follow-through on complaints and support measures taken. Authorities will respect industry's confidentiality concerns regarding information provided.

- Provide us with information on successful IP industry coalition models and explore how such models could be expanded to include industries in third countries.
14. Provide the US and EU with as much reliable and timely information as possible about the IP enforcement environment in key countries to equip senior government officials to address more effectively industry concerns with third country governments.
 15. Provide the US and EU with information on industry IP public awareness and other educational campaigns, including programmes for government officials and industry-developed sectoral best practices for enforcement.
-