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SUBJECT: EU CHEMICALS POLICY: USG DEMARCI

REF: STATE 263412 (2002)

1. THIS IS AN ACTION REQUEST. PLEASE SEE PARA 10.

2. SUMMARY: THE EUROPEAN COMMISSION IS CURRENTLY FINALIZING ITS PROPOSAL FOR A COMPREHENSIVE NEW EU REGULATORY REGIME FOR CHEMICALS, WHICH WILL LIKELY IMPOSE EXTENSIVE NEW TESTING REQUIREMENTS ON OVER 30,000 CHEMICALS, AND EXTEND DATA REQUIREMENTS TO DOWNSTREAM USERS OF CHEMICALS. THE USG IS CONCERNED THAT THE COMMISSION'S APPROACH APPEARS TO BE A COSTLY,

BURDENSOME, AND COMPLEX REGULATORY SYSTEM, WHICH COULD PROVE DIFFICULT, IF NOT UNWORKABLE, IN ITS IMPLEMENTATION. DEPENDING ON HOW DOWNSTREAM PRODUCTS ARE ULTIMATELY ADDRESSED, U.S. EXPORTS IN MOST INDUSTRIAL SECTORS - TOTALING TENS OF BILLIONS OF DOLLARS - COULD BE IMPACTED BY THE NEW POLICY. USG AGENCIES BELIEVE IT IS IMPORTANT TO REITERATE TO THE EUROPEAN COMMISSION AND EU MEMBER STATES OUR GENERAL CONCERNS BEFORE THE COMMISSION FINALIZES ITS FORMAL PROPOSAL IN EARLY MAY. END SUMMARY.

3. THE EUROPEAN COMMISSION IS WORKING ON A COMPREHENSIVE OVERHAUL OF EXISTING EU POLICY FOR CHEMICALS REGULATION. IN ITS FEBRUARY 2001 WHITE PAPER ON A "STRATEGY FOR A FUTURE CHEMICALS POLICY," THE COMMISSION PROPOSED A NEW, EU-WIDE REGULATORY FRAMEWORK CALLED "REACH" (REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS) APPLICABLE TO ALL EXISTING AND NEW CHEMICALS. UNDER THIS PROPOSED SYSTEM, WHICH WOULD BE GROUNDED ON THE PROBLEMATIC "PRECAUTIONARY PRINCIPLE," CHEMICAL PRODUCERS AND DOWNSTREAM USERS WOULD BE RESPONSIBLE FOR TESTING CHEMICALS, CONDUCTING RISK ASSESSMENTS, AND MAKING THIS INFORMATION AVAILABLE TO A CENTRAL DATABASE. THE LEGISLATION WILL LIKELY IMPOSE EXTENSIVE NEW TESTING REQUIREMENTS ON OVER 30,000 CHEMICALS, AND EXTEND DATA REQUIREMENTS TO DOWNSTREAM USERS OF CHEMICALS. OVER THIRTY PERCENT OF U.S. CHEMICAL EXPORTS GO TO THE EU - APPROXIMATELY $20 BILLION IN 2001. DEPENDING ON HOW DOWNSTREAM PRODUCTS ARE ULTIMATELY ADDRESSED, U.S. EXPORTS IN MOST INDUSTRIAL SECTORS - TOTALING TENS OF BILLIONS OF DOLLARS - COULD BE IMPACTED BY THE NEW POLICY.

4. SUBSEQUENTLY ENDORSED BY THE EUROPEAN COUNCIL AND PARLIAMENT, THE COMMISSION (CO-LED BY DG-ENVIRONMENT AND DG-ENTERPRISE) IS NOW FINALIZING INTER-SERVICE CONSULTATIONS ON DRAFT LEGISLATION TO IMPLEMENT THE NEW REGULATORY FRAMEWORK. THOUGH SIGNIFICANT DIFFERENCES WITHIN THE COMMISSION REGARDING KEY ELEMENTS OF THE DRAFT REGULATION HAS DELAYED THE EU RULEMAKING PROCESS, WE NOW UNDERSTAND THAT THE COMMISSION INTENDS TO CONCLUDE ITS INTER-SERVICE CONSULTATION PROCESS BY MID-MAY. AS A RESULT OF WIDE STAKEHOLDER INTEREST, AS WELL AS CRITICISM FOR THE LACK OF TRANSPARENCY, THE COMMISSION HAS INDICATED IT WILL PLACE ITS DRAFT

CHEMICALS REGULATION ON THE INTRNET I MID-MAY FOR PUBLIC COMMENT (THOUGH ONLY ON IS "WORKABILITY"). FOLLOWING THIS CONSULTATON PERIOD (OF PERHAPS 4-5 WEEKS), WE UNDESTAND THE COMMISSION AIMS TO ADOPT ITS FIAL PROPOSAL BEFORE ITS AUGUST BREAK. UNDER THE EU' RULEMAKING PROCESS, THE COUNCIL AND THE UROPEAN PARLIAMENT MUST THEN APPROVE THE CMMISSION'S PROPOSAL. ADOPTION OF A COUNCIL COMMON POSITION AND EUROPEAN PARLIAMENT FIRST READING NOW IS NOT EXPECTED BEFORE SPRING 2004.

5. WHILE WE DO NOT YET KNOW THE FULL DETAILS OF THE DRAFT LEGISLATION, THE WHITE PAPER OUTLINES WHAT APPEARS TO BE A COSTLY, BURDENSOME, AND COMPLEX REGULATORY SYSTEM, WHICH COULD PROVE DIFFICULT, IF NOT UNWORKABLE, IN ITS IMPLEMENTATION. THE SYSTEM COULD PRESENT OBSTACLES TO TRADE AND INNOVATION, POSSIBLY DISTORTING GLOBAL MARKETS FOR THOUSANDS OF PRODUCTS. THE COMMISSION CONCEDES THAT EU CHEMICALS TESTING CAPACITY IS CAPABLE OF UNDERTAKING ONLY 25-30 PERCENT OF THE TESTING THAT COULD BE POTENTIALLY REQUIRED OVER THE FIRST 10 YEARS. THE COMMISSION HAS ESTIMATED THE COSTS OF IMPLEMENTING REACH AT 18-32 BILLION EUROS OVER A PERIOD TO 2020.

6. RECENT COMMISSION COMMUNICATIONS INDICATE THAT SOME REACH REQUIREMENTS ARE LIKELY TO BE REDUCED SOMEWHAT FROM THOSE THAT COULD HAVE FLOWED FROM THE WHITE PAPER. FOR EXAMPLE, SUBSTANCES IN ARTICLES, POLYMERS, AND INTERMEDIATES COULD BE AFFORDED LESSER TREATMENT, AND TESTING DATA MAY NOT BE REQUIRED FOR CERTAIN SUBSTANCES. CONFIRMATION OF TREATMENT WILL DEPEND, HOWEVER, ON A DETAILED REVIEW OF THE COMMISSION'S PROPOSAL ONCE AVAILABLE.

7. WHILE THE UNITED STATES FULLY SUPPORTS THE EU'S OBJECTIVES TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT AND ACKNOWLEDGES THE NEED FOR MORE INFORMATION ON CHEMICALS, WE ARE CONCERNED THAT THE NEW POLICY COULD HAVE SIGNIFICANT ADVERSE TRADE IMPLICATIONS. THE USG HAS RAISED CONCERNS BILATERALLY AND MULTILATERALLY THAT THE COMMISSION APPROACH LACKS PRIORITIZATION AND DOES NOT ADEQUATELY ASSESS IMPLICATIONS (E.G., COSTS, TIMETABLES, ANIMAL TESTING, IMPACT ON INNOVATION, IMPACTS ON IMPORTS AND SMES). WE HAVE STRESSED THE IMPORTANCE OF TRANSPARENCY AND STAKEHOLDER INPUT IN THE

EU REGULATORY PROCESS. THE USG IS ALSO CONCERNED THAT THE EU'S APPROACH REPRESENTS A MOVE AWAY FROM GREATER HARMONIZATION OF CHEMICAL REGULATORY APPROACHES AMONG OECD COUNTRIES. EPA IS ENGAGED IN A CONSTRUCTIVE DIALOGUE WITH THE COMMISSION AT THE REGULATOR-LEVEL.

8. THERE IS GROWING INTERNATIONAL CONCERN ABOUT THE TRADE IMPLICATIONS OF REACH. MOST RECENTLY, AT THE MARCH 2003 WTO TBT COMMITTEE MEETING, JAPAN, CANADA, AUSTRALIA, CHINA, BRAZIL, KOREA, AND MALAYSIA JOINED THE UNITED STATES IN RAISING CONCERNS WITH THE APPROACH OUTLINED IN THE EC'S WHITE PAPER. THE ISSUE IS ALSO AN APEC PRIORITY THROUGH ITS CHEMICAL DIALOGUE. THE TRANSATLANTIC BUSINESS DIALOGUE (TABD) IDENTIFIED EU CHEMICALS POLICY AS A PRIORITY ISSUE AT ITS NOVEMBER 2002 CEO-LEVEL CONFERENCE.

9. EU MEMBER STATES (AND INCREASINGLY, THE ACCESSION CANDIDATES) WILL PLAY A KEY ROLE IN THE DEVELOPMENT AND APPROVAL OF ANY NEW EU CHEMICALS REGULATION. IN PARTICULAR, AS THE MEMBER STATES WILL HAVE THE RESPONSIBILITY OF IMPLEMENTING THE RESULTING REGULATION, AND AS THEIR OWN INDUSTRIES WILL BE IMPACTED, WE ANTICIPATE THAT THEY WILL BE MUCH MORE SENSITIVE TO IMPACTS ON EU COMPETITIVENESS, EMPLOYMENT, AND OTHER IMPLICATIONS THAN COMMISSION BUREAUCRATS. ALSO, THE COMPETITIVENESS COUNCIL'S INTEREST IN EU CHEMICALS POLICY SUGGESTS A MEMBER STATE INTEREST IN ENSURING BROADER CONCERNS ARE REFLECTED IN ANY FINAL REGULATION. PRESENTLY, IT APPEARS THAT MOST EU MEMBER STATES ARE WAITING TO SEE THE COMMISSION'S FORMAL REGULATORY PROPOSAL BEFORE FORMING A GOVERNMENT POSITION. HOWEVER, WE UNDERSTAND THAT GERMAN INDUSTRY, IN PARTICULAR, IS ACTIVELY EXPRESSING CONCERNS TO ITS GOVERNMENT.

10. ACTION REQUESTED: USG AGENCIES BELIEVE IT IS IMPORTANT FOR POSTS TO REITERATE TO THE EUROPEAN COMMISSION AND EU MEMBER STATES OUR GENERAL CONCERNS BEFORE THE COMMISSION REACHES AGREEMENT ON ITS FORMAL PROPOSAL. USEU IS REQUESTED TO COMMUNICATE PROMPTLY USG CONCERNS IN PARA 11 TO ALL RELEVANT COMMISSION DIRECTORATES-GENERAL. POSTS IN EU MEMBER STATES ARE REQUESTED TO COMMUNICATE USG CONCERNS TO APPROPRIATE HOST GOVERNMENT ENVIRONMENT, TRADE, INDUSTRY AND

FOREIGN MINISTRY OFFICIALS, DRAWING UPON THE TALKING POINTS IN PARA 11 AS APPROPRIATE. WASHINGTON AGENCIES WOULD APPRECIATE ANY REPORTS ON COMMISSION AND EU MEMBER STATE FEEDBACK.

11. BEGIN TALKING POINTS:

REGULATORY OBJECTIVES AND APPROACH

-- THE EU'S DEVELOPMENT OF A NEW, COMPREHENSIVE REGULATORY FRAMEWORK FOR CHEMICALS ("REACH") IS OF SUBSTANTIAL INTEREST TO THE UNITED STATES AND OTHER TRADING PARTNERS.

-- WE FULLY SUPPORT THE OVERARCHING REGULATORY OBJECTIVES OF THE POLICY TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT.

-- HOWEVER, THE COMPLEX REGULATORY APPROACH OUTLINED IN THE COMMISSION'S WHITE PAPER RAISES QUESTIONS ABOUT ITS WORKABILITY - AND THUS ITS ABILITY TO EFFECTIVELY ACHIEVE ITS HEALTH AND ENVIRONMENTAL POLICY OBJECTIVES.

-- OUR ASSESSMENT IS THAT THE PROPOSAL'S FOCUS ON TENS OF THOUSANDS OF CHEMICALS IS TOO BROAD AND LACKS PRIORITIZATION. IMPLEMENTATION MAY PROVE PROBLEMATIC. FOR EXAMPLE, WE NOTE THAT THE COMMISSION ESTIMATES THAT EU TESTING CAPACITY IS CAPABLE OF UNDERTAKING ONLY 25-30% OF THE TESTING THAT COULD BE REQUIRED OVER THE FIRST TEN YEARS.

-- WE BELIEVE THAT REGULATORY RESOURCES SHOULD FOCUS ON CHEMICALS POSING THE GREATEST HEALTH AND ENVIRONMENTAL RISKS. WE SUPPORT COMMISSION CONSIDERATION OF MECHANISMS TO BETTER TARGET RESOURCES AND REDUCE BURDENS.

-- IN THIS RESPECT, WE SUGGEST THE EXCLUSION OR MORE LIMITED TREATMENT OF CERTAIN LOW RISK TYPES OF CHEMICALS - SUCH AS CERTAIN POLYMERS AND INTERMEDIATES WHERE EXPOSURE IS NEGLIGIBLE - AND MOST CONSTITUENTS OF ARTICLES.

-- WE RECOGNIZE AND ENCOURAGE THE EU'S ONGOING CONSIDERATION OF THESE TYPES OF MECHANISMS THAT WE

BELIEVE CAN YIELD A MORE EFFICIENT REGULATION.

-- AN ADDITIONAL BENEFIT TO A MORE FOCUSED APPROACH WOULD BE REDUCED ANIMAL TESTING - AN OUTCOME WHICH WOULD BE CONSISTENT WITH EU ANIMAL WELFARE OBJECTIVES.

-- OUR EXPERIENCE SHOWS THAT ENVIRONMENTALLY SOUND MANAGEMENT OF CHEMICALS CAN BE ACHIEVED THROUGH APPROACHES THAT BETTER BALANCE RISK AND ECONOMIC CONSIDERATIONS.

-- WE CONTINUE TO SUPPORT MULTILATERAL EFFORTS IN THE OECD TO PROMOTE GREATER INTERNATIONAL REGULATORY COOPERATION AND HARMONIZATION IN THE AREA OF CHEMICALS. WE NOTE THAT THE COMMISSION'S APPROACH IN DEVELOPING ITS PROPOSAL HAS DEPARTED FROM THIS ONGOING OECD COOPERATION.

COSTS AND CONSEQUENCES

-- THE COSTS TO IMPLEMENT REACH ARE SUBSTANTIAL. THE COMMISSION'S OWN COST ESTIMATES FOR REACH TOTAL 18-32 BILLION EUROS, AND DO NOT TAKE INTO ACCOUNT EFFECTS ON PRICES, INTERNATIONAL COMPETITIVENESS AND EMPLOYMENT.

-- THESE COMPLIANCE COSTS MAY NEGATIVELY IMPACT INNOVATION AND EU DEVELOPMENT OF NEW, MORE EFFECTIVE, AND SAFER CHEMICALS AND DOWNSTREAM PRODUCTS.

-- THE PROPOSED APPROACH WOULD ADVERSELY IMPACT PRODUCTION AND TRANSATLANTIC TRADE IN TENS OF BILLIONS OF DOLLARS IN CHEMICALS AND DOWNSTREAM PRODUCTS - FROM AUTOS TO TEXTILES. WE'RE CONCERNED THAT THE ECONOMIC IMPLICATIONS ARE NOT BEING ADEQUATELY ASSESSED.

-- DOWNSTREAM USERS OF CHEMICALS ARE ESPECIALLY CONCERNED THAT REACH COULD SIGNIFICANTLY DISRUPT GLOBAL SUPPLY CHAINS. MANUFACTURERS OF CHEMICALS FOR MANY APPLICATIONS MAY HALT PRODUCTION WHERE DEMAND DOES NOT JUSTIFY REGISTRATION AND TESTING COSTS.

-- WE ALSO NOTE THAT THE COSTS OF COMPLYING WITH REACH COULD NEGATIVELY IMPACT EU COMPETITIVENESS, EMPLOYMENT AND FOREIGN INVESTMENT. THE CHEMICALS INDUSTRY IS THE TOP VALUE-ADDED SECTOR IN THE EU AND EMPLOYS 1.7

MILLION EUROPEANS.

– SMALL MANUFACTURERS, WHO ACCOUNT FOR THE MAJORITY OF THE EU CHEMICALS INDUSTRY, WOULD FACE A DISPROPORTIONATE BURDEN IN COMPLYING WITH REACH. SOME EU AND FOREIGN MANUFACTURERS OF CHEMICALS AND DOWNSTREAM PRODUCTS MAY SIMPLY EXIT THE EU MARKET.

CONCLUDING REMARKS

– TRANSPARENCY IS KEY TO ACHIEVING A BALANCED, EFFECTIVE REGULATORY APPROACH.

– BEFORE FINALIZING ITS PROPOSAL, WE URGE THE EC TO CONDUCT A COMPLETE IMPACT ASSESSMENT, INCLUDING THE IMPACTS ON DOWNSTREAM USERS AND FUTURE INVESTMENT AND INNOVATION.

– WE URGE THE COMMISSION TO PROVIDE ALL STAKEHOLDERS A MEANINGFUL OPPORTUNITY TO PROVIDE COMMENTS ON ITS 1200 PAGE DRAFT REGULATION, INCLUDING AN EXPLANATION FOR HOW SUCH COMMENTS WERE CONSIDERED IN ITS FINAL PROPOSAL.

– THE ANTICIPATED FIVE-WEEK INTERNET CONSULTATION SIMPLY IS NOT SUFFICIENT TIME GIVEN THE SCOPE, FAR-REACHING IMPLICATIONS AND GLOBAL INTEREST IN THIS REGULATION.

– WE REMAIN INTERESTED IN COOPERATIVE ENGAGEMENT WITH THE EU ON THIS IMPORTANT ISSUE.

END POINTS.

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