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TAGS: ETRD, EAGR, ECON,
SUBJECT: USG VIEWS ON THE EU CHEMICALS POLICY: ACTION REQUEST TO NON EU STATES

REFS: A) USEU BRUSSELS 003262; B) USEU BRUSSELS 04784; C) USEU BRUSSELS 005340; D) STATE 52550

1. THIS IS AN ACTION REQUEST FOR ADDRESSEE POSTS. PLEASE SEE PARA 7. A DEMARCHE TO EU MEMBER STATES HAS BEEN SENT SEPTEL (REF D).

2. SUMMARY: THE EUROPEAN COMMISSION ADOPTED A WHITE PAPER IN FEBRUARY 2001, WHICH OUTLINES A NEW POLICY FOR CHEMICALS REGULATION CALLED "REACH:" REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS. REACH SEEKS TO ADDRESS INFORMATION GAPS BETWEEN EXISTING AND NEW CHEMICAL SUBSTANCES (IN TOTAL OVER 30,000 SUBSTANCES). IT ALSO EXTENDS DATA REQUIREMENTS TO DOWNSTREAM USERS OF CHEMICALS (E.G., PRODUCERS OF CONSUMER GOODS). THE UNITED STATES FULLY SUPPORTS THE EUS OBJECTIVE TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT. HOWEVER, THE APPROACH CONTAINED IN THE EU CHEMICALS PROPOSAL RAISES SERIOUS CONCERNS. USG AGENCIES HAVE DEVELOPED THE ATTACHED NONPAPER, WHICH OUTLINES U.S. VIEWS AND CONCERNS WITH THE EU POLICY. THE PAPER IS TARGETED AT A NON-EU AUDIENCE AND IS INTENDED TO BE WIDELY SHARED. USG AGENCIES WOULD APPRECIATE ANY FEEDBACK THAT POSTS RECEIVE FROM LOCAL GOVERNMENT OFFICIALS, INDUSTRY, AND OTHER INTERESTED STAKEHOLDERS. END SUMMARY.

3. BACKGROUND. SINCE INTRODUCTION OF THE WHITE PAPER IN FEBRUARY 2001, THE EUROPEAN COUNCIL AND THE PARLIAMENT HAVE ENDORSED IT, AND IN SOME CASES ASKED THE COMMISSION TO GO BEYOND THE FRAMEWORK OUTLINED. THE COMMISSION (CO-LEAD OF DG ENVIRONMENT AND DG ENTERPRISE) IS EXPECTED TO PROPOSE DRAFT LEGISLATION THIS SUMMER, WHICH WILL BE SUBJECT TO CO-DECISION BY THE COUNCIL AND THE PARLIAMENT. EU LEADERS REQUESTED

IMPLEMENTATION BY 2004. THE COMMISSION ESTABLISHED WORKING GROUPS TO ADVISE ON MATTERS RELATED TO THE LEGISLATION, BUT THE ULTIMATE IMPACT OF STAKEHOLDER VIEWS IS UNCERTAIN. THERE IS A PERCEPTION AMONG INDUSTRY THAT THEIR VIEWS HAVE NOT BEEN HEARD BY KEY POLICY-MAKERS. THE WHITE PAPER CAN BE FOUND ON THE INTERNET AT HTTP://EUROPA.EU.INT/COMM/ENTERPRISE/CHEMICALS/INDEX.HTM. THE REFERENCED UK STUDY CAN BE FOUND AT HTTP://WWW.LE.AC.UK/IEH/WEBPUB/WEBPUB.HTML.

4. THE EUS WHITE PAPER WOULD FORMALLY PLACE RESPONSIBILITY ON BUSINESSES TO GENERATE DATA, ASSESS RISKS, AND DEMONSTRATE THE SAFETY OF CHEMICALS ON THE MARKET AND THEN TO SHARE THAT INFORMATION WITH A CENTRAL AUTHORITY (THE EUROPEAN CHEMICALS BUREAU - ECB). THE PROGRAM WOULD BE IMPLEMENTED OVER A TEN-YEAR PERIOD. EU MEMBER STATES WOULD MAINTAIN THEIR AUTHORITY TO REGULATE CHEMICALS, BUT THE ECB WOULD HAVE INPUT AS WELL, THE EXTENT OF WHICH IS STILL UNCLEAR. GENERALLY, SIGNIFICANT CONTRASTS WITH THE U.S. SCHEME INCLUDE A HIGHER LEVEL OF GOVERNMENT INVOLVEMENT (ASSESSMENT AND MANAGEMENT), PAIRED WITH A GENERAL - AND HEIGHTENED - MANDATE FOR INDUSTRY. THERE ALSO APPEARS TO BE A LOWER THRESHOLD FOR CONTROL ACTIONS, MEANING THAT SUBSTANCES WITH CERTAIN HAZARDOUS CHARACTERISTICS (E.G., PERSISTENCE, BIOACCUMULATION, TOXICITY, ETC) WOULD BE BANNED UNLESS AUTHORIZED ON A USE-SPECIFIC BASIS UNDER A LESS THAN CLEAR STANDARD. THE EU APPROACH WOULD FOCUS ON CHEMICALS HAVING A HIGHER LEVEL OF "CONCERN" (AS OPPOSED TO RISK) VIA A TIERED CHEMICALS/REGULATORY APPROACH. THE NEW APPROACH WOULD BE SIGNIFICANTLY MORE BURDENSOME TO INDUSTRY AND GOVERNMENT THAN CURRENT U.S. AND EU REGULATORY APPROACHES. ANOTHER FUNDAMENTAL DIFFERENCE WITH THE U.S. SYSTEM IS THAT THE WHITE PAPER APPROACH FLIPS THE BURDEN OF PROOF FROM GOVERNMENT HAVING TO DEMONSTRATE RISK, TO INDUSTRY HAVING TO PROVE THAT CERTAIN USES OF CHEMICALS ARE "SAFE." FINALLY, THE EU APPROACH APPEARS TO REACH FURTHER THAN ANY OTHER NATIONAL CHEMICAL REGULATORY SCHEME BY ADDRESSING CHEMICALS AS CONSTITUENTS IN IMPORTED ARTICLES, SUCH AS DYES IN TEXTILES.

5. WHILE ALL INDUSTRY SUPPORTS THE EU OBJECTIVES, THEY FEAR THAT THE NEW POLICY WILL HAVE SEVERE ADVERSE IMPACTS ON INNOVATION, COMPETITIVENESS, AND TRADE. U.S. INDUSTRY, AS WELL AS EUROPEAN INDUSTRY, HAVE EXPRESSED SERIOUS CONCERN WITH THE WHITE PAPER ON BOTH SIDES OF THE ATLANTIC. ON THE EUROPEAN SIDE, GERMAN AND UK INDUSTRIES HAVE BEEN ACTIVE IN THE WHITE PAPER DISCUSSIONS, AS WELL AS CEFIC (EUROPEAN CHEMICAL ASSOCIATION). JAPANESE AND CANADIAN INDUSTRIES HAVE BEEN MORE INQUISITIVE THAN ACTIVE.

6. VIRTUALLY ALL U.S. CHEMICAL EXPORTS - TOTALING $17 BILLION ANNUALLY - WILL BE AFFECTED, AND NEARLY EVERY U.S. INDUSTRIAL SECTOR WILL BE IMPACTED TO SOME EXTENT. PARTICULARLY AT RISK ARE CHEMICALS SUBJECT TO AUTHORIZATION (POPS AND CMRS), WITH THE ANNUAL EXPORT VALUE ESTIMATED TO BE BETWEEN $171 MILLION AND $918 MILLION. THE U.S. CHEMICAL INDUSTRY ESTIMATES THE

TOTAL COST OF REACH AT BETWEEN $5.5 BILLION AND $9.6 BILLION OVER THE COURSE OF THE PROGRAM, WITH A BEST ESTIMATE OF $7.2 BILLION. TOTAL INCLUDES ESTIMATED ADMINISTRATIVE COSTS, AS WELL TESTING AND EVALUATION COSTS. DEPENDING ON HOW DOWNSTREAM PRODUCTS ARE ULTIMATELY ADDRESSED, THE IMPACT ON U.S. EXPORTS COULD BE HUGE. EXAMINATION OF JUST FOUR COMMERCIALLY IMPORTANT CHEMICALS ON THE EU AUTHORIZATION LIST SHOWS THAT $8.8 BILLION WORTH OF U.S. PRODUCT EXPORTS ARE AT RISK FOR BANS OR SEVERE RESTRICTIONS. OTHER INDUSTRY CONCERNS INCLUDE: LIMITS ON CONFIDENTIAL BUSINESS INFORMATION; AUTHORIZATION SYSTEM COULD BAN USEFUL CHEMICALS, WITHOUT SIGNIFICANT ENVIRONMENT OR HUMAN HEALTH BENEFIT; IMPRACTICABLE TESTING AND EVALUATION SCHEDULE; APPARENT FOCUS ON SUBSTITUTION AND THE "PRECAUTIONARY PRINCIPLE" COULD LEAD TO ARBITRARY DISCRIMINATION AGAINST U.S. CHEMICALS AND PRODUCTS. END BACKGROUND.

7. ACTION REQUEST: POSTS ARE REQUESTED TO RAISE THE EU CHEMICALS POLICY WITH RELEVANT GOVERNMENT OFFICIALS (E.G. OFFICIALS FROM THE ENVIRONMENT MINISTRY, ECONOMICS/TRADE MINISTRY, AND FOREIGN AFFAIRS MINISTRY) AND THE LOCAL BUSINESS COMMUNITY AND OFFER THE NONPAPER AS A BRIEF DESCRIPTION OF USG VIEWS. POSTS SHOULD ALSO MENTION TO INTERESTED PARTIES THAT THE EU WILL HOST A CONFERENCE ON THE BUSINESS IMPACTS OF THE NEW POLICY IN BRUSSELS IN MAY. DETAILS CAN BE FOUND AT HTTP://WWW.EUROPA.EU.INT/COMM/ENTERPRISE/CHEMICALS/CONFERENCE/CONFERENCE2/INDEX.HTM. WASHINGTON AGENCIES WELCOME ANY FEEDBACK THAT POSTS RECEIVE, AS WELL AS IDEAS FOR FURTHER ENGAGING INTERESTED PARTIES ON THIS IMPORTANT ISSUE. THE UNITED STATES HAS ONE OF THE MOST ROBUST CHEMICAL REGULATORY SCHEMES IN THE WORLD BASED ON THE TOXIC SUBSTANCES CONTROL ACT (TSCA), WHICH GIVES EPA THE AUTHORITY TO TRACK AND SCREEN THE 75,000 CHEMICALS CURRENTLY PRODUCED OR IMPORTED INTO THE UNITED STATES. FOR MORE INFORMATION ON TSCA AND EPA PROGRAMS, PLEASE GO TO: WWW.EPA.GOV/REGION5/DEFS/HTML/TSCA.HTM. COMMENT: ADDRESSEE COUNTRIES WERE CHOSEN BASED ON THEIR RANK AS A TOP 25 SUPPLIER OF EU IMPORTS OF CHEMICALS AND/OR KEY DOWNSTREAM PRODUCTS (E.G., TOYS, TEXTILES, METALLIC COMPONDS). END COMET.

TEXT OF NONPAPER:

UNITED STATES NONPAPER ON EU CHEMICALS POLICY

I. BACKGROUND: THE EUROPEAN COMMISSION ADOPTED A WHITE PAPER IN FEBRUARY 2001, WHICH OUTLINES A NEW POLICY FOR CHEMICALS REGULATION CALLED "REACH": REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS. REACH SEEKS TO CLOSE INFORMATION GAPS IN BOTH EXISTING AND NEW CHEMICALS DATA (IN TOTAL OVER 30,000 CHEMICALS) AND EXTENDS DATA REQUIREMENTS TO DOWNSTREAM USERS OF CHEMICALS. VIRTUALLY EVERY INDUSTRIAL SECTOR COULD BE IMPACTED BY THE NEW POLICY.

ALL CHEMICALS PRODUCED OR IMPORTED ABOVE ONE TON PER

YEAR/MANUFACTURER/IMPORTER MUST BE REGISTERED IN A CENTRAL DATABASE, AND CHEMICALS PRODUCED IN HIGHER VOLUMES WOULD FACE INTENSIFIED TESTING AND EVALUATION REQUIREMENTS. CHEMICALS OF "VERY HIGH CONCERN" (ESTIMATED AT 1,400 CHEMICALS) WOULD BE BANNED UNLESS SPECIFICALLY AUTHORIZED FOR USE IN THE EU.

THE EUROPEAN COUNCIL AND THE PARLIAMENT ENDORSED THE WHITE PAPER, AND LEADERS REQUESTED IMPLEMENTATION BY 2004. THE COMMISSION IS EXPECTED TO PROPOSE DRAFT LEGISLATION THIS SUMMER, WHICH WILL BE SUBJECT TO CO-DECISION. THE COMMISSION ESTABLISHED WORKING GROUPS TO ADVISE ON MATTERS RELATED TO THE LEGISLATION. WHILE A DIVERSE GROUP OF STAKEHOLDERS PARTICIPATED, THERE IS A PERCEPTION THAT SOME VIEWS HAVE NOT BEEN HEARD BY KEY EU POLICY-MAKERS.

II. U.S. POSITION: THE UNITED STATES FULLY SUPPORTS THE EUS OBJECTIVE TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT. HOWEVER, WE ARE CONCERNED THAT THE NEW POLICY COULD HAVE SIGNIFICANT TRADE IMPLICATIONS FOR U.S. CHEMICALS AND DOWNSTREAM PRODUCTS. THE EUS WHITE PAPER OUTLINES WHAT APPEARS TO BE A COSTLY, BURDENSOME, AND COMPLEX REGULATORY SYSTEM, WHICH COULD PROVE UNWORKABLE IN ITS IMPLEMENTATION. THE SYSTEM COULD PRESENT OBSTACLES TO TRADE IN CHEMICALS - 9 PERCENT OF TOTAL WORLD TRADE - POSSIBLY DISTORTING GLOBAL MARKETS FOR THOUSANDS OF PRODUCTS. THE UNITED STATES IS ALSO CONCERNED THAT THE WHITE PAPER APPROACH REPRESENTS A MOVE BY THE EU AWAY FROM GREATER HARMONIZATION OF CHEMICAL REGULATORY APPROACHES AMONG OECD COUNTRIES.

III. CONCERNS WITH THE EU POLICY INCLUDE:
INCREASED COSTS: TESTING COSTS (AVERAGE $250,000 PER CHEMICAL) - WHICH WOULD APPLY TO ALL CHEMICALS, EVEN THOSE ON THE MARKET FOR DECADES - WILL TOTAL EURO 9 BILLION, ACCORDING TO A UK INSTITUTE FOR ENVIRONMENT AND HEALTH STUDY.
UNREALISTIC TIME LINES FOR TESTING: THE UK STUDY ESTIMATES THAT THE EU WOULD NEED TO EXTEND ITS TIME LINE BY 36 YEARS, TO 2048, TO ACCOMPLISH THE MINIMUM LEVEL OF TESTING.
UNWARRANTED INCREASES IN ANIMAL TESTING: THE SAME UK STUDY ESTIMATES THAT NEARLY 13 MILLION ANIMALS WILL BE REQUIRED FOR TESTING UNDER THE PROPOSED SYSTEM.
WTO INCONSISTENCY: THE EU APPROACH, PARTICULARLY THE SUGGESTION TO REGULATE CHEMICALS CONTAINED IN PRODUCTS MANUFACTURED OUTSIDE THE EU (E.G., DYES USED IN MANUFACTURING TEXTILES), RAISES SIGNIFICANT CONCERN WITH REGARD TO WORLD TRADE ORGANIZATION (WTO) RULES, AND MAY PROVE MORE TRADE RESTRICTIVE THAN NECESSARY.
IMPORT BANS: PRODUCTS (E.G., TOYS, TEXTILES) CONTAINING CHEMICALS THAT HAVE NOT BEEN REGISTERED, EVALUATED, AND/OR AUTHORIZED BY THE EU COULD FACE IMPORT BANS.
SHIFTING THE BURDEN OF PROOF: THE EU PROPOSAL WOULD FORMALLY PLACE RESPONSIBILITY ON BUSINESSES TO GENERATE DATA, ASSESS RISKS, AND DEMONSTRATE THE SAFETY OF CHEMICALS ON THE MARKET, AS OPPOSED TO THE CURRENT EU SYSTEM WHERE AUTHORITIES GENERALLY PERFORM RISK ASSESSMENTS AND TAKE ACTION IN CASES OF

UNREASONABLE RISK.
ARBITRARY DISCRIMINATION: UNDER THE NEW POLICY, AUTHORITIES MAY FORCE SUBSTITUTION OF CERTAIN CHEMICALS FOR OTHERS THAT HAVE BEEN DEEMED "SAFER." IT IS UNCLEAR WHETHER THIS COULD BE IMPLEMENTED WITHOUT RESULTING IN ARBITRARY DISCRIMINATION.
"PRECAUTIONARY PRINCIPLE": INVOCATION OF THE "PP," PARTICULARLY WHERE DATA ARE UNAVAILABLE OR DELAYED, COULD PROVIDE COVER FOR POLITICALLY-MOTIVATED BANS AND OTHER SEVERE RESTRICTIONS.
DISPROPORTIONATE IMPACTS ON SMALL AND MEDIUM BUSINESSES: SMES, WHICH GENERALLY PRODUCE SPECIALTY CHEMICALS IN SMALLER VOLUMES COULD PAY MORE PER TON PRODUCED TO IMPLEMENT THE SYSTEM THAN LARGE, MULTINATIONALS THAT SELL IN HUGE VOLUMES. INCREASED ADMINISTRATIVE BURDENS ARE MORE DIFFICULT FOR SMES TO DEAL WITH AS WELL.
LIMITS ON CONFIDENTIAL BUSINESS INFORMATION: IT IS UNCLEAR FROM THE WHITE PAPER THE EXTENT TO WHICH CONFIDENTIAL BUSINESS INFORMATION WOULD BE PERMITTED AND PROTECTED.
UNCERTAINTY FOR DOWNSTREAM BUSINESSES: AUTHORIZATION COMPONENT COULD REMOVE USEFUL CHEMICALS FROM THE MARKET, WHICH COULD IN TURN IMPACT HUNDREDS OF PRODUCTS. EXAMINATION OF JUST FOUR COMMERCIALLY IMPORTANT CHEMICALS ON THE AUTHORIZATION LIST SHOWS THAT $8.8 BILLION WORTH OF DOWNSTREAM PRODUCTS ARE AT RISK FOR BANS OR SEVERE RESTRICTIONS UNDER THE NEW SYSTEM.
ADVERSE IMPACTS ON INNOVATION: CURRENT EU POLICY APPLIES TO CHEMICALS IN COMMERCE, BUT THE NEW PROPOSAL WOULD APPLY TESTING REQUIREMENTS TO CHEMICALS AT THE PRE-PRODUCTION, RATHER THAN THE PRE-MARKETING TRIGGER IN THE CURRENT SYSTEM. INNOVATION COULD BECOME SIGNIFICANTLY MORE EXPENSIVE AND BURDENSOME UNDER THE NEW REQUIREMENTS, EVEN FOR CHEMICALS PRODUCED IN THE EU, BUT INTENDED FOR COMMERCIALIZATION ELSEWHERE.
MOVEMENT AWAY FROM INTERNATIONAL REGULATORY HARMONIZATION: THE EU PROPOSAL GOES FURTHER THAN ANY OTHER OECD COUNTRYS CHEMICAL REGIME, AND APPEARS TO REQUIRE NEW AND ADDITIONAL TESTING OF CHEMICALS BEYOND CURRENT OECD INITIATIVES. THIS MOVE COULD UNDERMINE EFFORTS TO CREATE A COHERENT SCHEME FOR INTERNATIONAL CHEMICALS MANAGEMENT.
OVERLY NARROW EXEMPTIONS: WHILE THE R & D EXEMPTION IS IMPROVED OVER CURRENT EU PRACTICE, IT COULD BE EXPANDED FURTHER TO ENCOURAGE INNOVATION. IT IS UNCLEAR IF PROVISIONS WILL BE AVAILABLE TO EXEMPT POLYMERS AND OTHER LOW-RISK CHEMICALS FROM THE NEW REQUIREMENTS.
DEVELOPING COUNTRIES: WHILE MOST DEVELOPING COUNTRIES ARE NET IMPORTERS OF CHEMICALS, MANY ARE MAJOR EXPORTERS OF PRODUCTS THAT CONTAIN CHEMICALS. TOYS AND TEXTILES ARE TWO SUCH PRODUCTS THAT THE EU APPEARS TO BE TARGETING UNDER ITS NEW PROPOSAL. DEVELOPING COUNTRY EXPORTERS MAY HAVE DIFFICULTIES COMPLYING WITH THE COMPLEX NEW REQUIREMENTS.

IV. U.S.-EU COOPERATION: THE U.S. GOVERNMENT AND INTERESTED STAKEHOLDERS ARE WORKING CLOSELY WITH THE EU TO ENSURE TRANSPARENCY AND TO EFFECT A BALANCED REGULATION THAT PROTECTS THE ENVIRONMENT AND HUMAN HEALTH WITHOUT UNNECESSARY

DISTORTIONS TO TRADE AND COMPETITIVENESS. THE UNITED STATES IS HOPEFUL THAT INCREASED COOPERATION AND DIALOGUE EARLY ON IN THE EU LEGISLATIVE PROCESS WILL LEAD TO MORE EFFECTIVE, PROTECTIVE, AND BALANCED REGULATION IN THE END.

V. THIRD COUNTRY VIEWS: THE UNITED STATES IS VERY INTERESTED IN HEARING THE VIEWS OF THIRD COUNTRIES, ESPECIALLY DEVELOPING COUNTRIES. THE COMPLEXITY OF THE EU SYSTEM AND ITS IMPLICATIONS FOR TRADE IN CHEMICALS AND DOWNSTREAM PRODUCTS REQUIRES AFFECTED PARTIES ATTENTION EARLY ON. AN EXCHANGE OF VIEWS MAY IDENTIFY COMMON AREAS OF CONCERN.
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