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FOR SCOS, ECONOFFS, ENVIRONMENTAL OFFICERS

E.O. 12958: N/A  
TAGS: ETRD, BEXP, SENV, USTR  
SUBJECT: EU'S "REACH" CHEMICALS REGULATION PROPOSAL -  
BACKGROUND AND TALKING POINTS

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

2. STATUS: ON OCTOBER 29, 2003, THE EUROPEAN COMMISSION (EC) ADOPTED A LEGISLATIVE PROPOSAL THAT WOULD CREATE AN EXPANSIVE NEW REGULATORY SYSTEM FOR CHEMICALS. THE PROPOSAL HAS BEEN PASSED TO THE EUROPEAN PARLIAMENT AND COUNCIL FOR EXAMINATION AND ADOPTION UNDER THE EU'S CO-DECISION PROCESS. THE PARLIAMENT WILL NOT COMPLETE A FIRST READING OF THIS PROPOSAL BEFORE THE NEW PARLIAMENT IS IN PLACE (POSSIBLE ACTION IN SEPTEMBER - OCTOBER 2004). PARLIAMENT COMMITTEES (ENVIRONMENT, INDUSTRY AND LEGAL SERVICES) ARE REVIEWING THE PROPOSAL. IN THE COUNCIL, AN AD HOC WORKING GROUP IS MEETING AND PERFORMING AN INITIAL REVIEW OF THE PROPOSAL, WITH THE INTENTION TO IDENTIFY KEY QUESTIONS AND ISSUES BY THIS SUMMER. THE COUNCIL WILL NOT ADOPT ITS COMMON POSITION (FIRST READING) UNTIL AFTER THE PARLIAMENT COMPLETES ITS FIRST READING. IN THE MEANTIME, THE EC IS WORKING ON A NEW IMPACT ASSESSMENT. THE EC HAS NOTIFIED THE PROPOSAL TO THE WTO, AND THE COMMENT PERIOD EXTENDS TO JUNE 21, 2004.



3. SUMMARY AND BACKGROUND: THE EC'S PROPOSED SYSTEM, REFERRED TO AS REACH (REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS), WOULD ESTABLISH NEW TESTING AND MARKETING REQUIREMENTS FOR THE VAST MAJORITY OF CHEMICALS AND PRODUCTS CONTAINING CHEMICALS ENTERING THE EU MARKET. THE LEGISLATION COULD POTENTIALLY AFFECT MANUFACTURERS, IMPORTERS, AND DOWNSTREAM USERS OF MORE THAN 30,000 CHEMICAL SUBSTANCES,

4. THE USG CONTINUES TO BE CONCERNED THAT THE PROPOSAL WILL CREATE A COSTLY, DISPROPORTIONATELY BURDENSOME, AND COMPLEX REGULATORY SYSTEM, WHICH COULD PROVE DIFFICULT, IF NOT UNWORKABLE, IN ITS IMPLEMENTATION. U.S. EXPORTS IN MOST INDUSTRIAL SECTORS - TOTALING TENS OF BILLIONS OF DOLLARS - WOULD BE AFFECTED BY THE NEW POLICY. THE CHEMICALS INDUSTRY IS A \$460 BILLION BUSINESS WORLDWIDE AND A KEY COMPONENT OF THE U.S. ECONOMY, ACCOUNTING FOR OVER 2.5 PERCENT OF U.S. GROSS DOMESTIC PRODUCT (GDP). THE IMPACT OF REACH GOES BEYOND THE CHEMICAL SECTOR AND COULD TOUCH VIRTUALLY ALL U.S. EXPORTS (IN 2003, U.S. EXPORTS TO EUROPE-15 WERE \$150.6 BILLION, AND TO EU-25 \$154.1 BILLION). USG AGENCIES BELIEVE IT IS IMPORTANT TO REITERATE TO GOVERNMENT OFFICIALS AND STAKEHOLDERS OUR GENERAL CONCERNS WHILE THE COUNCIL AND PARLIAMENT PROCEED THROUGH THE LEGISLATIVE PROCESS.

5. THE EU PROPOSAL HAS GENERATED SUBSTANTIAL WORLDWIDE CONCERN. THE EU COMMISSION RECEIVED OVER 6400 COMMENTS, FROM GOVERNMENTS (INCLUDING THE US), BUSINESS AND ENVIRONMENTAL GROUPS, COMPANIES AND INDIVIDUALS DURING AN EIGHT-WEEK INTERNET COMMENT PERIOD THAT ENDED IN JULY 2003.

6. IN RESPONSE TO COMMENTS RECEIVED, THE COMMISSION MADE LIMITED AMENDMENTS TO THE MAY TEXT. THE OCTOBER 29TH TEXT PROPOSED EXEMPTING ADDITIONAL ITEMS (SUCH AS POLYMERS AND SOME INTERMEDIATES); LIGHTER TREATMENT OF FINISHED PRODUCTS; ADDING AN APPEAL BOARD IN THE CHEMICAL AGENCY; AND LIMITING CHEMICAL SAFETY REPORTS FOR DOWNSTREAM USERS.

7. THE COMMISSION CONTINUES TO REVIEW CALLS FOR A REVISED IMPACT ASSESSMENT. THE INITIAL IMPACT ASSESSMENT THAT WAS COMPLETED ON THE OCTOBER 2003 PROPOSED LEGISLATION DID NOT INCLUDE THE ACCESSION COUNTRIES, NOR A FULL ACCOUNT OF THE IMPACT ON DOWNSTREAM USERS AND FINAL PRODUCTS. IN OCTOBER 2003, THE EC COMMISSIONED A STUDY FROM RISK POLICY ANALYSTS LIMITED (RPA), THAT ESTIMATES COSTS OF TESTING ALONE AT 41,000-62,000 EUROS FOR CHEMICALS (ONE TO ONE HUNDRED TONS), AND 287,000 EUROS FOR CHEMICALS (ONE HUNDRED TO ONE THOUSAND TONS). IN ADDITION, SEVERAL MEMBER STATES ARE COMPLETING THEIR OWN IMPACT ASSESSMENTS. CERTAIN RECENT EUROPEAN INDUSTRY STUDIES (WHICH HAVE NOT BEEN ENDORSED BY THE USG) INDICATE THE POTENTIAL FOR SUBSTANTIAL IMPACTS ON THE CHEMICALS INDUSTRY AND DOWNSTREAM USERS, AND WE UNDERSTAND OTHER STUDIES BY CERTAIN STAKEHOLDERS ARE ONGOING. ONE RECENT STUDY BY THE BELGIAN INDUSTRY INDICATED THAT 30 PERCENT OF CHEMICALS WOULD BE PULLED OFF THE MARKET IN



BELGIUM DUE TO THE COST OF REGISTRATION. THIS WOULD HAVE A TREMENDOUS IMPACT ON DOWNSTREAM USERS. ANOTHER STUDY, BASED ON THE MERCER STUDY (COMMISSIONED BY THE FRENCH GOVERNMENT AND INDUSTRY), INDICATED THAT THE COSMETICS INDUSTRY WOULD HAVE TO REFORMULATE 100 PERCENT OF THEIR PRODUCTS. BDI, THE GERMAN INDUSTRY ASSOCIATION, ESTIMATES THAT 20 TO 40 PERCENT OF CHEMICALS WILL BE WITHDRAWN FROM THE MARKET. DUE TO REGISTRATION COSTS OF BETWEEN 20,000-40,000 EUROS (FOR CHEMICALS BETWEEN ONE TON AND TEN TONS), AND 200,000 EUROS (FOR SUBSTANCES TEN TONS TO ONE HUNDRED TONS).

8. THE RELATIONSHIP OF EFFORTS UNDER REACH TO RELEVANT WORK BEING UNDERTAKEN IN THE OECD CHEMICALS PROGRAM IS UNCLEAR. SPECIFICALLY, IT IS NOT CLEAR THAT THE EU INTENDS TO USE THE ASSESSMENTS DEVELOPED UNDER THE OECD HIGH PRODUCTION VOLUME CHEMICALS PROGRAM AS A STARTING POINT IN THE CONTEXT OF THE REACH EVALUATION PROCEDURES.

9. EU MEMBER STATES, INCLUDING THE ACCESSION COUNTRIES, WILL ADOPT THE NEW EU CHEMICALS REGULATION. IN PARTICULAR, THE MEMBER STATES WILL HAVE THE RESPONSIBILITY OF IMPLEMENTING THE RESULTING REGULATION. AS THEIR OWN INDUSTRIES WILL BE IMPACTED, WE UNDERSTAND THAT THEY WILL BE MORE SENSITIVE TO IMPACTS ON EU COMPETITIVENESS, EMPLOYMENT, AND OTHER IMPLICATIONS THAN COMMISSION OFFICIALS. WE UNDERSTAND THAT MEMBER STATES ARE ACTIVELY RELAYING THEIR CONCERNS, AND PREPARING IMPACT ASSESSMENTS.

10. ACTION REQUESTED. POSTS ARE ENCOURAGED TO ENGAGE GOVERNMENT OFFICIALS AND EUROPEAN STAKEHOLDERS ON AN ONGOING BASIS TO GAIN A BETTER UNDERSTANDING OF THEIR CURRENT POSITIONS, CONCERNS, AND EXPECTATIONS, AS TO HOW THIS IMPORTANT ISSUE WILL MOVE FORWARD, GIVEN THE INSTITUTIONAL CHANGES EXPECTED IN EUROPE IN THE UPCOMING MONTHS. STAKEHOLDERS COULD INCLUDE CHEMICAL COMPANIES, DOWNSTREAM USERS AND FINAL PRODUCT PRODUCERS. POSTS IN EU MEMBER STATES MAY COMMUNICATE USG CONCERNS TO APPROPRIATE HOST GOVERNMENT ENVIRONMENT, TRADE, INDUSTRY AND FOREIGN MINISTRY OFFICIALS, DRAWING UPON THE TALKING POINTS IN PARA 10 AS APPROPRIATE. WASHINGTON AGENCIES WOULD APPRECIATE ANY REPORTS ON MEMBER STATE AND INDUSTRY FEEDBACK.

11. BEGIN TALKING POINTS:

-- WE FULLY SUPPORT THE EU,S EFFORTS TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT AS WELL AS EFFORTS TO PROMOTE CONSUMER AWARENESS AND TRANSPARENCY.

-- HOWEVER, WE BELIEVE THE REACH PROPOSAL CONTINUES TO TAKE AN OVERLY EXPANSIVE APPROACH TO THE MANAGEMENT OF CHEMICALS, AND FAILS TO FOCUS ON CHEMICALS THAT ARE MOST LIKELY TO POSE THE GREATEST RISK TO HUMANS AND THE ENVIRONMENT. THE COMMISSION,S APPROACH DOES NOT PROVIDE FOR SUCH PRIORITIZATION OR FOR THE FOCUSING OF RESOURCES ON THOSE SUBSTANCES THAT ARE LIKELY TO POSE THE HIGHEST RISK.

- FURTHER, WE BELIEVE THE EU SHOULD CLARIFY THE RELATIONSHIP OF EFFORTS UNDER REACH TO RELEVANT WORK BEING UNDERTAKEN IN THE OECD CHEMICALS PROGRAM.
- THIS IS A GLOBAL ISSUE. SEVERAL FOREIGN GOVERNMENTS HAVE ALSO EXPRESSED CONCERNS ABOUT THE PROPOSED LEGISLATION. THE EU'S DEVELOPMENT OF A NEW, COMPREHENSIVE REGULATORY FRAMEWORK FOR CHEMICALS IS OF SUBSTANTIAL INTEREST TO ALL TRADING PARTNERS.
- WHILE WE ACKNOWLEDGE THE EFFORTS OF THE COMMISSION, WE REMAIN CONCERNED ABOUT THE OVERALL WORKABILITY OF THE LEGISLATION AND ITS IMPACT ON INNOVATION. THE TEXT STILL LACKS CLARITY AND THE PROPOSAL WOULD REQUIRE MEMBER STATE GOVERNMENTS, MANUFACTURERS AND EXPORTERS TO COMPLY WITH AN EXTREMELY COMPLEX, COSTLY AND BURDENSOME REGULATORY SYSTEM.
- THERE IS A CONTINUING NEED TO PRIORITIZE CONSIDERATION OF CHEMICALS IN LIGHT OF POTENTIAL RISK, INCLUDING EXPOSURE.
- THE ABILITY OF SMALLER COMPANIES TO COMPREHEND AND COMPLY WITH ADMINISTRATIVE REQUIREMENTS REMAINS A CONCERN WITHIN AND OUTSIDE THE EU.
- WE STILL HAVE CONCERNS ABOUT THE IMPLEMENTATION AND COMPLIANCE COSTS ASSOCIATED WITH REACH. WE UNDERSTAND THAT THE COMMISSION CONTINUES TO WORK ON A REVISED IMPACT ASSESSMENT, AND THAT SEVERAL MEMBER STATES AND OTHER STAKEHOLDERS ARE COMPLETING ASSESSMENTS. WE NOTE THAT CERTAIN RECENT EUROPEAN INDUSTRY STUDIES INDICATE THAT REACH'S EFFECTS ON PRICES, INTERNATIONAL COMPETITIVENESS, EMPLOYMENT AND FOREIGN INVESTMENT COULD BE SUBSTANTIAL.
- WE'RE INTERESTED IN YOUR PERSPECTIVES ON THIS REGULATORY INITIATIVE. WHAT IS YOUR SENSE OF HOW THE LEGISLATION WILL MOVE FORWARD GIVEN THE CHANGES THAT WILL OCCUR IN THE EUROPE IN THE COMING MONTHS?
- WHAT IS YOUR ASSESSMENT OF THE WORKABILITY OF THE EC'S PROPOSAL? WHAT ARE YOUR MAIN CONCERNS AND WHY?
- WHAT SORT OF ANALYSIS OF THE IMPACTS OF THIS PROPOSAL IS YOUR COUNTRY/INDUSTRY CONDUCTING? WHAT ARE YOUR FINDINGS?
- (FOR NON-GOVERNMENT CONTACTS) WE ENCOURAGE YOUR ORGANIZATION TO SUBMIT COMMENTS IN RESPONSE TO THE EC'S TBT NOTIFICATION.
- ARE YOU CONDUCTING IMPACT ASSESSMENTS?
- (IF ASKED) YES, THE U.S. GOVERNMENT PLANS TO SUBMIT COMMENTS IN RESPONSE TO THE TBT NOTIFICATION.  
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