IMPLEMENTING THE '67 EEC DIRECTIVE

LUNCHEON SPEECH

by

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EUROPEAN COMMUNITY DELEGATION

before

THE CHEMICAL MANUFACTURERS' ASSOCIATION'S SEMINAR

on

COMPLIANCE WITH INTERNATIONAL CHEMICAL REGULATIONS

Washington, D.C., April 29th, 1981

MR. CHAIRMAN, LADIES AND GENTLEMEN,

THANK YOU VERY MUCH FOR HAVING INVITED ME TO THE HONOUR OF ADDRESSING YOU AT THE OCCASION OF YOUR SEMINAR ON "COMPLIANCE WITH INTERNATIONAL CHEMICAL REGULATIONS". I FEEL THAT FOR ME THIS IS HOWEVER AN HONOUR THAT COMES CLOSE TO THE MOST HAZARDOUS OF THE SUBSTANCES YOU ARE DISCUSSING HERE BEING A COMPLETE OUTSIDER TO THE AREA OF CHEMICAL MANUFACTURING. I FEEL LIKE THE SENIOR VISITOR WHO ONCED ASKED POPE JOHN XXIII HOW LONG IT WOULD TAKE TO KNOW ROME WELL, TO WHICH THE POPE REPLIED: "TWO DAYS IS VERY GOOD, TWO WEEKS IS BETTER, BUT TWO YEARS IS NOT LONG ENOUGH". YOU CAN BE CONVINCED THAT I AM A VISITOR OF THIS SUBJECT MATTER SINCE A FEW DAYS OR WEEKS ONLY.

NEVERTHELESS, I AM OF COURSE AWARE OF THE IMPORTANCE OF THE SUBJECT DISCUSSED ON THIS OCCASION, IF IT WERE NOT FOR THE FACT THAT I HAVE BEEN ASSURED OF THAT BY MANY FRIENDS MORE KNOWLEDGEABLE ON THE SUBJECT THAN I AM, THEN AT LEAST BY THE FACT THAT THE PRESS AND INFORMATION OFFICE OF MY DELEGATION HAS BEEN FLOODED RECENTLY BY QUESTIONS ON THE NATURE AND THE STATUS OF REGULATIONS OF THE EUROPEAN COMMUNITY REGARDING DANGEROUS SUBSTANCES. NEEDLESS TO SAY THAT I HAVE STRICTLY COMMITTED THEM NOT TO GIVE AWAY ONE SINGLE PIECE OF INFORMATION, LEST THEY DEPRIVE ME OF THE ONLY CHANCE FOR ME TO STATE HERE A FEW THINGS THAT MIGHT BE NEW TO YOU.

2. LET ME BRIEFLY SUM UP THE <u>BASIC OBJECTIVES</u> OF THE EC IN REGULATING THIS AREA FOR ITSELF AND IN ITS DEALINGS WITH OTHER PARTNERS THROUGHOUT THE WORLD.

THE EC AS YOU KNOW COMPRISES NOW 10 MEMBER STATES (SINCE GREECE JOINED ON THE 1ST JANUARY THIS YEAR). LET ME QUICKLY REMIND YOU THAT RATHER THAN A MERE FREE TRADE ZONE OR CUSTOMS UNION, THE EC IS AN ASSOCIATION OF STATES, JOINED TOGETHER BY A SET OF COMMON POLICIES AND COMMON PROCEDURAL AND LEGISLATIVE RULES AND WITH THE STATED GOAL OF DEVELOPING TOWARDS A UNION OF STATES. WHENEVER I SPEAK HEREAFTER OF COMMON RULES YOU SHOULD KEEP IN MIND THAT UNLIKE MOST INTERNATIONAL ORGANIZATIONS, THE EC HAS ACCEPTED A SYSTEM OF OBLIGATORY LEGISLATION, BINDING ITS MEMBER STATES AND ITS CITIZENS AND ENFORCEABLE BY LAW.

ROUGHLY SPEAKING WE HAVE TWO DIFFERENT TYPES OF EC LEGISLATION: THE REGULATION THAT BINDS THE MEMBER STATES AND THEIR CITIZENS DIRECTLY IN CONFORMITY WITH SUBSTANTIAL RULES GIVEN BY THE COMMUNITY REGULATION ITSELF AND THE DIRECTIVE THAT SETS PRECISE OBJECTIVES TO BE ACHIEVED BUT LEAVES IT TO MEMBER STATES' GOVERNMENTS TO IMPLEMENT THOSE OBJECTIVES THROUGH NATIONAL LEGISLATION.

IN THE CASE OF THE EC DIRECTIVE ON DANGEROUS SUBSTANCES WE HAVE AN EXAMPLE OF THE SECOND CATEGORY OF LEGISLATION. IT COMMITS EC MEMBER STATES TO ADOPT NATIONAL LEGISLATION ON THE SUBJECT MATTER WITH THE PURPOSE OF APPROXIMATION OF LAWS, REGULATIONS AND OTHER NATIONAL PROVISIONS AND ALIGNING THOSE IN VIEW OF THE IMPLEMENTATION OF UNIFORM PRINCIPLES WITH UNIFORM RESULTS.

IT SEEMS USEFUL TO REMIND YOU OF THIS BECAUSE SEEN FROM THE OUTSIDE ONE COULD EASILY BE LED INTO BELIEVING THAT MEMBER STATES HAVE A CERTAIN FREEDOM TO LEGISLATE THE WAY THEY WOULD THINK APPROPRIATE: THAT IS CERTAINLY THE CASE FOR SOME MARGINAL ASPECTS, FOR CASES LIKE REGULATORY SANCTIONS, OR THE WAY THE REGULATION IS LINKED UP WITH OTHER SUBJECT MATTERS. BUT THE SUBSTANCE OF THE REGULATION HAS BEEN ESTABLISHED AT COMMUNITY LEVEL AND ITS UNIFORM IMPLEMENTATION IN THE ENTIRE TERRITORY OF THE EC IS GUARANTEED BY MEMBER STATES AND WATCHED OVER BY THE EC INSTITUTIONS, INCLUDING THE EUROPEAN COMMISSION AND THE EUROPEAN COURT OF JUSTICE.

3. THE EC DIRECTIVE OF 18 SEPTEMBER 1979, COMMONLY REFERRED TO AS THE 6TH AMENDMENT, HAS BASICALLY A DOUBLE OBJECTIVE;

- TO PROTECT MAN AND HIS ENVIRONMENT FROM THE POTENTIAL HAZARDS OF NEW CHEMICALS, WHICH COULD ARISE FROM THEIR PLACING ON THE MARKET, THROUGH A COHERENT SYSTEM FOR THE MANAGEMENT OF THESE CHEMICALS BEFORE THEIR COMMERCIAL RELEASE;

AND

- TO ELIMINATE INSIDE THE AREA OF THE COMMON MARKET TECHNICAL BARRIERS TO TRADE: IT IS THE DECLARED AIM OF ARTICLE 100 OF THE ROME TREATY TO MAKE SURE THAT THE COMMON MARKET, FREED OF ALL IMPORT DUTIES AND IMPORT QUOTA IN THE TRADE BETWEEN MEMBER STATES, BE NOT SUBJECT TO OTHER, NEW BARRIERS TO FREE TRADE, WHICH WOULD RE-INTRODUCE FORMS OF PROTECTIONISM OR DISCRIMINATION INSIDE THE EC, WHICH THE ROME TREATY INDEED WANTED TO BAN.

I ASSUME THAT YOU ARE MORE OR LESS FAMILIAR WITH THE CONTENTS OF THE EC 6TH AMENDMENT SO I WILL JUST VERY BRIEFLY SUM UP ITS MAIN POINTS:

- IT BEARS ON PREMARKETING NOTIFICATION OF CHEMICAL SUBSTANCES AS WELL AS ON THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES PLACED ON THE MARKET, I.E. SUPPLIED OR MADE AVAILABLE TO OTHER PARTIES OR IMPORTED INTO THE EC CUSTOMS TERRITORY;

- THE PREMARKETING NOTIFICATION IS SUBJECT TO THE SUBMISSION OF A TECHNICAL DOSSIER REQUIRING A.O. THE RESULTS OF TESTS FOLLOWING A FLEXIBLE THREE LEVEL STEP SEQUENCE TEST SYSTEM BASED ON THE QUANTITIES OF THE SUBSTANCE THAT WILL BE PUT ON THE MARKET;

- THE MANUFACTURER OR IMPORTER WILL BE ENTITLED TO PUT HIS PRODUCT ON THE MARKET 45 DAYS AFTER THE NOTIFICATION AND BY VIRTUE OF THE NOTIFICATION: NO LICENSING IS INVOLVED;

- NOTIFICATION ONLY APPLIES ON NEW SUBSTANCES: EXISTING SUBSTANCES, I.E. SUBSTANCES THAT WERE PLACED ON THE MARKET BEFORE 18 SEPTEMBER 1981 WILL BE SUBJECT TO AN INVENTORY. SUBSTANCES ON THE INVENTORY WILL NOT HAVE TO BE NOTIFIED;

- THE NOTIFIER MAY CLAIM CONFIDENTIALITY FOR INFORMATION HE WANTS TO KEEP SECRET FOR OTHER PERSONS THAN THE AUTHORITIES: SOME TYPES OF INFORMATION ARE EXCLUDED FROM THIS CLAIM, BUT INFORMATION CONCERNING COMMERCIAL EXPLOITATION OR MANUFACTURING SHALL BE KEPT SECRET BY THE COMMISSION AND THE MEMBER STATES;

- MEMBER STATES ARE OBLIGED TO PREPARE DOMESTIC LEGISLATION TO IMPLEMENT THE 6TH AMENDMENT AS FROM 18 SEPTEMBER, 1981 AT THE LATEST;

4. SO FAR FOR THE EC SYSTEM. NOW LET'S MOVE ON TO THE REST OF THE WORLD BECAUSE OBVIOUSLY THE CHEMICAL INDUSTRY IN INDUSTRIALIZED COUNTRIES THROUGHOUT THE WORLD HAS COME TO A DEGREE OF SPECIALIZATION AND DISTRIBUTION OF LABOUR THAT MAKES IT NECESSARY TO SET INTERNATIONAL RULES THAT WILL FACILITATE INTERNATIONAL TRADE IN CHEMICAL SUBSTANCES IN BETWEEN THESE COUNTRIES. THAT IS WHY THE EC, THE US AND THEIR PARTNERS HAVE BEEN ENGAGED IN ONGOING DISCUSSIONS ESPECIALLY IN THE FRAMEWORK OF THE OECD AND HAVE ACTIVELY PARTICIPATED IN EFFORTS AND ACTIVITIES THAT WOULD LEAD TOWARDS BETTER INTERNATIONAL COOPERATION AND MORE HARMONIZED SYSTEMS WORLD WIDE. THERE ARE MANY ADVANTAGES IN SUCH INTERNATIONAL AGREEMENT IN THE FIRST PLACE FOR OUR INDUSTRIES (FROM THE POINT OF VIEW OF THE ELIMINATION OF AN IMPORTANT NON TARIFF BARRIER TO TRADE, THE REDUCTION OF THE COST BURDEN ASSOCIATED WITH TESTING AND THE RELIEF IN PROBLEMS ARISING FROM THE SHORTAGE OF TESTING AND ASSESSMENT RESOURCES). THERE ARE OBVIOUSLY ALSO GREAT ADVANTAGES FOR THE PROTECTION OF OUR CITIZENS, THEIR HEALTH AND THEIR ENVIRONMENT. THEREFORE THE EC IS STRONGLY IN FAVOUR OF A HARMONIZED INTERNATIONAL SYSTEM AND THE USE OF IDENTICAL METHODS WHICH WILL AVOID ARBITRARY DECISIONS.

NOBODY SHOULD BE MISTAKEN ON THE SERIOUSNESS AND THE IMPORTANCE OF THIS ATTITUDE. THE EC HAS THE BASIC POSITION THAT THE DESIRED INTERNATIONAL UNITY OF REGIME CAN BE REALIZED BY IMPLEMENTING THE SOLUTIONS WORKED OUT IN COMMON IN THE FRAME OF OECD AND IN THE SPIRIT OF THE BASIC OECD AGREEMENTS. NEEDLESS TO SAY THAT WE HOPE AND EXPECT THAT OUR NEGOTIATING PARTNERS WILL BE ABLE TO DO THIS WITH THE SAME DEGREE OF COMMITMENT THAT WE FEEL SO THAT WE CAN FULLY REALIZE THIS HARMONIZED INTERNATIONAL SYSTEM OF WHICH I JUST SPOKE.

FOR ITS PART THE EC HAS MADE AND IS STILL MAKING ALL NECESSARY EFFORTS TO MAKE SURE THAT OUR SYSTEM OF MARKETING CHEMICAL SUBSTANCES IN THE COMMON MARKET BE IN AGREEMENT WITH SOLUTIONS WORKED OUT IN THE OECD. BASICALLY WE THINK THAT THIS OBJECTIVE HAS BEEN LARGELY REACHED AND THAT THERE ARE NO PROBLEMS OF ANY IMPORTANCE LEFT. HOWEVER, GEORGE INGLE POINTED OUT TO ME THAT THERE SEEMS TO BE SOME UNCERTAINTY AS TO THE CONTENT AND METHODS OF THE TESTS REQUIRED BY THE NOTIFICATION DOSSIER. IN PARTICULAR HE REFERRED TO THE MINIMUM PRE MARKETING SET OF DATA (MPD) AND ITS IMPLEMENTATION BY THE EC. ACTUALLY I SOMETIMES WONDER WHY GEORGE ASKS ME SUCH QUESTIONS AS HE OFTEN SEEMS TO BE MUCH BETTER INFORMED ABOUT WHAT IS GOING ON IN BRUSSELS THAN I AM.

FIRST OF ALL THE EC HAS NOT ONLY ACCEPTED THE MPD, BUT IT HAS FORMALLY ADOPTED IT AS ANNEX VII OF THE EC DIRECTIVE. IT IS TRUE THAT THERE ARE A FEW MINOR DIFFERENCES BETWEEN THE MPD AND ANNEX VII, BUT GIVEN THE DEGREE OF FLEXIBILITY OF BOTH SYSTEMS AND GIVEN THE PROCEDURE OF DIALOGUE BETWEEN THE NOTIFIER AND THE AUTHORITIES PROVIDED BY THE EC DIRECTIVE, THIS SITUATION DOES NOT STRIKE US AS A PROBLEM. UNLIKE WHAT SOME SEEM TO THINK THERE ARE NO EC RESERVATIONS ON THE MPD. THERE IS ONLY A REQUEST THAT A DECLARATION BE ADOPTED ACCORDING TO WHICH THE MPD WILL BE IMPLEMENTED IN THE EUROPEAN COMMUNITY IN CONFORMITY WITH THE 6TH AMENDMENT. GIVEN THE VERY ADVANCED STATE OF IMPLEMENTATION OF THIS COMPREHENSIVE LEGISLATION IN THE EC WE THINK THAT THIS IS ALTOGETHER A VERY JUSTIFIED POSITION. WE THINK THAT OUR OECD PARTNERS ACCEPT THAT POSITION AND WE DO NOT EXPECT ANY DELAY OR ANY SIGNIFICANT PROBLEMS IN THE IMPLEMENTATION OF THIS OECD DECISION BY THE EC.

AS TO THE MUTUAL ACCEPTANCE OF DATA GENERATED IN THE TESTING OF CHEMICALS IN ACCORDANCE WITH OECD TESTING GUIDELINES AND OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP), THE EC HAS ACCEPTED THIS AS WELL. IT WILL INCORPORATE THE OECD TESTING GUIDELINES IN ANNEX V OF THE DIRECTIVE. THE DRAFT OF ANNEX V IS NOW FINALIZED; ITS DISCUSSION BY THE TECHNICAL COMMITTEE OF THE EC AND ITS TRANSLATION ARE UNDER WAY AND WE EXPECT ITS PUBLICATION IN A FEW MONTHS.

MOREOVER THE EC COMMISSION WILL PUBLISH A GUIDANCE DOCUMENT ON TESTING AND ENVIRONMENTAL HAZARD ASSESSMENT. THIS DOCUMENT IS INTENDED TO PROVIDE GUIDANCE TO THE NORMAL COURSE OF ACTION IN TESTING AND EVALUATION OF NEW CHEMICALS AND WILL BE PUBLISHED IN SEPTEMBER AT THE LATEST.

5. OTHER QUESTIONS THAT ACCORDING TO WHAT I UNDERSTOOD ARE OF SOME CONCERN TO YOU REGARD THE PRACTICAL IMPLEMENTATION OF THE 6TH AMENDMENT IN THE EC. SO LET ME MAKE A FEW REMARKS ON THAT SUBJECT.

IN THE FIRST PLACE I WANT TO REMIND YOU OF WHAT I SAID EARLIER, NAMELY THAT MANUFACTURERS AND IMPORTERS WILL BE ENTITLED TO MARKET THEIR PRODUCTS BY VIRTUE OF THEIR NOTIFICATION IN THE ENTIRE EC CUSTOMS TERRITORY. THE CUSTOMS TERRITORY SHOULD BE UNDERSTOOD AS A UNIQUE AND INDIVISIBLE AREA: ONCE A SUBSTANCE HAS BEEN PLACED ON THE MARKET IN CONFORMITY WITH THE RULES ESTABLISHED BY A PARTICULAR MEMBER STATE ON THE BASIS OF THE COMMON PRINCIPLES OF THE 6TH AMENDMENT, THAT SUBSTANCE HAS ACCESS TO ANY CUSTOMER AT ANY PLACE INSIDE THAT AREA. I UNDERSTAND THAT SOME OF YOU HAVE SOME DOUBT ABOUT HOW WELL THIS SYSTEM WILL WORK. THERE SEEMS TO BE SOME FEAR THAT THERE MIGHT BE DIFFERENCES IN DOMESTIC LEGISLATION FROM ONE COUNTRY TO ANOTHER AND THAT THESE DIFFERENCES MIGHT IN REALITY BE AN IMPEDIMENT FOR TRADE IN CHEMICAL SUBSTANCES.

LET ME RE-EMPHASIZE THAT COMMUNITY LEGISLATION AIMS AT A UNIFORMITY OF LEGAL PRINCIPLES INSIDE THE COMMON MARKET. EVEN IF FORMAL REGULATIONS ARE ADOPTED BY THE MEMBER STATES, SUCH REGULATIONS HAVE TO RESPECT THE EC DIRECTIVE. SO THE FIRST THING WE LOOK AT WHILE NATIONAL REGULATIONS TAKE SHAPE IS THAT THESE WILL HAVE FOR EFFECT A HARMONIZED SYSTEM OF RULES IN WHICH CHEMICAL SUBSTANCES CAN CIRCULATE FREELY AND WITHOUT ANY DISCRIMINATIONS FROM ONE COUNTRY TO ANOTHER, PROVIDED THE BASIC CONDITIONS OF THE DIRECTIVE HAVE BEEN COMPLIED WITH.

BUT EVEN IF WE ASSUME THAT GOVERNMENTS OF DIFFERENT MEMBER STATES WOULD REACT DIFFERENTLY TO A NOTIFICATION FROM THE PRODUCER OR IMPORTER, THEN A RECONCILIATION PROCEDURE IS PROVIDED, AT THE END OF WHICH THE COMMISSION WILL MAKE A DECISION ON THE BASIS OF THE CRITERIA PROVIDED BY THE 6TH AMENDMENT. IN ANY CASE THIS WOULD RATHER BE THE EXCEPTION: IN A UNIFORM SYSTEM LIKE OURS, THE NORMAL COURSE WILL ALLOW AN IMPORTER TO MARKET HIS PRODUCT THROUGHOUT THE ENTIRE COMMON MARKET AT THE END OF THE 45DAY PERIOD FOLLOWING NOTIFICATION.

CERTAINLY THERE ARE IN THE 6TH AMENDMENT RULES THAT WILL PERMIT A MEMBER STATE TO INVOKE A SAFEGUARD PROVISION THAT WILL ALLOW IT TO PROVISIONALLY PROHIBIT THE SALE OF A PRODUCT IN ITS TERRITORY. COMMUNITY PROCEDURES PROVIDE THAT CONSULTATIONS TAKE PLACE AND MEASURES BE TAKEN IN ORDER TO RESTORE THE FREE CIRCULATION OF THAT PRODUCT INSIDE THE COMMON MARKET. SUCH PROCEDURES CAN POSTPONE THE EFFECTIVE SALES OF THE PRODUCT BY A FEW WEEKS OR IN THE WORST OF ALL CASES BY A FEW MONTHS, IT CAN HOWEVER, NOT PREVENT THEM.

6. ANOTHER PROBLEM AREA FOR POTENTIAL SALES IN THE COMMON MARKET SEEMS TO BE THE ONE RELATED TO CONFIDENTIALITY, AND IN THAT CONTEXT ALSO OF THE COSTS OF THE NOTIFICATION AND TESTING PROCEDURES. SUCH COSTS CAN BECOME HIGH, AS YOU KNOW. ONE COULD TRY TO MINIMIZE THAT, LIKE GROUCHO MARX USED TO SAY: "FEAR NOT MY FRIEND, IT'S ONLY MONEY". THAT MIGHT BE TRUE BUT WE ALL KNOW THAT IT MAKES A LOT OF DIFFERENCE IF YOU PAY IT OR I PAY IT.

I ALREADY BRIEFLY INDICATED THE CONFIDENTIALITY REGIME OF THE 6TH AMENDMENT. INDUSTRIAL AND COMMERCIAL SECRECY IS AN ESSENTIAL ELEMENT OF THE PROTECTION OF FREE AND FAIR COMPETITION IN A MARKET ECONOMY. EXCEPTIONS WILL HAVE TO APPLY ONLY ON SUCH INFORMATION THAT IS INDISPENSIBLE FOR THE PROTECTION OF HEALTH AND SAFETY OF THE PUBLIC THAT WILL BE CONFRONTED WITH A CERTAIN CHEMICAL SUBSTANCE. CONFIDENTIALITY WILL ALSO APPLY ON SUPPORTING EXPERIMENTAL OBSERVATIONS CONTAINED IN THE NOTIFICATION DOSSIER, WHICH ACTUALLY IS RECOGNIZED IN MOST COUNTRIES AS BELONGING TO THE AREA OF INDUSTRIAL PROPERTY. GIVEN THE LEVEL OF COSTS INVOLVED IN TESTING, ESPECIALLY WHEN WE APPLY THE HIGHER TESTING LEVELS FOR PRODUCTS THAT WILL REACH THE MARKET IN LARGER QUANTITIES THIS IS OF GREAT IMPORTANCE TO PRODUCERS, EVEN IF PRODUCTS THAT ARE MARKETED IN SUCH LARGE QUANTITIES FORM ONLY A MINOR PART OF THE TOTAL TRADE IN CHEMICAL SUBSTANCES.

IN THE EC SYSTEM THE DETAILS OF THE STUDIES AND TESTS CONTAINED IN THE NOTIFICATION AS WELL AS ADDITIONAL TESTS THAT MIGHT BE REQUIRED, WILL BE REGARDED AS CONFIDENTIAL.

THIS IMPLIES THAT IN CASE THERE IS A SECOND MANUFACTURER OF THE SAME SUBSTANCE, WHO WANTS TO USE THE TESTS MADE BY THE FIRST MANUFACTURER, THE SECOND CAN ADDRESS THE FIRST MANUFACTURER AND TRY TO COME TO AN AGREEMENT ON THE PRICE TO PAY FOR THIS USE.

7. LET'S TURN NOW TO THE INVENTORY OF SUBSTANCES EXISTING ON THE MARKET ON 18 SEPTEMBER, 1981, FOR WHICH THERE WILL BE NO NOTIFICATION. THIS WILL BE AN IMPORTANT DOCUMENT BECAUSE ONCE IT WILL BE FINALIZED AND PUBLISHED THERE WILL BE NO MODIFICATIONS AND IT WILL DECIDE ONCE AND FOR ALL WHETHER A SUBSTANCE IS "OLD" OR "NEW" AND WHETHER NOTIFICATION WILL BE REQUIRED OR NOT.

WHERE ARE WE WITH THE INVENTORY? WE HAVE FINALIZED THE WORK ON THE SO-CALLED CORE INVENTORY WHICH IS BASED ON THE EC'S CUSTOMS TARIFF. FURTHERMORE, USE HAS BEEN MADE OF THE INITIAL INVENTORY OF THE EPA AND OF THE LISTING OF THE STANFORD RESEARCH INSTITUTE. ON THIS BASIS THE CORE INVENTORY WILL INDICATE SOME 34,000 SUBSTANCES THAT HAVE BEEN INTRODUCED ON THE MARKET BEFORE 18 SEPTEMBER, 1981. THE CORE INVENTORY WILL BE AVAILABLE IN PRINT PROBABLY IN SEPTEMBER.

AFTER THAT THE EC INDUSTRY WILL HAVE 9 MONTHS TO DECLARE OTHER SUBSTANCES, THAT ARE NOT ON THE CORE INVENTORY BUT THAT THEY HAVE MARKETED BEFORE 18 SEPTEMBER 1981. AT THE END OF THAT REPORTING PHASE THE EC WILL BEGIN TO ESTABLISH THE FINAL INVENTORY BASED UPON THE CORE INVENTORY AND THE DECLARATIONS. THE FINAL INVENTORY IS EXPECTED TO BE PUBLICLY AVAILABLE BY 1984.

HOW WILL MANUFACTUERS AND IMPORTERS HAVE TO MAKE THEIR DECISION AS TO NOTIFYING OR NOT A CHEMICAL AS LONG AS THE FINAL INVENTORY DOES NOT YET EXIST? THE BASIC ANSWER TO THAT IS THAT IF A CHEMICAL IS NEW, IT HAS TO BE NOTIFIED. NOW IF AN AMERICAN INDUSTRY WANTS TO EXPORT A PRODUCT TO EUROPE THAT IT KNOWS TO BE AN OLD CHEMICAL IN THE SENSE OF THE 6TH AMENDMENT, IT WILL HAVE TO CHECK WHETHER THAT CHEMICAL IS IN THE CORE INVENTORY. IF IT IS NOT IN THE CORE INVENTORY HE CAN AND ACTUALLY SHOULD CONTACT HIS IMPORTER IN EUROPE AND ASK HIM TO MAKE THE DECLARATION, WHILE GIVING HIM THE INFORMATION NEEDED TO DO SO. ONLY EUROPEAN COMPANIES CAN DECLARE SUCH OLD SUBSTANCES BUT THAT IS NO PROBLEM AS LONG AS HIS AMERICAN PARTNER REQUESTS HIM TO DO SO.

THERE MIGHT BE CASES WHERE AUTHORITIES HAVE A DOUBT AND WILL REQUIRE A NOTIFICATION EVEN IF THE US MANUFACTURER BELIEVES THAT THE CHEMICAL IN QUESTION IS AN OLD SUBSTANCE BUT SUCH CASES WILL BE HIGHLY EXCEPTIONAL IF THERE IS A GOOD AND EFFICIENT INTERACTION BETWEEN THE MANUFACTURER IN THE US AND THE IMPORTER IN EUROPE.

8. I UNDERSTAND THAT THERE ARE ALSO SOME QUESTIONS ON LABELLING TO WHICH I WILL TRY TO RESPOND. THE RULES REGARDING LABELLING ARE ENTIRELY AND COMPLETELY IN THE 6TH AMENDMENT. IT REQUIRES THAT DANGEROUS SUBSTANCES WILL BE PACKAGED AND LABELLED WITH THE USE OF LANGUAGE, SYMBOLS AND OTHER TECHNICAL REQUIREMENTS THAT YOU WILL FIND IN THE TEXT OF THE EC DIRECTIVE, AND ITS ANNEXES. NO OTHER REQUIREMENTS EXIST. THE CLASSIFICATION OF DANGEROUS SUBSTANCES WILL BE MADE ACCORDING TO THE CRITERIA OF THE DIRECTIVE.

ONE OF THESE REQUIREMENTS IS THE USE OF THE NATIONAL LANGUAGE OF THE COUNTRY WHERE DANGEROUS SUBSTANCES WILL BE MARKETED. LABELS FOR SUCH CHEMICALS CAN BE MULTI-LINGUAL AND THE ENGLISH LANGUAGE CAN BE USED AT ALL TIMES, BUT ONE SHOULD NOT BE SURPRISED TO LEARN THAT IN ITALY OR IN DENMARK THE SPECIAL RISKS OF A PARTICULAR CHEMICAL SHOULD BE SPELLED OUT FOR THE USE OF THE LOCAL CONSUMER IN ITALIAN OR DANISH, IN MANY CASES THE ONLY LANGUAGE THEY KNOW.

ON THE OTHER HAND, IF A CHEMICAL IS NOT DANGEROUS NO LABEL IS OBLIGATORY AND MANUFACTURERS CAN USE THE TYPE OF LABEL THAT SEEMS GOOD TO THEM.

ON THIS AND OTHER SUBJECTS THE EC COMMISSION IS DRAFTING A VERY ELABORATE GUIDE SPECIFYING HOW TO PROCEDE IN LABELLING OLD AND NEW DANGEROUS CHEMICALS. THIS GUIDE SHOULD ALSO BE AVAILABLE IN ENGLISH BY SEPTEMBER OF THIS YEAR.

9. MR. CHAIRMAN, ALL THIS TECHNICAL INFORMATION REMINDS ME OF THE STORY A GOOD FRIEND OF MINE WHO LIVES IN CAMBRIDGE (MASS.) TOLD ME THE OTHER DAY. HE WAS SHOPPING IN A CAMBRIDGE SUPER MARKET AND HE SAW THERE A SOMEWHAT FATIGUED GENTLEMAN PUSHING HIS SHOPPING CART LOADED WITH SOME HUNDRED ARTICLES TOWARDS THE ONE CASH REGISTER THAT WAS LOUD AND CLEARLY LABELLED: 8 ARTICLES OR LESS. THE GIRL AT THE STAND LOOKED AT HIM AND SAID: "SIR, YOU MUST EITHER BE FROM HARVARD AND YOU CAN'T COUNT OR FROM MIT AND YOU CAN'T READ".

I HAVE THE FEELING, MR. CHAIRMAN THAT I TRIED TO PUSH INTO THIS CONFERENCE A CART WITH MANY ITEMS THAT, ALTHOUGH I GOT MY EDUCATION IN A DECENT EUROPEAN UNIVERSITY, I AM NOT QUITE SURE I CAN MYSELF EITHER COUNT OR READ. BUT I HOPE THAT NEVERTHELESS MY MESSAGE IS CLEAR: THE EC IS COMMITTED TO AND ACTIVELY INVOLVED IN SETTING UP A SYSTEM FOR THE MANAGEMENT OF INDUSTRIAL CHEMICALS, FOR ITSELF AS WELL AS FOR ITS TRADE WITH OTHER PARTNERS, BASED ON EQUAL TREATMENT, INTERNATIONALLY HARMONIZED RULES, PROTECTION OF MAN AND HIS ENVIRONMENT AND FAIR TRADE.

THANK YOU VERY MUCH.