

QNET LLC



**EU PRODUCT SAFETY (CE)
VERSUS
ENVIRONMENTAL DIRECTIVES
AS IT RELATES TO MEDICAL DEVICE MANUFACTURERS**

**EU PRODUCT SAFETY VERSUS
ENVIRONMENTAL DIRECTIVES
AND HOW THEY RELATE TO
MEDICAL DEVICE MANUFACTURERS**

WHITE PAPER

**COMPOSED BY THE MEDICAL DEVICE PROJECT
MANAGERS AT QNET LLC IN THE USA AND
QNET BV IN THE NETHERLANDS AND THE UK**

DEAR CLIENT,

COMPLIANCE WITH MEDICAL DEVICE OR IN-VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVES, UP TO NOW HAS BEEN SUFFICIENT TO PLACE CE-MARKED DEVICES ON THE EUROPEAN MARKET. THIS HAS CHANGED.

DURING THE LAST FEW YEARS DIRECTIVES THAT DO NOT REQUIRE CE-MARKING HAVE BEEN PUBLISHED. THESE ARE ENVIRONMENTAL DIRECTIVES AND REQUIRE ADDITIONAL COMPLIANCE ACTIVITY. THEY APPLY TO SPECIFIC TYPES OF MEDICAL AND IN-VITRO DIAGNOSTIC DEVICES. IN SOME CASES THEY REQUIRE A CROSSED OUT WHEELED BIN SYMBOL.

IN ORDER TO ASSIST WITH DETERMINING IF SOME OR ALL OF THESE DIRECTIVES APPLY TO YOUR DEVICES, NOW OR IN THE FUTURE, WE HIGHLIGHT THE FOLLOWING ENVIRONMENTAL DIRECTIVES IN THIS WHITE PAPER:

DIRECTIVE ABBREVIATION	DESCRIPTION	NUMBER
WEEE	WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT	2002/96/EC
ROHS	RESTRICTIONS OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT	2002/95/EC
PHthalATES	RESTRICTIONS ON THE MARKETING AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS	2005/84/EC (AMENDMENT TO 76/769/EEC)
BATTERY	BATTERIES AND ACCUMULATORS AND WASTE BATTERIES AND ACCUMULATORS	2006/66/EC
REACH	THE REGISTRATION, EVALUATION AND RESTRICTION OF CHEMICALS (DATE SENSITIVE)	REACH REGULATION 1907/2006

SINCERELY,

YVONNE HALPAUS

WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE 2002/96/EC (WEEE)

EFFECTIVE DATE: AUGUST 13, 2005

TYPES OF DEVICES AFFECTED

DEVICES (EEE) DEPENDENT ON ELECTRICAL CURRENTS OR ELECTROMAGNETIC FIELDS IN ORDER TO WORK PROPERLY. FOR THE GENERATION, TRANSFER, AND MEASUREMENT OF SUCH CURRENTS WHICH FALLS UNDER ONE OF 10 CATEGORIES. CATEGORY NUMBER 8 IS MEDICAL DEVICES. DESIGNED FOR USE WITH A RATED ALTERNATING VOLTAGE NOT EXCEEDING 1000 VOLTS OR RATED DIRECT VOLTAGE OF 1500 VOLTS FOR DIRECT CURRENT.

RESPONSIBLE PARTY

ONE OF 3 PARTIES REFERRED TO AS PRODUCERS:

1. MANUFACTURES EEE
2. REBRANDS EEE PRODUCED BY OTHER MANUFACTURERS
3. IMPORTS OR EXPORTS EEE ON PROFESSIONAL BASIS INTO A MEMBER STATE

COMPLIANCE ACTIVITY REQUIRED

PRODUCER OR THIRD PARTIES ACTING ON THEIR BEHALF, DULY RECORDED IN THE MEMBER STATE 'S REGISTER OF PRODUCERS, MUST SET UP A SYSTEM TO PROVIDE TREATMENT OF WEEE USING BEST AVAILABLE TREATMENT RECOVERY, RECYCLING TECHNIQUES.

SYMBOL

CROSSED OUT WHEELED BIN SYMBOL ON DEVICE LABEL IN ACCORDANCE WITH STANDARD EN 50419:2006 IS **MANDATORY**.

DOCUMENTED PROOF

1. WRITTEN AGREEMENT BETWEEN MANUFACTURER AND THIRD PARTY (REBRANDER OR IMPORTER) TO PROVIDE EVIDENCE OF A) REGISTRATION OF EEE DEVICES WITH AGENCY WITH WHOM THEY HAVE MADE ARRANGEMENTS FOR TREATMENT, RECOVERY OR RECYCLING AND B) THAT IT HAS BEEN CARRIED OUT AT THE END OF THE LIFE-CYCLE.
2. NEW SYMBOL ON DEVICE LABEL IS ACCESSIBLE – DURABLE – LEGIBLE- INDELIBLE
COMPLIANCE IS CHECKED BY INSPECTION AND BY RUBBING BY HAND FOR 15 S WITH A PIECE OF CLOTH AND AGAIN FOR 15 S WITH A PIECE OF CLOTH SOAKED WITH PETROLEUM SPIRIT. AFTER THE TEST THE MARKING SHALL BE LEGIBLE, IT SHALL NOT BE EASILY POSSIBLE TO REMOVE THE MARKING. IF USED, MARKING PLATES OR LABELS SHALL SHOW NO CURLING.
3. NOTIFIED BODY CERTIFICATION OR LABORATORY TESTING IS NOT REQUIRED.

RECOMMENDATION/OBSERVATION

THE WEEE REGISTRATION AND ENFORCEMENT IS CARRIED OUT ON A COUNTRY-BY-COUNTRY BASIS, IT IS NOT POSSIBLE TO REGISTER EU WIDE. THE REGISTRATION FORMS IN SEVERAL EU COUNTRIES REQUIRE A VAT (VALUE ADDED TAX) NUMBER, WHICH ONLY LOCAL COMPANIES CAN PROVIDE. THIS IS SEEN AS AN EXPRESSION OF PREFERENCE FOR REGISTRATION BY PROFESSIONAL IMPORTERS BY LOCAL AUTHORITIES.

HOWEVER, IF YOU NEED ASSISTANCE TO REGISTER DIRECT IN EACH COUNTRY PLEASE CONTACT:
MR. MARK WANDERS – RECYDUR, WILMERSDORF 36/38, 7327 APELDOORN, THE NETHERLANDS
PH: 011-31-55-533601 OR E-MAIL: INFO@RECYDUR.NL

WEB LINK: WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE 2002/96/EC
[HTTP://WWW.CE-MARK.COM/WEEE.PDF](http://WWW.CE-MARK.COM/WEEE.PDF) + QNET POWERPOINT PRESENTATION AT [HTTP://WWW.CE-MARK.COM/WEEE_2008.PPT](http://WWW.CE-MARK.COM/WEEE_2008.PPT)

THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE 2002/95/EC (RoHS)

EFFECTIVE DATE JULY 1, 2006

TYPES OF DEVICES AFFECTED

DEVICES (EEE) DEPENDENT ON ELECTRICAL CURRENTS OR ELECTROMAGNETIC FIELDS IN ORDER TO WORK PROPERLY. FOR THE GENERATION, TRANSFER, AND MEASUREMENT OF SUCH CURRENTS WHICH FALLS UNDER ONE OF 8 CATEGORIES. **CATEGORY NUMBER 8: MEDICAL DEVICES IS EXEMPT UNTIL 2012-14 (ESTIMATED BY EU COMMISSION BASED ON ERA TECHNOLOGIES STUDY).**

DESIGNED FOR USE WITH A RATED ALTERNATING VOLTAGE NOT EXCEEDING 1000 VOLTS OR RATED DIRECT VOLTAGE OF 1500 VOLTS FOR DIRECT CURRENT.

RESPONSIBLE PARTY

ONE OF 3 PARTIES REFERRED TO AS PRODUCERS: A COMPANY THAT:

- MANUFACTURES EEE AND SELLS UNDER HIS OWN BRAND NAME
- REBRANDS EEE PRODUCED BY OTHER SUPPLIERS
- IMPORTS OR EXPORTS EEE ON PROFESSIONAL BASIS INTO A MEMBER STATE

NOT A PRODUCER; A RESELLER SELLING EEE WITH THE BRAND NAME OF THE ORIGINAL PRODUCER STILL ON THE EEE.

COMPLIANCE ACTIVITY REQUIRED

AT THE TIME OF MANUFACTURING THE PRODUCER MUST EXERCISE DUE DILIGENCE TO ENSURE THAT ALL COMPONENTS AND SUB-ASSEMBLIES & MATERIALS USED IN THEIR PRODUCTS DO NOT CONTAIN ANY OF THE SIX BANNED SUBSTANCES: 1) LEAD (Pb) 2) CADMIUM (Cd) 3) MERCURY (Hg) 4) HEXAVALENT CHROMIUM (Cr (VI)) 5) POLYBROMINATED BIPHENYLS (PBBS) 6) POLYBROMINATED DIPHENYL ETHERS (PBDEs).

MANUFACTURER MUST VERIFY THAT THE COMPONENTS USED IN THEIR END PRODUCTS ARE ROHS COMPLIANT. DOCUMENTED COMPLIANCE MUST BE AVAILABLE FOR EACH COMPONENT. IF DOCUMENTATION IS NOT AVAILABLE, THE ONLY ALTERNATIVE MAY BE TO HAVE THE COMPONENT ANALYZED FOR HAZARDOUS SUBSTANCES.

MANUFACTURERS SHOULD REQUEST A DECLARATION FROM EACH SUPPLIER AND IF IN DOUBT REVIEW FOR ACCURACY AND TEST IF NECESSARY. PERFORM INTERNAL AUDITS OF PROCEDURES AND RECORDS.

SYMBOL: NONE! NOTIFIED BODY CERTIFICATION OR TESTING NOT REQUIRED!

DOCUMENTED PROOF

STANDARD PROCEDURE AND RECORDS SHOWING DUE DILIGENCE OBTAINING DOCUMENTED PROOF OF ROHS COMPLIANCE FOR EACH COMPONENT.

RECOMMENDATION/OBSERVATION

START IMPLEMENTING NOW! MAKE IT PART OF YOUR ISO 13485 QM SYSTEM. GIVE YOURSELF PLENTY OF TIME.

WEB LINK: ROHS DIRECTIVE 2002/95/EC [HTTP://WWW.CE-MARK.COM/ROHS.PDF](http://www.ce-mark.com/rohs.pdf) AND QNET POWERPOINT PRESENTATION AT [HTTP://WWW.CE-MARK.COM/ROHS_2008.PPT](http://www.ce-mark.com/rohs_2008.ppt)

RESTRICTIONS ON THE MARKETING AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS (PHTHALATES DIRECTIVE 2005/84/EC 22ND AMENDMENT TO DIRECTIVE 76/769/EEC)

EFFECTIVE DATE: JANUARY 16, 2007

TYPES OF DEVICES AFFECTED BY THIS AMENDMENT:

RESTRICTS THE PLACING ON THE MARKET OF PHTHALATES IN PLASTICISED MATERIAL IN TOYS AND CHILD CARE ARTICLES. 'CHILDCARE ARTICLE' MEANS ANY PRODUCT INTENDED TO FACILITATE SLEEP, RELAXATION, HYGIENE, THE FEEDING OF CHILDREN OR SUCKING ON THE PART OF CHILDREN. THE PHTHALATES DINP, DIDP, DNOP SHALL NOT BE USED AS SUBSTANCES OR AS CONSTITUENTS OF PREPARATIONS, AT CONCENTRATIONS GREATER THAN 0.1% BY MASS OF THE PLASTICISED MATERIALS

RESPONSIBLE PARTY: MANUFACTURER

COMPLIANCE ACTIVITY REQUIRED:

AT THE TIME OF MANUFACTURING THE MANUFACTURER MUST EXERCISE DUE DILIGENCE TO ENSURE THAT ALL MATERIALS USED IN THESE TYPE OF PRODUCTS DO NOT CONTAIN PHTHALATES DINP, DIDP, DNOP AT CONCENTRATIONS GREATER THAN 0.1% BY MASS OF THE PLASTICISED MATERIALS.

SYMBOL: NONE! NOTIFIED BODY CERTIFICATION NOT REQUIRED.

DOCUMENTED PROOF:

DOCUMENTATION INCLUDES MATERIAL SAFETY DATA SHEETS AND/OR LETTERS FROM RAW MATERIAL SUPPLIERS.

RECOMMENDATION/OBSERVATION

PHTHALATES/DEHP IN PVC MEDICAL DEVICES OTHER THAN CHILDCARE ARTICLES IS CONTROLLED THROUGH THE MEDICAL DEVICES DIRECTIVE. THIS REQUIRES THAT THE MANUFACTURER SHOULD ELIMINATE ANY RISKS WHERE FEASIBLE OR REDUCE THEM AS FAR AS POSSIBLE IN LINE WITH THE GENERALLY ACKNOWLEDGED STATE OF THE ART. THE ACCEPTABILITY OF ANY RESIDUAL RISKS IS THEN DETERMINED BY THE LEVEL OF BENEFITS THAT THE PRODUCT BRINGS. THIS SHOULD BE COVERED IN THE RISK ANALYSIS AND ESSENTIAL REQUIREMENTS.

EXAMPLE MEDICAL DEVICES CONTAINING DEHP:

- INTRAVENOUS (IV) BAGS AND TUBING
- UMBILICAL ARTERY CATHETERS
- BLOOD BAGS AND INFUSION TUBING
- TUBING USED IN CARDIOPULMONARY BYPASS PROCEDURES, DURING HEMODIALYSIS ETC.
- NASOGASTRIC TUBES
- ENTERAL NUTRITION FEEDING BAGS
- TUBING USED IN EXTRACORPOREAL MEMBRANE OXYGENATION

PVC/DEHP PHASE-OUT STEPS ARE BEING TAKEN IN HOSPITALS IN AUSTRIA, DENMARK. SLOVAKIA, SWEDEN, CZECH REPUBLIC.

WEB LINKS: PHTHALATES DIRECTIVE [HTTP://WWW.CE-MARK.COM/2005_84_EC_PHTHALATES.PDF](http://www.ce-mark.com/2005_84_ec_phtthalates.pdf)
MHRA (UK MEDICAL COMPETENT AUTHORITIES) [WWW.MHRA.GOV.UK/SAFETYINFORMATION](http://www.mhra.gov.uk/safetyinformation)
[WWW.NOHARM.ORG/EUROPE](http://www.noharm.org/europe)

**BATTERIES AND ACCUMULATORS AND WASTE BATTERIES AND ACCUMULATORS
BATTERY DIRECTIVE 2006/66/EC**

EFFECTIVE DATE: SEPTEMBER 26, 2008

TYPES OF DEVICES AFFECTED:

ALL TYPES OF BATTERIES AND ACCUMULATORS. INCLUDES: BATTERY OR ACCUMULATORS, BATTERY PACKS, PORTABLE BATTERY, BUTTON CELL, AUTOMOTIVE BATTERY, INDUSTRIAL BATTERY, WASTE BATTERY. INDUSTRIAL – PORTABLE – AUTOMOTIVE

PROHIBITIONS:

MEMBER STATES SHALL **PROHIBIT** THE PLACING ON THE EU MARKET OF:

- A.) ALL BATTERIES OR ACCUMULATORS WHETHER OR NOT INCORPORATED INTO APPLIANCES, THAT CONTAIN MORE THAN 0,0005% OF MERCURY BY WEIGHT. THIS SHALL NOT APPLY TO BUTTON CELLS WITH MERCURY CONTENT OF NO MORE THAN 2% BY WEIGHT.
- B.) PORTABLE BATTERIES OR ACCUMULATORS INCLUDING THOSE INCORPORATED INTO APPLIANCES THAT CONTAIN MORE THAN 0,002% OF CADMIUM BY WEIGHT. THIS SHALL NOT APPLY TO PORTABLE BATTERIES AND ACCUMULATORS INTENDED FOR USE IN: 1) EMERGENCY AND ALARM SYSTEMS, INCLUDING EMERGENCY LIGHTING; 2) MEDICAL EQUIPMENT; 3) CORDLESS POWER TOOLS.

RESPONSIBLE PARTIES:

MANUFACTURER: ARTICLE 11 REQUIRES THAT 'MANUFACTURERS DESIGN APPLIANCES IN SUCH A WAY THAT WASTE BATTERIES AND ACCUMULATORS CAN BE READILY REMOVED' AND THAT 'APPLIANCES INTO WHICH BATTERIES AND ACCUMULATORS ARE INCORPORATED SHALL BE ACCOMPANIED BY INSTRUCTIONS SHOWING HOW THEY CAN BE REMOVED SAFELY'.

PRODUCER: ANY PERSON IN A MEMBER STATE THAT IRRESPECTIVE OF THE SELLING TECHNIQUE USED, INCLUDING MEANS OF DISTANCE SELLING COMMUNICATION, PLACES BATTERIES OR ACCUMULATORS, INCLUDING THOSE INCORPORATED INTO APPLIANCES OR VEHICLES, ON THE MARKET FOR THE FIRST TIME WITHIN THE TERRITORY OF THAT MEMBER STATE ON A PROFESSIONAL BASIS.

DISTRIBUTOR: ANY PERSON THAT PROVIDES BATTERIES AND ACCUMULATORS ON A PROFESSIONAL BASIS TO AN END-USER.

ECONOMIC OPERATORS: ANY PRODUCER, DISTRIBUTOR, COLLECTOR, RECYCLER, OR OTHER TREATMENT OPERATOR.

COMPLIANCE ACTIVITY REQUIRED:

INSTRUCTIONS FOR USE: MUST INCLUDE HOW BATTERIES CAN BE SAFELY REMOVED AND TYPE OF BATTERIES AND ACCUMULATORS INCLUDED. EXCEPTION: WHERE FOR SAFETY, PERFORMANCE, MEDICAL OR DATA INTEGRITY REASONS CONTINUITY OF POWER SUPPLY IS NECESSARY AND REQUIRES A PERMANENT CONNECTIONS BETWEEN THE APPLIANCE AND THE BATTERY/ACCUMULATOR.

LABELING: WHEELED BIN SYMBOL ON LABEL ON BATTERY AND ACCUMULATORS IS **MANDATORY**. CHEMICAL SYMBOL, IF APPLICABLE, IS MANDATORY, COVERING AT LEAST, AN AREA OF ONE QUARTER OF THE WHEELED BIN SYMBOL:

- HG IF CONTENT EXCEEDS 0,0005% MERCURY
- CD IF CONTENT EXCEEDS 0,0002% CADMIUM
- PB IF CONTENT EXCEEDS 0,0004% LEAD

TAKE BACK SCHEMES: BY PRODUCER, DISTRIBUTOR OR ECONOMIC OPERATOR IN ACCORDANCE WITH WEEE DIRECTIVE.

BATTERIES AND ACCUMULATORS AND WASTE BATTERIES AND ACCUMULATORS
BATTERY DIRECTIVE 2006/66/EC CONTINUED

NOTIFIED BODIES: NOTIFIED BODY CERTIFICATION OR LABORATORY TESTING IS NOT REQUIRED.

SYMBOL: THE SYMBOL SHALL COVER AT LEAST 3% OF THE AREA OF THE LARGEST SIDE OF THE BATTERY, ACCUMULATOR OR BATTERY PACK, UP TO MAXIMUM SIZE OF 5 X 5 CM. IN THE CASE OF CYLINDRICAL CELLS, THE SYMBOL SHALL COVER AT LEAST 1,5% OF THE SURFACE AREA AND SHALL HAVE MAXIMUM SIZE OF 5 X 5 CM. IF THE SIZE OF THE BATTERY, ACCUMULATOR OR BATTERY PACK IS SUCH THAT THE SYMBOL WOULD BE SMALLER THAN 05, X 0,5 CM, A SYMBOL MEASURING AT LEAST 1 X 1 CM SHALL BE PRINTED ON THE PACKAGING. SYMBOL MUST BE ACCESSIBLE – DURABLE – LEGIBLE- INDELIBLE

DOCUMENTED PROOF: INSTRUCTIONS FOR USE, LABELS, AND WEEE ARRANGEMENTS. WRITTEN AGREEMENT BETWEEN MANUFACTURER AND IMPORTER/DISTRIBUTOR AND OTHER RESPONSIBLE PARTIES.

RECOMMENDATION/OBSERVATION

ONCE THE BATTERIES AND ACCUMULATORS HAVE BEEN REMOVED THEY BECOME SUBJECT TO THE WEEE REGULATIONS. THE WEEE REGISTRATION AND ENFORCEMENT IS CARRIED OUT ON A COUNTRY-BY-COUNTRY BASIS, IT IS NOT POSSIBLE TO REGISTER EU WIDE. THE REGISTRATION FORMS IN SEVERAL EU COUNTRIES REQUIRE A VAT (VALUE ADDED TAX) NUMBER, WHICH ONLY LOCAL COMPANIES CAN PROVIDE. THIS IS SEEN AS AN EXPRESSION OF PREFERENCE FOR REGISTRATION BY PROFESSIONAL IMPORTERS BY LOCAL AUTHORITIES.

HOWEVER, IF YOU NEED ASSISTANCE TO REGISTER DIRECT IN EACH COUNTRY PLEASE CONTACT:
MR. MARK WANDERS – RECYDUR , WILMERSDORF 36/38, 7327 APELDOORN, THE NETHERLANDS
PH: 011-31-55-533601 OR E-MAIL: INFO@RECYDUR.NL

WEB LINKS: BATTERY DIRECTIVE [HTTP://WWW.CE-MARK.COM/2006_66_EC_BATTERIES.PDF](http://www.ce-mark.com/2006_66_EC_BATTERIES.PDF)
QNET: WHAT MANUFACTURERS NEED TO KNOW AND DO ABOUT BATTERY DIRECTIVE 2006/66/EC
[HTTP://WWW.CE-MARK.COM/EU%20BATTERY%20DIRECTIVE.PDF](http://www.ce-mark.com/EU%20BATTERY%20DIRECTIVE.PDF)

**THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS
REACH REGULATION 1907/2006**

EFFECTIVE DATE: JUNE 1, 2007

TYPES OF DEVICES AFFECTED:

ARTICLES DEFINED AS AN OBJECT WHICH DURING PRODUCTION HAS GIVEN SPECIAL SHAPE SURFACE OR DESIGN WHICH DETERMINES IT'S FUNCTION TO A GREATER DEGREE THAN ITS CHEMICAL COMPOSITION. THAT ARE DESIGNED TO RELEASE CHEMICAL AND THAT CONTAIN SUBSTANCES OF VERY HIGH CONCERN.

DEVICES THAT ARE THEMSELVES CHEMICAL OR PREPARATIONS. 30,000 CHEMICALS ARE AFFECTED OF WHICH 3,000 WILL BE BANNED OR RESTRICTED, THESE ARE CALLED SUBSTANCES OF VERY HIGH CONCERN. (SVCH)

RESPONSIBLE PARTIES:

MANUFACTURER OF PREPARATIONS OR ARTICLES/MEDICAL DEVICES
IMPORTERS AND DISTRIBUTORS
CHEMICAL SUPPLIERS
DOWNSTREAM USERS
EUROPEAN CHEMICALS AGENCY (ECHA) (NEW AGENCY)

EXEMPTIONS: TOTAL EXEMPTIONS:

- RADIOACTIVE SUBSTANCES WITHIN THE SCOPE OF COUNCIL DIRECTIVE 96/29/EURATOM
- SUBSTANCES , ON THEIR OWN, IN A PREPARATION OR IN AN ARTICLE, WHICH ARE SUBJECT TO CUSTOMS SUPERVISION, PROVIDED THAT THEY DO NOT UNDERGO ANY TREATMENT OR PROCESSING, AND WHICH ARE IN TEMPORARY STORAGE, OR IN A FREE ZONE OR FREE WAREHOUSE, WITH A VIEW TO RE-EXPORTATION, OR IN TRANSIT
- NON-ISOLATED INTERMEDIATES
- MEDICINAL PRODUCTS
- COSMETIC PRODUCTS
- THE CARRIAGE OF DANGEROUS SUBSTANCES AND DANGEROUS SUBSTANCES PREPARATIONS BY RAIL, ROAD, INLAND WATERWAY, SEA OR AIR.
- WASTE AS DEFINED IN DIRECTIVE 2006/12/EC

PARTIAL EXEMPTIONS: (EXAMPLES, NOT A COMPLETE LIST)

- MEDICINAL PRODUCTS FOR HUMAN USE (DIRECTIVE 2001/83/EC)
- FOOD AND FEEDINGSTUFFS IN ACCORDANCE WITH REGULATION No. 178/2002
- SUBSTANCES CONTAINED WITHIN PRODUCTS IN THE FINISHED STATE, INTENDED FOR THE END-USER EXEMPT ONLY FROM TITLE IV (INFORMATION IN THE SUPPLY CHAIN) OF REACH:
 - MEDICAL DEVICES WHICH ARE INVASIVE OR USED IN DIRECT PHYSICAL CONTACT WITH THE HUMAN BODY IN ACCORDANCE WITH DIRECTIVE 1999/45/EC (DANGEROUS PREPARATIONS)

**THE REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS
REACH REGULATION 1907/2006 CONTINUED**

COMPLIANCE ACTIVITIES MAY INCLUDE: REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS; NOTIFICATION OF ARTICLES WITH SVCH.

HOW TO GET STARTED:

MANUFACTURER:

- 1) LIST THE DEVICE CHEMICAL COMPOSITION
- 2) DETERMINE IF THESE SUBSTANCES ARE ON THE CANDIDATE SVCH LIST RELEASED?
- 3) DETERMINE THE WEIGHT PERCENT OF EACH OF THESE SUBSTANCES PER DEVICE.
- 4) DETERMINE IF THE SUBSTANCES PRESENT IN THE DEVICE WITH INTENDED USE EXCEEDS 1 TONNE PER YEAR PER IMPORTER.
- 5) USE THE NAVIGATOR SYSTEM PROVIDED BY THE EUROPEAN CHEMICALS AGENCY (ECHA) TO DETERMINE YOUR OBLIGATION UNDER REACH, PLEASE PROCEED IMMEDIATELY TO MEET A **DEADLINE THAT MAY APPLY TO YOUR DEVICES WHICH EXPIRES NOVEMBER 30, 2008**. IF YOU MISS THE DEADLINE THE PRODUCT MAY HAVE TO BE REMOVED FROM THE MARKET UNTIL A REGISTRATION WITH FEE IS FILED.

INSTRUCTIONS TO USE THE NAVIGATOR: [HTTP://REACH.JRC.IT/NAVIGATOR_EN.HTM](http://reach.jrc.it/navigator_en.htm)

WHAT IS THE NAVIGATOR?

THE NAVIGATOR IS A TOOL TO HELP MANUFACTURERS, IMPORTERS, DOWNSTREAM USERS, DISTRIBUTORS OF CHEMICAL SUBSTANCES, AND **PRODUCERS OR IMPORTERS OF ARTICLES** TO FIGURE OUT THEIR OBLIGATIONS UNDER REACH. THE NAVIGATOR WILL PROVIDE A LIST OF OBLIGATIONS **FOR A GIVEN SUBSTANCE**, BASED ON THE ANSWERS THE USER GIVES TO A SERIES OF QUESTIONS: WHETHER HE MANUFACTURES OR IMPORTS THE SUBSTANCE, AT WHAT TONNAGE, FOR WHAT USE, WHETHER THE SUBSTANCE IS CLASSIFIED AS DANGEROUS, ETC. BELOW EACH QUESTION, EXPLANATIONS ARE PROVIDED TO HELP ANSWERING IT.

A NAVIGATOR SESSION IS NOT ALWAYS THE SAME FOR ALL SUBSTANCES: THE USER WILL BE ASKED ONLY THE RELEVANT QUESTIONS FOR EACH CASE, BASED ON THE ANSWERS HE GAVE AT EACH STEP.

WHAT TO PREPARE BEFORE STARTING A SESSION?

YOU NEED TO RUN THE NAVIGATOR FOR EACH SUBSTANCE SEPARATELY AS THE QUESTIONS MIGHT DIFFER FROM SUBSTANCE TO SUBSTANCE. THEREFORE, BEFORE USING THE NAVIGATOR, IDENTIFY ALL THE SUBSTANCES YOU ARE DEALING WITH, OR A SELECTION OF SUBSTANCES FOR WHICH YOU WANT TO RUN A NAVIGATOR SESSION (REACH POTENTIALLY APPLIES TO ALL SUBSTANCES, WHETHER ON THEIR OWN, IN A PREPARATION OR IN AN ARTICLE).

IT MIGHT BE THE CASE THAT YOU MANUFACTURE, IMPORT OR USE SEVERAL SUBSTANCES IN THE SAME WAY SO THAT YOUR ANSWERS TO THE QUESTIONS WILL BE SIMILAR. IN THIS CASE IF YOU RUN DIFFERENT SESSIONS OF THE NAVIGATOR YOU WILL GET THE SAME LIST OF OBLIGATIONS FOR THESE SUBSTANCES.

HOW TO USE THE NAVIGATOR?

THE NAVIGATOR WILL ASK YOU A SERIES OF QUESTIONS CONCERNING YOUR CHEMICAL SUBSTANCE ON THE ASSUMPTION THAT YOU ARE A EUROPEAN COMPANY. WHEN ANSWERING THINK OF YOURSELF AS THE EUROPEAN IMPORTER OF THE PRODUCT AND ITS CHEMICAL COMPONENTS. IT IS IMPORTANT THAT YOU ANSWER CORRECTLY OTHERWISE THE NAVIGATOR WILL GIVE YOU AN INCORRECT LIST OF

**THE REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS
REACH REGULATION 1907/2006 CONTINUED**

OBLIGATIONS. THEREFORE, IT IS HIGHLY RECOMMENDED TO READ THE EXPLANATIONS BELOW EACH QUESTION CAREFULLY BEFORE ANSWERING THE QUESTIONS.

IF YOU NEED ASSISTANCE WITH THE NAVIGATOR OR THE LIST OF OBLIGATIONS IDENTIFIED BY THE NAVIGATOR FOR YOUR DEVICE, PLEASE CONTACT QNET FOR A PROPOSAL FOR CONSULTING SERVICES BY ITS NEWEST TEAM MEMBER, MS. GEORJEAN ADAMS, CHEMICAL REGULATORY SPECIALIST, HER BIOGRAPHY IS AVAILABLE UPON REQUEST.

DOCUMENTED PROOF MAY INCLUDE: REGISTRATION, EVALUATION, AND AUTHORIZATION DOCUMENTATION AND MSDS AND TECHNICAL DATA SHEETS SHOWING CHEMICAL COMPOSITION BY CAS OR EINECS.

RECOMMENDATION/OBSERVATION: FOLLOW THE NAVIGATOR PROCESS IMMEDIATELY TO DETERMINE YOUR OBLIGATIONS UNDER THIS DIRECTIVE BY **NOVEMBER 30, 2008**.

WHAT IS THE INTENT OF REACH?

REACH DIRECTIVE 67/548/EEC AND ITS AMENDMENT EC REGULATION 1907/2006 ARE INTENDED TO UNIFY THE REGULATORY ENVIRONMENT IN WHICH SUBSTANCES ARE USED. REACH REPLACES OVER 40 OTHER REGULATIONS. ITS AIM IS TO IMPROVE THE PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT THROUGH THE BETTER, AND EARLIER, IDENTIFICATION OF PROPERTIES OF SUBSTANCES. IT IS INTERESTING THAT THE WORD SUBSTANCE IS USED BECAUSE THIS HAS A BROADER MEANING AND EMBRACES CHEMICALS, AS WE KNOW THEM AND ELEMENTS, WHICH INCLUDES ABOUT EVERYTHING ELSE.

REACH IS ALSO INTENDED TO ESTABLISH AN INTEGRATED SYSTEM FOR REGISTRATION, EVALUATION AND AUTHORISATION OF SUBSTANCES. SUBSTANCES THAT ARE BEING USED MUST BE REGISTERED WITH THE EUROPEAN CHEMICALS AGENCY AND THERE ARE SEVERAL ACTIONS THAT MUST BE TAKEN BY THE MANUFACTURERS' OF SUBSTANCES INCLUDING STRINGENT TESTING THAT WAS INTRODUCED IN 1981 TO CATER FOR SUBSTANCES THAT WERE ALREADY IN USE. IT IS ESTIMATED THAT 30,000 SUBSTANCES HAVE ALREADY BEEN REGISTERED. RESPONSIBILITY FOR PROVIDING INFORMATION AND TAKING EFFECTIVE RISK MANAGEMENT MEASURES LIES PRINCIPALLY WITH THE MANUFACTURER OF SUBSTANCES.

ONE OBJECTIVE OF REACH IS TO ENCOURAGE AND IN CERTAIN CASES ENSURE THAT LESS DANGEROUS SUBSTANCES OR TECHNOLOGIES EVENTUALLY REPLACE DANGEROUS SUBSTANCES AS ECONOMICALLY AND TECHNICALLY VIABLE ALTERNATIVES BECOME AVAILABLE. THIS HAS IMPACT ON THE MANUFACTURERS' OF PRODUCTS OR ARTICLES THAT ARE INTENDED FOR SALE ON THE EUROPEAN MARKET BECAUSE THEY MUST NOW WORK TOWARDS USING LESS DANGEROUS SUBSTANCES IN THEIR PRODUCTS OR ARTICLES. EUROPEAN BUYERS OR IMPORTERS OF PRODUCTS

**THE REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS
REACH REGULATION 1907/2006 CONTINUED**

OR ARTICLES ARE ALSO INVOLVED BECAUSE THEY NEED TO KNOW WHAT SUBSTANCES HAVE BEEN USED IN THE MANUFACTURE OF PRODUCTS AND IF THESE ARE REGISTERED.

GUIDANCE HAS BEEN PUBLISHED BY THE UK COMPETENT AUTHORITY THE HSE AND CAN BE FOUND AT: [HTTP://WWW.HSE.GOV.UK/REACH/DEFINITIONS.HTM#ECHA](http://www.hse.gov.uk/reach/definitions.htm#echa)

HERE ARE A FEW DEFINITIONS THAT MAY BE HELPFUL:

PREPARATIONS PREPARATIONS ARE MIXTURES OR SOLUTIONS OF TWO OR MORE SUBSTANCES, SUCH AS DENTAL FILLING MATERIALS, LUBRICANTS, BONE, CEMENT, CONTACT LENS SOLUTIONS, AND ANTI –CLOTTING AGENTS AND OTHER PHARMACEUTICAL INGREDIENTS. REACH REGISTRATION APPLIES TO THE SUBSTANCES CONTAINED IN PREPARATIONS AND NOT THE PREPARATION PER SE.

SVCH SUBSTANCES OF VERY HIGH CONCERNS – CHEMICALS THAT ARE IDENTIFIED BY ECHA THAT MAY INCLUDE (BUT NOT LIMITED TO): CATEGORY 1 AND 2 CARCINOGENS, MUTAGENS AND TOXIC TO REPRODUCTION SUBSTANCES (CMR'S), PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES (PTB'S), VERY PERSISTENT AND VERY BIOACCUMULATIVE TOXIC SUBSTANCES('VPVB'S'), AND OTHER SUBSTANCES GIVING RISE TO "AN EQUIVALENT LEVEL OF CONCERN". "CANDIDATE" SVHC (TO BE PROPOSED LATE OCTOBER 2008) AND SVHC (FINAL) BOTH TRIGGER REACH REQUIREMENTS. THESE LISTS CAN BE FOUND ON THE ECHA WEBSITE.

MANUFACTURE THE PRODUCTION OR EXTRACTION OF SUBSTANCE IN THE NATURAL STATE

SUBSTANCE A CHEMICAL ELEMENT AND ITS COMPOUNDS IN THE NATURAL STATE OR OBTAINED BY ANY MANUFACTURING PROCESS, INCLUDING ANY ADDITIVE NECESSARY TO PRESERVE ITS STABILITY AND ANY IMPURITY DERIVING FROM THE PROCESS USED, BUT EXCLUDING ANY SOLVENT WHICH MAY BE SEPARATED WITHOUT AFFECTING THE STABILITY OF THE SUBSTANCE OR CHANGING ITS COMPOSITION.

EUROPEAN CHEMICALS AGENCY

ESTABLISHED FOR THE PURPOSE OF MANAGING AND IN SOME CASES CARRYING OUT THE TECHNICAL, SCIENTIFIC AND ADMINISTRATIVE ASPECTS OF THE REACH REGULATION AND TO ENSURE CONSISTENCY AT COMMUNITY LEVEL IN RELATION TO THESE ASPECTS. THE AGENCY IS IN HELSINKI.

ARTICLES

OBJECTS WHICH DURING PRODUCTION ARE GIVEN A SPECIAL SHAPE, SURFACE OR DESIGN, WHICH DETERMINES ITS FUNCTION TO A GREATER DEGREE THAN DOES ITS CHEMICAL COMPOSITION. IF THESE SUBSTANCES ARE INTENDED TO BE RELEASED IT IS POSSIBLE THAT SOME MANUFACTURERS/IMPORTERS OF SUCH ARTICLES WILL BE REGISTRANTS.

**THE REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS
REACH REGULATION 1907/2006 CONTINUED**

REGISTRANTS	MAY BE THE MANUFACTURER OR THE IMPORTER OF A SUBSTANCE OR THE PRODUCER OR IMPORTER OF AN ARTICLE SUBMITTING A REGISTRATION FOR A SUBSTANCE.
EINECS	EUROPEAN INVENTORY OF EXISTING COMMERCIAL CHEMICAL SUBSTANCES
ELINCS	EUROPEAN LIST OF NOTIFIED CHEMICAL SUBSTANCES

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