LIFE09 ENV/GR/000291

REACH Protocol for Emissions and Accident Scenarios in Supply and Distribution of Fuels and Petrochemical products

SUB ACTION 2.2 Transportation and loading/unloading of dangerous petrochemical products (with different modes: road, rail, sea, pipelines): Identification of legislation and standards related to users requirements and the implementation of related regulations

SUB ACTION 2.2

Executive Summary of REACH Regulation in English (Chapter A)

LIFE+ Environment Policy & Governance

Executive summary

In this deliverable, REACH Regulation is shortly described and the main legislative obligations of the parties involved in REACH Regulation are summarized. REACH Regulation (EC) No 1907/2006 constitutes the new Community legislation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals with date of entry into force on 1 June 2007. The purpose of REACH Regulation is to ensure a high level of protection of human health and the environment, promote the development of alternative methods for the assessment of hazards of substances, as well as the free movement of substances within the internal market.
Competent body for the implementation of REACH Regulation in Europe is the European Chemicals Agency (ECHA) and in each EU Member State the National Enforcement Authorities. In Greece, the National Enforcement Authority is the General Chemical State Laboratory. In this deliverable, the main legislative obligations of the Competent Authorities are recorded. REACH Regulation includes four implementation stages: pre-registration, registration, evaluation and authorization of chemicals. For every substance either on its own or in a mixture or article, which is produced or imported in quantity of more than one tone per year, a registration shall be submitted, i.e. submission of a technical dossier to the European Chemicals Agency (ECHA).
The main parties involved in REACH Regulation include the following:

- Producers/ Importers that produce/ import substances on their own or in mixtures in a quantity ≥ 1 tonne/ per year: Registration of substances
- Producers/ Importers of an article: Registration of a substance ≥ 1 tonne/ per year which is intentionally released from the article
- Producers/ Importers of an article which contains a substance that is not released in the environment but is of very high concern: Notification of the substance to ECHA
- Downstream users, i.e. users of a substance on its own or in a mixture, during industrial or professional activity (e.g. standardization, dilution, repackaging): Promotion of information to the supplier concerning the uses of the substance by the downstream user and communication of information to the next actor or distributor up the supply chain where and as required.

The legislative requirements of the above mentioned main parties are recorded in detail in the deliverable. In the deliverable reference is made to the time schedule of REACH Regulation implementation and to main issues of REACH Regulation e.g. pre-registration and registration of substances, Joint Submission of Technical Dossiers, Substance Information Exchange Forum (SIEF), Safety Data Sheets (SDS), Evaluation, Authorization and Restrictions on the manufacturing, placing on the market and use. For the substances which have been pre-registrated (June 2008 – December 2008: pre-registration of any chemical substance produced or imported in a quantity ≥ 1 tonne/ per year, to ECHA) the deadlines of gradual registration depending on the substance and its quantity (2010, 2013, 2018) are followed. The deadline for registration of substances produced or imported in the Community at least once after 1 June 2007 in quantities ≥ 1 tonne/ per year per producer or importer is 1 June 2018. If the deadline of pre-registration is exceeded, enterprises cannot produce or import the substance until they submit full registration dossier.
Registration includes the submission of technical dossier of the substance to ECHA (Article 10 of Regulation 1907/2006/EC) with details of the manufacturer/ importer, the identity of the substance, the manufacture and the uses of the substance, study and robust study summaries with physicochemical, toxicological and ecotoxicological information, the classification and labeling of the substance, guidance on safe use of the substance, etc. For quantities ≥ 10 tonnes/ per year chemical safety report dossier is submitted with detailed description of risks and proposed risk management measures, exposure estimation and description of alternative exposure scenarios to the substance during its production and use.
If a substance is intended to be manufactured/ imported by one or more manufacturers/ importers, a lead registrant is defined, and there is the possibility of sharing and joint submission of information concerning technical data and information related to the intrinsic properties of substances. In the deliverable reference is made to Substance Information Exchange Forums with the purpose to share data and other information for a specific substance.
One of the main implementation tools of REACH Regulation is Safety Data Sheets (SDS). According to REACH Regulation, the supplier of a substance or mixture shall provide the recipient of the substance

or mixture with a safety data sheet in accordance with Annex II of REACH Regulation as amended. Until 1 June 2015, the Safety Data Sheets for substances shall contain the classification according to both Directive 67/548/EEC and CLP Regulation (EC) No 1272/2008. Moreover, until 1 June 2015, where substances or mixtures are classified and labelled in accordance with CLP Regulation, that classification shall be provided in the Safety Data Sheet, together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively.

The evaluation of the dossiers of the substances is carried out by ECHA including completeness check on the technical dossier of every substance. The evaluation of substances can lead either to a restriction on the manufacturing, placing on the market and use or to authorization of the substance. As far as authorization is concerned, it concerns substances of very high concern mainly due to PBT or vPvB properties, high volumes and wide dispersive use. Through authorization it is ensured that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. When a substance is included in the list of substances subject to authorization, it shall not be placed on the market, before authorization is granted by the European Commission for a specific use within the envisaged time limits.

In conclusion, as far as restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles are concerned, a substance on its own, in a mixture or in an article for which Annex XVII of REACH Regulation contains a restriction, shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. Adoption of new restrictions or amendment of current restrictions in Annex XVII is carried out when a substance meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers or when there is an unacceptable risk to human health or the environment arising from the manufacture, placing on the market or use of a substance.