THE NEW CHEMICALS POLICY OF THE EU AND ITS ENVIRONMENTAL IMPLICATIONS ON EU AND TURKEY

A THESIS SUBMITTED TO
THE GRADUATE SCHOOL OF SOCIAL SCIENCES
OF
MIDDLE EAST TECHNICAL UNIVERSITY

BY

ZELİHA BACAKOĞLU

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR
THE DEGREE OF MASTER OF SCIENCE
IN
THE DEPARTMENT OF EUROPEAN STUDIES

NOVEMBER 2016

Approval of the Graduate School of Social Sciences

_____
Prof. Dr. Tülin GENÇÖZ
Director

I certify that this thesis satisfies all the requirements as a thesis for the degree of Master of Science.

_____
Assoc. Prof. Dr. Galip YALMAN
Head of Department

This is to certify that we have read this thesis and that in our opinion it is fully adequate, in scope and quality, as a thesis for the degree of Master of Science.

_____
Assoc. Prof. Dr. Şule GÜNEŞ
Supervisor

Examining Committee Members

Assist. Prof. Dr. Gamze Aşçıoğlu ÖZ	(METU, ADM)	_____
Assoc. Prof. Dr. Şule GÜNEŞ	(METU, IR)	_____
Assist. Prof. Dr. M. Pınar Gözen ERCAN	(Hacettepe Univ., IR)	_____

I hereby declare that all information in this document has been obtained and presented in accordance with academic rules and ethical conduct. I also declare that, as required by these rules and conduct, I have fully cited and referenced all material and results that are not original to this work.

Name, Last name : Zeliha BACAKOĞLU

Signature :

ABSTRACT

THE NEW CHEMICALS POLICY OF THE EU AND ITS ENVIRONMENTAL IMPLICATIONS ON EU AND TURKEY

Bacakoğlu, Zeliha

M.Sc., Department of European Studies

Supervisor: Assoc. Prof. Dr. Şule GÜNEŞ

November 2016, 107 pages

This thesis aims at analysing the REACH Regulation which constitutes the backbone of the New Chemicals Policy of the EU in the context of the environmental framework. Related to that aim, basic instruments of the Regulation are considered in order to clarify what kind of health and environmental benefits to be obtained with them. Secondly, the EU-Turkey relations is examined with its twofold nature under the Customs Union and candidacy process by seeking an answer to the question of possible legislative and economic impact of REACH Regulation on Turkey.

Keywords: EU, New Chemicals Policy, REACH Regulation, Environment, Turkey

ÖZ

AB'NİN YENİ KİMYASALLAR POLİTİKASI VE AB VE TÜRKİYE ÜZERİNDEKİ ÇEVRESEL ETKİLERİ

Bacakoğlu, Zeliha
Yüksek Lisans, Avrupa Çalışmaları Bölümü
Tez Yöneticisi: Doç. Dr. Şule GÜNEŞ

Kasım 2016, 107 sayfa

Bu çalışmada AB'nin Yeni Kimyasallar Politikası'nın omurgasını teşkil eden REACH Tüzüğü çevresel bir çerçevede analiz edilmektedir. Bu amaçla, Tüzüğün temel enstrümanlarına değinilerek, sağlık ve çevre açısından belirlenen hedeflerden hangilerinin bu araçlarla elde edilebileceği hususu ortaya konulmaktadır. Ardından, Gümrük Birliği ve üyelik süreci kapsamında iki başlı yürüyen AB-Türkiye ilişkileri ele alınarak, REACH Tüzüğü'nün Türkiye'ye idari ve ekonomik etkilerinin ne olacağı sorusuna cevap aranmaktadır.

Anahtar Kelimeler: AB, Yeni Kimyasallar Politikası, REACH Tüzüğü, Çevre, Türkiye

To my family for their support and encouragement

ACKNOWLEDGEMENTS

First and foremost, I wish to express my sincere gratitude to Assoc. Prof. Dr. Şule GÜNEŞ for her guidance, academic assistance, advice, and criticism throughout the research.

I would also like to thank Assist. Prof. Dr. Gamze AŞÇIOĞLU ÖZ and Assist. Prof. Dr. Pınar GÖZEN ERCAN for their suggestions and comments.

Last but not the least I am grateful to my family for their unconditional support and encouragement through my life.

TABLE OF CONTENTS

LIST OF TABLES

TABLES

LIST OF FIGURES

FIGURES

LIST OF ABBREVIATIONS

ATP	Adaptation to Technical Progress
CAS	Chemical Abstract Service
CEFIC	European Chemical Industry Council
CJEU	Court of Justice of the European Union
CLP	Classification, Labelling, Packaging
CMR	Carcinogenic, Mutagenic and Toxic for Reproduction
DALY	Disabled Adjusted Life Year
DG	Directorate General
EU	European Union
EC	European Commission
EEC	European Economic Community
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EIA	Environmental Impact Assessment
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ETUC	European Trade Union Confederation
GHS	Globally Harmonized System
GLP	Good Laboratory Practice
GNP	Gross National Product
ICCM	International Conference on Chemicals Management
ILO	International Labour Organization
IMMIB-IMMEU	İstanbul Maden Metal İhracatçıları Birliği - Istanbul Minerals and Metals Exporters Union
IPPC	Integrated Pollution Prevention and Control
MEU	Ministry of Environment and Urbanization
NGO	Non-Governmental Organization

NLP	No Longer Polymers
OECD	Organization for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic
PCB	Polychlorinated Biphenyl
PCT	Polychlorinated Terphenyl
PIC	Prior Informed Consent
POP	Persistent Organic Pollutants
QALY	Quality Adjusted Life Year
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SAICM	Strategic Approach to International Chemicals Management
SDS	Safety Data Sheet
SDS	Sustainable Development Strategy
SVHC	Substance of Very High Concern
SIEF	Substance Information Exchange Forum
SIN	Substitute It Now
SMEs	Small and Medium Sized Enterprises
TKSD-TCMA	Turkish Chemical Manufacturers Association
TUBİTAK	Türkiye Bilimsel ve Teknolojik Araştırma Kurumu - Scientific and Technological Research Council of Turkey
IEAS-UÇES	Integrated Environmental Approximation Strategy
UNEP	United Nations Environment Programme
vPvB	Very Persistent and Very Bioaccumulative
VOSL	Value of Statistical Life
VOLY	Value of a Life Year
WTO	World Trade Organization
WTP	Willingness to Pay

CHAPTER 1

INTRODUCTION

As a global actor, the EU plays a central role to become a part of international environmental efforts addressing the issue of water and soil degradation, acid rain, thinning of the ozone layer, sustainable energy etc. The EU, somewhat applying the world's highest environmental standards, is a party to all major multilateral environmental accords.

However, when the beginning of the EU's environmental policy is investigated; there was no reference to environmental policy in the founding treaty of the European Economic Community, and not any obvious attempt until the beginning of 1970s. In Paris Summit of 1972, an environmental declaration was adopted assigning the European Commission to draw up an environmental action programme. The adoption of the EU's first Environmental Action Plan laying down the EU's first environmental policy in 1973, accelerated the formation of an independent Directorate General (DG) for the Environment in 1981. Apart from the growing international appeal towards the environmental issues and politicisation of environmental problems; the basic motivation driving the EU to touch thoroughly upon the environmental issues was the diverse environmental standards applied by the member states which in turn creating a trade barrier and distorting the competition. With the adoption of the Single European Act in 1986, aiming to remove all barriers to free trade among the members, the environmental objectives had an equal footing with that of the economic ones. The Single European Act amended the Rome Treaty in terms of adding the Environment Title that defined the environmental policy of the EEC and empowered the Council to follow up the implementation of those policy objectives. Furthermore, the Single European Act,

considering the requirement to coordinate and standardize national environmental policies, also launched changes to decision making processes. In 1992, the Treaty on European Union (Maastricht Treaty) that extended voting procedure in favour of environmental articles was enacted and the Treaty of Amsterdam (1997) put the sustainable development at the top of the EU agenda and underlined the commitments to policy integration for environmental issues. The Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (shortly the Treaty of Lisbon) gave a specific title pertinent to the environment comprising Articles 191,192 and 193 and identified the environment as an area of shared competence.

Apart from the primary legislation consisting of the Treaties, there are also secondary legislation comprising regulations, directives and decisions resulting from the principles and objectives defined in the Treaties. However, in choosing environmental policy instruments, the EU decision-making bodies act in accordance with the Treaties defining the legal act to be adopted. As per the Article 296 of the Lisbon Treaty, "Where the Treaties do not specify the type of act to be adopted, the institutions shall select it on a case-by-case basis, in compliance with the applicable procedures and with the principle of proportionality".[1]

Furthermore, the Court of Justice of the European Union (CJEU) also plays a key role in environmental politics of the EU by inspecting the policy is consistent with the provisions of the Treaty or rules how to apply EU law to a domestic legal case. In a large number of rulings since the 1970s, the Court developed an expanded role for environmental policy action, and clarified relationships between single market operation and the need for regional and national measures to protect human health

[1] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - Consolidated version of the Treaty on the Functioning of the European Union - Protocols - Annexes - Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007, Official Journal C 326, 26/10/2012 P.0001-0390, Article 296 (1).

and the environment, including how protective measures should be taken when they intersect with economic and trade issues.[2]

When formulating an environmental legislation, DG Environment works closely with the DG Industry and other relevant DGs. Because, the environment policy also focuses on maintaining the competitiveness of the EU economy in terms of integrating green politics to the economy, namely green growth. Such as chemicals industry generates jobs for millions of European people and constitutes one of the largest industrial sectors in European economy. Hence, regulating such a crucial sector through streamlining a unique legislation and identifying certain tasks to the relevant authorities was an obligatory action for the European Commission. Factually, European chemical industry was facing rigorous challenges from some internal factors as well as suffering from growing global competition. As a source of sustainable prosperity in almost all other industrial sectors, the technical progress of European chemical industry was undermined by relatively declining research and development (R&D) investment and troublesome regulation. Additionally, growing appeal towards environmental problems by the European public coupled with the international environmental efforts obliged the EU decision makers to construct a functioning chemical management framework.

In this respect, the REACH Regulation[3] (a regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007, thus the relevant authorities of all member states were charged with the responsibility to

[2] Vandeveer SD., Selin H., *EU Environmental Policy Making and Implementation: Changing Processes and Mixed Outcomes*, p.6 Selin H, VanDeveer SD. Politics of Trade and Environment in the European Union. In Handbook on Trade and the Environment, ed. K Gallagher, Edward Elgar Publishing, UK, 2008, pp. 194-203.

[3] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC,* EN Official Journal of the European Union L 396/1 (30.12.2006). Since its publication, REACH Regulation has been subjected to several amendments and corrigenda. (See Appendix A).

ensure fully compliance with the Regulation.[4] The REACH Regulation does not fill a regulatory vacuum in chemicals, rather it replaces -amends or repeals- a very complex set of chemicals legislation and establishes a broad based legislative guideline for the control of chemicals in the course of ensuring greater safety in manufacturing and use of chemicals.

The EU promoted REACH Regulation as a functioning regulatory framework considering the protection of human health and environment as well as development of a business-friendly industrial policy. REACH system is built up to eliminate heavy burden of testing obligations for substances used for R&D through excluding R&D chemicals from the costly registration process. Besides, with the improved risk management, number of accidents stemming from deficient occupational health measures is expected to minimize and thus the damage payments. In addition, complexity of European chemicals legislation including numerous regulations and directives is overcome through streamlining a unique regulation covering almost all environmental requirements. Moreover, having a trustworthy inventory of all chemicals whether imported or produced by domestic manufacturers enables European Union to outline future strategic plans.

On the other hand, the new system, based on gathering adequate information about dangerous properties of chemicals in order to construct an appropriate risk management and restricting the disposal of some persistent and bioaccumulative chemicals to the environment, will reduce some certain diseases. Besides, the potential environmental benefits in terms of raising the awareness about the hazards

[4] The enactment of regulations is legally based on Article 249 of the *Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community*, Official Journal of the European Union, 29/12/2006, C321 E/1 53. Regulation is a directly applicable legislative act of the EU which becomes simultaneously enforceable in all member states without any need to transpose into national law. When a regulation enters into force it overrides all national laws dealing with the same subject and subsequent national legislation must be consistent with and made in the light of the regulation. On the other side, directive is also a legislative act however differently from regulations; directives are not self-executing and give member states a timetable for the implementation of the intended outcome. As regards, REACH Regulation is, since the enforcement date, automatically applicable in all Member States without any need for transposition. However, the regulation assigned some certain tasks for competent authorities of member states to carry out in a gradual scheme.

of chemicals and paving the way of replacing most dangerous ones with safer alternatives are targeted with the permission system. Furthermore, some instruments of the REACH Regulation together with successor legislation known as Classification Labelling and Packaging Regulation[5], introduces a system identifying all processes of chemical substances such as classification, labelling, packaging, test methods, risk assessment, handling, usage, hazard communication, disposal etc.

This thesis examines the possible effects of the REACH Regulation, as an instrument of the New Chemicals Policy[6] of the EU, on the environmental targets of the Union to improve human health and the environment from the risks posed by chemicals, as well as touching upon relevant European industries making use of chemicals as an input in manufacturing processes. Additionally, since Turkey is an associate member of the EU under the Customs Union Decision and a candidate for membership; the Union's most of the legislative arrangements have a direct impact on Turkey in terms of legislation harmonization. Besides, remaining as the major export and import partner of Turkey, the EU's attempts to adopt a piece of legislation with an economic dimension automatically have significant impact on Turkey's various economic sectors. For this reason, the impact of the REACH Regulation on Turkish chemical management system is analysed on grounds of a cost-benefit analysis.

In this regard, the core question of this study is twofold. The first one is *"What would be the reflections of the new chemicals policy on the environmental targets of the European Union".* The second question deals with the *"possible legislative and economic impact of REACH Regulation on Turkey having less than a member more than a non-EU status".*

[5] *Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC* published on Official Journal of European Union, L 353/1 (31/12/2008)

[6] This concept is mentioned firstly in White Paper Strategy for a future Chemicals Policy, Brussels, 27.2.2001 COM(2001) 88 final presented by the Commission of the European Communities. (also available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF retrieved on 15.10.2014)

To this end, the next chapter is dedicated to the state of play before the REACH Regulation through touching upon pre-REACH legislative era and identifying the setbacks of the previous legislation. In view of the fact that the REACH Regulation is a very complex and comprehensive legislation having a myriad of technicalities, third chapter of this thesis is devoted to identify the institutions and instruments of the Regulation such as competent authorities, registration, authorization and the rationale behind it. The fourth chapter focuses on the current and prospective impact of the REACH Regulation on environmental targets of the EU identified for the justification for the enactment of the Regulation, as well as environmental commitments of the EU in White Paper and Sustainable Development Strategy. The fifth chapter addresses the international arrangements governing global chemicals management and considers the Turkey's position in relation to the EU with respect to the REACH Regulation from a legal and environmental point of view.

This dissertation is highly dependent on the relevant EU legislation, reports and publications released by the European Commission and European Chemicals Agency, the European chemicals industry reports, studies carried out by the environmental NGOs more than the limited primary academic sources such as books and articles. Throughout the literature analysing period, there was certainly not any academic study touching upon the REACH Regulation at this manner other than the studies briefing the ex-ante impact assessments carried out by the EU itself and some partial cost-benefit analysis performed by the industry. Since the implementation of the REACH Regulation involves a gradual timeline which will end up in 2018, the precise time for having a comprehensive cost benefit analysis will be after that year. Besides, the REACH Regulation is a living organism in terms of increasing number of restricted or prohibited chemicals, therefore every chemical included in the ban list will foster the benefits expected from the Regulation. On the other hand, according to the non-EU community although the registration period will be over, the data regarding the economic reflections of the REACH Regulation will be kept confidential or be shared partially due to the reservations of the industry as well as

EU’s hesitation to underline the business benefits. That is why; it is intentionally preferred in this study to focus on the potential health and environmental benefits which are publicly available and observable from the reports released by the EU, European Chemicals Agency, some NGOs or industry leaders.

This study is carried out by considering the approaches and methods applied in the studies of the Commission, member states and some of the consulting firms including NGOs and some of their assumptions are recalled to draw a general picture of the environmental benefits of the REACH Regulation. Therefore, the study aims to contribute to the existing literature by providing a comprehensive analysis of the New Chemicals Policy of the EU on the grounds of compiling those reports, legislation, recent developments or analyses and will be the first to address the Turkey case in an inclusive manner.

CHAPTER 2

THE EUROPEAN PRE-REACH LEGISLATIVE ERA

The REACH Regulation became one of the most criticized and rumoured legislation of the EU in recent years due to its bureaucratic nature and heavy burden on chemical exporting countries to the Union. Therefore, the full picture of the previous European chemicals management system is required to be shown in order to indicate the factors pushing the EU to formulate such a wide ranging Regulation. To this end, the previous EU legislative framework will be mentioned firstly and the problems arising from pre-REACH legislative environment secondly.

2.1 EU Legislative Framework Prior to REACH

Previous legislation governing the European chemicals management comprises more than 40 Directives and Regulations in addition to amendments including adaptation to technical progresses (ATPs). However, the main legal instruments were Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (CLP Directive of Substances), Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Limitations Directive), and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (CLP Directive of Preparations). In general, the two Directives regulated classification, labelling and packaging of

chemicals and preparations, while the other one administered restriction of dangerous chemicals.

Prior to REACH, there were basically three chemical substance inventories in the EU, specifically European Inventory of Existing Commercial Chemical Substances (EINECS), European List of Notified Chemical Substances (ELINCS) and No Longer Polymers (NLP). Due to the amendment to the Directive 67/548/EEC[7], ELINCS was published in 1981 and hereafter, 1981 became a cut-off date for the definition of the chemicals. The chemicals marketed after 1981 and listed in ELINCS were named as new chemicals. As per the amendment, of all chemicals produced after 1981, notification and risk assessment procedures required to be completed before being placed on the market. Existing chemical substances were those substances listed in EINECS, an inventory of substances that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981.[8] In this regard, substances took place in EINECS were called as existing substances and subject to none of the notification or risk assessment procedures.[9] In 1993, Council Regulation (EEC) No 793/93 (Inventory Regulation)[10] was adopted in order to create an inventory for evaluation and control of existing chemicals. Lastly, as a result of the seventh amendment to the 67/548/EEC, some of the substances previously deemed to be polymers started to be called as NLP[11] and regarded as existing substances.

[7] 6th amendment to 67/548/EEC which introduced the notification system for new chemicals was adopted with 79/831/EEC Directive and the Commission Decision of 21 December 1984 concerning the list of chemical substances notified pursuant to Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ No. 30/33, 2.2.85.

[8] https://eurl-ecvam.jrc.ec.europa.eu/laboratories-research/predictive_toxicology/information-sources/ec_inventory retrieved on 24 September 2014.

[9] The EINECS list was published in the Official Journal of the EC on 15th June 1990.

[10] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances.

[11] No Longer Polymers are also subject to the REACH Regulations and required to be registered in accordance with the Article 6(3) of the Regulation.

Despite there are also plenty of EU regulations and directives formulated to transpose international treaties to acquis communautaire; that legislation is not mentioned above since they are not affected by the REACH Regulation.

2.2 Problems Stemming From Pre-REACH Legislation

The system set forth by the REACH Regulation is configured to eliminate numerous shortcomings of the previous system. Lack of information on the substances placed on the market before 1981 and heavy burden of testing obligations for substances even used for R&D, lower quality safety data sheets deficient in risk management measures can be listed among the shortcomings. Furthermore, burden of legal responsibility placed on the shoulders of competent authorities rather than the manufacturers and importers, insufficient mechanisms to identify risks and to recommend proper measures deriving from the life-cycle of a substance and for the last unnecessary reiterated tests carried out on vertebrates are other deficiencies of the previous system.

2.2.1 Internal Market Fragmented by Patchwork Legislation

The chemical legislation prior to REACH was literally a patchwork of directives and regulations that had been enacted since 1967 when the first Dangerous Substances Directive[12] was introduced. The legislation governing the EU's chemicals management contains tens of directives and regulations of which complexity is coupled when amendments, repeals and adaptation to technical progresses are considered. Every amendment or new regulation made this fragmented legislation more cumbersome in terms of defining tasks and responsibilities of public authorities and businesses. Therefore, functioning of this legislation by relevant authorities

[12] 67/548/EEC, OJ L 196, 16.8.1967

varied from one member to another, besides creating problems and disparities. The efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State.[13]

In this regard, chemical firms have pressed the German government to spread their higher costs of compliance with environmental standards by means of stricter European laws across the other member states.[14] Due to the fact that the regulatory framework had a major and direct influence on European chemical industry's ability to compete on global markets, one of the targets identified by the Commission was to achieve better regulation free from cumbersome procedures and heavy compliance burden.

2.2.2 Lack of Sufficient Data for Chemicals in the Market

As mentioned in previous parts, the distinction between existing and new chemicals derives from a Community Directive 67/548/EEC. Those chemicals, exactly called as new chemicals, are put in ELINCS list containing 3,800 chemicals which are subject to a periodical update.[15] On the other hand, the chemicals reported to be in the market before 1981, and almost not subjected to any testing requirement are identified by the European Chemicals Bureau (ECB) in EINECS list. According to ECB, EINECS contains 100,204 chemical substance entries, placed in European market until 1981.[16]

---

[13] The REACH Regulation, Recital (2).

[14] Börzel, A. *Tanja, Pace-Setting, Foot-Dragging, and Fence-Sitting: Member State Responses to Europeanization,* JCMS 2002 Volume 40. Number 2., Blackwell Publishers Ltd, 2002, Oxford, p.197.

[15] The figures are gathered from the European Chemical Substance Information System (ESIS) which is available at http://ecb.jrc.ec.europa.eu/elincs/ retrieved 24 February 2016.

[16] The figures are gathered from ESIS which is available at http://ecb.jrc.ec.europa.eu/esis/ , retrieved 24 February 2016.

As a result, even though the ‘new chemicals’ marketed after 1981 are subject to more thorough and strict rules, existing chemicals regardless of their intrinsic properties and huge number on the market, move more freely. There was a common belief that public authorities were detectives to check new chemicals at every stage while ignoring the unseen part of the iceberg as existing chemicals with a huge number. Hence, the need for a new chemicals strategy arises from the existing chemicals legislation’s incapability to respond properly to public concern for the health and the environmental considerations.

2.2.3 Burden of Proof on Public Authorities

The previous system was also burdensome when the allocation of responsibilities among the manufacturers, importers, downstream users and public authorities is considered. Carrying out risk assessment was deemed as the public authorities’ duty rather than that of the enterprises manufacturing, importing or using those chemical substances. When an unseen hazard of a chemical was detected on the market, the responsible authority to take necessary measures and to compensate was public authorities. The importer or manufacturer was free from the responsibilities of redressing, recalling, etc. Additionally, previous legislation required only importers and manufacturers to hold information about the substances, while downstream users were left free from this obligation unless the substance was classified as dangerous.

2.2.4 Heavy Testing Requirements for New Substances

As a result of the legislative amendment concerning ELINCS chemicals aforementioned, every new substance placed on the market has to be tested intensely. In addition to the expensive and extensive testing requirements, low threshold was a remarkable hurdle on the way of innovation. Every chemical above 10 kg had to be subjected to burdensome testing requirements and for higher volumes more in-depth tests were required to discover long term effects. Furthermore, there was no

derogation for those of the chemicals not intended to be marketed and planned to be used for research and development. The current system, in particular for new substances, has hampered research and innovation, causing the EU chemicals industry to lag behind its counterparts in the US and Japan in this regard.[17]

2.2.5 Environmental Targets of EU under SDS and UNEP

European Union, undoubtedly, deserves a righteous place in terms of pioneering the integration with international environmental efforts. Besides becoming a party to the almost every international arrangement, the EU also adjusted most of the international environmental treaties to its internal law as the examples were given in the previous part.

Moreover, sustainable socio-economic development is a core element of the European Union's Sustainable Development Strategy[18] which complements the Lisbon Strategy. The Sustainable Development Strategy sets out the objective of promoting a prosperous, innovative, knowledge-rich, competitive and eco-efficient economy, which provides high living standards and full and high-quality employment throughout the European Union.[19] In this regard, the issue of chemicals needs to be overhauled in order to promote environmental protection while boosting competitiveness of the Community.

---

[17] Fasey, A., *Reach is Here; The Politics are Over, Now the Hard Work Starts*, Lowell Center For Sustainable Production, University of Massachusetts, Lowell, MA 011854, p.3

[18] The Strategy for Sustainable Development is the content of a Commission Communication of 15 May 2001 'A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development' COM(2001) 264 Final, not published in the Official Journal. Tha Strategy and other related documents are also available from www.europa.eu/legislation_summaries/environment/sustainable_development/l128117_en.htm

[19] http://epp.eurostat.ec.europa.eu/portal/page/portal/sdi/indicators/theme1 retrieved on 14 October 2014.

Furthermore, EU's environmental policy has been developed in a series of environmental action programmes initialized in 1972. Chemistry-related subjects were placed on the top of the agenda of the EU's 7th Research Framework Programme as a far-reaching research program gathering academia and businesses to share their innovative solutions to common problems in chemicals area. A combination of legislation, economic instruments and additional finance as advocated in the Fifth Environmental Action Programme is an obvious requirement for effective environmental policy.[20] As a matter of fact, REACH Regulation has been influential in delivering environmental objectives in areas where the national governments might otherwise have been slow or reluctant to be involved.

One of the chief targets of the Community by implementing REACH regulation appears to improve the protection of human health and the environment by identifying dangerous and intrinsic properties of chemical substances. However, enhancing the innovative capability thus promoting the competitiveness of the EU chemicals industry may be pointed out as the innermost and vital objective of the regulation. This issue is also clear in pledge of European chemicals leaders "we are working with EU policymakers to ensure that REACH will deliver the intended health and environmental benefits in the most efficient and cost-effective manner, while preserving our industry's capacity to deliver growth and jobs."[21]

[20] Barnes, P. M., Barnes, I. G., *Environmental Policy in the European Union*, Edward Elgar Publishing Limited, UK, 1999, p.16.

[21] Perroy, A., *Trust and Partnership: Towards A New Vision for Europe's Chemical Industry*, Cefic Review 2004 – 2005, also available from www.cefic.org retrieved on 19 November 2014.

CHAPTER 3

REACH AND THE INSTRUMENTS

The REACH Regulation constitutes the backbone of the New Chemicals Policy, dealing with the Registration, Evaluation, Authorization and Restriction of Chemical substances. As it is clear, the name of the New Chemicals Policy of the Union is made up of the initials of the courses into which the chemicals to be phased. Henceforth, this part is dedicated to clarify those specific courses and the authorities responsible to carry out the tasks deriving from the implementation of the Regulation.

3.1 EU's New Chemicals Policy: REACH

After the proposal of the European Commission concerning the safe use of chemicals passed its readings in the European Parliament and the European Council of Ministers, the REACH Regulation[22] came into force in 1st June 2007. The Regulation is a comprehensive legislation not only consists of legal text, with its amendments or corrigenda but also includes implementing legislation, authorization decisions, implementing measures and case law.[23] The Regulation as umbrella legislation,

[22] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC published on EN Official Journal of the European Union L 396/1 (30.12.2006).

[23] The case law involves the Court (Court of Justice of the European Union) cases related to the specific issues regarding the identification of a chemical as substance of very high concern, inclusion of a chemical to the Authorization list, incorrectness about the evaluation procedure or reclassification of a chemical etc.

amends or repeals almost all legislation regarding chemicals only with a few exceptions.[24] Apart from the pharmaceuticals, wastes, radioactive substances and -partially- biocides, all variety of chemicals fall within the scope of REACH Regulation.

3.2 Administrative Structure of REACH

The REACH Regulation introduces a very complex network of duties and responsibilities allocated to different bodies and authorities. The implementation and administration of the tasks defined under the relevant articles of the Regulation are basicly carried out by the European Chemicals Agency and competent authorities entitled by the each member state.

3.2.1 European Chemicals Agency

European Chemicals Agency (ECHA) was established in accordance with Article 75[25] of the REACH Regulation and its composition, tasks, committees, etc. are also defined in succeeding articles. ECHA was located in Helsinki and assigned to run the database to operate the system and to receive registration dossiers submitted by companies. Besides, in accordance with the Classification, Labelling and Packaging Regulation[26], companies shall convey classification and labelling notifications to the ECHA. Thus, ECHA assists companies to comply with the REACH and delivers information on chemicals to advance safe use of chemicals.

[24] Please see Appendix B for an indicative list of the legislation amended or repealed by the REACH Regulation.

[25] REACH Regulation, Article 75, "*A European Chemicals Agency is established for the purposes of managing and in some cases carrying out technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects*."

[26] CLP Regulation (EC) No.1272/2008 which repealed 67/548/EEC Directive. OJ L.353.

3.2.2 Competent Authorities

The competent authorities are designated units by the Member States to carry out the REACH procedures in collaboration with ECHA. Some members entitle environmental ministries or agencies while some members authorize the environment, health and labour ministries each as competent authorities. ECHA is responsible for coordinating the substance evaluation process and ensuring that substances on the Community action plan are evaluated by relying on the competent authorities of the Member States. In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf.[27] Competent authorities may also propose hazardous chemicals to be included in the authorization or restriction procedure.

3.3 REACH Procedures

REACH system comprises of the following four elements; one of which is the r*egistration* of basic information concerning every substance exceeding a production volume of one tonne per year to a central database. The second is *evaluation* which is the review by the competent authorities of the substances exceeding a production volume of 100 tonnes per year and those of lower tonnage chemicals that are considered dangerous. *Authorisation* permits the substances -regardless of tonnage threshold- that have dangerous properties with a specific permission to be granted by the competent authorities for a particular purpose of usage. The last one, *restriction* regulates to limit or ban some or all usage areas of some of the dangerous chemicals, preparations and articles.

[27] The REACH Regulation, Article.45(1), 'Competent Authorities'.

3.3.1 Registration

Concisely, registration of basic information for all the chemicals above 1 tonne per annum to the REACH database system is the main instrument of the system in terms of creating a trustworthy inventory of all existing chemicals in the market. Registration is a two-phased process comprising pre-registration and registration.

3.3.1.1 Pre-registration

In accordance with the Article 28[28] of the Regulation, only those manufacturers pre-registering their substances to the ECHA can take the advantage of transitional timelines for registration. Pre-registration is the first phase to be completed by companies under REACH. Although the information required is limited, pre-registration is an important and necessary step in order to benefit from the tiered registration timetable.[29] Companies that failed to preregister had to register their substances from 1 December 2008 on so as to continue importing or manufacturing them. As started on 1 June 2008 and finished by the following sixth month, pre-registering was a costless process requiring firms to upload substance dossiers containing a short list of information pertinent to that chemical substance to ECHA via the REACH-IT[30] system until 1 December 2008. Although 1 December 2008 is proclaimed as the deadline of pre-registration, the doors will be kept open for the manufacturers exporting to the EU for the first time. In this respect, those manufacturers will be granted a 6 month pre-registration period up to the final

[28] Article 28(1) 'Duty to Pre-register for Phase-in Substances': "*In order to benefit from the transitional regime provided for in Article 23 each potential registrant of a phase-in substance in quantities of 1 tonne or more per year, including without limitation intermediates, shall submit all the following information to the Agency."*

[29] Please see Appendix C for timetable.

[30] REACH-IT is a central data-base serving as an online platform to submit data and dossiers (pre-registration, registration, etc.) on chemicals. Besides, ensures the ECHA and member states to review the dossiers as well as informing public via website about non-confidential information on chemicals. REACH-IT is available from https://reach-it.echa.europa.eu

registration date. This process is called as *late pre-registration* and identified in Article 28(6) of the REACH Regulation.

To carry out works with respect to pre-registration and registration, ECHA inaugurated as a first step progress for the implementation of the Regulation. However, merely the EU firms have right to directly apply to ECHA; the non-EU manufacturers are not allowed to apply by themselves unless they appoint an 'only representative' who is a natural or legal person established within the EU borders and responsible for performing the obligations assigned for importers.[31]

3.3.1.2 Registration

Registration is basically the process of submitting a registration dossier containing information on intrinsic properties, usage areas and hazard classification of the chemicals by the manufacturer or importer to the ECHA via REACH-IT system. Within this context, the chemicals produced more than 1000 tonne per year should be registered by 2010, 100 tonnes per year by 2013 and 1 tonne per year by 2018 respectively. If those chemicals were considered as SVHC,[32] the registration process was required to be completed by 2010 regardless of tonnage band. At this point, it is noteworthy that the chemical substance referred in the Regulation means substances on their own, in a preparation or in an article.[33] Since the chemicals are processed in almost every industrial product, the issue of identifying articles to be subjected to

[31] According to Article 8 (1) of the 1907/2006/EC REACH Regulation, Only Representative is *'A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title'.*

[32] SVHC is the abbreviation of Substance of Very High Concern and will be discussed in 'Authorization' part.

[33] According to Article 3(3) of the Regulation, the chemicals used in the production process of an article to be intendly released -if it is above some specific concentration levels- should be registered by the producer of that article.

registration process paved the way of confusion.[34] Both the EU manufacturers and those non-EU manufacturers exporting to the EU should register their chemical substances by using REACH-IT system for uploading their substance information dossiers to the system and getting the approval of the ECHA.

Accordingly, the registration system is designed to phase in 'existing chemicals' through laying down a volume-triggered calendar and testing requirements. As mentioned in the previous chapter, registration under REACH Regulation aims to gather notification and risk assessment for those 'existing chemicals' and 'no longer polymers' that were exempted from systematic testing regime.

The further step under the Regulation is to share data and to prepare for joint submission of some parts of the registration dossier in Substance Information Exchange Fora (SIEFs)[35]. This requires extensive communication between companies, something that would be difficult to achieve without the appropriate IT sources and tools that are fully secure and confidential. Appointing an only representative that is located in the EU seems another problematic area where most of the non-EU chemical producers are concerned about the disclosure of their business secrets through only representatives notably in the formation of SIEFs.

[34] To tackle this problem, *Guidance on Requirements for Substances in Articles* was published on the website of the ECHA and available at http://guidance.echa.europa.eu/guidance_en.htm, retrieved 22 October 2014.

[35] SIEF is the acronym of the Substance Information Exchange Forum which is prescribed in *Article 29 of REACH Regulation* in order to facilitate the exchange of information between potential registrants thereby avoiding duplication of required tests.

3.3.2 Evaluation

Although the REACH Regulation entered into force on 1 June 2007, the implementation of the Regulation is a gradual process. As per the Article 5[36] of the Regulation, the chemicals within the Community borders should be registered depending on their volume and hazardous properties on a definite time schedule. In this regard, high volume substances above a production volume of 100 tonnes per year and SVHCs regardless of volume will be registered earlier. Evaluation is a review process of substances exceeding 100 tonnes per year and dangerous chemicals. The rationale behind it is that, high volume chemicals and dangerous substances create high risk for the environment and human health, so extensive testing procedures should be completed for their long-term effect. The central features of the evaluation system are examination of testing proposals and conformity control of dossiers submitted by registrants and evaluation of the chemical substance. The dossier evaluation is to check the correctness of the information therein, substance evaluation concerning its hazardous properties and evaluation of intermediates.[37]

3.3.2.1 Dossier Evaluation

Dossier evaluation is the review of those uploaded dossiers of the substances during registration process by the ECHA. In accordance with the Article 40, ECHA will examine the testing proposal defined in the registration dossier. By doing so, priority will be given to those dossiers of chemicals which is or might have SVHC characteristics. Since the prevention of unnecessary animal testing is one of the main targets of the REACH Regulation, ECHA checks whether testing proposals include

[36] Article 5 (No data, no market): *Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required*.

[37] Intermediates are chemical substances produced in a factory and processed for production of another substance without being placed in the market.

repeated or unnecessary tests carried out on animals. The ECHA may also demand chemical safety report and chemical safety assessment in addition to substance-tailored tests performed by the companies. To ensure that registration dossiers comply with this Regulation, ECHA shall select a percentage of those dossiers no lower than 5 percent of the total received by the Agency for each tonnage band, for compliance checking.[38] In this regard, whether registrations are in compliance with the requirements laid down in the Regulation will be controlled.

3.3.2.2 Substance Evaluation

As per the Regulation, natural or legal persons, entitled to handle chemicals, take the risk management measures so as to assess the risks of substances and deliver the risks stemming from the production, use and disposal of them, throughout the supply chain. In this regard, the registrants should describe the hazardous properties of the chemicals in the dossiers. The Agency (ECHA), in conjunction with Member State authorities, may clarify suspicions of risks to human health or the environment by requesting further information from industry on particular substances.[39] Hence, ECHA, with the assistance of the competent authorities, considers the hazard information, exposure information and aggregated tonnage of the registrations.

3.3.3 Authorization

As an instrument of REACH system, authorization targets the proper functioning of the market through ensuring dangerous substances are controlled and replaced if economically and technically possible. Under this system, dangerous substances have a specific name as Substance of Very High Concern (SVHC) including those of chemicals qualifying the criteria of persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); carcinogenic, mutagenic and toxic for

[38] Article 41(5), *Compliance Check of Registrations*, REACH Regulation.

[39] Fasey, A., *Reach is Here; The Politics are Over, Now the Hard Work Starts*, Lowell Center For Sustainable Production, University of Massachusetts, Lowell, MA 011854, p.11.

reproduction (CMR). Besides, other dangerous substances such as endocrine disruptors are also subject to authorization. In this regard, a substance will be proposed as SVHC if it meets one or two of the criteria defined in the Article 57 of the REACH Regulation. In addition, Annex XIII[40] of the Regulation lays down the criteria for PBT and vPvB substances in a detailed manner while the Regulation 1272/2008/EC identifies the criteria for classification as CMR. Previously, 67/548/EEC Directive Classification, Labelling and Packaging Directive classified some chemicals as CMR and PBT category and set out some rules for the labelling and packaging of them and for the time being this Directive is amended by the REACH Regulation and repealed by 1272/2008/EC CLP Regulation.[41]

The first step of the authorization procedure is the listing of substances which are identified as SVHC by the ECHA. The proposal for identifying a chemical as SVHC may come either from member states or the European Commission and is open for public view for a definite time period. Later on, these substances are included in a list named as "Candidate List of Substances of Very High Concern for Authorization". To this end, substances defined as SVHC and included in Candidate List are possibly included in Annex XIV[42] of the REACH Regulation and will subject to authorization procedure.

Authorization procedure is the main instrument for progressively substituting the hazardous chemicals with safer alternatives. A substance in Annex XIV will no longer be placed on the market or used for a given time period. Merely, those of the substances will be allowed where a specific use is granted or exempted from authorization procedure. Meanwhile, the companies applying for authorisation are obliged to demonstrate that risks related with the usage of these SVHCs are

[40] Annex XIII, "*Criteria for the Identification of Persistent, Bioaccumulative and Toxic Substances, and Very Persistent and Very Bioaccumulative Substances*."

[41] The Directive repealed on 1 June 2015 after a transitional period and 1272/2008/EC is now being fully implemented.

[42] "List of Substances Subject to Authorization" is Annex XIV of the Regulation and subject to periodical update.

sufficiently controlled or at least to demonstrate that the socio-economic benefits from their use outweigh the risks. Applicants will also have to investigate the possibility of substituting these substances with safer alternatives or technologies, and prepare substitution plans, if appropriate.

3.3.4 Restriction

The restriction system is another main instrument to protect human health and the environment from the risks posed by the chemicals. The restriction limits totally or partially the manufacturing, placing on the market and usage of some of the chemical substances, mixtures or articles presenting serious risks. The chemical substances, mixtures and articles subject to fully or partly restriction, are listed in the Annex XVII of the REACH Regulation. Annex XVII contains the name of the substance or mixture in one column and the conditions of restrictions in other column. According to Annex XVII, for instance, acrylamide is prohibited for all uses after 5 November 2012 while the lead is banned for usage in jewellery or imitation jewellery as well as individual components of the jewellery articles. As per the Article 69 of the Regulation, a Member State or ECHA on request of the European Commission can propose a chemical to be subject to restriction and proposal is open to public opinion. Final decision is taken by ECHA with the assistance of the member states.

Prior to REACH, the restriction procedure was being implemented by the 76/769/EEC Directive which known as Limitations Directive for Dangerous Chemicals and Preparations. Besides, there were also some other substance specific legislation restricting or banning the usage area of that chemical. With the enactment of REACH, the Limitations Directive is consolidated within the Annex XVII of the Regulation. While assuring the risks from dangerous substances are properly controlled, restrictions system coupled with the authorization attempts to facilitate the good functioning of internal market most of which is fragmented.

CHAPTER 4

THE ENVIRONMENTAL BENEFITS OF REACH

A variety of environmental and health problems are linked to the manufacture, usage and disposal of chemicals containing hazardous properties. REACH, as an instrument of New Chemicals Policy, enacted for increasing the protection of the environment and human health to tackle these problems. Aforementioned instruments of the Regulation; registration, evaluation, authorization and restriction are expected to meet the environmental goals used for justification of enacting such a burdensome legislation. Therefore, Article 117 of the REACH Regulation obliges Member States and the ECHA to submit a report on the operation of the Regulation. Besides, 3rd paragraph of the Article is as follows:

"Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation."[43]

The main objective of the REACH is that registering and testing of chemicals under REACH would eliminate the problem of lack of data to carry out a comprehensive quantitative assessment of impacts of the substances on human health and the environment. Since some of the procedures under REACH are to be completed over a long time frame, in addition to difficulty to easily identify the positive effects of better developments; it is really tough to agree upon a standard quantitative assessment.

[43] Article 117(3) of the REACH Regulation.

Therefore, in parallel to specific legal requirement ruled by Article 117(3), there are also status reports and impact assessment studies being carried out by the Commission, ECHA, inspection agencies, consulting companies and NGOs. To asses expected environmental and health benefits of the Regulation, a comprehensive model needed to be build up to lay down qualitative and quantitative improvements based on figures, estimations and reports. Therefore, firstly the impact assessment studies carried out under the leadership of the European Commission will be examined with illustrative figures to clarify what is expected and what has done up to now and secondly the environmental targets will be investigated one by one to show whether those targets are traceable by now or will be reached over time.

4.1 Impact Assessment of Environmental and Health Benefits

Before the enactment of the REACH Regulation, the European Commission performed an extended impact assessment for both to check out what the proposed legislation would bring and to have a sound proof against opponents. In the report, human health benefits of the REACH Regulation are defined as occupational health and public health that are regulated by specific legislation. The Regulation is expected to make occupational health more effective via restricting or prohibiting hazardous chemicals to protect workers exposing to those chemicals and to reduce diseases. According to assessment, the total health benefits would be in the order of magnitude of €50 billion over the next 30 years, in other words, a 0,1% reduction in the burden of disease due to REACH would yield health benefits of €50 billion.[44]

Chemicals pollute the environment through emissions to the air, disposal to the soil and water, fertilizers or toxics absorbed by animals, plants, soil or groundwater. The

[44] Commission Staff Working Paper, Regulation of the European Parliament and of the Council concerning REACH Regulation, Extended Impact Assessment of REACH Brussels, 29/10/2003, SEC (2003) 1171/3, p.30.

potential environmental consequences of chemical substances are exposure, toxic profile and its potential for bioaccumulation or persistence in the environment. The total amount of hazardous waste from the chemicals industry is reported by CEFIC to be 3,2 million tonnes for the EU 15 (excluding Luxembourg and Greece) in 2000, although this figure does not allow any conclusions on the amount of emissions entering from landfills into the open environment.[45] At that point, some experts argue that such environmental impacts cannot be regarded as benefits of REACH due to the historically existence of this pollution. However, it gives an idea of potential costs to be avoided when the awareness regarding the environmental effects of chemicals increased.

Directorate General Enterprise and Directorate General Environment of the European Commission, when proposing the REACH Regulation, argued that REACH would further the control of persistent, bioaccumulative and toxic substances, lessen the damage in wildlife, improve air, water and soil quality and biodiversity. In terms of health benefits, the number of respiratory and bladder cancers, mesothelioma, skin disorders, respiratory diseases, eye disorders, asthma originating from chemical substances would be reduced, occupational hazards and diseases would be mollified. European Commission, depending on a World Bank study based on the fact that 0,6 to 2,5% of disease burden due to agro-industrial chemicals and chemical pollution, estimated health and environmental benefits of the REACH Regulation in figures. Hence assuming that 1% of disease is deriving from chemicals, the Commission stated that the Regulation would tackle 10% of this figure which in turn create a health cost saving of €50 billion.[46] Several impact assessments demonstrate that the positive effects regarding health benefits are assumed to be observed in 10 years after

[45] Commission Staff Working Paper, Regulation of the European Parliament and of the Council concerning REACH Regulation, Extended Impact Assessment of REACH Brussels, 29/10/2003, SEC (2003) 1171/3, p.26.

[46] The presentation of "The Environmental and Health Benefits" of Directorate General Enterprise and Directorate General Environment of the European Commission, Stakeholder meeting, 21 November 2003, also available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/presentat8-2003_11_21_en.pdf retrieved on 17/12/2015.

the start of implementation and total health benefits will be fully observed after 30 years.

European Commission assigned several consulting firms to forecast potential health benefits of REACH by using a logic framework. In this respect, number of cases (injury, disability, death) and annual costs avoided are calculated by using the method of DALY, QALY and WTP[47] for basis of estimation. At these reports, the analysis of costs is gathered under three categories including health service costs, productivity reduction costs and the value of quality of a healthy life. For environmental impact calculations, the effects of substances are analysed under aquatic toxicity, degradation, fate and behaviour in the environment, effects on aquatic and terrestrial organisms and toxicity on organisms and wildlife. Importantly, in order to fully characterise the potential environmental consequences that might arise from the use of a substance it is essential to consider not just the exposure and toxic profile of the substance but also it's potential for bioaccumulation or persistence within the environment[48]. Hence, the change in productivity deriving from the change in environmental quality and economic value of this calculated in addition to the annual environmental damage costs avoided. Analyses are carried out by considering the health and environmental benefits due to the studies under restriction and authorization procedure and registration procedure to identify hazardous properties of chemicals.

Another study was carried out by DHI[49] assigned by the European Commission in 2005 to estimate potential health and environmental benefits of REACH. Since there

[47] Disabled adjusted life year (DALY) and quality adjusted life year (QALY) are health outcomes used in economic valuation. Willingness to pay (WTP) is another measure of the value of reductions in health risk, but widely preferred for estimating environment related risks.

[48] Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis Under REACH, Final Report (Part-2), Prepared for DG Environment, ENV.D.1/SER/2009/0085r, RPA, Imperial College, March 2011, p.62.

[49] The Impact of REACH on Human Health and the Environment, Report to DG Environment by DHI Water and Environment, ENV.C.3/SER/2004/0042r, Executive Summary, September 2005, p.3.

is limited data to forecast potential benefits, the tables below prepared by DHI in accordance with the applying three approaches; use of willingness to pay (WTP) estimations, damage function approach and avoided or saved costs approach.

Table 1. Overview of Potential Benefits of REACH Determined as Potentially Saved Costs (Most Robust Approach)

Case	2017 (million Euro)	2017-2041(million Euro)
Building of sewage treatment plants	7.1-24	131-440
Drinking water purification	49-302	896-5.564
Disposal of dredged sediment	13.1-78 (78-470)*	241-1.450 (1.444-8.660)*
Sewage sludge	83	1.520
Cleaning of fish meal	0.9	16
Total potential benefits for cases.	153-488	2.804-8.990

* Based on 60% reduction of contaminated sediment.

Source: The Impact of REACH on Human Health and the Environment, Report to DG Environment by DHI.

Table 2. Overview of Potential Benefits of REACH Determined as Population's Willingness to Pay (Weaker Approach)

Case	2017 (million Euro)	2017-2041(million Euro)
Willingness to pay for clean drinking water	1.730	34.000

Source: The Impact of REACH on Human Health and the Environment, Report to DG Environment by DHI.

Table 3. Overview of Potential Benefits of REACH Determined by Extrapolation from Case Substances (Weaker Approach)

Case	2017 (million Euro)	2017-2041(million Euro)
Avoidance of severe health effects	210-2.500	4.000-50.000
Improved reuse of sewage sludge	16-133	300-2.600
Total benefits for cases	226-2.633	4.300-52.600

Source: The Impact of REACH on Human Health and the Environment, Report to DG Environment by DHI.

Reasonably, the most robust approach foresees lower benefits regarding cleaning and handling of polluted water, sludge, sediment, fish products while weakest approach, focusing on saved health costs, estimates largest benefits. In conclusion, ex-ante calculations forecast a minimum 150-500 million Euros saving regarding human health and the environment by 2017 and 2.800-9.000 billion Euros saving between 2017 and 2041.

Table 4. Estimated Percentage of Substances by Production Tonnages

Substance type	**1-1.000 tonne/year**	**>1.000 tonne/year**
Good test data	11.9%	15.4%
Poor data	35%	35%
Not identified yet	23.1%	19.6%
Not dangerous	30%	30%

Source: Impact Assessment of Implementing GHS, Risk&Policy Analysts (RPA), Work Package 1, prepared for DG Enterprise and Industry, April 2006.

As can be observed clearly, 70% of all substances have one or more dangerous properties and more than 50% of chemicals are with poor knowledge or not identified.

Table 5. Predicted Numbers of Substances with Hazardous Properties by Tonnage Band and by Data Availability

	<10	**10-100**	**100-1.000**	**>1.000**	**Total**
Number of substances	19.200	4.977	2.461	2.704	29.342
Good test data	2.285	592	293	416	3.586
Poor test data	6.720	1.742	861	946	10.270
Not identified yet	4.435	1.150	568	530	6.683
Not dangerous	5.760	1.493	738	811	8.803

Source: Impact Assessment of Implementing GHS, Risk&Policy Analysts (RPA), Work Package 1, prepared for DG Enterprise and Industry, April 2006.

According to the table, for 6.683 chemical substances, new data will be available to be classified as having dangerous properties following the information gathered via REACH.

Table 6. Number of Substances Re-classified After Registration

Substance types	**< 10**	**10-100**	**100-1000**	**>1.000**	**Total**
Good test data	457	118	59	83	717
Poor data	2.668	697	344	378	4.108

Source: Impact Assessment of Implementing GHS, Risk&Policy Analysts (RPA), Work Package 1, prepared for DG Enterprise and Industry, April 2006.

The table demonstrates that the classification of 717 of well-known substances and 4.108 of poor test data available substances of different tonnage bands are expected to be changed after registration.

Table 7. Changes in Substances Classification - Further Analysis of Baseline Study Information

	% classified substance (before registration)	**% classified substance (after registration)**	**% with no changes**	**% less restrictive**	**% more restrictive**
Physical hazard	21	27	58	16	26
Acute toxicity	41	51	39	22	44
Acute toxicity-irreversible damage after single exposure (R39)	0	0	-	-	-
Repeated dose toxicity	6	15	36	0	64
Irritation/corrosion	49	52	41	43	19
Sensitisation	15	24	41	6	59
Carcinogenicity	21	23	50	38	25
Mutagenicity-Genetic toxicity	7	13	56	0	44
Reproduction toxicity	4	13	22	11	78
Environmental hazard	32	51	28	28	58

Source: Assessment of the Health and Environmental Benefits of REACH, RPA, 2012.[50]

According to the table, a considerable percentage of chemical substances will be more restrictive and their intrinsic dangerous properties will be widely noticeable due to the extended data available during the registration process requiring the classification of each substance. Hence, the changes in information regarding the properties of chemicals are expected to improve the safe use of chemicals and to develop new risk management measures to be delivered to downstream users.

4.2 Filling the Information Gap for Existing Chemicals

Registration under REACH Regulation targets to gather the information for notification and risk assessment of those existing chemicals that were exempted from a systematic testing regime. As mentioned in the previous parts, the chemicals placed on the market until 1981, namely existing chemicals were allowed to be used without any data requirement while the new chemicals used after 1981 were subjected to a strict testing procedure. This issue also takes place in recital part as follows "the efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State"[51].

Therefore, roughly 100.000 existing chemicals, no longer polymers and the substances placed on the market pursuant to the REACH Regulation have been subjected to the registration process. According to ECHA figures, at the end of the first registration deadline for substances over 1000 tonne per year, 24.675 registration dossiers of 4.300 chemical substances were submitted to ECHA. As of the end of second deadline, total registration dossiers have increased to 38.711 covering 8.729 substances. The chemicals imported or manufactured between 100-

[50] Assessment of the Health and Environmental Benefits of REACH, RPA, 2012, Final Report Part B-Assessment of Benefits, prepared for DG Environment, DHI and Okopol, RPA, April 2012.

[51] The REACH Regulation, p.396/2.

1000 tonne per year were registered in second deadline, 31 May 2013. The rest of those chemicals, whose tonnage is more than 1 tonne per year, will be registered by the third and last deadline of 2018 and hence integration of the markets regarding chemical safety will be achieved. Since most of the existing chemicals are no more in the market for now, it is forecasted by ECHA that the total number of the chemicals registered will be around 30.000.

4.3 Identification of Intrinsic Properties of Chemicals

The Article 5 of the REACH Regulation has a heading which turned out to be the motto of the New Chemicals Policy, as "*no data no market*". Since more than 100.000 chemicals were placed on the market with a little or no safety information, there was a data gap regarding those chemicals posing risks to health and the environment. To fill this data gap, the REACH Regulation required every chemical above 1 tonne per year placed on the market to accompany a set of data demonstrating required information about the intrinsic properties of that chemical.

As mentioned previously, data requirements for chemical substances depend on the volume and hazardous properties of the chemical. Therefore, wide ranging toxicity tests are required for chemicals in large quantities vis-à-vis lighter requirements for substances in small volumes. However, for those chemicals posing risks for human health and the environment, the data requirement is wide and strict regardless of the quantity. To clarify data requirement, there are mainly four Annexes of the REACH Regulation, respectively VII, VIII, IX and X[52]. Hence, the data should include the information on substance identity, physicochemical properties, toxicity and ecotoxicity, environmental degradation and risk management measures. The manufacturers or importers of substances more than 10 or more tonnes per year should submit a chemical safety assessment which is documented in a chemical

[52] Standard Information Requirements for Substances Manufactured or Imported in Quantities of 10 Tonne or More; 10 Tonne or More; 100 Tonne or More; 1000 Tonne or More.

safety report accompanying the registration dossier. Besides, during the evaluation process, ECHA checks whether the industry fulfils its obligations in terms of submitting the required tests. The competent authorities also evaluate the dossiers as to whether further information is required for chemicals suspected posing serious risks to human health and the environment.

Furthermore, safety data sheets (SDSs) are the major tool for hazard communication and risk management measures in the supply chain of the chemical products. REACH introduces exposure scenarios derived from chemical safety reports to the safety data sheets, which are called as extended SDS (e-SDS). Since extended safety data sheet summarises the key information from the chemical safety report, the quality of the information delivered to the down customers and downstream users has improved dramatically. Every time a safety data sheet is required, you (firms) in turn have to provide your customers with information on the hazards, conditions of safe use and appropriate risk management advice.[53]

Benefits of the REACH Regulation arise from the application of appropriate risk reduction measures -by the industry in the first instance and mandated by authorities in the second- enabled by a systematic collection and generation of information on hazards and uses of chemicals.[54]

4.4 Promoting Non-Animal Testing

Under the REACH Regulation, use of animals is required be the latest remedy, allowed only when it is not possible to scientifically assess the risks of a chemical having potential effects on human health and the environment. Hence, reduction in

[53] Key Information for Down Stream Users, Safety Data Sheets and Exposure Scenarios, ECHA Factsheet, ECHA-12-FS-01-EN, Helsinki, Finland, p.1.

[54] *General Report on REACH, Report From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions*, Brussels, 5.2.2013 COM(2013) 49 Final, European Commission, p.3

the number of laboratory animals used for scientific purposes constitutes the one of the pillar of the environmental targets. Besides, with the introduction of obligation for data sharing, unnecessary or duplicated tests are avoided which in turn improve the animal welfare.

4.4.1 Legal Requirements for Animal Welfare and Data Sharing

The welfare and protection of animals used for scientific purposes are not the issues firstly introduced by the REACH Regulation. The Council Directive 86/609/EEC[55] and Council Decision 1999/575/EC[56] were the specific legislation laying down the requirements for reducing the number of laboratory animals as well as raising minimum standards for care and protection of vertebrate animals used for experiments.

When the legal text of the REACH Regulation is scrutinized, in addition to highlighting non-animal testing in recitals part, Article 25 of the REACH Regulation also emphasizes avoidance of unnecessary testing:*"(1) In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests."* Pursuant to the REACH Regulation, Directive 2010/63/EU[57] replacing the Directive 86/609/EEC has entered into force to promote welfare of laboratory animals and to foster the principle of Three Rs[58] -replace,

[55] Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC), OJ No L 358/1, 18/12/86.

[56] 1999/575/EC: Council Decision of 23 March 1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, Official Journal L 222, 24/08/1999.

[57] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, L 276/33, 20/10/2010.

[58] The report of W.M.S. Russell and R.L. Burch dated 1959, namely, "The Principles of Humane Experimental Techniques", proposed the principle of Replacement, Reduction and Refinement (the

reduce and refine the use of animals- as also mentioned in the Article 138(9) of the REACH Regulation.

Briefly, promoting non-animal tests and avoiding unnecessary tests are the main targets for animal welfare under the REACH Regulation. Promoting non-animal tests is an approach to indicate available alternatives; such as comparing chemical substances with similar ones, grouping them to gather common information, preferring non-animal tests if human exposure is limited or using in vitro tests rather than in vivo tests.[59] In terms of avoiding unnecessary testing, there are many legal instruments encouraged by the REACH, such as data sharing and joint submission, accessing the previous data submitted for the same chemical, consulting the competent authorities or third parties for testing proposals, getting in touch with data holders etc.

One of the most important instruments for avoiding animal testing seems to be the obligation of data sharing. Pursuant to the Article 27, the registrant of a chemical substance should request from the previous registrants to share the data carried on vertebrate animals and avoid duplicating the same tests. The Article 29 obliges the same substance registrants to participate a substance information exchange forum (SIEF) as mentioned in previous parts. In SIEFs, registrants have the chance to ask from other registrants of the same substance to share testing data or jointly submit the registration dossier in order to avoid duplication of tests and studies.

Furthermore, registrants will consult the competent authorities or third parties for data requirements whether any animal testing is required or not. In addition, if human or environmental exposure is very limited, data waiving is also possible under Annex VII and Annex X of the REACH. Hence, data requirements will be met by the

three Rs) as a framework to achieve the target of 'humanist possible treatment of experimental animals. http://www.animalethics.org.au/three-rs, retrieved on 8 December 2015.

[59] In vitro tests are the studies carried out in a laboratory by using, cells, tissues or organs. In vivo tests are performed on living organisms, such as animals.

information other than animal test results as long as the risks are at a manageable level with that data. With the backup of the Directive 2010/63/EU also, instead of performing experiments on live animals, the tests on cells, tissues, namely in vitro tests, will be encouraged while the care and reduction of the pain of the experimented animals will be improved.

Meanwhile, as per the Article 117(3) of the REACH Regulation, ECHA is entitled to submit a report regarding the status of the implementation for non-animal test methods and promotion of other testing strategies for risk assessment of intrinsic properties of chemical substances.

4.4.2 Recent Improvements

REACH sets out a number of detailed obligations aiming to reduce animal testing and provides incentives for the use and development of alternative methods for hazard assessment.[60] To assess what has been achieved so far, tri-annual ECHA Reports, the Commission Reports, Commission Working Papers and some of the NGOs' studies are examined.

To begin with, ECHA released second tri-annual report regarding *The Use of Alternatives to Testing on Animals for the REACH Regulation*[61] which indicates positive developments regarding non-animal testing and data sharing. According to the Report; by the end of second registration deadline in 2013, ECHA received 8.317 registrations submitted jointly by registrants who preferred to use the same tests. For skin and eye irritation, 60% of the registrants benefited from existing data rather than

[60] *General Report on REACH, Report From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions*, Brussels, 5.2.2013 COM(2013) 49 Final, European Commission, p.3.

[61] The Second Report under the Article 117(3) of the REACH Regulation is published by European Chemicals Agency on 2 June 2014. First report was published in 2011 and the next report will be published in 2017.

gathering new data through performing animal tests. In vitro tests are performed almost 20% of the registration dossiers, while only 2,5% (skin irritation) and 4% (eye irritation) of dossiers contained new in vivo tests. The total number of in vitro tests for skin and eye irritation increased from 442 in 2011 to 1.410 in 2013. As of 1 January 2014, 500 public consultations regarding testing proposals were carried out by ECHA despite most of them failed to fill the data gaps and only proposed alternative approaches.

The number of animals used for scientific experiments is another issue expected to be handled under the REACH's environmental targets. According to the Seventh Report of the Commission on the statistics on number of laboratory animals, more than 60% of animals were used for research and development in the fields of human medicine, veterinary medicine, dentistry and biological studies of fundamental nature.[62] Besides, 14% of total laboratory animals are used for production and quality control of products of those fields. For toxicological and other safety concerns, 8.75% of the laboratory animals used while 9% of them used for other experimental purposes. According to the Commission Staff Working Paper[63]; compared with 2008, the number of laboratory animals used in EU decreased from 12 million to 11,5 million in 2011, despite the accession of Bulgaria and Romania. 80% of total laboratory animals consist of rodents (rats, mice) and rabbits, while cold-blooded animals come the second and the birds the third. The number of birds has decreased by 85.000, while there is a sharp rise for use of fish (310.307). Over 500.000 animal reductions for rodents and 122.876 decrease in numbers observed for mice. There is

[62] Seventh Report from the Commission to the Council and the European Parliament on the Statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union COM(2013)859/final, Brussels, 5/12/2013. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0859 retrieved on 9 February 2016.

[63] Commission Staff Working Paper, Commission Staff Working Document accompanying document to the Report from the Commission to the Council and the European Parliament Seventh Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union SWD/2013/0497 final. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013SC0497 retrieved on 10 March 2016.

no use of great apes and a significant decrease for use of some primates for the last four statistical reports.

Apart from the current efforts to reduce the number of laboratory animals and to promote non-animal test methods, EU also funds the R&D studies carried out for the same purpose. During 7th Framework Programme, altogether some €200 million have been dedicated to animal-free toxicology projects mainly from the Health theme.[64] According to European Commission report[65], €330 million is funded to finance research and other relevant activities to improve alternative methods to animal testing. Furthermore, alongside several projects financed by the Commission to foster Three Rs, Horizon 2020[66] also targets to further Three Rs for non-animal approaches.

Last but not least, depending on the legal basis of Directive 2010/63/EU, European Union Reference Laboratory for Alternatives to Animal Testing, EURL ECVAM was established in 2011 to encourage the use of alternative approaches to animal testing.

4.5 Restriction of Hazardous Chemicals

One of the most important health and the environmental objective of the REACH Regulation is expected to be achieved through (1) better knowledge on the properties and uses of substances resulting in better safety and control measures, reducing

[64] http://ec.europa.eu/environment/chemicals/lab_animals/3r/research_en.htm retrieved on 14 March 2016.

[65] General Report on REACH, European Commission, COM(2013)49 final, Brussels 5.2.2013.

[66] Horizon 2020 is the European Union's largest research and innovation programme covering 7 years from 2014 to 2020 with a budget of €80 billion. http://ec.europa.eu/programmes/horizon2020 retrieved on 18 April 2016.

exposure and hence, the negative impacts on human health and the environment; and (2) the use of less dangerous alternative substances or technologies to SVHC.[67]

Instead of searching for the means to deal with toxicity problems, eliminating at the source seems to be the most effective way. Therefore substitution of hazardous chemicals with safer ones becomes the priority under the REACH for sound management of chemicals, besides paving the way for innovation for the development of environment-friendly alternatives. Authorisation and restriction are the two main instruments of the REACH Regulation to limit or ban the usage of hazardous substances as long as replacing them is technically and economically viable.

ECHA or Member States can propose a substance to be categorised as substance of very high concern (SVHC) meeting the criteria defined in Annex XV to the REACH. In this manner, ECHA publishes the Candidate List of SVHCs including carcinogenic, mutagenic or reproductive toxins; persistent, bioaccumulative, toxic characteristics or endocrine disruptors. Following the enclosure to the Candidate List, those chemicals eventually included to the Annex XIV of the REACH Regulation where the usage of them will subject to authorisation and permitted under strict conditions if risks posed by the chemical are effectively managed and a feasible alternative exists. Unless there is a way for accurately controlling the risks and a safer alternative, a socio-economic analysis required to be carried out by the Commission. In pursuant to the analysis, if the economic advantages prevail over the risks, those of the chemicals can be authorized on a case by case basis.

Recently, there are 195 chemical substances included in the Candidate List as per the recommendation of ECHA and under public consultation. As of 17 December 2015, 8 new chemicals or chemical compounds were added to the list. After the inclusion

[67] *General Report on REACH, Report From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions*, Brussels, 5.2.2013 COM(2013) 49 Final, European Commission, p.3.

of the Candidate List, firms -exporting to the EU the articles including those chemicals more than 0,1% in concentration- should attach required documents regarding safe use of that article. However, the candidate list and the procedure are highly criticized by most of the environmentalists and NGOs. They argue that the process of inclusion in the Candidate List and transfer to Annex XIV is so slow and the chemicals in the current list are very limited when compared to the number of hazardous chemical lists prepared by several institutions. One of them is SIN (Substitute It Now) List which includes the chemicals recognised as SVHC with the efforts of Chemsec, an international non-profit organization. By defining SIN list, ChemSec used the same criteria laid down in the REACH to speed up to identify all harmful chemicals and force legislators to ensure dangerous chemical free environment.

The European Commission has stated that the SIN List is a major driver for innovation, and the United Nations Environment Programme has highlighted the SIN List as a useful tool for chemical hazard assessment and chemical and product prioritisation.[68] In addition to the SIN list, European Trade Union Confederation (ETUC) prepared a Priority List including 334 substances proposed for inclusion to the authorization list by putting pressure on industry to develop safer alternatives for protection of workers as well as the environment.[69]

The restriction procedure under the REACH Regulation limits or if necessary bans the manufacture, usage and placing on the market of the chemicals posing uncontrollable risk to human health and the environment. There was also a restriction mechanism prior to the REACH, provided by Directive 76/769/EEC, commonly known as the Limitations Directive. As of 1 June 2009, 76/769/EEC Directive was replaced by Annex XVII of the REACH Regulation including the restricted

[68] http://www.chemsec.org/what-we-do/sin-list/about-sin retrieved on 13 March 2016.

[69] Detailed information about Priority list is available at http://www.etuc.org/trade-union-priority-list retrieved on 15 March 2016.

chemicals on their own, in mixtures or in articles. Hence, Annex XVII contains the chemicals limited or banned since 1976 following a terminology revision and consolidation. Therefore, since the restriction system is a continuation of 76/769/EEC Directive, the REACH has a minor effect mainly through making registered all existing chemicals to identify their intrinsic dangerous properties to be subjected to restriction or authorization.

As of today, there are 521 chemical substances -when different CAS numbers[70] considered 464 chemicals- take place in the Annex XVII with a total or partial ban.[71] Meanwhile, Article 129, the safeguard clause, of the REACH also enables Member States to implement further restrictions on justifiable grounds for the protection of human health and the environment. If European Commission approves the national restriction request, Member State will implement a provisional measure in terms of restricting the usage of a chemical for a certain time period.

4.6 Ensuring Proper Handling, Usage and Disposal of Chemicals

The intrinsic properties of most of the chemicals, by their nature, can cause serious hazards or disasters if not handled accordingly even though not identified as hazardous. So, in order to deliver the information throughout the supply chain, countries developed some systems laying down the conditions for safe usage, transport and disposal of the chemicals. In this manner, labelling requirements and safety data sheets (SDSs) are the major tool for hazard communication and risk management measures in the supply chain of the chemical products. However, every

[70] CAS number is an identifier determined by Chemical Abstract Service (CAS) to define every organic or inorganic compounds, alloys, minerals within a chemical substance. For instance, asbestos is a chemical substance, however asbestos fibres, crocidolite, amosite, anthophyllite, actinolite, tremolite, chrysotile have different CAS numbers to identify each of them as a specific substance.

[71] The consolidated version of REACH merely includes the restrictions adopted by the publication date. Therefore, recent list available on the website of the ECHA presents all chemicals included to the list by amending regulations. Please visit https://echa.europa.eu/addressing-chemicals-of-concern/restrictions for the current Restriction List.

country regulates different labelling systems obliging importers to meet different requirements and creating information gaps for the users in the supply chain. As mentioned previously, so as to cope with this problem, Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is initiated at UN level to define criteria for the classification and labelling requirements. And, in parallel to the REACH Regulation, EU adopted the Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation) incorporating GHS to internal law. Pursuant to a transitional period, CLP Regulation is being fully implemented since 1 June 2015, and previous Directives 67/548/EEC and 1999/45/EC are all repealed. Some parts of this previous legislation are considered in addition to new classification requirements, labelling criteria, signal words, precautionary statements and hazard symbols.

Since a harmonized approach is necessary to deliver targeted objectives, Member States carry out inspections of CLP together with the REACH inspections and ECHA performs its duties with respect to both Regulations. As per the Article 46(2) of the CLP Regulation, Member States are required to report to the Commission about the official controls and inspections. Although CLP is another piece of legislation; ECHA, through the EU market surveillance, considers the other requirements to be fulfilled as identified in the REACH because the hazard communication to be delivered to the workers and consumers in the EU is one of the components of the REACH Regulation.

4.7 Shifting Burden of Proof from Public Authorities to Manufacturers

In the previous system it was public authorities' legal responsibility to prove a substance placed on the market is safe for human health and environment. Under the provisions of the REACH, the assessment of the risks and hazards of substances is given to the natural or legal persons placing that substance, in quantities exceeding a certain volume, on the market. Entitled to handle chemicals, natural or legal persons will take the risk management measures so as to assess the risks of substances and

deliver the risk information stemming from the production, use and disposal of the chemicals, throughout the supply chain.

The roles and duties of companies, specifically the manufacturer, importer, downstream user or distributor under the REACH depend on their place in the supply chain. In this manner, manufacturer is considered to be any company producing that chemical within EU and the importer is the company bringing the chemical into the EU and regarded the same as the manufacturer in terms of responsibilities. Being placed at the top of the supply chain, manufacturer and importer are the actors having more responsibilities compared to the other actors. Their first responsibility is to register a chemical substance on its own, in a mixture or in an article exceeding certain concentration to ECHA.

Apart from the submission of a registration dossier, the registrants are also responsible for delivering information to the downstream users for risk management measures providing safe use of chemicals and communicate with other users. However, since the importers have not the chance to directly submit the registration dossier to ECHA, they should appoint a legal entity established within the EU borders to act on behalf of the importer. Downstream users, buying those chemicals from the importer or manufacturer have the responsibility to implement safe use of chemicals and communicate relevant information to the customers. Similar to downstream users, distributors are also assigned to keep data for safe use of chemicals and deliver it when required. Therefore, all the actors taking part in the supply chain have a proportional responsibility and it is binding under the REACH. In the previous system, only some of the manufacturers were responsible for delivering safety information and labelling requirement while downstream users and distributors were left as free riders. Regarding the importers, there was a limited compensation in case of the infringement of responsibilities due to the difficulty to track of importers notably one-shot ones. In case of any hazard or accident stemming from a chemical substance, the public authorities were addressed for failing to take necessary measures, although they had a limited responsibility for placing that

chemical on the market. The current system proportionately delivers roles and duties throughout the supply chain where public authorities are considered responsible accordingly.

The users and distributors of a hazardous chemical have responsibilities to provide safety data sheets defining how to handle, store, dispose and what to do in case of an accident. Also, manufacturer, importer or in some cases, downstream users are obliged to pre-register and register that chemical under the REACH. When submitting a registration dossier; these actors in the supply chain are required to prepare and present the relevant tests, exposure scenarios, chemical safety assessments and safety reports. In addition, supplier or distributor of a chemical substance should check whether there is any specific control applied on it or not. Furthermore, suppliers should consider whether that chemical is restricted or totally banned or in case of a candidate list chemical, supplier should apply to relevant authorities for authorization if there is no economically or technically viable alternative.

When enacting such a burdensome legislation; replacing burden of proof from government authorities to the manufacturers was an argument bespoken for several times. However, this argument has been highly criticized by the REACH opponents depending on increasing government intervention at every phase of the implementation of the REACH. In their book, Bergkamp and Hanekamp argue that the REACH's justification creates a paradox, government failure calls for more government action.[72]

[72] Bergkamp, L., Hanekamp J. C., *The Draft REACH Regime: Costs and Benefits of Precautionary Chemical Regulation,* Environmental Liability, 2003, Rotterdam, p.1.

4.8 Improving Chemical Risk Management

Protection of the environment and human health are intensely used as the dual reasoning on the grounds of proposing such a wide-ranging, complex and costly legislation. According to the European Commission, little safety information exists for 99 percent of the tens of thousands of chemicals placed on the market before 1981.[73] As mentioned previously, there were more than 100.000 chemicals in use within the EU till 1981, with a very limited knowledge about their hazardous properties.

As a result of the registration process completed up to now, the data of the registered chemicals regarding risk management, will reduce the potential risks even it is difficult to demonstrate it with figures. Moreover, some testing obligations are also stipulated for the importers which are placing chemicals to the EU market and with the help of the recognition of non-EU test results notably toxicological and ecotoxicological information gathered from GLP (good laboratory practice) laboratories, importers' duty to verify safety of their chemicals is simplified. As a matter of fact, full implementation of testing procedures for all chemicals in the market will eliminate those disparities between the chemicals. Hence, adequate risk management will be fully ensured which in turn facilitate the safer handling of chemicals and lessen the hazards deriving from exposure to dangerous chemicals.

Industry introduces additional risk management measures as a consequence of either having re-classified substances as a result of additional information on substance properties leading to additional s-phrases or having identified risks by preparing a chemical safety assessment in relation to registration of their chemicals.[74] With

[73] *"European Parliament OKs world's toughest law on toxic chemicals"*, this article is available at http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2006/12/14/MNGR2MV8UT1.DTL&type=politics retrieved on 26 March 2016.

[74] Assessment of the Health and Environmental Benefits of REACH, Final Report, prepared for DG Environment by DHI and Okopol, April 2012, ENV.D.3/SER/2011/0027r, p.21.

respect to the predictability of damage, manufacturers or users will no more defend themselves against a legal action in case a damage occurs by claiming that they were unaware of the dangerous properties of that chemical.

As per the Article 126 of the REACH Regulation, Member States are in charge of fully enforcing the REACH and applying penalties in case of infringements. Later on, Member States shall notify the European Commission about the offences, penalties and sanctions to be compiled for a comparison to ensure a common understanding of the provisions of the REACH. Registration, evaluation, authorization and restriction procedures as well as the actors throughout the supply chain are topics requiring legal enforcement. According to the Report on Penalties of the European Commission, fines applied by countries vary between €50.000 and €1.000.000 while some countries' penalties are lower compared to higher ones such as €55.000.000 in Belgium and unlimited fines in the UK.[75] So, although member states enforce somewhat effectively the REACH provisions under national law, there is still way to be paced in order to ensure consistency among them. Hence, just and better regulating will be achieved which in turn improve the safe management of chemicals. For now, it is not possible to predict the total costs and benefits of risk management measures taken as a consequence of the REACH until information is available for each substance on its intrinsic properties, its exposure and the availability of substitutes.[76] Following the completion of the registration process, a healthy cost-benefit comparison will be carried out.

[75] Report on penalties applicable for infringements on the provisions of the REACH Regulation in the Member States, European Commission, DG Environment, Milieu Environment&Law, March 2010, p.69.

[76] Commission Staff Working Paper, Regulation of the European Parliament and of the Council concerning REACH Regulation, Extended Impact Assessment of REACH Brussels, 29/10/2003, SEC (2003) 1171/3, p.29.

CHAPTER 5

THE GLOBAL OUTLOOK OF CHEMICALS AND TURKEY IN THE REACH SYSTEM

Chemicals are everywhere as a crucial component of a variety of things such as addictive or fertilizer in our food, colorant of the clothes we wear, the medicine we intake or the cosmetics we make up. However, the critical economic role of the chemicals and their contribution to the improvement of living standards needs to be balanced when their potential costs, such as adverse impacts on the environment and human health are considered. The growing number of allergic incidents, certain cancer types, and reproductive diseases is to some extent can best be explained by the common usage of chemicals. Furthermore, striking increase in health problems and environmental pollution not only in areas where chemicals are widely used but also chemical-free zones such as the poles and jungles reveals the significance of worldwide environmental protection efforts. Therefore, it will be useful to firstly mention those efforts, namely international agreements and conventions articulated to lessen the hazards posed by the chemicals. Afterwards, Turkey's obligations deriving from this peculiar position will be clarified and the outlook of chemicals management will be handled. Subsequently, potential environmental and health benefits of the REACH Regulation for Turkey will be discussed by considering the observable and prospective outputs.

5.1 International Arrangements Governing Chemicals Management

The international fora to cope with the environmental problems, particularly chemicals, comprise the United Nations (UN), World Trade Organization (WTO),

the Organization for Economic Cooperation and Development (OECD) which enacted global and regional agreements regarding climate change, desertification, acidification, and so on.

United Nations Environmental Programme (UNEP), as the main driving force in the UN system for organizing international activities and raising the awareness with respect to the sound management of chemicals, promotes chemical safety by providing policy advice, technical guidance and capacity building to developing countries. Since the Johannesburg Summit issues related to environment and health have become unusually noticeable on the international agenda, United Nations Environment Programme (UNEP) and World Health Organization (WHO) engaged in a longstanding relationship addressing the interaction between health and the environment in the context of sustainable development.[77]

5.1.1 Strategic Approach to International Chemicals Management (SAICM)

One of the reliable activities of UNEP is the implementation of the Strategic Approach to International Chemicals Management (SAICM) as a policy framework to foster the sound management of chemicals, which was adopted by the International Conference on Chemicals Management (ICCM) on 6 February 2006 in Dubai, United Arab Emirates. The SAICM is a milestone in international cooperation to protect human health and the environment from the risks posed by the chemicals. The objectives of this policy are grouped under five themes: risk reduction, knowledge and information, governance, capacity-building and technical cooperation, and illegal international trafficking of chemicals. While considering the crucial contribution to modern societies, the Strategic Approach underlines probable hazards to the environment and human health of chemicals unless managed thoroughly. The overall objective of the Strategic Approach is to achieve the sound

[77] *UNEP 2008 Annual Report*, UNEP Division of Communications and Public Information, UNON, Publishing Section Services, Nairobi, 2009.

management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment.[78] Other than UNEP's global efforts to improve chemical management, there are also international treaties pertinent to chemicals.

5.1.2 Montreal Protocol on Substances that Deplete the Ozone Layer

The Montreal Protocol as a protocol to the Vienna Convention for the Protection of the Ozone Layer[79] is designed to reduce and phase out ozone depleting chemical substances among the participant states. Under the auspices of the UNEP, the Montreal Protocol was signed[80] on 16 September 1987 through scheduling a gradual phase-out of ozone depleting chloroflorocarbon (CFC) production and consumption by the industrialized countries to 50 percent of their 1986 levels in ten year time period and an additional ten years period for developing nations. According to the UNEP data, production and consumption of the majority of harmful ozone-depleting chemicals have been successfully phased out, both in developed and developing countries; over 98 per cent of the consumption of all ozone-depleting substances has now been phased out.[81] Besides, the current best estimate is that global ozone will return to pre-1980 levels around the middle of the 21st century, at or before the time when stratospheric abundances of ozone-depleting gases return to pre-1980 levels.[82]

---

[78] *Strategic Approach to International Chemicals Management*, SAICM texts and resolutions of the International Conference on Chemicals Management, UNEP, Geneva, March 2007.

[79] Vienna Convention for the Protection of the Ozone Layer is a multilateral environmental agreement in force since 1985 and has 197 signatory parties.

[80] The Treaty was opened for signature in 1987 and entered into force in 1989 and until now has undergone seven revisions, in 1990(London), 1991 (Nairobi), 1992 (Copenhagen), 1993 (Bangkok), 1995 (Vienna), 1997 (Montreal) and 1999 (Beijing).

[81] http://ozone.unep.org/new_site/en/Treaties/treaties_decisions-hb.php?sec_id=2 retrieved on 14 November 2015.

[82] *Scientific Assessment of Ozone Depletion:2006*, World Meteorological Global Ozone Research and Monitoring Project Report No.50, Executive Summary, UNEP, Geneva, 2006.

Since, those ozone depleting substances have also greenhouse gases characteristics; the Protocol is appreciated also because of its contribution to the fight against climate change. In this regard, most experts are in consensus that the Montreal Protocol is working with clear evidence of stratospheric ozone recovery.

5.1.3 Stockholm Convention on Persistent Organic Pollutants

Another specific international treaty pertinent to chemicals is *Stockholm Convention on Persistent Organic Pollutants* which was adopted in 2001 and entered into force in 2004. The Convention, aiming to eliminate production and usage of persistent organic pollutants (POPs), is another initiative of the UNEP. Persistent organic pollutants possess toxic properties, resist degradation, bioaccumulate and are transported through air, water and migratory species, across international boundaries and deposited far from their place of release, where they accumulate in terrestrial and aquatic ecosystems.[83] UNEP, being aware of the serious adverse effects in the environment and human health, called for a global action to handle POPs. Initially, a list of 12 POPs under three categories is released and following the decision of the Parties new chemical lists were recognized. As of today, there are 179 countries that are party to the Convention, including the EU which has also transposed the Convention as an internal legislation namely, Regulation EC No 850/2004.[84]

5.1.4 Rotterdam Convention

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade is another multilateral environmental treaty to control international trade of dangerous chemical substances.

[83] This definition is taken from the preamble of the Stockholm Convention available at http://chm.pops.int/Convention retrieved on 17 November 2014.

[84] Regulation EC No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

The Convention, adopted in 1998 and entered into force in 2004, has 154 parties including the EU.[85] The Rotterdam Convention fosters to get the approval of the target country by the exchange of information throughout the import and export of hazardous chemicals, chemical formulations and pesticides. In this regard, exporters will inform the importers about the proper usage, safe handling, labelling and packaging requirements of the chemicals listed in the annex of the Convention. Parties are free to decide to ban or allow the import of chemicals while exporting countries are obliged to check that chemical is not banned by the target country.

5.1.5 Basel Convention

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal is an international convention formulated to reduce the free movement of hazardous waste and to prevent handover of hazardous waste from developed countries to underdeveloped countries. Although, the Convention is dedicated to waste transportation, it also addresses some types of hazardous wastes including hazardous chemicals. The Convention, with 181 parties including the EU, was signed in 1989 and entered into force in 1992. Following the discovery of toxic wastes of the industrialized world in Africa and other underdeveloped regions as cheap disposal locations, a public uproar occurred under the name of "toxic colonialism". Most of the developed countries preferred to export hazardous wastes to the least developed countries, where environmental awareness is less developed, in order to minimize disposal costs of hazardous wastes at their homeland. The Convention, as a response to such kind of abusive activities of the developed world, combats toxic trade and assists the least developed countries in terms of awakening environmental awareness and improving their hazardous waste management. Furthermore, the Parties agree not to allow the export of hazardous wastes or other wastes for disposal within the area south of 60º South Latitude, whether or not such

[85] The European Union, incorporated this Convention also into EU legislation with a *Regulation (EC) No 304/2003 of the European Parliament and of the Council Concerning the Export and Import of Dangerous Chemicals*.(This Regulation is also repealed by another Regulation No 689/2008 EC.)

wastes are subject to transboundary movement.[86] A waste fall within the scope of the Convention only if listed in Annex I of the Convention and having hazardous characteristics such as being explosive, corrosive, flammable, etc. or considered as hazardous waste under domestic law by the exporting country or transit countries.

5.1.6 Chemical Weapons Convention

The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction as an international arms control treaty, entered into force in 1997. The Convention aims to eliminate an entire category of weapons of mass destruction by prohibiting the development, production, acquisition, stockpiling, retention, transfer or use of chemical weapons by Parties.[87] The main responsibility of the parties under the Convention is to outlaw the use and production of chemical weapons and to destroy stockpiles and facilities. There is also a data flow between parties for some chemicals listed in the annex of the Convention but used only for other purposes not prohibited.

5.1.7 Globally Harmonized System of Classification and Labelling Chemicals

Following the 1992 Rio Conference with a declaration of a globally harmonized hazard classification and labelling system, 2002 Johannesburg World Summit on Sustainable Development launched a target such as, by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.[88] In this respect, a *"Globally Harmonized System for Chemical Classification and Labelling (GHS)"* partnership was announced by

[86] Article 4(6) of the Basel Convention, also available at http://www.basel.int/TheConvention/docs/text retrieved on 10 November 2014.

[87] http://www.opcw.org/chemical-weapons-convention/ retrieved on 12 November 2014.

[88] Doran, P., *World Summit on Sustainable Development-An Assessment for IISD*, Briefing Paper, 3 October 2002, p.9.

UNITAR[89]. This initiative seeks to create a new global system for classifying chemical hazards and to ensure that dangerous chemicals, which are traded internationally and produced locally, are appropriately classified and labelled in accordance with international standards.[90]

Prior to GHS, there were plenty of classification and labelling systems used by different countries which failed to ensure the safe use of chemicals due to the lack of a world-wide classification about the intrinsic properties of hazardous chemicals, proper handling or packaging requirements. Variations in the definitions of the hazards paved the way for a dangerous chemical to be labelled for instance flammable in one country but not in another. The GHS is invented to replace those divergent systems and standards by applying the same criteria for classification and labelling worldwide. Although GHS is not compulsory, most of the countries voluntarily preferred to apply GHS such as the EU that incorporated GHS into *acquis communautaire* as CLP Regulation. It is anticipated that, the GHS will reduce the need for testing and evaluation of chemicals and facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis.[91]

5.2 Turkey's Harmonization Process of the REACH Regulation

Turkey's relationship with the EU, with its peculiar nature, is endlessly debated as something more than a trade partner but less than a member. The twofold connection with the EU is going on under the Customs Union and candidacy period based on

[89] The United Nations Institute for Training and Research (UNITAR) is a branch of United Nations, contributing to the capacity development in the fields of environment, peace & security and governance.

[90] *World Summit on Sustainable Development(WSSD)*, Johannesburg, August 26-September 4, 2002, available at http://www.worldsummit2002.org/ retrieved on 22 October 2014.

[91] *Globally Harmonized System of Classification and Labelling of Chemicals*, Fourth Revised Edition, UN, New York and Geneva, 2011, p.3.

different dynamics such as one is built on purely economic expectations while the other is based on political conditions. However, these two processes coincide when the requirement for adoption of the EU legislation comes to the agenda of Turkey as in the case of the REACH Regulation.

5.2.1 Rights and Obligations Arising From the Customs Union

Following the formation of the European Economic Community (EEC), Turkey, with a determination to stand beside the western part of the bipolar world order, unsurprisingly applied to become a member of this establishment in 1959. However, Turkey's application was met with a half-hearted reaction by the EEC and an association partnership until Turkey would become ready for accession was established. Hence, the Ankara Agreement, envisaging a progressive integration between the EEC and Turkey, was contracted and the first phase of the customs union was initialized in 1963.

With the signature of the Additional Protocol, 22 years long transition process began to end with the initiation of the final phase in 1 January 1996. The customs union stipulated the adaptation of the EEC policies regarding internal market going beyond a mere removal of all kind of tariff and quantitative barriers between Turkey and EEC. As per the Article 8 of the Decision No 1/95 of the Association Council, "*Within five years from the date of entry into force of this Decision, Turkey shall incorporate into its internal legal order the Community instruments relating to the removal of technical barriers to trade*."[92]

In accordance with the second paragraph[93] of the Article thereof, the list of technical legislation and its instruments were laid down in the Decision No 2/97 of the

[92] Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union, 96/142/EC, OJ L 035, 13/02/1996 P. 0001-0047.

[93] Article 8(2): "*The list of these instruments and the conditions and detailed arrangements governing their implementation by Turkey shall be laid down by decision of the Association Council within a*

Association Council.[94] Therefore, it became Turkey's responsibility to transpose all kind of technical regulation[95] which could distort the fair trade or become a technical barrier to trade. The directives and regulations which were repealed or amended by the REACH Regulation, take place in the Annex II of the Decision No 2/97, under the XV. Title: Dangerous Substances. Therefore, the REACH Regulation is regarded as a legal continuation of that legislation that should be harmonized in accordance with the responsibilities under the Customs Union.

Although the Decision No. 2/97 of the Association Council is published in the Official Journal in 1997, Turkey paced slowly in terms of harmonizing the technical EU legislation. Since the alignment with the technical legislation is a prerequisite for the elimination of trade barriers, EU upholds this issue by giving place in every Progress Report. Pertinent to the REACH Regulation, Turkey was lagging behind the schedule because the previous legislation repealed or amended by the Regulation had not been transposed to domestic law until 2008. This piece of legislation harmonized following the publication of the REACH Regulation, will be broadly mentioned in the "Chemicals Management Legislation in Turkey" part.

5.2.2 Requirement to Conform with Acquis Communautaire in Candidacy Process

Apart from the examples of EU's trade engagements with other countries, the arrangement with Turkey seems remarkably peculiar. In parallel to the ongoing customs union, Turkey applied to become a full member to the EEC in 1987. Turkey,

---

period of one year from the date of entry into force of this Decision." Decision No 1/95 of the EC-Turkey Association Council.

[94] Decision No 2/97 of the EC-Turkey Association Council of 4 June 1997 establishing the list of Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey, OJ L 191, 21/07/1997 P.0001-0067.

[95] According to the WTO definition, digested from the Agreement on Technical Barriers to Trade, a technical regulation is a document laying down the mandatory conditions for a product, process or production method including terminology, symbols, packaging or labelling requirements.

despite kept outside of the massive enlargement process in the beginning of 1990s and 2000s, is given the candidacy status in Helsinki Summit in 1999.

Despite the EU membership was not that much demanding formerly, following the European Council Summit in Copenhagen in 1993, countries willing to access to the EU need to have stable democratic institutions, functioning market economy and capacity for the adoption of the *acquis communautaire*. The membership negotiations require candidate countries to adjust the EU law that is divided into 'chapters' such as transport, energy, environment, food safety etc. The candidate country will become a member following the closure of all chapters when the negotiations on each chapter are concluded.

The accession negotiations were launched at the European Council in December 2004 with the adoption of the "Negotiation Framework Document" and Turkey was assigned to fully harmonize the *acquis communautaire* in all chapters to be negotiated. This examination of relevant Turkish legislation vis-à-vis the *acquis* is called the Screening Process and the examination of the 'Environment Chapter' was conducted in June 2006. Predictably, the REACH Regulation came to the agenda of Turkey together with other environmental legislation as a prerequisite to be harmonized as early as possible. In 2008, Turkey submitted a Strategy Document to the DG Environment laying down the adoption calendar for the REACH Regulation.

Overall, transposition of the REACH Regulation into domestic law is a precondition both under the Customs Union in order to keep the internal market functioning and in the candidacy process for the closure of the environment chapter.

5.3 The Outlook of Turkey Regarding Chemicals Management

Turkey, as a developing country, endeavours to confront the challenge of ensuring economic growth while considering the environmental and social development. Despite the increasing economic pressures from industry, agriculture, energy and transport sectors, a wide range of institutional and legislative reforms are initiated so as to catch up with the OECD levels and to ensure the convergence with the EU environmental legislation. Since, the legislation adaptation will be dysfunctional without the formation of adequate technical and institutional infrastructure, Turkey is required to satisfy both of the pre-conditions.

As a roadmap outlining the current situation and steps to be taken, the EU Integrated Environmental Approximation Strategy (IEAS in English or UÇES in Turkish) (2007-2023), is prepared by the Ministry of Environment and Urbanization in 2006 and adopted by the High Planning Council in 2007. UÇES covers thorough information including objectives, strategies and activities pertinent to the technical and organizational infrastructure and transposition arrangements to ensure alignment with the environmental acquis. This spurred the updating of large parts of environmental legislation: overall, 44 new pieces of legislation and/or major amendments were adopted on horizontal issues (e.g. access to information, environmental impact assessment, environmental inspection) and sectoral issues such as air pollution (e.g. VOC emissions, motor fuel quality, control of air pollution from industrial plants), waste (e.g. hazardous, medical and packaging waste, excavation and construction waste, waste oils, and used batteries and accumulators), water (e.g. drinking and bathing water, urban waste water treatment, nitrates) and chemicals (e.g. dangerous chemicals, phasing out of ODS).[96]

[96] OECD Environmental Performance Reviews Turkey, OECD, 2008, Paris, p. 130, also available from http://www.oecd.org/env/country-reviews/environmentalperformancereviewsturkey2008.htm retrieved on 14.05.2016.

According to the Strategy, investment and operational costs of complying with the targets defined thereof up to 2023, estimated to be around €60 billion. The UÇES indicates that the EU Directives requiring the highest amount of investments are those relating to water management and waste management: the sectoral distribution of environmental investments between 2007 and 2023 is estimated to be €34 billion for the water sector (including wastewater) and €10 billion for the waste sector.[97] While preparing UÇES, outputs from "National Environmental Strategy and Action Plan" prepared previously and "Integrated Harmonization Strategy Project" implemented with EU resources and "Environmental Heavy Cost Investment Planning Project"; in addition, it was taken into consideration that prepared strategy is coincided with the strategies and policies of the Development Plan, Annual Programs and National Programme of year 2003.[98]

Since the Strategy covers a long period, the Ministry of Environment and Urbanization together with the Scientific and Technological Research Council of Turkey (TUBİTAK), initialized a project to identify what had done from 2007 to 2014 and to update the strategies and activities for the period of 2014-2023.

5.3.1 Turkey and Multilateral Arrangements

Differently from other developing countries foot dragging or looking for a waiver when the environmental protection concerned, Turkey has made noteworthy improvements to become a party to the most of the international environmental accords and programmes. As of today, Turkey is a party to more than 30 multilateral environmental agreements regulating climate change, waste management, biodiversity, desertification, marine pollution etc.

[97] Commission Implementing Decision of 11.12.2014 adopting a multi-annual Action Programme for Turkey on Environment and Climate Action, Brussels, 11.12.2014, C(2014) 9575 final, p.2.

[98] EU Integrated Environmental Approximation Strategy (UÇES), p.1-2, also available https://www.joi.or.jp/modules/investment/custom/documents/TUR_EU_INTEGRATED_ENVIRONMENTAL_APPROXIMATION_STRATEGY.pdf retrieved on 12.05.2016.

With respect to chemical management, Turkey has also a good record of progress thanks to the pre-accession harmonization efforts stipulated by the EU. Despite falling short of EU legislation both at implementation and infrastructure stages, Turkey is ahead of the several developing countries to address the environmental problems deriving from chemicals. Turkey met its commitments under the Montreal Protocol to phase out ozone depleting substances four years ahead of the target date, which was especially noteworthy given its policy of rejecting international pollution reduction targets based on its "special circumstances" (i.e. Turkey's low per capita income level requires it to emphasise economic growth).[99] Turkey completed the ratification procedure of the 1985 Vienna Convention for the Protection of the Ozone Layer and its 1987 Montreal Protocol in 2000.

Besides, as a party to the Basel Convention on the transboundary movement of hazardous wastes since 1994, Turkey implements and enforces relevant internal regulation by also considering the requirements of the Waste Shipment Regulation and Waste Framework Directive.[100] The Stockholm Convention on Persistent Organic Pollutants (POPs) was signed by Turkey in 2001 and ratified in 2009. Meanwhile Turkey implements a technical assistance project to carry out an industrial impact assessment of the convergence with the corresponding EU Regulation[101] to the Stockholm Convention.

Turkey signed the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade in 1998 but

[99] OECD Environmental Performance Reviews Turkey, OECD, 2008, Paris, p. 24, also available from http://www.oecd.org/env/country-reviews/environmentalperformancereviewsturkey2008.htm retrieved on 14.05.2016.

[100] Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, Celex number 02006R1013-20160101 and Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312,22.11.2008.

[101] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, OJ L 158, 30.04.2004.

not ratified yet. Therefore, adoption of the Regulation 689/2008/EC on export and import of dangerous chemicals as an implementing legislation of the Rotterdam Convention is impending until the ratification of the Convention. As mentioned in the Progress Reports, Turkey needs some technical assistance for the alignment and enforcement of the Rotterdam Convention and the Regulation thereof.

5.3.2 The Chemicals Management Legislation in Turkey

The Law on Environment No.2872 is the main instrument regulating the general environmental sphere in Turkey. The law was subjected to comprehensive amendments in 2006 to include 'polluter pays principle' and some participatory and precautionary approaches. Specifically, By-Law on Dangerous Chemicals No. 21634 lays down the general framework regarding the definition, classification, labelling of dangerous chemicals, import control and market surveillance mechanisms, duties and responsibilities of relevant actors. As touched upon in multilateral arrangements, the By-Law on the Phase-Out of Ozone Depleting Substances No. 23766 is enforced as an implementing legislation of the Montreal Protocol.

Regarding animal testing issue, Turkey enforces two basic by-laws one of which is By-Law on the Working Principle and Procedures of Ethical Councils Concerning Animal Experiments No. 26220 and the other one is By-Law on the Protection of Experimental Animals and on the Basic Principles of the Establishment, Operation and Inspection of Experimental Laboratories.

Prior to the REACH Regulation, there were four main regulations and directives governing chemical management in EU as mentioned previously. And Turkey was obliged to harmonize this piece of legislation since listed in the annex of the Decision No 2/97 of the Association Council. Therefore with the support of an EU

financed project, Technical Assistance in the field of Chemicals (TEACH)[102], The Safety Data Sheet Directive (91/155/EEC), the Directives on Dangerous Substances (67/548/EEC), Dangerous Preparations (99/45/EC), Regulation on Inventory of Chemicals are transposed into internal law.

These outputs of the Project have reinforced the legislative structure in the area of setting up a database and inventory of the substances and preparation of a priority list for dangerous chemicals. By-law on Classification, Packaging and Labelling of Dangerous Substances and Preparations, was prepared to harmonize Directives 67/548/EEC and 99/45/EC; By-law on the Preparation and Distribution of Safety Data Sheets to transpose Directive 91/155/EEC and By-law on Inventory, Notification and Risk Assessment of Substances to transpose Regulation 793/93/EC for gathering data on production and import of chemicals and associated risks.

As of 1 June 2007, the REACH Regulation is in force which introduced fundamental revision in legislation concerning the manufacture and importation of chemicals, placing on the market and use of chemical substances. Since two of the above mentioned directives (93/67/EEC, 91/155/EEC) and Regulations 793/93/EC and 76/769/EEC were repealed or amended by REACH, Turkey had to turn back to the starting point in harmonization process. However, the by-laws in question will be in force until the convergence with the REACH Regulation is ensured.

5.3.3 Institutional Framework

Protection of environment and prevention of environmental pollution are the duties of all public institutions and citizens according to the Constitution. Regarding the institutional framework responsible for chemical management issues, Ministry of Environment and Urbanization is the main competent authority preparing and

[102] Those directives and regulations (67/548/EEC, 99/45/EC, 91/155/EEC and 93/67/EEC) were harmonized as the output of another EU Technical Assistance Project, "Technical Assistance in the field of Chemicals (TEACH) (EuropeAid/122020/TR).

executing environmental legislation and chemicals legislation in specific. The Ministry of Food, Agriculture and Livestock is responsible for the chemicals used for plant and animal protection in rural areas and for aquatic products and Ministry of Health is responsible for chemicals used in drugs and drug precursors. These ministries carry out their duties by central authorities in the capital and at the provincial level by the branch offices responding to common needs of public of provinces, municipalities and villages.

Regarding the harmonization of the REACH Regulation, the Ministry of Environment and Urbanization is the main beneficiary while other relevant institutions are co-beneficiaries. In this respect, the REACH Help Desk was founded by the Ministry in order to carry out all relevant tasks regarding the REACH Regulation and CLP Regulation. Besides this official help desk of the Ministry, there is another help desk established by the Istanbul Mineral and Metals Exporters' Association (IMMIB) to respond information requests of the chemicals exporters beforehand.

5.3.4 Ongoing Harmonization Studies

As mentioned previously, Turkey scheduled the harmonization timetable for the REACH Regulation in the Strategy Document submitted to the DG Environment in 2008. In this regard, under the IPA[103] National Programmes, Turkey launched Technical Assistance for Implementation of REACH Regulation Project with a budget of € 2,5 million to harmonize the Regulation. In the Project Fiche, the purpose is defined as strengthening the existing capacity of the governmental institutions involved in implementation of the chemicals management legislation and establishing the necessary system, institutional structure and legal framework, and increasing the institutional capacity for the implementation of the REACH

[103] IPA is the acronym of the Instrument for Pre-Accession that channels financial support to the all candidate and potential candidate countries during the pre-accession period.

Regulation in Turkey.[104] With an objective to improve the protection of human health and environment in Turkey by implementation and enforcement of the REACH Regulation, the Project was scheduled to start in 2011 and finalize by the end of 2013. The Project concluded with delay of a year and draft By-Law on REACH will be released for public consultation in the upcoming months.

5.4 Potential Environmental and Health Benefits

The potential environmental and health benefits are expected to be achieved with the implementation of the REACH Regulation by increasing awareness with respect to the hazards of substances and a high level of control of risks stemming from the use of chemicals. These benefits will arise from the following instruments constituting the backbone of the REACH, as mentioned in previous parts;

- Registration procedure clarifying the risk and hazard information of chemical substances.
- Safety data sheets delivered to downstream users to be informed about the handling and storage conditions of the chemicals,
- Authorization procedure for gradually substituting the hazardous chemicals with safer alternatives,
- Restriction procedure for partially or fully prohibiting the usage of hazardous chemicals. Therefore, current prohibited or restricted chemicals list of Turkey is compared with the REACH Authorization and Restriction List, SVHC Candidate List to display an ex-ante and ex-post dangerous chemicals picture of Turkey.

5.4.1 The Methodology Applied for the Environmental and Health Benefits

According to the chemical substance analysis, 6.077 substances were identified within the Chemicals Inventory of the Ministry of Environment and Urbanization

[104] http://ec.europa.eu/enlargement/pdf/turkey/ipa/2008/tr080202_reach_chemicals_project-final_en.pdf Retrieved on 30 April 2016.

and grouped if taking place in one of the above mentioned chemicals lists.[105] However, the registration process in EU under the REACH Regulation is still going on due to the last registration deadline covering the 1-100 tonne per year chemicals which constitute the majority of chemicals in the market.

As a second instrument, international statistics regarding the occupational injuries and mortalities due to the exposure to dangerous chemicals are utilized to estimate the number of severely affected workers. The estimations are used for monetization of aggregate utility with the assistance of value of statistical life (VOSL) and value of a life year (VOLY). As per the Cost Benefit Analysis carried out by the MEU under the Technical Assistance for Implementation of REACH Regulation, VOSL is determined as €1-2 million, while VOLY is €50.000-100.000.[106] The monetization of environmental and health benefits is focused on the specific chemical substances and their usage areas.

5.4.2 Potential Health Benefits

According to ILO data[107], annually, more than 160 million people have an occupational disease or injury of which approximately 25% is deriving from the directly or indirectly exposure to dangerous chemicals. The number of occupational diseases resulting from contact with chemicals is expected to decrease by 35-50 percent together with the fully implementation of REACH Regulation[108].

[105] http://www.csb.gov.tr/gm/cygm/index.php?Sayfa=sayfa&Tur=webmenu&Id=422 retrieved on 30.05.2016.

[106] Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR, p.16.

[107] Estimating the Economic Costs of Occupational Injuries and Illnesses in Developing Countries: Essential Information for Decision-Maker, International Labour Organization, Peter Dorman, September 2012.

[108] The Overview of 36 Studies on the Impact of the New EU Chemicals Policy (REACH) on Society and Business, Ecorys and Opdenkamp Adviesgroep, Workshop REACH Impact Assessment, 2004, Netherland.

In Turkey, with a population of 76 million, 46.272 new cancer cases are diagnosed per year with a cancer mortality rate of 60,5 per 100.000 patients[109]. The Cost Benefit Analysis estimated economic burden cancer for Turkish economy to be approximately €10.304.190.659 per year. As 0,7% of all cancers is seen to be work related, the direct economic burden can be calculated to be €72.129.335 and implementation of REACH will lead to reduction of cost between €24.043.112 and €48.086.223.[110] Since these figures do not take into account any productivity loss, an additional study performed within the Analysis, assuming 80% of cases, the cancer is diagnosed in employees aged more than 60 years, in 10% of cases when they are 52-59 years old and in the remaining 10% when they are 45-52 years old.

Table 8. Annual Cost Related to Cancers Caused by Workplace Exposure to Hazardous Chemical Substances

	Costs	**Low estimation REACH benefits**	**High estimate REACH benefits**
Healthcare costs	€ 72.129.335	€ 24.043.112	€ 48.086.223
Productivity costs	€ 17.866.397	€ 5.955.466	€11.910.931
Loss of human life (VSL)	€ 191.285.479	€ 63.761.826	€ 127.523.652
Welfare loss(VSLY)	€ 231.912.979	€ 77.304.326	€ 154.608.653
	€ 513.194.190	**€ 171.064.730**	**€ 342.129.459**

Source: Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR

As shown in the table, the methods utilized for the calculation of welfare loss due to the increasing mortality are the value of statistical life (VOSL) and the number of fatal cases related with the exposure to hazardous chemicals. The welfare loss from mortality in the VOLY approach is estimated at €231.912.979 where there will be a

http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/chemikalien/Impact_of_REACH.pdf retrieved on 12.06.2016.

109 Turkish Journal of Cancer, 2007, Volume 37, Number 4, pages 148-153.

110 Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR, p.30.

reduction ranging between €77.304.326 and €154.608.653 following the implementation of the REACH Regulation. Based on cancer cases per year associated with the occupational use of substances, the annual productivity cost will be €17.866.397 while the implementation of the REACH will lead to a reduction of cost between € 5.955.466 and € 11.910.931.[111]

Furthermore, the Analysis also estimated non-cancer benefits by considering 25% of occupational diseases are resulting from exposure to hazardous chemicals. Accordingly, the implementation of the REACH Regulation will result in an annual saving of cost €1.213.909.348 in a worst-case scenario and €2.427.818.697 in the best one.

5.4.3 Environmental Benefits

Despite progress in aligning with the EU's environmental legislation, harmonization is still waiting for several pieces of legislation concerning chemicals in Turkey. As mentioned above, together with the enactment of By-Law on Inventory, the Ministry of Environment and Urbanization set up an inventory system to register current chemical substances or mixtures in the market. However, since there is no legal obligation such as 'no data no market' as in the REACH Regulation and limited diligence for submitting a dossier; the current inventory system is required to be replaced.

With the start-up of REACH registration system, about 3.000 chemical substances are expected to be registered which will make available the reliable information on the hazardous properties of substances. The delivery of risks associated with a chemical throughout the supply chain through proper labelling and packaging will reduce the harmful effects of the chemicals to the environment. Filling the data gap

[111] Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR, p.33.

for existing chemicals in the market, identification of hazardous properties of substances and ensuring proper handling, usage and disposal of chemicals will reduce potential risks even it is not likely to be illustrated with figures.

The restriction of chemicals is an instrument fostering both health and environmental benefits, since the chemicals are restricted or prohibited if they pose a threat to human health and environment. At this point, the Ministry has taken some steps further to adapt the REACH Annex on Restrictions beforehand and achieved the partial alignment with the existing Restrictions List. The current By-Law on Restrictions is envisaged to replace the Annex XVII of the REACH Regulation when the legislation becomes fully operational.

An increased knowledge of hazardous properties of the substances will lead to more substances to be classified as dangerous to the environment. The Analysis forecasts the cost of reduced emission to the environment by considering the costs associated with environmental cleaning. When the environmental expenditure of governmental organizations and private provincial administrations is taken as 1.479.396.336 TL, the REACH system will lead to annual reduction of cost between 493.132.112 TL and 986.264.224 TL. The latency period of environmental benefits, in the Analysis, is set at 30 years which in turn made the estimation of the environmental benefits of REACH for Turkey between €5.117.456.366 and €10.234.912.733 within 30 years.[112]

5.4.4 Cost-Benefit Comparison of REACH for Turkey

The Market Profile Analysis Report, issued by the MEU as an output of Technical Assistance for Implementation of REACH Regulation, comprises the relevant

[112] Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR, p.33.

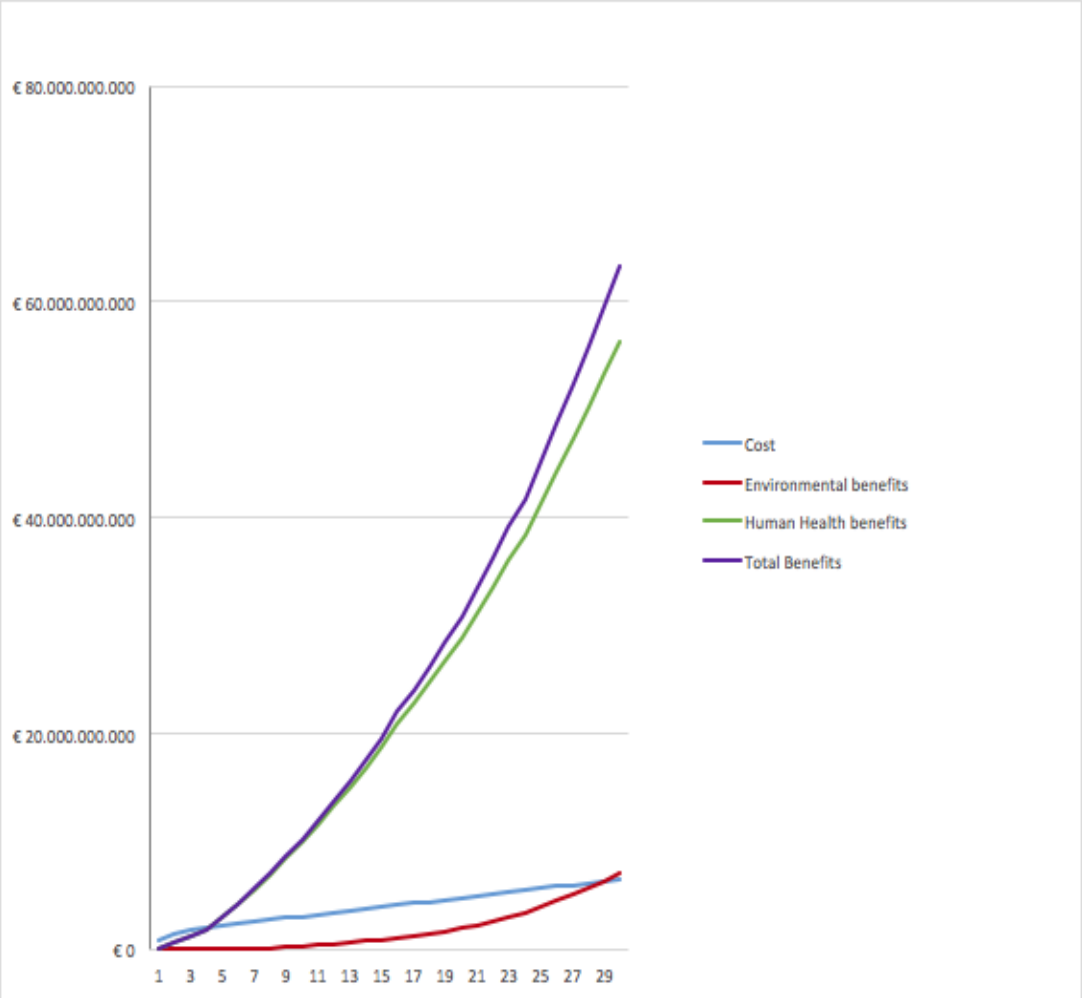
industries and downstream users to be affected by REACH Regulation and the chemical substances subject to registration, authorization and restriction.

According to the Report, the industry preferred Turkish REACH should be closely aligned with EU REACH and that any difference should preferably result in fewer obligations for Turkish industry and not more in comparison with the EU-REACH. Since Turkish chemical industry is composed of SMEs, it is deemed the critical vulnerable point of the REACH for Turkey. The SMEs are not well equipped to deal with REACH in terms of qualified personnel, necessary IT technologies and infrastructure, lack of financial capability for registration and testing fees, limited number of accredited laboratories. In order to minimize the negative effects, it is advised to start capacity building and to improve the Turkish consultancy market so as to promptly respond to the information requests of the industry when the Turkish REACH starts up. Besides, it is recommended by the industry to implement REACH in Turkey with different deadlines based upon tonnage band and hazard classification as in the case of EU-REACH.[113]

Based on the assumption of the Cost Benefit Analysis, there are two graphics of cumulative costs and benefits of the implementation of REACH for both lower and upper band estimate of the benefits. In calculating the cumulative costs, MEU has assumed that all substances that require registration for a tonnage band >1000 T/A is registered in the first year, the substances in a volume >100 T/A are registered evenly over the first 3 years and all other are registered evenly over a period of 8 years.[114]

[113] Technical Assistance for Implementation of REACH Regulation, The Market Profile Analysis Report, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR.

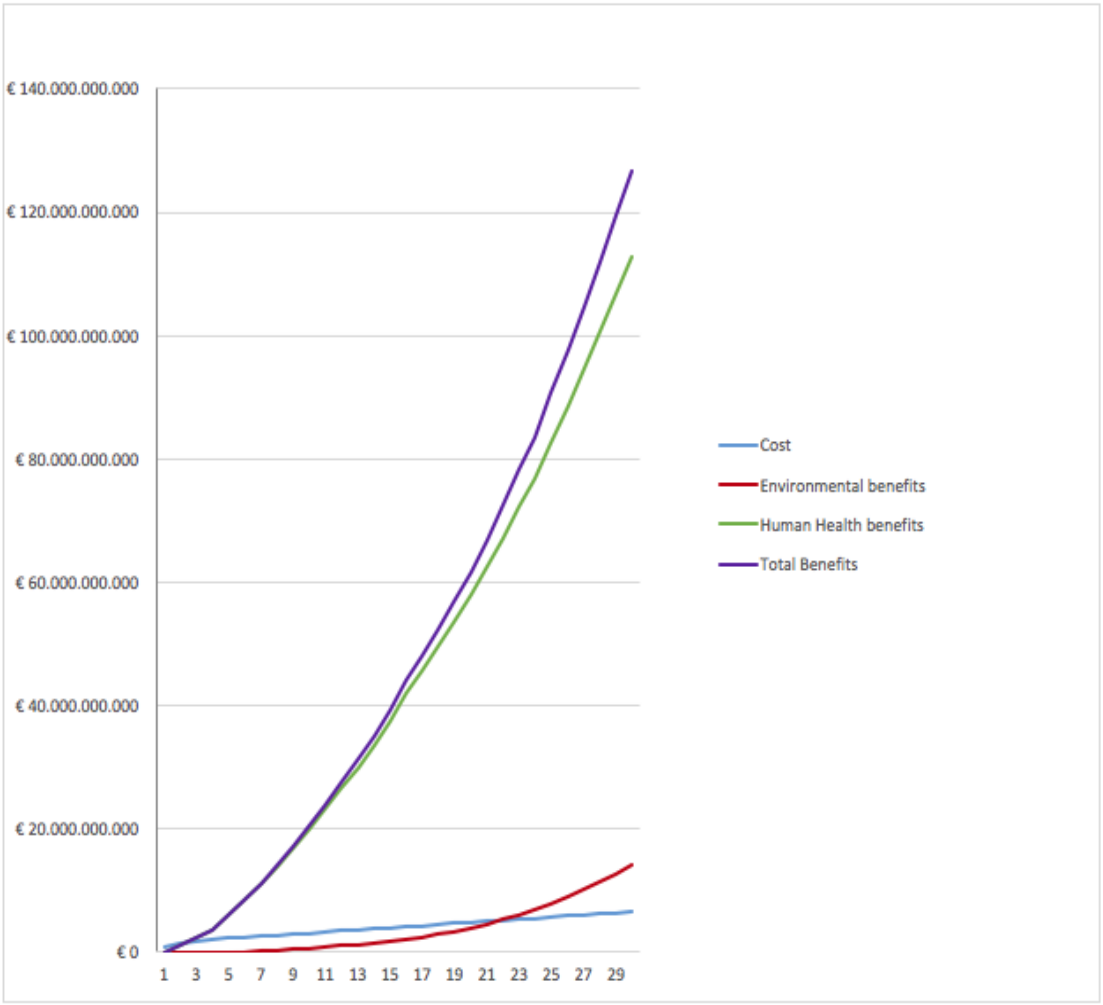
[114] Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR, p.33.



Source: Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR

Figure 1: Cumulative overview of costs and lower bound estimate of benefits of Turkish REACH over the first 30 years upon implementation

The Figure illustrates the cumulative benefits of the REACH Regulation outweigh the cumulative costs despite a conservative scenario by considering the lower band estimation of benefits.



Source: Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR

Figure 2. Overview of cumulative costs and upper bound estimate of benefits of Turkish REACH over the first 30 years upon implementation

At this Figure, based on higher band estimation, the environmental and health benefits significantly surpass the costs of the REACH Regulation.

Due to the limitations to calculate environmental benefits, according to two graphs, benefits of increased protection of human health are higher than the environmental

benefits. But in both cases, cumulative benefits of REACH outweigh the cumulative costs.

CHAPTER 6

CONCLUSION

The environmental debate gained a new prominence on the political agenda of all governments during the 1970s. Industrial production processes and increased use of chemicals were widely recognized as the source of severe problems of environmental degradation.[115] Hence, towards mid-1990s, the growing reaction against the possible negative effects of chemicals for the environment, led to the awareness both at global and regional level.

Today, the EU is the champion of those multilateral environmental efforts to address the problems necessitating regional or global action. While there was no direct reference to the environment in the Founding Treaty of the EEC, with the adoption of the Single European Act the legal basis of environmental policy was established. In the Union's history, the EU countries with high environmental standards such as Finland, Sweden, Denmark, Netherlands, Austria pushed the European decision makers to make remarkable reforms notably for water and chemicals management. Despite the foot-dragging countries' resistance to implement less demanding environmental legislation in order to promote economic growth; those green leaders succeeded to shift the political balance to raise environmental standards. By doing so, the competitive disadvantage of their domestic industries subject to higher and more stringent standards would decrease and uniform set of environmental rules throughout the Europe would be ensured. Börzel argues that these countries, namely pace-setters, are also willing to upload their policies to the European level so as to

[115] Barnes, P. M., Barnes I. G., *Environmental Policy in the European Union,* Edward Elgar Publishing Limited, UK, 1999, p.1.

refrain from the implementation burden.[116] Henceforth, with each enlargement process, increasing number of green leaders made the environmental law-making an indispensable part of decision making process. However, various DGs assist to the DG Environment when an environmental legislation is being drafted so as not to sacrifice economic, financial, social benefits.

The consumption of chemicals by all industries for almost all manufacturing processes makes chemicals industry one of the chief and most globalized sectors of the world economy. Today, every developed country which completed its industrialization process is backed up with at least one leading chemical producing company. The completion of internal market with the help of the removal of trade barriers within Union borders fostered the growth and innovative capability of the EU chemicals industry. Despite the services sector is rapidly growing in European economy, industry maintains to be an essential source of prosperity for Europe. As the chemical industry constitutes the main supplier of various other industrial sectors, success in the chemical industry has a dramatic reflection on the success of other sectors. As such, Europe's chemical industry is a key contributor to sustainable development, a vital source of new applications in other sectors of the economy and an essential success factor in the European Union's employment and growth agenda.[117]

Since the leading position in world chemicals industry and competitiveness was challenged by numerous factors; business and political leaders of Europe came together to combine their efforts to map out the future of the European chemical industry. Due to the fact that the regulatory framework has a major and direct influence on European chemical industry's ability to compete on global markets, one

[116] Börzel, A. *Tanja, Pace-Setting, Foot-Dragging, and Fence-Sitting: Member State Responses to Europeanization,* JCMS 2002 Volume 40. Number 2., Blackwell Publishers Ltd, 2002, Oxford, pp.193-197.

[117] Cefic Review 2004 – 2005, *"Trust and Partnership: Towards A New Vision for Europe's Chemical Industry*", also available from www.cefic.org retrieved 30 December 2014.

of the targets identified by the Commission was to achieve a better regulation free from cumbersome procedures and heavy compliance burden. By this occasion, this time, started with the articulation of REACH Regulation, industry and policymakers came together to act synchronously to prevent its unfavourable effects on European economy and the environment. The Commission emphasized the main goals of the new chemicals policy strategy to achieve sustainable development targets of protection of human health and environment on the one hand and to enhance competitiveness in the chemical industry on the other. Günter Verhaugen expressed in a speech "*There are clear signs that it is facing unprecedented challenges both from the effects of global change and the expectations of our citizens; with this initiative we aim to ensure the right framework conditions for the chemicals industry to continue operating and investing in the EU on a sustainable basis*."[118]

With the support of industry and business cycles as well as NGOs, the REACH Regulation was drafted and put into implementation. Nonetheless, the Regulation was the first, in terms of bursting growing regulatory pressure, to consult industry every phase of legislation making and to counterbalance their costs through systematic impact assessments. The two most significant objectives of the REACH Regulation are to improve protection of human health and the environment from the risks of chemicals and to enhance the competitiveness of the EU chemicals industry.[119]

The business benefits of the REACH Regulation, which are not referred in this study, are essentially cost savings and non-monetary advantages. Cost savings will be achieved by improved risk management and better knowledge about the intrinsic

[118] Verheugen, Günther, Commission Vice President, Cefic Review 2007 – 2008, "The European Chemical Industry: A Global Leader in Innovation, Supporting Growth and Well-Being in Europe", p.10 also available from www.cefic.org retrieved on 27 January 2016.

[119] These objectives are noticeably defined in the 1st Article of the REACH Regulation *"The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."* EN Official Journal of the European Union L 396/1 (30.12.2006)

properties of chemicals while the non-monetary benefits would derive from liability claims. Several studies mention the prevention of business risks related to liability claims as benefit for enterprises, which would be realised through the generation of new information on substance properties enabling the development and improved control of chemical products through the chemical safety assessment as well as enforcing the general duty of care.[120] Chemical safety assessment regarding the hazards posed by the substance coupled with the shared responsibility in the supply chain and communication of risk information will reduce the business risks. The detailed information delivered throughout the supply chain will reduce hazards stemming from unknown properties of the chemical substances.

The full integration of the internal market regarding chemicals will be achieved thanks to the registration system taken hold of all substances either new chemicals or existing chemicals. Apart from the environmental and health benefits noted in the relevant chapter, the comprehensive inventory of internal chemicals market is expected to cease the disparities between chemicals moving freely in market without any risk management mechanisms.

Meanwhile, increasing communication throughout the supply chain will also reduce the company costs related to occupational health. Safety data sheets defining the conditions with respect to chemical substance and restriction, authorization procedures keeping SVHCs away from the workers are expected to improve workers health and to ensure a safe working environment. In this regard, decreasing number of casualties and occupational damage does not count only for the environment and health benefits but also for business benefits. Besides, standard procedures to facilitate communication for safe use and handling of chemicals will reduce the enterprises' communication efforts. However, since there are considerable differences between the Member States regarding the liabilities to be born by whom

[120] Reihlen A., Lüskow H., Analysis of Studies Discussing Benefits of REACH, Ökopol, February 2007, p.10.

and how, it is not possible to calculate the exact costs but to estimate the average costs.

Furthermore, registration of basic information for all the chemicals to the database is the primary instrument of the system in terms of creating a trustworthy inventory of all existing chemicals in the market. Evaluation of the information on registered substances and adequacy of the substance-tailored testing programmes and authorization of substances with some hazardous properties namely SVHCs by the competent authorities to grant permission for that chemical to be used only for a safer purpose could be enumerated as other significant instruments. According to the forecasts and calculations of the EU Commission and European chemical industry, compliance to the REACH Regulation will be a costly and cumbersome process if only environmental and health benefits were the basic motivation. Therefore, it was inevitable for EU leaders to lean on economic advantages to be gathered by the Regulation as mentioned above, although in public speeches economic and the environmental objectives are presented equally.

However, there is a common problem of which every actor agrees on, about the difficulty to exercise the assessment of the economic, social and environmental impact of the REACH Regulation depending on several factors varying from the complexity of supply chain to the behaviour of downstream users, from dangerous chemicals to be discovered to liability problem as mentioned above. Besides, a great deal of chemical substances is not registered yet due to the volume based registration deadlines which will end in 2018 with the registration of 1-100 tonne per annum chemicals. Therefore, it was not the aim of this study to develop an in-depth assessment of cost and benefit analysis since most of the data is not publicly available and only submitted to the government authorities. As argued by the non-EU countries highly critical about the REACH Regulation, although the registration period will be over, the data regarding the economic reflections of the REACH Regulation will be kept somewhat confidential or will be publicised partially due to the reservations of the EU to highlight the business benefits rather than calling

attention to the health and the environmental benefits. Therefore, in this study, it is preferred to mention the potential environmental benefits which are willingly shared with public and have some observable outputs (eg. reduced number of laboratory animals, restricted or banned dangerous chemicals).

In the case of Turkey, legislation alignment became a legal obligation both under the Customs Union and EU candidacy period. Despite Turkey delayed the transposition of the environmental technical legislation identified in the Annexes of the Decision 2/97 of the Association Council, the requirement for becoming a member to close all chapters including the Environment Chapter pushed Turkey to speed up the harmonization process. These pre-accession harmonization efforts improved Turkey's ability to address environmental problems better than a great deal of the developing countries. However Turkey is still falling short of the EU members both at implementation and capacity building stages.

Turkey's chemicals management comprises a wide-ranging legislation varying from the international chemical conventions to some relevant EU law. Nonetheless, the inadequacies of infrastructure and insufficient staff make the harmonized legislation non-functional and keep the implementation away from the core of the environment policy. That is why the burden of transposition of the Environment Chapter is going beyond the expected budget and forcing the government authorities to extend deadlines as much as possible for some heavy legislation such as Integrated Pollution Prevention and Control Directive, Large Combustion Plants Directive and the REACH Regulation.

In accordance with the national legislation[121], the regulatory impact assessment is required to be carried out in order to estimate possible economic, social and environmental impact of draft legislation. In this regard, there are two assessment

[121] The Circular of the Prime Ministry No.2007/6, Official Gazette, 03/04/2007, No:26482.

studies one is performed by an NGO, namely TEPAV in order to calculate potential costs of the REACH Regulation to the industry and the other one is executed by the Ministry of the Environment and Urbanization to estimate possible costs and benefits comprehensively. The Cost Benefit Analysis forecasts a total cost saving of €58-116 billion in health sector while €5-10 billion in environmental protection. The Analysis comprises of two graphics of cumulative costs and benefits of the implementation of the REACH Regulation for both lower and upper band estimate of the benefits. According to the both graphs, the benefits of increased protection of human health are higher than the environmental benefits and the cumulative benefits of the Regulation outweigh the cumulative costs.

To conclude, the most rightful criticisms of the REACH Regulation is about pacing quite slowly, due to the considering the voice of the industry more than the environmental NGOs, for compiling the hazardous chemicals under the restricted or prohibited lists. Besides, with the articulation of the REACH Regulation, the legislative mass was targeted to be streamlined to lessen the compliance burden of companies. However, the Regulation was regarded as the most burdensome legislation by the companies both inside and outside of the EU. Although unifying the complicated legislation, the REACH Regulation with its complexity and bureaucracy in terms of paperwork, challenging enterprises notably SMEs. Therefore, in terms of legislative dimension, REACH is required to be counted as cost rather than benefit for most of the actors from industry. Ongoing disparities among the each member state regarding the REACH inspections and anxieties of non-EU manufacturers about the disclosure of the business secrets in SIEFs or registration database are the other prevailing criticized points. However, although REACH has been subjected to harsh criticism on the grounds of being drafted for economic purposes other than environmental ones, the Regulation is noteworthy for defining serious instruments for the protection of the environment that is open to positive externalities. Notably for Turkey, it is expected to gather serious environmental benefits following the capacity building and improving the administrative infrastructure with the assistance of those instruments. Therefore, the

REACH Regulation will undoubtedly have more than expected benefits for human health and the environment in the long term.

REFERENCES

Books, Articles, Official Documents and Reports

Assessment of the Health and Environmental Benefits of REACH, RPA, 2012, Final Report Part B-Assessment of Benefits, prepared for DG Environment, DHI and Okopol, RPA, April 2012.

Assessment of the Health and Environmental Benefits of REACH, Final Report, prepared for DG Environment by DHI and Okopol, ENV.D.3/SER/2011/0027r. April 2012.

Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis Under REACH, Final Report (Part-2), Prepared for DG Environment, ENV.D.1/SER/2009/0085r, RPA, Imperial College, March 2011.

Barnes, P. M., Barnes I. G., *Environmental Policy in the European Union*, Edward Elgar Publishing Limited, UK, 1999.

Bergkamp, L., Hanekamp J. C., *The Draft REACH Regime: Costs and Benefits of Precautionary Chemical Regulation*, Environmental Liability, 2003, Rotterdam.

Börzel, A. *Tanja, Pace-Setting, Foot-Dragging, and Fence-Sitting: Member State Responses to Europeanization*, JCMS 2002 Volume 40. Number 2. pp.193-214, Blackwell Publishers Ltd, 2002, Oxford.

Cefic Review 2004 – 2005, *"Trust and Partnership: Towards A New Vision for Europe's Chemical Industry*", Brussels, 2006.

Cefic Review 2007 – 2008, "*The European Chemical Industry: A Global Leader in Innovation, Supporting Growth and Well-Being in Europe*", Brussels, 2009.

Commission Staff Working Paper, Regulation of the European Parliament and of the Council concerning REACH Regulation, *Extended Impact Assessment of REACH*, Brussels, 29/10/2003, SEC (2003) 1171/3.

Commission Staff Working Paper, Commission Staff Working Document accompanying document to the Report from the Commission to the Council and the European Parliament Seventh Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union SWD/2013/0497 final.

Commission Implementing Decision of 11.12.2014 Adopting a Multi-Annual Action Programme for Turkey on Environment and Climate Action, Brussels, 11.12.2014, C(2014) 9575 final.

Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community, Official Journal of the European Union, 29/12/2006, C321 E/1 53.

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances.

Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC), OJ No L 358/1, 18/12/86.

Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union, 96/142/EC, OJ L 035, 13/02/1996.

Decision No 2/97 of the EC-Turkey Association Council of 4 June 1997 establishing the list of Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey, OJ L 191, 21/07/1997.

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, L 276/33, 20/10/2010.

Doran, P., *World Summit on Sustainable Development-An Assessment for IISD*, Briefing Paper, 3 October 2002.

Dorman, P., *Estimating the Economic Costs of Occupational Injuries and Illnesses in Developing Countries: Essential Information for Decision-Maker*, International Labour Organization, ISBN 978-92-2-127015-7, 2012.

Fasey, A., *Reach is Here; The Politics are Over, Now the Hard Work Starts*, Lowell Center For Sustainable Production, University of Massachusetts, Lowell, MA 011854.

General Report on REACH, Report From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions, Brussels, 5.2.2013 COM(2013) 49 Final, European Commission.

Globally Harmonized System of Classification and Labelling of Chemicals, Fourth Revised Edition, UN, New York and Geneva, 2011.

Key Information for Down Stream Users, Safety Data Sheets and Exposure Scenarios, ECHA Factsheet, ECHA-12-FS-01-EN, Helsinki, Finland.

OECD Environmental Performance Reviews Turkey, OECD, Paris, ISBN 9789264049154, 2008.

Perroy, A., *Trust and Partnership: Towards A New Vision for Europe's Chemical Industry*, Cefic Review 2004 – 2005.

Reihlen A., Lüskow H., *Analysis of Studies Discussing Benefits of REACH*, Ökopol, February 2007.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93

and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, EN Official Journal of the European Union L 396/1 (30.12.2006).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC published on Official Journal of European Union, L 353/1 (31/12/2008).

Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, Celex number 02006R1013-20160101 and Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312,22.11.2008.

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, OJ L 158, 30.04.2004.

Report on penalties applicable for infringements on the provisions of the REACH Regulation in the Member States, European Commission, DG Environment, Milieu Environment&Law, March 2010.

Scientific Assessment of Ozone Depletion:2006, World Meteorological Global Ozone Research and Monitoring Project Report No.50, Executive Summary, UNEP, Geneva, 2006.

Selin H, VanDeveer SD. Politics of Trade and Environment in the European Union. In Handbook on Trade and the Environment, ed. K Gallagher, Edward Elgar Publishing, UK, 2008.

Seventh Report from the Commission to the Council and the European Parliament on the Statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union COM(2013)859/final, Brussels, 5/12/2013.

Strategic Approach to International Chemicals Management, SAICM texts and resolutions of the International Conference on Chemicals Management, UNEP, Geneva, March 2007.

Technical Assistance for Implementation of REACH Regulation, The Market Profile Analysis Report, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR.

Technical Assistance for Implementation of REACH Regulation, Cost-Benefit Analysis, HaskoningDHV Nederland, EuropeAid/129602/D/SER/TR.

The Impact of REACH on Human Health and the Environment, Report to DG Environment by DHI Water and Environment, ENV.C.3/SER/2004/0042r, Executive Summary, September 2005.

The Overview of 36 Studies on the Impact of the New EU Chemicals Policy (REACH) on Society and Business, Ecorys and Opdenkamp Adviesgroep, Workshop REACH Impact Assesment, 2004, Netherland.

The Strategy for Sustainable Development is the content of a Commission Communication of 15 May 2001 'A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development' COM(2001) 264 Final.

UNEP 2008 Annual Report, UNEP Division of Communications and Public Information, UNON, Publishing Section Services, Nairobi, 2009.

White Paper Strategy for a future Chemicals Policy, Brussels, 27.2.2001 COM(2001) 88 final.

1999/575/EC: Council Decision of 23 March 1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, Official Journal L 222, 24/08/1999.

Web Sources

http://www.oecd.org/env/country-reviews/environmentalperformancereviewsturkey2008.htm

https://www.joi.or.jp/modules/investment/custom/documents/TUR_EU_INTEGRATED_ENVIRONMENTAL_APPROXIMATION_STRATEGY.pdf

http://ec.europa.eu/enlargement/pdf/turkey/ipa/2008/tr080202_reach_chemicals_project-final_en.pdf

http://www.csb.gov.tr/gm/cygm/index.php?Sayfa=sayfa&Tur=webmenu&Id=422

http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/chemikalien/Impact_of_REACH.pdf

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF

http://ozone.unep.org/new_site/en/Treaties/treaties_decisions-hb.php?sec_id=2

http://chm.pops.int/Convention

http://www.basel.int/TheConvention/docs/text

http://www.opcw.org/chemical-weapons-convention/

http://www.worldsummit2002.org/

https://eurl-ecvam.jrc.ec.europa.eu/laboratories-research/predictive_toxicology/information-sources/ec_inventory

http://ecb.jrc.ec.europa.eu/elincs/

http://ecb.jrc.ec.europa.eu/esis/

www.europa.eu/legislation_summaries/environment/sustainable_development/l12817_en.htm

http://epp.eurostat.ec.europa.eu/portal/page/portal/sdi/indicators/theme1

https://reach-it.echa.europa.eu

http://guidance.echa.europa.eu/guidance_en.htm,

http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/presentat8-2003_11_21_en.pdf

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0859

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013SC0497

http://ec.europa.eu/environment/chemicals/lab_animals/3r/research_en.htm

http://ec.europa.eu/programmes/horizon2020

http://www.chemsec.org/what-we-do/sin-list/about-sin

http://www.etuc.org/trade-union-priority-list.

APPENDICES

APPENDIX A: THE LIST OF AMENDING OR IMPLEMENTING LEGISLATION OF THE REACH REGULATION

Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Commission Regulation (EC) No 134/2009 of 16 February 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XI.

Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII.

Commission Regulation (EU) No 276/2010 of 31 March 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds).

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (‘REACH’), and, related Corrigendum OJ L 49/52 of 24 February 2011.

Commission Regulation (EU) No 207/2011 of 2 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Diphenylether, pentabromo derivative and PFOS).

Commission Regulation (EU) No 252/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex I.

Commission Regulation (EU) No 253/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XIII.

Commission Regulation (EU) No 366/2011 of 14 April 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Acrylamide).

Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium), and, related Corrigendum OJ L 136/105 of 24 May 2011.

Commission Regulation (EU) No 109/2012 of 9 February 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances) amended Annex XVII of REACH in order to include a number of newly classified CMR substances in Appendices 1 to 6 so that they are aligned to the entries concerning CMR substances in Regulation (EC) No 790/2009 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH').

Commission Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (DMF).

Commission Regulation (EU) No 835/2012 of 18 September 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium).

Commission Regulation (EU) No 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead.

Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury.

Commission Regulation (EU) No 848/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards phenylmercury compounds.

Commission Regulation (EU) No 126/2013 of 13 February 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). (Technical amendment)

Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Council Regulation (EU) No 517/2013 of 13 May 2013 adapting certain regulations and decisions in the fields of free movement of goods, by reason of the accession of the Republic of Croatia. (the adaptations to REACH are on the page L 158/24).

Commission Regulation (EU) No 1272/2013 of 6 December 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons. Corrigendum: In German language version only, OJ L 109, page 49, 12.4.2014.

Commission Regulation (EU) No 301/2014 of 25 March 2014 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards chromium VI compounds.

Commission Regulation (EU) No 317/2014 of 27 March 2014 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances).

Implementing legislation

Commission Regulation (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency.

Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and, related Corrigendum OJ L 143/55 of 3 June 2008.

Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules on the organisation and procedure of the Board of Appeal of the European Chemicals Agency.

Commission Regulation (EC) No 761/2009 of 23 July 2009 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Decision 2010/226/EU of 20 April 2010 on the re-examination of the restriction concerning short-chain chlorinated paraffins (SCCPs) listed in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

Commission Regulation (EU) No 1152/2010 of 8 December 2010 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EU) No 640/2012 of 6 July 2012 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013 amending Regulation (EC) No 340/2008 on the fees and charges payable to the

European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EU) No 260/2014 of 24 January 2014 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EU) No 900/2014 of 15 July 2014 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Implementing Decision of 7 August 2014 granting an authorisation for a use of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council, OJ C260 of 9 August 2014.

Communication from the Commission pursuant to Article 67(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ C 130/03 of 9 June 2009.

Commission Implementing Decision of 14 October 2013 authorising the provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use of ammonium salts in cellulose wadding insulation materials.

APPENDIX B: THE LIST OF LEGISLATION REPEALED OR AMENDED BY THE REACH REGULATION

DIRECTIVE 2006/121/EC (Corrigendum, May 2007), Corrigendum to Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

DIRECTIVE 2006/121/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

DIRECTIVE 1999/45/EC of the EUROPEAN PARLIAMENT and of the COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

DIRECTIVE 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. [Annex I of Directive 67/548/EEC]

COUNCIL REGULATION (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances.

COMMISSION REGULATION (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No793/93.

COUNCIL DIRECTIVE 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.

COMMISSION DIRECTIVE 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC.

COMMISSION DIRECTIVE 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of subtances notified in accordance with Council Directive 67/548/EEC.

COMMISSION DIRECTIVE 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC.

COMMISSION DIRECTIVE 2000/21/EC of 25 April 2000 concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC.

REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

COMMISSION DIRECTIVE 2005/80/EC of 21 November 2005 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II and III thereto to technical progress.

APPENDIX C: REACH DEADLINES

Date	Activity
1 December 2008	End of Pre-registration for Substances
1 December 2010	End of registration period for substances in quantities ≥ 1,000 tonnes per year.
30 November 2010	End of registration period for substances classified as CMR in quantities ≥ 1 tonne per year.
30 November 2010	End of registration period for substances classified as very toxic to aquatic organisms in quantities ≥ 100 tonnes.
1 June 2013	End of registration for substances in quantities ≥ 100 tonnes per year.
1 June 2018	End of registration for substances in quantities ≥ 1 tonne per year.

APPENDIX D: TURKISH SUMMARY

Günümüzde en üst düzey çevresel standartları uygulamasına rağmen, Avrupa Birliği'nin çevre politikasına bakıldığında, kurucu anlaşmalarda çevreye ilişkin doğrudan bir referans olmadığı görülür. Çevre politikasının oluşturulması konusunda ilk ciddi adımlar 1973'te atılmış, 1986 Avrupa Nihai Senedi ile birlikte Roma Anlaşması'nda bir değişiklik yapılarak, çevre başlığı Anlaşmaya eklenmiştir. Müteakip Anlaşmalarla birlikte çevre konusunda karar alma süreçlerinde de değişiklikler yapılarak, çevresel hedeflerin ekonomik hedeflerle tam olarak eşit şartlara sahip olması sağlanmıştır. Ancak, çevresel düzenlemeler ticari ve mali hedefleri de doğrudan etkilediğinden, Avrupa Komisyonundaki ilgili birimler bu konuda bir karar alırken koordineli bir biçimde hareket etmektedir.

Bu bağlamda, Avrupa Komisyonunda başta Çevre Komisyonu olmak üzere, Ticaret, Rekabet, Sağlık Komisyonu gibi ilgili tüm Komisyonların katkılarıyla nihai şekli verilen ve Avrupa Birliği'nin Yeni Kimyasallar Politikasının temelini teşkil eden REACH Tüzüğü 1 Haziran 2007'de yayımlanarak yürürlüğe girmiştir. Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanmasına İlişkin bu Tüzük adından da anlaşılacağı üzere kimyasalların tabi tutulacağı süreçleri düzenlemektedir. 800 sayfayı aşan REACH Tüzüğü, düzeltme ve değişiklik mevzuatı ve ilgili içtihat kararları ile birlikte AB'nin son dönemde dış dünyada özellikle Dünya Ticaret Örgütü (DTÖ) nezdinde en fazla ses getiren mevzuatı olmuştur. 40'tan fazla Tüzük ve Direktifi değiştiren ya da yürürlükten kaldıran REACH Tüzüğü oldukça bürokratik yeni süreçler içermesi ve kompleks bir mevzuat olması nedeniyle şiddetle eleştirilmiştir. Oldukça uzun süren bir mevzuat hazırlama ve görüş alma sürecinin ardından hazırlanan Tüzüğün temel hedefleri çevresel ve ekonomik hedefler olarak iki başlık altında toplanmaktadır. Bu hedeflere değinmeden önce, AB'yi böyle kapsamlı ve karmaşık bir mevzuat hazırlamaya iten süreçlere bakmakta fayda bulunmaktadır.

REACH öncesi Avrupa Birliği'nin kimyasallar politikası pekçok Tüzük ve Direktif çerçevesinde yürütülmekte ve 1960'lı yıllara dayanan bazı eski mevzuata yapılan teknik değişikliğe adaptasyon (ATP) çalışmaları ve diğer değişiklik düzenlemeleri de göz önünde bulundurulduğunda, bir kimyasal üreticisi tarafından sorumluluk ve görevlerin neler olduğunun anlaşılması konusunda ciddi sorun yaşanmaktaydı. Ayrıca sözkonusu toplama mevzuatın uygulanması konusunda hangi kurum ve otoritelerin yetkili olacağı konusunda da üye ülkeler arasında farklı uygulamalar mevcut olduğundan, idari yaptırım ve denetimler de değişiklik göstermekteydi. Bir diğer önemli konu, 1981'de ilgili mevzuatta yapılan bir değişiklikle, bu tarihten sonra piyasaya sunulan bütün 'yeni kimyasallar'ın ELINCS adlı bir envanterde yer alması ve bu kimyasalların ciddi bir test ve değerlendirme sürecine tabi tutulması, ancak bu tarihten önce piyasada olan 'mevcut kimyasallar'a ilişkin böyle bir düzenleme yapılmamış olmasıydı. Yaklaşık 100.000'den fazla kimyasalı içeren mevcut kimyasallar EINECS adlı bir envanter kaydında yer almakta, bu kimyasallara ilişkin herhangi bir test veya değerlendirme yapılmamaktaydı. REACH Tüzüğü ile denetim dışında olan mevcut kimyasalların kaydı bir zorunluluk haline getirilerek, sözkonusu sorunun aşılması hedeflenmiştir.

Öte yandan, eski sistemde ELINCS kimyasalları olarak bilinen yeni kimyasalların pahalı ve oldukça kapsamlı test prosedürlerine tabi tutulması inovasyon yolunda oldukça büyük bir engel teşkil etmekteydi. 10 kg'ı aşan her kimyasalın teste tabi tutulması ve miktar arttıkça daha detaylı test prosedürlerinin yapılma zorunluluğu ve ArGe amaçlı kimyasallara herhangi bir istisna tanınmaması Avrupa Birliği'nin kimyasallar alanındaki inovasyon faaliyetlerinin rakipleri ABD, Çin ve Japonya'dan geri kalmasına sebep olmuştur.

Ayrıca, REACH öncesi sistemde üretilen, ithal edilen veya piyasaya arz edilen bir kimyasalın risk değerlendirmesini yapmak kamu kurumlarının görev alanında yer almaktaydı. Piyasada bir kimyasal maddenin yarattığı herhangi bir sorun tespit edilirse, piyasadan toplatma, geri çağırma, zararı tazmin etme vb gibi tedbirler kamu otoriteleri tarafından alınmak durumundaydı. Bu konuda üretici, ithalatçı ve ara

kullanıcılarının, sözkonusu ürün tehlikeli bir kimyasal olarak sınıflandırılmadığı müddetçe yasal bir sorumluluğu bulunmamaktaydı.

Ayrıca, AB'nin sürdürülebilir kalkınma hedefleri ve Birleşmiş Milletler Çevre Programı (UNEP) kapsamındaki taahhütleri de rekabetçi, ekolojik açıdan etkili ve yenilikçi bir mevzuatın hazırlanması sürecini hızlandırdı.

Sözkonusu sorunları giderme adına hazırlanan REACH Tüzüğü kapsamında, komiteleri, görev ve yetkileri tanımlanan Avrupa Kimyasallar Ajansı(AKA) kurulmuş, veri tabanının işletilmesi ve kayıt dosyalarının kabul edilmesi konusunda yetkilendirilmiştir. Buna ilaveten Tüzükte yetkili otoriteler tanımlanmış ve görevleri belirlenmiş olup, her ülkenin bağımsız olarak belirlediği yetkili otoritenin AKA ile koordinasyon içinde çalışması hedeflenmiştir.

REACH Tüzüğünün araçlarına bakılacak olursa kayıt, değerlendirme, izin ve kısıtlama olarak dört temel enstrüman karşımıza çıkmaktadır. *Kayıt,* kısaca 1 tonu aşan mevcut kimyasallara ilişkin temel bilgilerin REACH veritabanına kaydedilmesi işlemidir. Tonaj bandı ve tehlike kategorisine göre değişen kademeli bir süreç olan kayıt işlemi, 1 ton ile 100 ton arasındaki kimyasallar için 2018'de tamamlanacaktır. Şimdiye kadar gerçekleşen ve 2010 ve 2013'te sonlanan iki kayıt sürecinde sırasıyla 100-1000 ton arası ve 1000 ton üzeri kimyasallar ile tonaj bandından bağımsız tehlikeli kimyasalların kayıt işlemleri tamamlanmıştır. REACH veritabanına yüklenecek kayıt dosyasının içeriğinde yer alacak testler ve ilave belgeler kimyasalın tonajına ve tehlike arz edip etmediğinde göre değişiklik göstermektedir. Bu bağlamda, 100 tonu aşan ve/veya tehlike arz eden kimyasalların gözden geçirildiği aşama *değerlendirme* aşaması olup dosya değerlendirilmesi ve kimyasal madde değerlendirilmesi olarak iki başlıkta yürütülmektedir. Bu aşamada, yüksek tonajlı ve tehlikeli kimyasallar çevre ve insan sağlığı açısından daha ciddi riskler oluşturduğu düşüncesinden hareketle, daha geniş kapsamlı test prosedürleri gerekmekte ve uygunluk kontrolleri bu minvalde yapılmaktadır.

İzin aşamasında ise piyasadaki tehlikeli kimyasalların kontrol edilmesi ve ekonomik ve teknik açıdan daha uygun alternatifleri ile değiştirilmesi amaçlanmaktadır. Bu süreçte; kalıcı, biyobirikimli ve toksik (PBT), çok kalıcı, çok biyobirikimli (vPvB) ve kanserojen, mutajen ve üreme için toksik (CMR) kriterlerini karşılayan kimyasallar da dahil olmak üzere, tehlikeli kategorisinde bulunan kimyasallara Yüksek Önem Arz Eden Madde (SVHC) adı verilmektedir. Sözkonusu SVHC kategorisine giren kimyasallar, SVHC Aday Liste'de yayımlanmakta ve bir süre sonra REACH Tüzüğü'nün EK-14'ünde yer alan İzne Tabi Kimyasallar Listesine taşınarak, izin sürecine tabi tutulmaktadır.

Kısıtlama, kimyasalların insan sağlığı ve çevre üzerinde yarattığı risklerin azaltılması veya bertaraf edilmesi için bir maddenin tamamen veya kısmen kullanımının yasaklanmasına yönelik bir araçtır. REACH öncesi sistemde de kısıtlama uygulaması Kısıtlamalar Direktifleri aracılığıyla yapılmakta olup, sözkonusu Direktiflerin ekinde yer alan kimyasallar REACH Tüzüğü'nün Kısıtlamalar Listesi'ni içeren Ek-17'sine dercedilmiştir. Kullanım alanlarına göre Ek-17'nin Kısıtlamalar Listesine yeni kimyasal maddeler, müstahzarlar ve eşyalar eklenmektedir.

Pekçok çevresel problem ve sağlık sorunları tehlikeli kimyasalların üretimi, kullanımı veya bertaraf edilmesi aşamasında ortaya çıkmaktadır. REACH Tüzüğü ile kimyasalların kayıt altına alınarak test prosedürlerine tabi tutulması ve tehlikeli kimyasalların kısıtlama veya yasaklamaya tabi tutularak veya daha güvenilir alternatiflerle değiştirilmesi sağlanarak bu olumsuz etkilerin azaltılması amaçlanmaktadır. Bu kapsamda Tüzüğün araçlarının ne kadar başarılı işlediğini göstermek üzere, Komisyon, AKA, denetim ve danışmanlık firmaları ile bazı kar amacı gütmeyen kuruluşlar (NGO) tarafından durum değerlendirme raporları hazırlanmakta ve etki analizleri yapılmaktadır. Bu bağlamda mevcut tez çalışmasında, Tüzüğün çevre ve insan sağlığına yönelik beklenen hedefler açısından etkilerinin kapsamlı bir şekilde yapılabilmesi için sözkonusu analiz ve raporlardan, sanayi raporlarından, AKA tarafından yayımlanan rapor ve bildirimlerden faydalanılmış ve niteliksel ve niceliksel bu çalışmalara ilaveten daha erişilebilir

bilgilerden (yasaklanan, kısıtlanan kimyasal madde sayısı, veri paylaşım oranları, laboratuar hayvanı kullanım oranındaki azalma) de yola çıkılarak kapsamlı bir değerlendirme yapılması amaçlanmıştır.

Bu bağlamda, Avrupa Komisyonu tarafından REACH Tüzüğü taslak aşamasındayken yapılan kapsamlı etki analiz çalışmasına göre; özellikle tehlikeli kimyasallara maruz kalan işçilerin korunması yoluyla iş sağlığının iyileştirilmesi kapsamında, Tüzüğün sağlık açısından faydası, 30 yıllık süreçte 50 milyar Avro olarak öngörülmüştür. Solunum ve mesane kanserleri, astım, cilt bozuklukları, göz problemleri gibi kimyasal kaynaklı sağlık sorunlarının azaltılması ve iş kazaları ve yaralanmaların bu bağlamda giderilmesi hedeflenmiştir. Avrupa Komisyonu tarafından görevlendirilen danışmanlık firmalarınca, kaza sayıları, yaralanma, sakatlanma, ölüm oranları ve bunların yıllık maliyetlerinin hesaplanması konusunda DALY, QALY ve WTP methotları kullanılarak hesaplamalar yapılmıştır. Bu çalışmalarda maliyet hesaplamalarında ise, sağlık hizmeti maliyetleri, üretim kaybı maliyeti ve sağlıklı yaşam kalitesinde oluşan azalmalar maliyet hesabında gözönünde bulundurulmuştur.

Çevresel açıdan bakılacak olursa, kimyasalların verdiği zarar maruziyet, toksik profil, kalıcı ve doğada biyobirikimli olma kriterleri bakımından değerlendirilebilir. Sözkonusu çalışmalar kapsamında yapılan değerlendirmelerde sucul ortamlarda toksisite, doğada parçalanma, dağılma açısından kimyasalın davranışı ve sucul ve karasal canlıların üzerindeki toksik etkiler irdelenmiştir. Yine Komisyon tarafından görevlendirilen başka bir firma tarafından yapılan çalışmada, kirlenmiş suyun, tortunun ve çamurun temizlenmesi, bu kapsamda temiz deniz ürünlerinin elde edilmesi ve içme suyunun iyileştirilmesi temel kriterler olarak belirlenmiştir. Bu kapsamında 2017 itibarıyla 150-500 milyon Avro, 2017-2041 arasında ise 2,8-9 milyar Avroluk bir tasarruf elde edilmesi öngörülmüştür. Yapılan bir çalışmaya göre tüm kimyasalların %70'inden fazlası bir ya da daha fazla tehlikeli madde içermekte ve kimyasalların yarısından fazlası hakkında ya hiçbir bilgi bulunmamakta ya da oldukça eksik bilgi bulunmaktadır. REACH Tüzüğü sayesinde 6.683 kimyasal

madde hakkında yeni bilgiler elde edilebilecek bu bağlamda tehlike sınıflandırması değişebilecektir. Öte yandan 717 iyi bilinen kimyasal ile 4.108 hakkında yetersiz bilgiye sahip olunan kimyasalın da tehlike sınıflandırmasının değişmesi beklenmektedir. Sınıflandırması ve tehlike kategorisi değişen bu kimyasallar sayesinde, güvenli kullanım imkanları artacak ve yeni risk yönetim tedbirleri alınabilecektir.

Bu çalışma kapsamında erişilebilir verilerden yola çıkılarak yapılan değerlendirmede, mevcut kimyasallara ilişkin bilgi eksikliğinin giderilmesi konusu ele alınmıştır. Daha önce de bahsedildiği gibi 1981'den itibaren piyasaya arz edilen yeni kimyasalların tabi tutulduğu sistematik test prosedürlerinden mahrum bırakılan mevcut kimyasalların kayıt altına alınması ile bu bilgi boşluğu ortadan kaldırılacaktır. İlk kayıt dönemi bitiş yılı olan 2010 itibarıyla 24.675 kayıt dosyası kapsamında 4.300 kimyasal madde kayıt altına alınmış, ikinci dönem bitiş yılı olan 2013 itibarıyla da 38.711 dosya kapsamında 8.729 kimyasal maddenin kaydı gerçekleşmiştir. Son kayıt yılı olan 2018'de, 1 ila 100 ton arasında yer alan ve hacim ve kimyasal madde sayısı açısından en ciddi kayıt dönemi olan yaklaşık 30.000 kimyasal maddenin kaydının yapılması beklenmektedir. Daha önce de bahsedildiği gibi, 1981 itibarıyla mevcut kimyasalların sayısının 100.000 olduğu öngörülmekle birlikte bu sayının bazı kimyasalların kullanımdan kalkması veya daha uygun ve ucuz alternatiflerinin bulunması nedeniyle üretilmemesi gibi gerekçelerle, kayıt süreci sonunda kayıt altına alınan kimyasalların toplam sayısının 50 bini geçmeyeceği tahmin edilmektedir.

REACH Tüzüğü'nün omurgasını oluşturduğu Yeni Kimyasallar Politikasının '*veri yoksa pazar yok*' mottosu kapsamında, eski sistemde kayıt altında bulunmayan ve hakkında ciddi veri eksikliği olan kimyasalara ilişkin bir veri tabanının oluşturulması hedeflenmektedir. Bu kapsamda 1 kg'ı aşan her kimyasal maddeye kayıt aşamasında gerekli bilgileri gösterir bir veri seti eşlik etmek durumundadır. Kimyasal maddenin tonajı arttıkça veya tehlikeli madde kategorisinde yer alması halinde istenen bilgi ve belgelerin sayısı artmaktadır. Tüzüğün 7, 8, 9 ve 10 nolu Eklerinde tonaj bandına

göre değişen kimyasallar için istenen fizikokimyasal özellikler, toksisiste, ekotoksisite, doğada yaratacağı olumsuz etkiler ve risk yönetim tedbirleri gibi bilgilere yer verilmektedir. Öte yandan tedarik zincirinde bir kimyasalın tehlike ve risk bildirimi için en temel iletişim aracı olan güvenlik veri formlarında da (SDS) iyileştirmeye gidilmiştir. Güvenlik veri formlarına maruziyet senaryoları da eklenerek geliştirilmiş güvenlik veri formları (e-SDS) oluşturulmuş, böylece risk yönetimi konusunda tedarikçiden nihai tüketiciye kadar bilgilendirme düzeyinin artması hedeflenmiştir.

REACH öncesi sistemde kamu otoritelerinin sorumluluğunda olan ispat yükümlülüğü, REACH sisteminde kimyasalı üreten, kullanan veya piyasaya arz eden gerçek veya tüzel kişilerin sorumluluğuna verilmiştir. Bu itibarla, bir kimyasalın yaratacağı riskler, bu risklerin önlenmesi için gerekli bildirimlerin yapılması ve tedbirlerin alınmasından, alt kullanıcılara gerekli bilgilerin iletilmesinden sözkonusu gerçek veya tüzel kişiler sorumlu bulunmaktadır.

Tüzüğün bir diğer önemli hedefi hayvan testlerinin azaltılması kapsamında veri paylaşımının arttırılmasının sağlanması ve kimyasal testlerinde laboratuar hayvanı kullanımının azaltılmasıdır. Bu kapsamda, hayvan testlerine son çare olarak başvurulması, mümkünse vücut içinde yapılan *invaziv* testler yerine doku ve hücreler üzerinde yapılan *invitro* testlerin kullanılmasının önemi vurgulanmaktadır. Ayrıca, gereksiz testlerden kaçınılmasını teminen kimyasalların benzerleriyle kıyaslanması, gruplandırılması ve insanların maruziyeti sınırlı ise hayvan testlerine başvurulmaması bir diğer hedeftir. Hayvan testlerinden veya gereksiz testlerden kaçınılmasını teminen veri paylaşımı zorunlu kılınmakta, bu bağlamda Madde Bilgi Değişim Forumlarında (SIEFs) veri sahipleri ile irtibata geçilerek o kimyasala ilişkin daha önce yapılan test dosyalarının ortaklaşa kullanımı hedeflenmektedir. AKA'nın üç yılda bir hazırladığı *REACH Tüzüğü Kapsamında Hayvan Testlerine Alternatif Test Raporları* incelendiğinde, 2013'te biten ikinci kayıt dönemi sonunda aynı test dosyasının kullanıldığı 8.317 ortak kayıt dosyasının Ajansa sunulduğu tespit edilmektedir. Yapılan kayıtlarda cilt ve göz tahrişine yönelik dosyaların % 60'ında

yeni test yaptırmak yerine, mevcut test verilerinin kullanıldığı, ayrıca kayıt dosyalarının % 20'sinde invaziv testler yerine, invitro testlerin tercih edildiği görülmektedir.

Öte yandan Avrupa Komisyonu'nun laboratuar hayvanlarının kullanımına yönelik istatistiklerini içeren raporu ve çalışma dokümanı incelendiğinde 2008 ile kıyaslandığında, 2011 yılında kullanılan laboratuar hayvanı sayısının 12 milyondan 11,5 milyona düştüğü (iki yeni üyenin katılımına rağmen) tespit edilmektedir. Testlerde kullanılan laboratuar hayvanı sayısında ciddi azalmalar olduğu, büyük maymunların ise testlerde kullanılmadığı gözlemlenmektedir. Buna ilaveten, hayvan testlerinin azaltılması ve testlerde hayvan kullanılmamasına yönelik ArGe çalışmaları AB tarafından ciddi biçimde desteklenmektedir. Bu bağlamda 7. Çerçeve Programı kapsamında 200 milyon Avronun hayvanların kullanılmadığı toksikolojik testlerin desteklenmesi için tahsis edildiği görülmektedir.

Bir kimyasalın çevre ve insan sağlığına yönelik olumsuz toksisite problemleri ile başa çıkmaya çalışmaktansa, bu sorunları kaynağında yok etmek daha etkin bir yöntemdir. Bu kapsamda REACH Tüzüğü'nün izin ve kısıtlama prosedürleri kapsamında tehlikeli kimyasalların kısmen veya tamamen yasaklanması, tehlikeli olanların daha güvenli alternatiflerle değiştirilmesi, böylece yaratacağı olumsuz etkilerin ortadan kaldırılması hedeflenmektedir. İzin süreci kapsamında Ek-14'e taşınması beklenen Yüksek Önem Arz Eden Maddelerin yer aldığı Aday Liste kapsamında yer alan 195 maddeye 8 yeni madde eklenmiştir. Ancak çevresel pekçok NGO tarafından hazırlanan tehlikeli kimyasallar listeleri ile kıyaslandığında bu sayının çok yetersiz olduğu ve SVHC'lerin Aday Listeye ve buradan Ek-14'e taşınması sürecinin oldukça yavaş işlediği ve yeterince etkin olmadığı görülmektedir. Öte yandan, kullanım alanı itibarıyla veya tamamen kısıtlanan, yasaklanan kimyasalların yer aldığı Ek-17'ye 521 kimyasalın eklendiği tespit edilmiştir.

Etki analizi çalışmaları kapsamında, sağlık ve çevresel etkilerin uygulamadan itibaren 30 yıllık bir süreçte tam olarak ortaya çıkacağı öngörülmektedir. Zira

kademeli kayıt süreci henüz tamamlanmamış olup, 2018'de son kayıt döneminde en fazla kayıt dosyasının sunulması beklendiğinden, bu kayıt sürecini müteakip analiz çalışmaları biraz daha netleşecektir. Ancak sağlık ve çevresel hedeflerin etkileri uzun vadede ortaya çıktığından, kayıt sürecinin tamamlanmasının hemen ardından bu konuda bir netleşme sağlanamayacaktır. Ayrıca üye ülkelerin REACH uygulamaları konusunda yeknesak hareket etmeleri sağlanmış olsa bile uygulanan cezai yaptırımlar konusunda ciddi farklılıklar olduğu görülmektedir.

Türkiye konusuna gelecek olursak, Türkiye'nin AB ile ilişkilerinin tamamen ekonomik temele dayanan Gümrük Birliği ve siyasi kıstaslarla hareket edilen AB üyeliği gibi iç dinamikleri farklı iki süreç altında yürüdüğünü görmekteyiz. Türkiye'nin 1959'da Avrupa Ekonomik Topluluğu'na (AET) yaptığı başvurunun ardından başlayan Gümrük Birliği 1 Ocak 1996'dan itibaren tamamen işlevsel hale gelmiş ve Türkiye Ortak Pazarın bir parçası olmuştur. Ortak Pazarın üyeleri arasında malların serbest dolaşımının sorunsuz bir şekilde sağlanmasını teminen teknik mevzuattan kaynaklı engellerin de ortadan kaldırılması hedeflenmiştir. Bu bağlamda 2/97 sayılı Ortaklık Konseyi Kararı (OKK) ile Türkiye'nin uyumlaştırmakla yükümlü olduğu teknik mevzuat listesi belirlenmiştir. REACH Tüzüğü 2007 yılında yürürlüğe giren bir mevzuat olması nedeniyle sözkonusu listede yer almamaktadır. Ancak Tüzüğün yürürlükten kaldırdığı mevzuat 2/97 sayılı OKK ekinde yer aldığından ve REACH Tüzüğü bu mevzuatın doğal uzantısı olduğundan Gümrük Birliği kapsamında Türkiye'nin bu mevzuatı da uyumlaştırma yükümlülüğü bulunmaktadır.

Öte yandan, devam eden Gümrük Birliği sürecine ilaveten Türkiye AET'ye 1987'de tam üye olmak için başvurmuştur. Bu tarihten sonra, 1990'lar ve 2000'lerin başında pekçok üyenin kabul edildiği genişleme dalgalarında dışarıda bırakılsa da, 1999 Helsinki Zirvesinde Türkiye'ye adaylık statüsü verilmiştir. Eski genişleme dalgalarında, AB, üyelik için çok fazla talepkar olmamasına rağmen 1993 Kopenhag Zirvesinin ardından Birliğe katılım için ciddi katılım kriterleri ortaya koymuştur. Demokratik kurumlara sahip olunması, işleyen bir market ekonomisi ve AB

müktesebatını uyumlaştırabilme kapasitesi, üye olmak isteyen adaylarca karşılanması gereken temel kriterlerdir. Bu kapsamda, aday ülkelerce müktesebat uyumlaştırması yapılmasını teminen AB mevzuatı fasıllara bölünmüş ve her fasılda müzakerelerin tamamlanması ve tüm fasılların kapatılması hususu üyelik yolunda ön koşul olarak belirlenmiştir.

2004 yılında, Türkiye ile üyelik müzakerelerinin başlamasının ardından '*Müzakere Çerçeve Dokümanı'* kabul edilmiş ve Türkiye'ye AB müktesebatını tamamen uyumlaştırma görevi verilmiştir. Bu bağlamda, Çevre Faslına ilişkin tarama süreci Haziran 2006'da tamamlanmış ve REACH Tüzüğünü uyumlaştırma zorunluluğu yine Türkiye'nin gündemine gelmiştir. 2008 yılında sunulan Strateji Dokümanı ile REACH mevzuatını uyumlaştırma takvimi Türkiye tarafından AB'ye iletilmiştir. Özetle, Türkiye'nin REACH Tüzüğünü gerek Gümrük Birliği gerekse üyelik süreci kapsamında uyumlaştırma zorunluluğu bulunmaktadır. Tüzüğün uyumlaştırılmasını teminen, Katılım Öncesi Yardım (IPA) bileşeni altında Türkiye bir teknik yardım projesi yürütmektedir. 2011 yılında başlayan Proje, 2014 yılında tamamlanmış olup, hazırlanan taslak REACH Yönetmeliği'nin kısa vadede görüşe açılması beklenmektedir.

REACH Tüzüğünün uyumlaştırılarak uygulamaya başlanması halinde, Türkiye'ye olası çevresel ve sağlık etkileri kapsamında kullanılacak metodoloji açısından bakıldığında, AB kısmında bahsedilen enstrümanların tamamı Türkiye kısmında da kullanılmıştır.

Kısıtlama konusunda yapılan analizde, mevcut yasaklı ya da kısıtlı kimyasallar ile REACH İzin ve Kısıtlama Listeleri mukayese edilerek, Türkiye'nin REACH öncesi ve sonrası tehlikeli kimyasallar tablosu ortaya çıkarılmıştır. Yapılan kimyasal madde analizinde, Çevre ve Şehircilik Bakanlığı'nın hazırladığı kimyasallar envanterinde 6.077 madde tespit edilmiştir. Ancak sözkonusu çalışmanın, 2018'de REACH Tüzüğünün son kayıt döneminin tamamlanmasının ardından daha netleşmesi beklenmektedir.

Diğer taraftan, Çevre ve Şehircilik Bakanlığı tarafından yürütülen teknik projenin bir bileşeni olarak yapılan fayda maliyet analizi kapsamında, yapılan tahminler VOSL ve VOLY metodları kullanılarak parasal olarak ifade edilebilmiştir. Uluslararası Çalışma Örgütü'nün verilerine göre her yıl 160 milyondan fazla kişi iş kazasına veya hastalığına maruz kalmakta ve bunların % 25'i doğrudan veya dolaylı olarak kimyasallara maruziyet sonucu ortaya çıkmaktadır. Bu rakamların Türkiye'ye uyarlanmasıyla, iş kazaları ve hastalıklarında % 35-50 oranında bir azalma beklenmektedir. Türkiye'deki kanser vakaları ve bunların ekonomiye olan maliyeti göz önünde bulundurularak yapılan tahminlerde ise, REACH Tüzüğünün uygulamaya girmesiyle birlikte 24 milyon Avro ile 48 milyon Avro arasında bir maliyet azalması beklenmektedir. Üretim kayıplarını da dikkate alarak yapılan tahminlemelerde ise, kimyasallardan kaynaklanan kanser türlerinin yarattığı üretim kaybının maliyetinin yaklaşık 18 milyon Avro civarında olduğu tespit edilmiştir. REACH Tüzüğünün uygulamaya konması ile birlikte bu maliyetlerde 6 milyon ile 12 milyon civarında bir azalma beklenmektedir.

Çevresel faydalar konusunda ise, öncelikle kimyasal emisyonlarının azaltılması ile oransal olarak düşmesi beklenen çevre temizlik maliyetleri ele alınmıştır. Kamu kurumlarının ve ilgili taşra teşkilatının çevre harcamalarının yaklaşık 1,5 milyar TL civarında olduğu tahmin edilmekte ve Tüzüğün bu harcamalarda 500 milyon ile yaklaşık 1 milyar TL arasında bir azalma sağlaması beklenmektedir. Çevresel faydaların gecikmeli olarak ortaya çıkacağı hususu göz önünde bulundurulduğunda, 30 yıllık bir süreçte, 5 ile 10 milyar Avroluk bir fayda sağlanması öngörülmektedir. REACH Tüzüğü'nün uygulanmaya başlamasıyla birlikte oluşacak maliyetler ile faydalar kıyaslandığında, elde edilecek faydanın iyimser ve karamsar senaryorların her ikisinde de maliyetlerin oldukça üzerinde olduğu görülmektedir.

REACH Tüzüğü kapsamında yasaklama ve kısıtlamalar konusunda yavaş hareket edilmesi, bu konuda sanayinin görüşlerinin daha çok dikkate alınıyor olması uygulamaya dair en büyük haklı eleştiri noktalarından birisidir. Ayrıca REACH

öncesi dağınık olan çok başlı kimyasallar mevzuatının tek bir çatı altında toplanmaya çalışılması olumlu gibi gözükse de, özellikle KOBİ'ler açısından görev ve sorumluluklarının tespiti ve anlaşılması oldukça zor, teknik ve bürokratik bir düzenleme olduğu aşikardır. Üye ülkelerce REACH kapsamında yürütülen denetimlerde uygulanacak ceza ve yaptırımların ciddi farklılıklar göstermesi, uygulamada yeknesaklığın ve başarının yakalanması yönünde bir diğer ciddi eleştiri noktası olarak ortaya çıkmaktadır. SIEF'lerde veri paylaşımı ve Ajansa kayıt dosyası sunumu konusunda iş dünyasının ticari sırların ortaya çıkmasına dair korkularının da haklılık payı bulunmaktadır. Bu açıdan REACH Tüzüğü, çevresel hedeflerden ziyade ekonomik saiklerle hazırlanan bir mevzuat olarak ciddi eleştiriye tabi tutulsa da, pozitif ve negatif dışsallıklara oldukça açık olan çevre konusunda ciddi araçlar ortaya koyması bakımından dikkate değerdir. Özellikle Türkiye bakımından sözkonusu araçların etkin biçimde kullanılmasını teminen gerekli kapasite inşası ve idari altyapının oluşmasını müteakip ciddi çevresel faydalar elde edileceği görülmektedir. Bu bağlamda Tüzüğün uzun vadede, çevre ve insan sağlığı bakımından öngörülenden daha fazla fayda sağlayacağı şüphesizdir.

APPENDIX E: TEZ FOTOKOPİSİ İZİN FORMU

ENSTİTÜ

Fen Bilimleri Enstitüsü ☐

Sosyal Bilimler Enstitüsü ☒

Uygulamalı Matematik Enstitüsü ☐

Enformatik Enstitüsü ☐

Deniz Bilimleri Enstitüsü ☐

YAZARIN

Soyadı: BACAKOĞLU
Adı: Zeliha
Bölümü: Avrupa Çalışmaları

TEZİN ADI (İngilizce) : The New Chemicals Policy of the EU and Its Environmental Implications on the EU and Turkey

TEZİN TÜRÜ : Yüksek Lisans ☒ Doktora ☐

1. Tezimin tamamından kaynak gösterilmek şartıyla fotokopi alınabilir. ☐
2. Tezimin içindekiler sayfası, özet, indeks sayfalarından ve/veya bir bölümünden kaynak gösterilmek şartıyla fotokopi alınabilir. ☐
3. Tezimden bir (1) yıl süreyle fotokopi alınamaz. ☒

TEZİN KÜTÜPHANEYE TESLİM TARİHİ: