

## **European Union's REACH Proposal: Chemical Regulations and International Economics**

**Natalia H. Gapinski**

University of Pittsburgh, Pittsburgh, Pennsylvania, USA, [nhg3@pitt.edu](mailto:nhg3@pitt.edu)

**Andrzej J. Gapinski, PhD**

Penn State University-Fayette, Uniontown, Pennsylvania, USA, [ajg2@psu.edu](mailto:ajg2@psu.edu)

**Ewa A. Rudnicka, MS**

University of Pittsburgh at Greensburg, Greensburg, Pennsylvania, USA, [rudnicka@pitt.edu](mailto:rudnicka@pitt.edu)

### **Abstract**

The process of regulation of chemicals, in Europe, started in the 1960s and 1970s. The standards were set for European nations to, ultimately, break down trade barriers. The regulation system set up a harmonized classification system, which included standards for labeling and packaging of hazardous substances. The paper discusses the new European Union's REACH (Registration, Evaluation, and Authorization of Chemicals) proposal, which proposes a new system designed to unify the regulatory structure for chemicals manufactured and imported in the EU market. Also, EU's impact on global economics is investigated.

### **Keywords**

Chemicals, regulation, European Union.

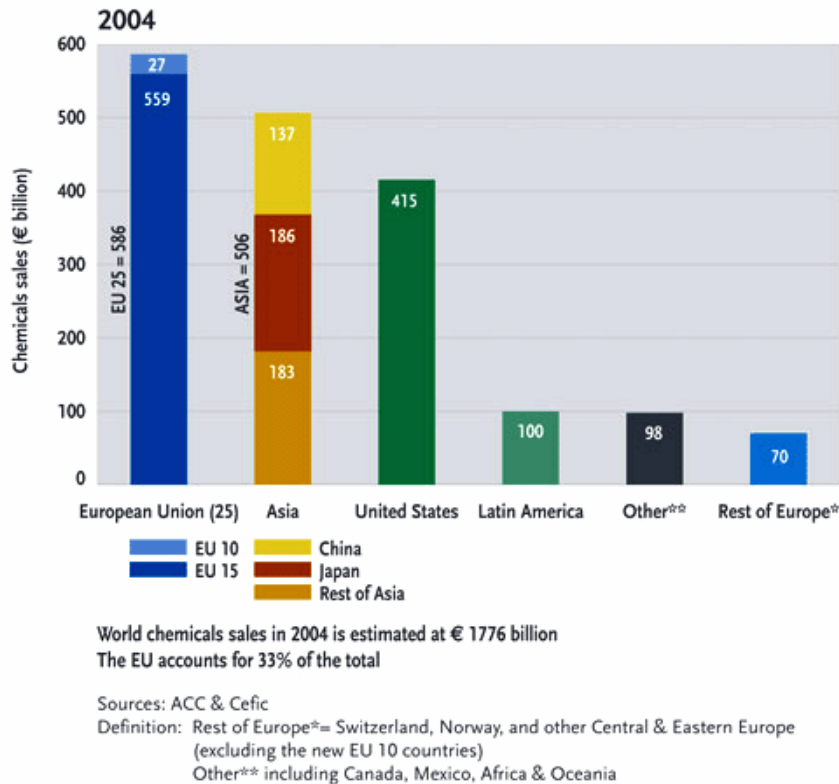
### **1. Introduction: Nice Smell Turns Smelly**

No one ever complains about the 'new car' smell; most even enjoy it. What many people do not know is that it is very harmful. The chemicals that produce the smell come from volatile organic compounds and can cause headaches, sore throats, nausea, drowsiness, and lengthened exposure to high concentrations can lead to cancer (Griemel, 2005).

Leading studies are now showing the hazardous effects of chemicals, "70% of the new products, subject to preliminary tests, have been classed as 'dangerous'" (Tanuro, 2005). Why have the chemical substances not been tested before coming out on to the market? REACH (Regulation, Evaluation, and Authorization of Chemicals), a new European Commission accepted proposal begins to tackle the problems associated with the current chemical manufacturing and importation regulations in Europe. If REACH is accepted by European member states, it will alter the global chemical industry structure, thus affecting trade relations with the US.

## 1.1 Overview of Chemical Industry

Chemical substances are at the top of the manufacturing supply chain and can be found in food, clothes, electronics, cars, healthcare and just about anything else that is manufactured. Historically, chemical substance production has been concentrated in Western Europe, United States, and Japan, also known as 'the triad' ("World: Chemicals Industry...", 2002). The EU is the world's largest producer, with 31% of the world market. See figure 1 below.



**Figure 1: World Chemical Sales ("Fact and Figures," 2005)**

Currently, the triad with its dominance in chemicals production is facing issues concerning the labor costs, utility costs, economic growth rates, feedstock availability and price, and currency exchange rates. Countries with lower production costs outside triad, such as Nigeria, Trinidad, Thailand, Brazil, and Venezuela are starting to benefit economically in the global market ("World: Chemicals Industry...", 2002).

Significant changes in the industry structure should not be dramatic. For the low production cost nations regulatory standardization will pose a significant threat in garnering foreign direct investment (FDI), which currently goes predominantly to the developed nations. What has changed the industry structure is the increase in input costs, which led to an increase of mergers and acquisitions of large chemical producers - Glaxo Wellcome with Smith Kline Beecham and Texaco with Chevron are just two of many recent cases ("World: Chemicals Industry...", 2002).

## 2. Current EU Regulation

Chemical regulation in Europe started in the 1960s and 1970s when regulation was developed to set standards across European nations to ultimately break down trade barriers. This system set up a

harmonized classification system, which included description, labeling, and packaging of hazardous substances (“New Chemicals policy in the EU ...,” 2003).

As people became more and more conscious of health and environmental concerns, stricter chemical regulations followed. In the 1980s a new policy, “Existing Substances Programme,” was made to include the risk assessment of chemical substances. The two parallel systems were created; the first stipulated that substances marketed before 1981 do not necessitate risk assessment or data collection (100,106 substances). The second one stipulates that substances marketed after 1981 are required to have a risk assessment and data collected, approximately 3,000 substances (“REACH in brief,” 2004).

Since 1981, there have been no further major changes in the regulation of chemical substance manufacturing or importation.

Recent EU enlargement with new member states created new impetus for standardization across Europe but also created “enlargement fatigue,” as mentioned by Jose Manuel Barroso, European Commission President during his last visit to Pittsburgh, Pennsylvania, USA (Simpson, 2006).

## 2.1 Problems with Current EU Regulations

There are several major problems facing current regulation in the EU. The first of these is that it is very inefficient. Public authorities are in charge of doing the risk assessment and not the manufacturers/importers/users (MIUs) of chemical substances. MIUs are then free to keep going forward while the authorities are swamped with thousands upon thousands of substances to assess, most of which have never been tested (“REACH in brief,” 2004).

Secondly, the risk assessment is comprehensive and not use specific. This presents a problem because information may not be presented in an approachable way for downstream users. If risk assessment is not done on a use specific basis, then risks may be missed. Even though assessing the risk for every use of every chemical substance seems overwhelming, there needs to be a system in place where the assessment process is very thorough due to the inherent risks (“REACH in brief,” 2004).

Lastly, the current system creates barriers for innovation. New chemicals need to be notified and tested starting at a production level of 10 kg per year. At the 10 kg level, manufacturers of chemical substances are more inclined to develop current substances than create new ones to circumvent costly testing procedures (“REACH in brief,” 2004).

## 3. REACH

“REACH” stands for Registration, Evaluation, and Authorization of Chemicals. It is a new European Union regulatory system designed to unify the legislative structure for chemicals manufactured and imported in the EU market (“A new chemicals policy in Europe...,” 2003). Below is a chart (Table 1) explaining the three main components of REACH pertaining to registration, evaluation, and authorization.

**Table 1: REACH**

Registration	Chemical producers/importers required to provide safety data by fixed deadlines on all quantities above 1 ton per year to authorities.
Evaluation	Data on high volume and concern chemicals are evaluated by Member State experts with a central co-coordinating body.
Authorization	Chemicals of very high concern are subject to authorization. They will either be phased out or kept if it can be proven that a specific use presents negligible risk or that it's acceptable.

Under REACH, approximately 30,000 chemical substances will be registered and controlled (Barnes, 2005). The burden of proof will be transferred from public authorities to the actual manufacturers, importers, and users of chemical substances. This makes MIU's accountable for gathering information on substances and registering them on a central database. A central agency, The Chemicals Agency, will monitor the process ("Reach," 2005).

### **3.1 Benefits of REACH**

One benefit of REACH is the standardization of information across all marketed chemicals. There are currently over 100,000 substances that are not required to be assessed for risk, and REACH will change that. It will streamline the process of assessing substances to make it more uniform throughout the European countries and make the information far more accessible.

The Chemicals Agency will manage the registration process and provide recommendations for the authorization and restriction procedures. It will also manage a central database where all information will be stored, making it more accessible for those who want to know substance information. Currently, it is very hard for consumers and professionals to obtain information, mostly because there is not any available! "In volume, 99% of the hundred thousand substances put on sale have never been analyzed." (Tanuro, 2005).

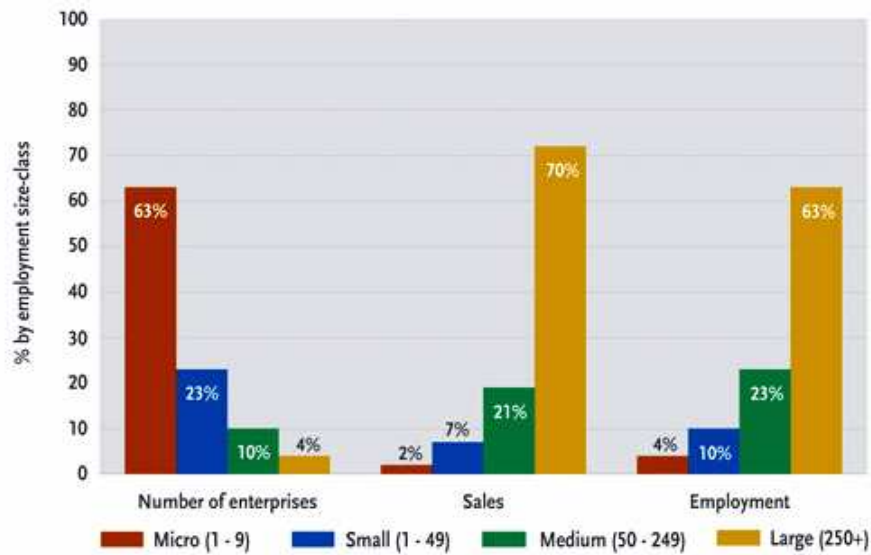
The largest benefit is the health and environmental information which will be made available, the aim of REACH. Although it is difficult to calculate the total, exact monetary savings REACH will have on health costs, it is estimated to be at €50 billion (approximately \$58.5 billion) over 30 years ("EU CHEMICALS POLICY," 2005). A specific example: the cost of occupational injuries and fatalities could potentially be reduced by £64-129 million (approximately \$111-224 million) over the course of 10 years. ("A new chemicals policy in Europe...," 2005). Not only is REACH beneficial for those in the workplace but also for the companies themselves. Companies being sued for exposing employees to carcinogenic substances can avoid increasingly complicated lawsuits by having the proper information supplied by the central database. The chances of even being exposed to harmful substances in schools, offices, banks, etc will be greatly reduced if better information on chemical substances is available.

### **3.2 Concerns about REACH**

A big concern is the cost of implementing REACH; CEFIC (Conseil European des Federations de l'Industrie Chimique) currently estimates it at a maximum of €7 billion (approximately \$8.19 billion). ("A new chemicals policy in Europe...," 2005). When the total cost is compared to the total annual sales of the European chemical industry, €586 billion (approximately \$686 billion) the benefits definitely outweigh the costs. ("Facts and Figures...," 2005).

Financing problems may be more pronounced at the small and medium enterprise (SME) level. SMEs make up 33% (based on employment size-class) of the European chemical industry while large enterprises hold 4% of the share. On top of this, sales are not distributed in the same proportion as defined by employment sales-class; large enterprises hold 70% of sales and SMEs hold 28%. ("Facts and Figures...," 2005). See figure 2.

As a result of implementation costs incurred by firms, job losses are possible. The chemical industry is a huge provider of jobs in Europe, generating 1.7 million direct jobs plus 3 million jobs indirectly (Barnes, 2005). On top of future potential losses, Europe is undergoing declining employment growth rate over the past few years. The average employment growth rate from 1999 to 2004 in the European chemical industry was -1.4%, however it's a better figure than -3.3% seen in the USA and -2.8 Japan had to endure ("Facts and Figures...," 2005).

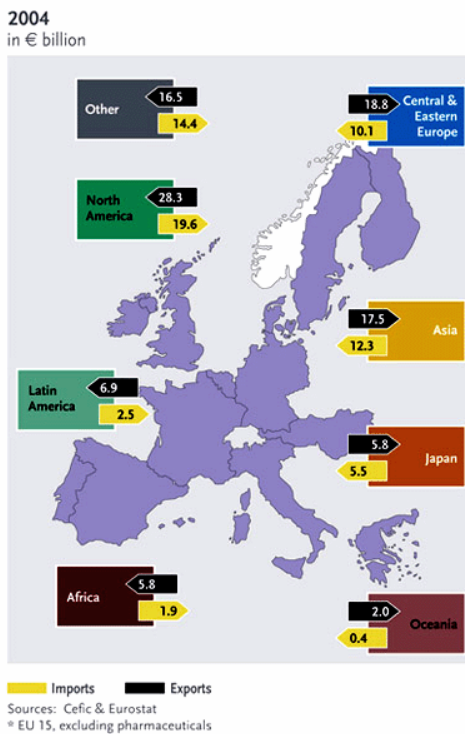


Sources: Cefic and Eurostat  
 \* Excluding pharmaceuticals

**Figure 2: Number of Enterprises and Sales in EU by Employment Sales Class (“Facts and Figures,” 2005)**

### 3.3 REACH and Global Economics

The European Union is a major trading partner worldwide-see figure 3.



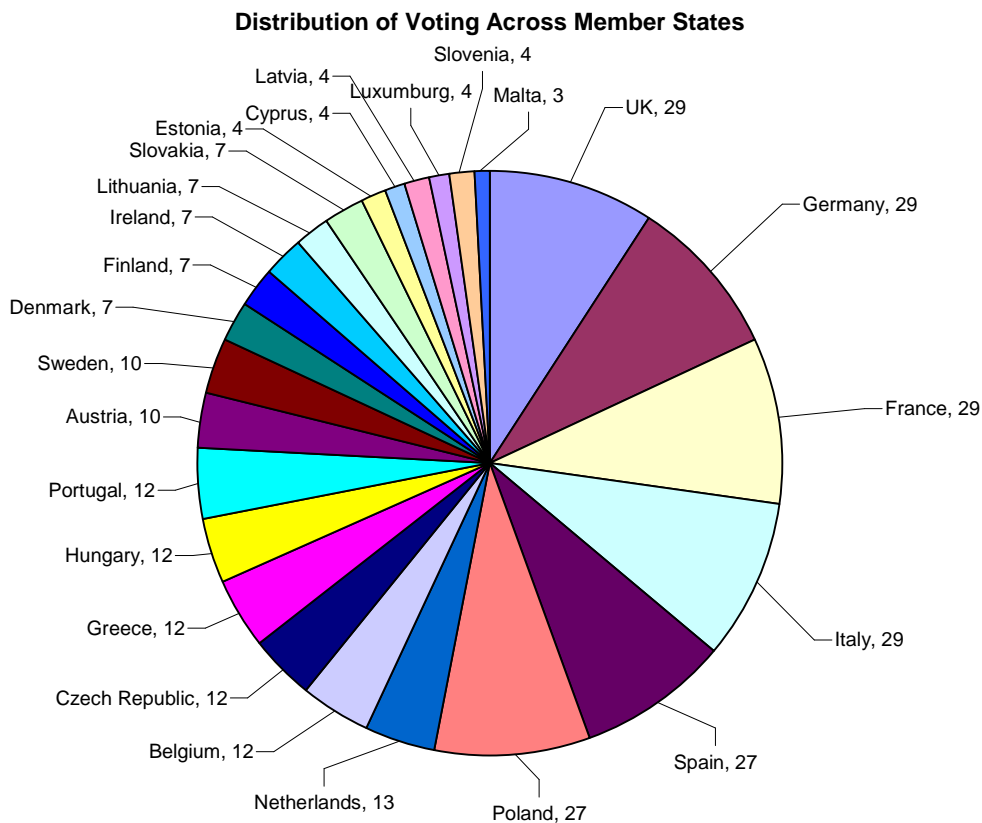
**Figure 3: Extra-EU Chemical Trade with Major Trading Blocs (“Fact and Figures,” 2005)**

REACH will transform international trade by forcing trading entities to adhere to new regulations on a worldwide, global scale. REACH will affect exporters and importers located outside of the EU. Namely, exporters will have to obey the same regulations as manufacturers and users within Europe. Enforcing the same regulations by the countries that export into Europe will be a difficult task. Who would fund the costs for exporters to adapt? Who will act as the central authority as the Chemical Agency does in Europe? What deadlines will be set for adapting new standards? Will REACH become the new global chemical industry standard? These are just a few of the questions that are on the minds of the chemical industry worldwide.

One of the issues, foreign direct investment, is also a major cause for concern at the moment. FDI should be viewed as having two components: internal, within EU boundaries and external, affecting UE external trading partners. Although, the Euro has depreciated recently against the US Dollar—usually a prompter of FDI—concerns over the stability and uncertainty of the industry standards structure will negatively affect the FDI in European countries (“X-rates.com,” 2005).

Individual property and intellectual rights are considered as possible cause for concern as well. Under REACH, transparency will be enacted in an attempt to allow downstream manufactures to have better access to information regarding the chemicals they are using to produce their goods. The EU commission states that provisions will be taken to ensure trade secret privacy; however, the US Department of Commerce fears that the competitive advantage of many individual firms will be compromised. US support of REACH will not come without insurance that American companies are able to keep their trade secrets private (Litman, 2003).

### 3.4 Recent Developments Concerning REACH



**Figure 4: Distribution of Voting Across EU Member States (“UK Presidency of the EU 2005”)**

The European parliament backed REACH on November 17, 2005. The next step in the process is for the Council of Ministers—specifically two sub-councils, on competitiveness and environment—to vote on the issue. Currently, the UK holds the Presidency of the EU and Tony Blair is giving time for Germany's new chancellor, Angela Merkel, to get settled in before tackling the issue (“Compromises move REACH closer to reality,” 2005). An important country to keep one's eye on is Germany, Europe's largest producer of chemicals and one of four countries with the largest percentage of votes (“Voting in The Council,” 2005). Figure 4 shows distribution of voting across EU member states.

Before the EU's parliament voted, concessions were made with business lobbyists to drastically reduce the regulatory burden that REACH would place on European chemical manufacturers and users (Buck, 2005). This shows that the business impact may not be as dramatic as expected by the industry.

If EU member states vote on REACH, the US and other trading partners will need to react accordingly to keep trade afloat. However, since the US and Japan are an integral part of the European chemical industry, they will have tremendous leverage in the bargaining of concessions.

## References

- Barnes, Kirsty. (2005). “REACH agreement in final stages,” *Decision News Media*, 21 October 2005, <http://www.in-pharmatechnologist.com/news/ng.asp?id=63397>, November/1/2005.
- Buck, Tobias. (2005). “EU backs restricted chemical testing law,” *The Financial Times*, 18 November 2005, p.1, *InfoTrac Web: InfoTrac OneFile*, December/1/2005.
- “Compromises move REACH closer to reality,” *Chemical & Engineering News*, 21 November 2005, Volume 83, Number 47, <http://pubs.acs.org/cen/news/83/i47/8347notw9.html>, December/1/2005.
- “EU CHEMICALS POLICY,” *Parliament Office of Science and Technology*, September 2004: Number 229, [http://www.rsc.org/images/jennysteere\\_tcm18-11931.pdf](http://www.rsc.org/images/jennysteere_tcm18-11931.pdf), Dec/1/2005.
- “Facts and Figures: The European chemical industry in a worldwide perspective,” *Conseil Europeen des Federations de l'Industrie Chimique*, July 2005, <http://www.cefic.be/factsandfigures/downloads/allgraphs/F&FJuly2005.pdf>, Dec/1/2005.
- Griemel, Hans. (2005). “New-car smell is going away: It's no good for you,” *USA Today on the Web*, 28 September 2005, [http://www.usatoday.com/money/autos/2005-09-26-new-car-smell\\_x.htm](http://www.usatoday.com/money/autos/2005-09-26-new-car-smell_x.htm), Dec/1/2005.
- Litman, Gary. (2003). “Comments on the EU Commission Consultation Document Concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH),” *U.S. Chamber of Commerce*, 9 July 2003, <http://www.uschamber.com/international/regional/europe/030710litmancommentary.html>, Dec/1/2005.
- “A new chemicals policy in Europe –new opportunities for industry,” *WWF European Toxics Programme and the Environmental Bureau (WWF and EEB)*, January 2003, <http://www.eeb.org/activities/chemicals/Newchemicalspolicy-industry-29-01-03.pdf>, Nov/1/2005.
- “New Chemicals policy in the EU – Good or bad for companies,” *International Chemical Secretariat*, May 2003, [http://www.chemsec.org/documents/Good\\_or\\_bad.pdf](http://www.chemsec.org/documents/Good_or_bad.pdf), Nov/1/2005.
- “REACH,” *Europa*, 10 November 2005, <http://europa.eu.int/comm/environment/chemicals/reach.htm>, Dec/1/2005.
- “REACH in brief,” *European Commission, Environment Directorate General, and Enterprise Directorate General*, 15 September 2004, [http://ecb.jrc.it/DOCUMENTS/REACH/OVERVIEW/REACH\\_in\\_brief-2004\\_09\\_15.pdf](http://ecb.jrc.it/DOCUMENTS/REACH/OVERVIEW/REACH_in_brief-2004_09_15.pdf), Nov/1/2005.
- Simpson, Dan. (2006). “The pulse of Europe. The head of the EC comes to Pitt with a frank assessment of the continent's state.” *Pittsburgh Post-Gazette*. February 15, 2006. B-7.
- Tanuro, Daniel. (2005). “Toxic chemical defense sabotaged,” *International Viewpoint*, July/August 2005, [http://www.internationalviewpoint.org/print\\_article.php3?id\\_article=854](http://www.internationalviewpoint.org/print_article.php3?id_article=854), Dec/1/2005.

“Voting in The Council,” *UK Presidency of the EU 2005*,  
[http://www.eu2005.gov.uk/servlet/Front?pagename  
=OpenMarket/Xcelerate/ShowPage&c=Page&cid=1109176671862](http://www.eu2005.gov.uk/servlet/Front?pagename=OpenMarket/Xcelerate/ShowPage&c=Page&cid=1109176671862), Dec/1/2005.  
“World: Chemicals Industry - Global Chemical Industry Overview,” *MBendi*, 30 January 2002,  
<http://www.mbendi.co.za/indy/chem/p0080.htm>, Dec/1/2005.  
*X-rates.com*, December 2005, <http://www.x-rates.com/d/USD/EUR/hist2005.html>, Dec/1/2005.