Understanding EuP and REACH

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Abstract
There has been a global trend towards legislation meant to encourage sustainable manufacturing and minimize the environmental impact of product manufacturing. In the global economy, with its distributed supply chain, local environmental laws may affect companies located anywhere in the world. Often, these laws are targeted at the finished goods manufacturer on the assumption that changes will propagate through the supply chain all the way to the raw material suppliers. Penalties for non-compliance may include monetary fines and/or trade restrictions. Compliance will likely require modifications to existing manufacturing processes, the use of alternative materials or chemicals, and new data systems to track relevant information. In order to be prepared, companies need to look ahead to identify new and future legislation and determine how it might impact their business. Companies will need to be prepared well before new legislation goes into effect. This paper takes a closer look at two upcoming European Union legislative acts that will have significant impacts on the future of electronics and semiconductor industries in Europe. Specifically, it gives an overview of the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation and Energy Using Products (EuP) Directive. REACH creates a mechanism for the registration of chemical substances manufactured or imported into the EU, a methodology for the evaluation of those chemicals and their associated safety risks, and finally establishes an authorization requirement for chemicals of high concern. Instead of concentrating on materials, the focus of EuP is on energy. EuP is part of the EU Energy Efficiency Action Plan and seeks to reduce energy usage. While these directives will affect companies within the European Union, due to global nature of modern industry, their impact will be felt far beyond the borders of the European Union.

Introduction
In the 21st century, managing the environmental impact of manufacturing has become an important aspect of electronics production. To protect both human health and the environment, governments worldwide have enacted legislation that has started to place restrictions on the manufacture, use, and reclamation of products. Due to the complex material composition of electronics and their high resource usage, many of these restrictions are directly impacting the electronics industry. Complying with these new laws and regulations requires changes in product design and manufacturing processes, and an increase in the exchange of environmental data. A difficulty in achieving these goals is the number of environmental regulations affecting the electronics industry; many of these new regulations cover the same territory but have subtly different and unique requirements. This has created an unfortunate situation where companies are left struggling to determine what changes need to be made to their manufacturing supply chains in order to ensure compliance for their product in any given market or country.

Successful manufacturing in this new environment requires companies to be forward thinking and to prepare not just for current legislation but forthcoming ones. By the time laws are passed and entered into force, it is often too late to update a given supply chain in order to ensure compliance. This can lead to companies facing product delays, having products banned from certain markets, or being open to facing stiff monetary fines. Unfortunately, companies need to actively keep track of pending and potential legislation in order to have enough time to modify their business models. However, that is simply not an option for many small and medium manufacturers who are very resource limited. As such, they are often turning to third party agencies, groups, and venues to receive insight into these forthcoming laws and how best to prepare. This paper is designed to be one such tool and seeks to provide an overview of two new pieces of legislation that are coming from Europe: REACH and EuP. Specifically, this paper will discuss the key points of both pieces of legislation, attempt to identify their potential impact on the US electronics industry, and highlight their new electronic data exchange requirements.

Purpose and History behind REACH
The European Union's new Registration, Evaluation, and Authorization of Chemicals (REACH) regulation (EC) No 1907/2006 [1] was created in response to concerns over Europe's existing chemical regulatory system. Prior to REACH, the existing system was a patchwork constructed from a variety of both directives (Dangerous Substances, Preparations) and regulations (Existing Substances) that were created over time during the history of the EU's member countries. A series of investigations determined that the existing system had a number of weaknesses that needed to be addressed.

One of the major issues identified is that the existing system codified a difference for chemical substances produced before and after 1981. All chemicals listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) [2]

from 1971 to 1981 were considered "existing" chemicals while chemicals listed after 1981 are considered "new" chemicals. The major difference is that the "new" chemicals had to be tested before being placed on the market while there was no such requirement for the "existing" chemicals. This created multiple differences between the two groups of chemicals. For the more than 100,000 existing substances, there was a substantial lack of publicly available safety information. The "new" group, which numbered around 3800, had to be tested in volumes as low as 10 kg per year, which effectively increased the cost of these chemicals. This disparity also had the unintended consequence of limiting research into new substances. It was often cheaper and easier to use an "existing" chemical rather than a "new" one due to the costs and effort needed to bring a new chemical onto the market.

In 2001, the EU commission published a white paper [3] on the proposed REACH system. The paper established several key goals for the proposed new chemical system including:

- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international environmental efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO.

The new system proposed in the white paper, and finalized in 2006, consisted of a new process by which all chemicals would be registered, evaluated, and potentially authorized (for chemicals considered potentially dangerous) by a new central European Chemical Agency (ECHA) [4]. One of the key points is that there would be no separation between existing and new chemicals under the new system. All chemicals would be covered under the new EU system unless specifically exempted. The new system would create a single chemical system for the entire EU (replacing some 40 separate legislative entities) and would promote technical innovation by removing incentives to rely on existing substances rather than developing new ones. Also, it would shift the burden of providing chemical safety information to the producers rather than relying on EU officials. This is based on the idea that the chemical producers / importers are best situated to determine chemical safety information. It would also mandate the flow of safety information through the supply chain to downstream users. The real key to understanding REACH is to look at its three main phases: Registration, Evaluation, and Authorization.

Registration

At the heart of the new REACH system is the requirement to register substances. In essence, registration means that a manufacturer or an importer has provided a complete dossier to the new ECHA for each substance (on its own, in a preparation, or in an article intended to be released) that has been manufactured or imported in excess of 1 ton. This does not necessarily mean that the substance registration is in compliance with REACH nor does it mean that all of the substance's properties have been identified. Determining how companies can comply with the registration process involves asking four main questions: who needs to register, what substances need to be registered, what information needs to be provided to the ECHA, and when does the substance need to be registered.

Who needs to register?

While REACH is rather straightforward with regard to who needs to register substances (manufacturers and importers), there are quite a few nuances to the process. In order to participate in the REACH system, a company must have, or be represented by, a legal entity within the EU. In order to accommodate external legal entities (companies based outside of the EU), there is the possibility that they can appoint an "*only representative*" (OR) [5]. In this case, an OR is a legal entity based within the EU that will acquire the full responsibility of fulfilling REACH obligations for the external company.

What needs to be registered?

While the scope of REACH covers all substances (manufactured, imported, used on their own, in preparations, or within articles) there are substances that are exempted. Identifying whether a substance is exempted from REACH can be difficult due to its complexity. Exemptions have been established due to a wide variety of reasons ranging from substances being adequately covered by existing legislation, to basic substances for which hazards are known (such as hydrogen and oxygen), to substances being needed for national defense. Compiling a complete list of the substance exemptions is beyond the scope of this paper. However, the following substances categories listed below are some of the key exemptions.

- Radioactive Substances
- Substances subject to customs supervision
- Medicinal Products (for human or veterinary use)
- Food / Feedstock

- Polymers
- Substances listed in REACH Annexes IV and V

The EU commission will re-examine the exemptions coming from Annexes IV and V within 12 months of REACH entering into force. In addition, it is expected that the commission will review the scope of REACH five years after its start on June 1, 2007.

What information gets registered?

The information that is provided by manufacturers and importers during the registration process is designed to assess the risks associated with each substance and to ensure that those risks are properly managed. In order to handle a wide variety of data, the REACH system was developed with different levels of data reporting requirements based on a substance's risk and potential for exposure. Using a "trigger" system, the level of potential exposure is determined by the quantity of a substance produced or imported (for all uses and product lines) for a company over one year. As the quantity of the substance increases, the level of data that needs to be provided to the ECHA increases. In essence, REACH can require two different forms to be submitted with the registration: a technical dossier and a chemical safety report.

Technical Dossier

The technical dossier, required for substances in quantities of one ton or more, contains the substance's properties, classification, how it will be used, and guidance on safe use. All technical dossiers are required to provide some basic common information such as:

- Identity of the manufacturer or importer
- Identity of the substance
- Information on the manufacture and use of the substance
- Classification and labeling of substance
- Guidance on safe uses
- Exposure information

The technical dossier is required to contain additional information shown in Table 1, which is determined by both quantity of the substance produced in a given year and a set of criteria established in ANNEX III (shown in Table 2).

Table 1: Additional Information Requirements

Tonnage	Information Requirements
1 Ton to 10 Tons	• Information specified in Annex VII for non-phase-in substances and for phase-in substances meeting at least one of the criteria specified in Annex III • Physicochemical properties specified in Annex VII and relevant (eco)toxicological information for phase-in substances that do not meet the criteria in Annex III
10 Tons to 100 Tons	• Information from testing Annexes VII and VIII
100 Tons to 1000 Tons	• Information from testing Annexes VII and VIII, test proposals from Annex IX
Greater than 1000 Tons	• Information from testing Annexes VII and VIII, testing proposals from Annexes IX and X

Table 2: Annex III criteria

Substances predicted to be category 1 or 2 classification for carcinogenicity, mutagenicity, or reproductive toxicity (CMR)
Persistent, bioaccumultative, and toxic (PBT)
Very persistent and very bioaccumulative (vPvB)
Potentially dangerous to human health and the environment and used in dispersive uses

Chemical Safety Report (CSR)
According to REACH, a chemical safety assessment shall be performed and a chemical safety report generated for all substances generated in quantities of 10 tons or more a year per registrant. Except for a few exemptions for substances in preparations, most registrants will have to perform a chemical safety assessment for each substance. This assessment will consist of four parts: a human health hazard assessment, a physiochemical hazard assessment, an environmental hazard assessment, and a PBT and vPvB assessment. If during the assessment the substance is determined to be dangerous (as determined in Directive 67/548/EEC) [6], a PBT, or a vPvB, the registrant must also perform an exposure assessment (including the generation of exposure scenarios) as well as a risk characterization. Exposure scenarios are a set of conditions that identify how the substances are manufactured or used during their lifecycle, the substances' operational conditions, and recommended controls designed to limit the exposure to humans and the environment. The exposure scenarios need to cover all identified "uses" including both the manufacturer's / importer's intended usages as well as any known uses by downstream users. The risk characterization addresses risk management controls designed to control the risks from the substance being exposed to humans and the environment during use and during waste disposal or recycling.

When does registration occur?
In order to facilitate the transition to the new REACH system, the registration process will be implemented in a stepwise approach over a 10 year period for phased-in substances. Phased-in substances are ones listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), having been manufactured within an EU member state at least once in the 15 years prior to REACH, or is a "no-longer polymer." A "no-longer polymer" is a substance that was once classified as a polymer but is no longer due to rule changes. Starting with the substances introduced into the EU in the greatest quantities (greater than 1000 tons), the phase-in process will continue for smaller quantities until full registration is required 10 years after REACH enters into force. In order to qualify, manufacturers / importers need to pre-register their substances in a pre-registration process that starts 12 months after and ends 18 months after REACH goes into force. In addition, certain substances that are considered substances of high concern (CMR, PBT, vPvB) will also require early registration.

Evaluation
Evaluation within REACH consists of performing checks on two possible items: the technical dossier and the substance. The ECHA, when looking at a submitted technical dossier, can check both for regulation compliance and the validity of any proposed tests. In a compliance check, the ECHA will look to make sure that a given technical dossier will comply with any regulations laid down in the REACH system. It is stated that the ECHA will check at least 5% of the submitted dossiers. The ECHA can also evaluate a dossier's testing proposals to identify ways to prevent unnecessary testing. This can be done by identifying poorly designed tests, repetition of tests, or ways in which third party information can avoid the need for testing.

REACH also provides a mechanism by which the ECHA along with EU Member States can request action to further evaluate a given substance's potential environmental and health impacts. In conjunction with a Member State, the ECHA will request additional information from industry that the Member State will then use to evaluate the health risk of the substance. This evaluation can lead to the substance being restricted or requiring authorization under REACH if evidence of risk to human health or the environment is found.

Authorization and Restriction
Under REACH, hazardous chemicals are subject to additional rules. This is done through the authorization process which requires companies to get authorization before using any chemical that is on the REACH list of chemicals requiring authorization. Authorization with the REACH system is a two-step process in which substances that are considered very harmful are regulated to ensure their safe use. In the first step, the EU community compiles a list of potential candidate substances, along with the acceptable usages of those substances due to existing safety controls, and deadlines for the substances to be evaluated about being placed on the authorization list. By default, no substances on the candidate list will have any uses banned. As resources allow, substances will be evaluated and, if necessary, be placed into the authorization system. Once a substance is placed in the authorization system, any user or producer of the substance must apply for authorization to use that substance. As part of the authorization request, the producer / importer must include an analysis of possible alternative substances. Authorization will be granted to a requestor if they can prove that the risks are adequately controlled, that the benefits of the substance outweigh the risks, and that there are no suitable alternatives.

REACH provides the EU a mechanism in order to place restrictions on substances that are in the authorization system. These restrictions can range from establishing conditions that must be met for a substance to be manufactured or placed on the market to an outright ban of the substance. In general, EU authorities must decide that a substance is risky or hazardous to the entire EU in order for restrictions to be needed. As such, restrictions will be established by the EU commission after input from Member States or the ECHA and following a suitable comment period for interested third parties.

Impact on Electronic Manufacturing and Data Exchange

REACH will likely have two major impacts on the manufacturing of electronic components and equipment. First, REACH introduces a much stronger data exchange requirement in the supply chain. In fact, several new communication channels need to be developed to support REACH. Downstream users of chemicals need access to chemical safety information and exposure information from suppliers in order to use the substance safely. For proper registration, downstream users will need to communicate with their chemical suppliers their proposed chemical usage. Registration information needs to reach the ECHA from both importers and producers. Finally, new mechanisms to share expanded substance information between potential registrants are needed to reduce the burden of complying with REACH (i.e., sharing test data). Additionally, while the chemical industry has some experience with sharing certain types of information such as the chemical safety sheet, the REACH requirements go far beyond a safety data sheet and no system or standard currently exists that will provide all the data required by REACH.

The second way that REACH will impact the electronics industry is in the way it will alter the list of available substances used in manufacturing. With REACH, there is no grandfathering of old chemicals which means that many substances will need to undergo testing and evaluation in order for them to stay on the market. These tests are expensive despite several mechanisms within REACH designed to mitigate those costs. It is highly likely that it will not be cost-effective for some low volume substances to be adequately tested thereby effectively driving those substances from the market. In addition, companies will likely move to avoid substances that are in the REACH authorization system or on the candidate list. The risks and costs associated with substances within that system will force companies to find alternative substances to reduce both costs and litigation risk.

History and Purpose of the EuP

The EU Directive 2005/32/EC [7] which established a framework for the setting of eco-design requirements for energy-using products was created through the combination of several efforts. Starting back as early as 1998 [8], the EU started engaging in efforts to create an Integrated Product Policy (IPP). Built around the core concept that all products and services cause environmental degradation in some way, the IPP is a strategy for helping EU policy makers establish policies that seek to minimize the environmental impact of products and services. Because those environmental impacts can occur at any point within a product's creation, use, or reclamation, the IPP targets the product lifecycle. The IPP concept was formally established in the EU Commission's Communication on IPP I 2003 [9].

As part of the IPP Communication, a toolbox of potential policies was identified as a resource for EU policy makers. One of those tools was one on product design obligations. Within this section, the communication laid out plans on how to promote the implementation of IPP in companies by creating potentially mandatory requirements. The communication promised to take feedback on two existing draft proposals (Directive on eco-design on end-use equipment and the Directive on eco-design of electronic and electrical using equipment) and to use them to create a new one focused on eco-design of Energy Using Products (EuP). In this case, eco-design reflects a principle that the integration of environmental considerations at the products design phase is one of the best ways to reduce the environmental impact of products. By making modifications to a product design it is possible to alter the amount of energy used during the normal usage of the product. Therefore, the EuP (Directive 2005/32/EC) is seen as creation of both the IPP process as well as the merger of two different draft proposals on eco-design.

Key Elements of EuP

Understanding the EuP Directive requires knowledge of a few key elements of the Directive. First, as is common with many of the EU Directives, it seeks to create a common legislative background across the entire EU. This is largely to ensure the free flow of products across the member countries borders. Second, it is part of the EU's efforts on both sustainability and ensuring its strategic energy supplies. As such it will be pushing efforts for increased energy efficiency in order for the EU to make the most of its current resources. One example of this is pushing for products to use the lowest possible energy idle state. Finally, the EuP is a framework directive and therefore does not make any generic or specific requirements for the eco-design of products. However, it does define conditions and criteria for setting requirements regarding environmentally relevant product characteristics (such as energy consumption). Specific eco-design requirements will then be established by following new pieces of legislation called implementing measures (IM). Companies wishing to put their products and services on the EU market must ensure their products comply with those implementing measures. Therefore, the real key to understanding the EuP directive is to understand the process by which the IM's will be created.

Establishing Implementing Measures

While in principle the EuP covers all electrical using products (dependant on energy input to function as intended) or energy generating products (used to generate, transfer, or measure energy) no single measure could possibly cover such a broad scope. Rather, the first step in establishing whether an eco-design requirement should be established for a given product is to study ways by which the product can be improved. As part of the EuP effort, a list of products was identified as potential

targets for preparatory studies. These preparatory studies are being performed by contractors and they will study ways in which the environmental performance of the product can be improved. At the time this paper was written, 20 different preparatory studies [10] had been established and were in various stages of completion, as seen in Table 3. Battery chargers, external power supplies, and public lighting are completed while solid fuel boilers, laundry dryers, vacuum cleaners, complex set top boxes, and domestic lighting were just started in January of 2007.

Table 3: List of product preparatory studies

Boilers	**Water Heaters**
Personal Computers and Monitors	**Imaging Equipment**
Televisions	**Domestic Refrigeration**
Washing Machines and Dishwashers	**Simple Set-Top Boxes**
Battery Chargers and External Power Supplies	**Office Lighting**
Public Lighting	**Residential Air Conditioners**
Commercial Refrigeration	**Motors, Pumps, Fans, Circulators**
Standby Losses	**Solid Fuel Boilers**
Laundry Driers	**Vacuum Cleaners**
Complex Set-Top Boxes	**Domestic Lighting**

Structure and Timeline for IMs

At the time of writing, there are no new completed IMs to examine that have been created through the process laid out in the EuP directive. However, article 21 of the EuP directive retroactively altered three earlier directives: 2000/55/EC [11] on energy efficiency requirements for ballasts for fluorescent lighting, 96/57/EC [12] on energy efficiency requirements for household electric refrigerators and freezers, and 92/42/EEC [13] of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels. These directives became IMs and provided a likely guideline as to how future IM's will be structured. In all likelihood, each IM will contain the following information:

- Scope of products covered
- Relevant application Dates
- Generic and specific design requirements
- Measurement standards / methods
- Conformity assessment procedures
- Information requirements

As the preparatory studies continue to be completed it is likely that additional proposals for IMs will begin surfacing within the 2007-2008 timeframe. With the EU expecting to provide time for industry negotiation on the IMs it is likely that no implementing measures will be enacted until 2009.

Impact on Manufacturing and Data Exchange

Without example IMs to study, determining the impact of the EuP on manufacturing is difficult. However, the EuP directive does offer several pieces of information that companies can use to guide their design choices until the IMs are established. First, a recurring theme within the EuP directive is a call to a have a product use the lowest possible energy during its idle state. This follows from the EuP's role in helping to secure Europe's energy supplies. Second, while the best technical designs on the market will likely be used as a reference in making design requirements, they will not become the requirements. Rather, the new requirements will be set on the basis of technical, economic, and environmental analysis. After consultations with industry, it is likely that phase-in requirements will be produced that will move industry towards more efficient designs over time. Finally, it is possible that few restrictions will be established since the EuP is designed to encourage voluntary action by industry. However, the EU does retain the right to establish mandatory design requirements if market action fails to correct problems. When combined, these considerations imply that any mandated design requirement

will restrict designs that use excessive amounts of energy (as determined by the IMs) rather than requiring the use of the most efficient design available. So within the scope of the current IMs and with the focus on energy being consumed during a product's usage, there will likely be little impact on manufacturing. The only direct connection is that the new, efficient product designs will ultimately lead to some corresponding changes in the manufacturing process. It is worth noting that the EuP scope covers a product's entire lifecycle from cradle to grave. Therefore, it is not outside the realm of possibility that some future IM will require companies to start tracking energy used in the manufacturing process. If that were to occur, the impact on manufacturing would be enormous.

Beyond product design requirements, the EuP will also create greater information exchange requirements for the electronics industry. As part of the IPP, the EuP was designed to involve greater participation by the stakeholders including the product consumers. The concept is that a better-informed customer will make a better choice. Therefore, if the energy usage information is available at the time of the purchase of a product, it is hoped an informed customer will gravitate to a product that consumes less energy (all other factors being equal). This means that producers will likely have two new responsibilities. First, they need to measure the amount of energy consumed during the product usage. While some companies already know this information, with no new IMs yet established, it is difficult to say how the EU will want this information measured and reported. Secondly, the information will then need to be passed along to the consumer. This will likely be done in conjunction with other EU product labeling directives. Still this information will have to be exchanged within the supply chain until it reaches the party responsible for the end product labeling.

Conclusions

REACH and EuP are just two in a series of EU environmental legislative acts affecting the electronics industry. The burden placed on the electronics industry by these new regulations is very high. The REACH regulation is very complex and requires significant resources just to clarify the effects of the regulations on industry stakeholders. Manufacturing systems will have to be modified, and the supporting information management systems must be re-designed to handle the vast new information requirements. As of the writing of this paper, the EuP directive is much more difficult to prepare for as the new IMs have not been written. The directive is written in such a way as to move industry toward building more energy efficient products, but how this will impact the actual manufacturing process is not clear. What is clear is that the EuP will require greater amounts of information to flow along with the product itself. The energy usage information must flow from the manufacturer to the end product user. While the current focus is on energy being used by a product, the directive explicitly covers the product's entire lifecycle. Therefore, it is possible that some future IM might also require that manufacturers start to track energy used in the manufacturing process itself. While it is clear industry will have to adjust to each new piece of legislation on a one-on-one basis, there is a clear lesson to be learned from REACH and EuP. Almost every single new piece of environmental legislation will have an information exchange component. It is important for companies to start tracking as much product and manufacturing process information as their information management systems can handle in a way that can be disseminated throughout the supply chain. If the information is already collected, tracked, and stored it would ease compliance with future laws and regulations.

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