Selected Article

Corporate Strategies on the European Environmental Regulations on Products

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The European environmental regulations on products have been increasing its impacts in North and South America and Asian countries, and they are becoming global standards as intended by EU[*1]. Therefore, nowadays, working on such regulations appropriately is one of major business tasks for global companies. The essential point of this issue is that it's not only a matter of compliance, but these environmental regulations clearly spur companies to technological competition. Four years have passed since the entry into force of the RoHS[*2] Directive. However, the directive is still under development, so a lot of companies are continuing lobbying activities on it with great concern. With the background mentioned above, this paper will discuss how each company is able to deal effectively with those regulations focusing on the current progress of the European chemical regulations such as the RoHS Directive and the REACH[*3] Regulation.

*1: The European Union

*2: The Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment Regulation

*3: Registration, Evaluation, Authorisation and Restriction of Chemical Substances

Introduction

The RoHS Directive which restricts six hazardous substances in products came into force in June 2006. It was quite a symbolic event opening a new era of environmental regulations on products in Europe. Following RoHS, several environmental regulations on products (Figure 1) such as EuP[*4] and REACH became effective, and today a large number of companies are taking measures on them regardless of their business size in Europe. As it is well known, there is a fundamental difference between Japan and Europe in terms of "legal culture". "Precautionary Principle" mentioned in the 6th Environment Action Programme is typical and influential policy of Europe developing the environmental regulations. Under this precautionary principle, a substance which is likely hazardous is also restricted by regulations (without sufficient scientific evidence) in Europe. And as written above, the European environmental regulations on products are expanding worldwide. Thus better corporate strategies on these

Type of regulations	Regulation	Outline
Recycle	WEEE Directive (2002/96/EC)	It applies to 10 Categories products from 2005. Article 175 of EU treaty legal basis, thus producers have to comply with each EU member state law. This Directive is now under the reviewing process by Co-decision procedure.
Chemical	RoHS Directive (2002/95/EC)	It applies to categories 1 to 7 and 10 products which cover consumer electronics, tools, toys and vending machines etc from 2006. Categories 8 and 9 products would be within the scope from 2014. This Directive is now under the reviewing process by Co-decision procedure.
	REACH Regulation (No 1907/2006)	Most of REACH obligations has started from 2008. REACH is covering all substances, mixtures and articles with some exclusions. The member states authorities have also started market surveillance. In UK for example, penalty and/or imprisonment will be imposed on company for violation.
	Battery Directive (2006/66/EC)	New Battery Directive applies from 2008. Batteries in equipment are also covered by this Directive. Capacity labeling obligation was originally scheduled to start from latter of 2009, however details of this obligation (i.e. regulation) are not published yet.
Eco-designe	EuP Directive (2005/32/EC)	30 products categories are already covered by this Directive, and hereafter many industrial products also will be covered. Medical equipment and industrial tools manufacturers are trying to make a voluntary agreement.
	ErP Directive (2009/125/EC)	EuP Directive was recast by ErP Directive in order to extend the scope to energy related products e.g. window, shower head etc. in the future.

Figure 1 The summary of major environmental regulations on products

environmental regulations are essential for companies nowadays.

*4: Energy Using Products Regulation

The RoHS Directive

The RoHS Directive became effective four years ago with the exception of Category 8 (medical equipment) and 9 (monitoring and control equipment). Today, Almost all EU member states are carrying out surveillance for the RoHS compliance in each market and/or customs, and publishing the briefs of its results. Since Japanese companies took actions quickly and were well prepared for the RoHS compliance, I assume any serious violations have not been reported so far. Now the RoHS Directive is at a great turning point due to the following two review processes.

One is that the RoHS Directive will be recast. The European Commission published and submitted the proposal (so called the RoHS recast) to the European Parliament and the Council on 3 December 2008. The RoHS recast is still being discussed under the co-decision procedure, and it would be passed by the end of 2010 at the earliest. The key points of the RoHS recast is indicated by Figure 4.

Figure 2 The Chamber of the European Parliament in Brussles

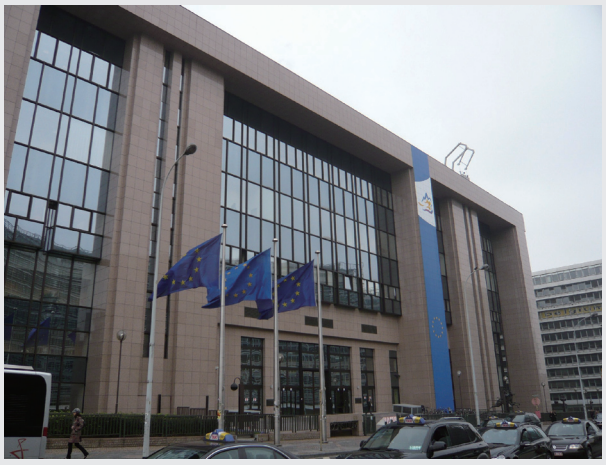

Figure 3 Council of the European Union

- Harmonization of the Scope
- Reference to NLF and CE marking compliance
- 4 candidates for additional restricted substance
- NEW Exemption mechanism and 4 years maximum validity period
- Review of the definition of “a part of another type of equipment”
- Inclusion of Category 8/9
  - Category 8 (Medical devices): 2014
    - In vitro diagnostic medical devices: 2016
    - Active implantable medical devices: review by 2020
  - Category 9 (Monitoring and control instruments): 2014
    - Industrial monitoring and control instruments: 2017
- Exemptions list for Category 8/9 (Annex VI)

Figure 4 Key points of the European Commission proposal

The other is that the existing exemption was reviewed. As of March 2010, 39 items (e.g. mercury in lamps, lead in steel, lead in high melting temperature solder, cadmium contact and etc.) are accepted as exemptions. Among them, 29th item was reviewed for adaptation to scientific and technical progress. Consequently, the exemption list will be revised and published on the Official Journal in 2010.

To adapt regulations to scientific and technical progress, the European Commission normally submits a tender for an organization engaged in such review firstly. This time, Öko-Institut e.V. was selected in 2007. Until the beginning of 2009, many associations and/or companies of Europe, America, Japan and other countries had been involved in that work with their request.

This review reminded associations and/or companies that every item was exempted as an exceptional and temporary measure. The exemptions of the RoHS Directive are not being exemptions forever because the RoHS Directive bans the use of six hazardous substances in principle. In this way, industry is facing severer situation. The European Parliament increasing its power and giving “green” opinions, and the European Commission being sensitive to the European Parliament point of view are leading to such circumstances.

The REACH Regulation

The REACH Regulation came into force in June 2007, and it applies from June 2008 after the establishment of European Chemicals Agency (ECHA) (Figure 5).

Before REACH, safety evaluations of existing chemicals

(i.e. around 100 thousand substances, around 30 thousand substances of them are produced more than 1 ton per year) were delayed compared with new chemicals. Thus the REACH Regulation has been introduced in order to integrate several existing chemical regulations into a single comprehensive system for both existing and new chemicals. The REACH Regulation does not only apply to substances and/or preparations, but also articles. Therefore article manufacturers (parts or products manufactures in other words) in Europe might also have obligations such as notification, information provision, authorization and restriction. It means that any manufacturers should know REACH requirements.

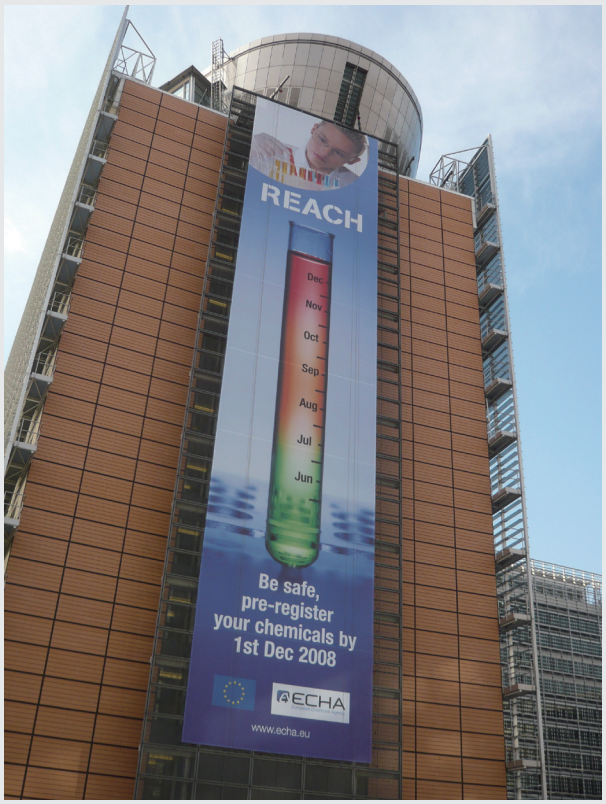

Figure 5 The REACH announcement on the wall of the European Commission

Manufactured / Imported	Registrations / Notifications					Autho risation	Restric tions
	Hazard assessment	Risk assessment	Deadline for the registration of the existing substances	Substances in article: Intended to be released	Substances in article: SVHC contained up to 0.1%(w/w)		
~1t/y	Unnecessary	Unnecessary	-	Registration Unnecessary	Notification Unnecessary	Autho -risation Necessary, If substance in Annex 14	Annex 17
1~10t/y	Necessary	Unnecessary	June of 2018	Registration Necessary	Notification Necessary		
10~100t/y	Necessary	Necessary	June of 2018	Registration Necessary	Notification Necessary		
100~1000t/y	Necessary	Necessary	June of 2013	Registration Necessary	Notification Necessary		
1000t/y~	Necessary	Necessary	December of 2010	Registration Necessary	Notification Necessary		

* Pre-registration was also required for substances in EINECS etc. (The period of Pre-registration is already over.)

Figure 6 REACH Obligations

In particular, Article manufacturers have to be very careful of their obligations when their products contain the substance(s) identified as Substances of Very High Concern (SVHC), because they are required to provide information according to the article 31 and 33 of the REACH Regulation if applicable. As of January 2010, 29 substances are identified as SVHC. However hereafter ECHA will regularly update the SVHC list, thus we should keep track of it. ECHA is planning to add or renew the SVHC list twice a year.

The REACH Regulation is similar to the RoHS Directive in that it bans the use of the substances subject to authorization or on the restrictions list unless they are authorized or permitted with certain conditions. This is almost the same approach to the exemptions of the RoHS Directive. While so many trade associations requested integration of both regulations, the majority of authorities had a different idea. The REACH Regulation and the RoHS Directive will maintain being separate for the time being.

How to leverage the European Environmental Regulations on Products

As mentioned above, the European environmental regulations on products are expanding its scope , and strengthening steadily. Reflecting such a situation, there are two points of central importance for companies.

Position of Each Company on Regulations

Lobbyists in Brussels are actively contributing to each process of policy-making and decision-making by authorities. In order to be involved in legislative process, it is necessary to know the intention and needs of authorities by daily information gathering and communication with them, and to identify technical issues and trends of industry at the same time. Hence, smooth communication between headquarters of each company that has technical expertise and lobbyists in Europe is one of keys especially in the case of the technical regulations such as the RoHS Directive and the EuP Directive. In other words, position of each company might influence the contents of regulations. A company taking actions actively based on “what we want to do”

instead of "what we have to do" may take advantage of regulations more. In short, giving effective information and/or opinions is as important as gathering information for a company as regards the European environmental regulations on products.

Technology Development Competition Arising from Regulations

In the case of the RoHS Directive, if a company cannot keep up with technology development, their products are to be withdrawn from the market after the exemption is expired. On the other hand, if a company leads other companies on technology development and/or alternative technology, they can create business opportunities. And moreover, there is a possibility that those companies not to be affected by the RoHS Directive directly have to change their product design because procurement parts are changed for technology development caused by RoHS. Therefore, companies have to keep in mind that the European environmental regulations on products clearly spur them to technology development competition.

Conclusion

The environment regulations in Europe seems to be difficult for Japanese companies to work on because there is no clear answer to sufficient measures. The regulations intentionally contain ambiguity, and in addition to that, legal culture is very different by state. Thus each company has to decide by themselves to what degree they take risks and/or with what they offset the risks considering the regal requirements. Results of these risk assessments differ by company resources, market share and corporate policy. Hence, as mentioned, each company has to gather a wide range of information of high quality (including unofficial information) actively and make an own decision from a comprehensive perspective.

The HORIBA Group, a leading company of analytical and measurement systems which are mother tools of industry, will continue to keep close watch on trends of both the regulations and industry in order to meet customer expectations and needs.

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