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Science & Technology Trends

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Executive Summary

Life Sciences

1 A New Movement in Drug Development Technology — Microdosing and its challenges —

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Japan has contributed to a significant proportion of the world's drug development as one of the few countries that can develop new drugs domestically. In recent years, however, the pharmaceutical industry has been facing problems, and this is reflected in the decreased number of new drugs that are being approved and sold, as well as the increased costs of research and development. In the development of a drug, a great number of candidate compounds are subjected to nonclinical tests using test tubes and animals, and are subsequently tested in clinical trials on humans to verify their efficacy and safety, before one final compound is selected. However, the extremely low probability of the compounds in the clinical trials being approved as drugs has a negative impact, as it protracts the time for development and increases its cost.

Within this context, microdosing trials were proposed around the beginning of this century. Microdosing is a technique for selecting the most viable candidate compounds for clinical trials by administering extremely low doses of candidate compounds to humans, in order to examine their metabolism and tissue distribution when multiple candidate compounds remain after non-clinical trials. Due to the extremely low doses, there is almost no risk of side effects, and since the success rate increases significantly, it cuts the development cost and time. In the U.S. and Europe, some pharmaceutical companies have accepted and actively incorporated this technique into their drug development process; however, such examples are few in Japan.

In order to use microdosing techniques to activate drug development in Japan, the development of a system for implementing microdosing studies in collaboration with private contract research organizations, as well as the fundamental techniques for running such studies, are urgently needed. It is hoped that microdosing will provide a way for Japan to lead global drug development, so that many efficiently developed drugs can help people suffering from various diseases around the world.

(Original Japanese version: published in January 2011)

Environmental Sciences

2 Research on Health Effects of Environmental Chemicals — New Developments through Introduction of Epigenetics —

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In 2009, the number of chemicals that have been discovered or synthesized by human beings exceeded 50 million. Japan and other industrialized countries have been benefiting tremendously from such chemicals. However, in line with the development of new scientific technologies and increased use of chemicals, a wide variety of chemicals, including non-regulated chemicals and unintentionally-generated chemicals, have been released into the environment. These chemicals are suspected to be associated with the recent changes in human physical constitution, such as a sharp increase in the number of people having pollen allergies or bronchial asthma. Fetuses and children are highly susceptible to chemicals and there exists a concern that such exposure causes various adverse effects, including adult-onset lifestyle diseases.

"Epigenetics" has been drawing attention as the key to elucidating the mechanism of late-onset effects of chemicals. It has been reported that various chemicals cause epigenetic modifications and change the function of genes. Since epigenetic modification is susceptible to the effects of environment factors and is accumulative, it is thought to be closely related to late-onset effects. There are also concerns about transgenerational adverse effects of epigenetic modifications.

Epigenetics research has made substantial progress in the field of developmental biology and cancer. On the other hand, research on the epigenetic effects of chemicals is still in an early stage and needs to be further promoted. Japan's contribution of research is limited and the country is facing a challenge of securing and fostering human resources in this area. In order to efficiently conduct productive research on specific chemicals and environment factors, it would be necessary to promote international collaboration. In order to nurture an environment for protecting human health and make up Japan's contribution to the international community, Japan needs to play a significant role in establishing such a research framework.

(Original Japanese version: published in January 2011)

Environmental Sciences

3 Progress in the Technical Development and Dissemination of the Recycling of Waste Plastics

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The recycling of solid wastes is the core challenge for establishing a sustainable society. Despite to the various recycling technologies, the high processing cost and the low market value of the recycled product are the major obstacles in recycling waste plastics, comparing with those of metal and glass. However, with soaring resource prices, its value as a resource is increasing. In Japan, over 10 years have passed since the Basic Act on Establishing a Sound Material-Cycle Society entered into force, the more companies have developed an interest in the effective use of resources derived from solid wastes. The Ministry of the Environment and the Ministry of Economy, Trade and Industry has even formulated their policies on promoting the technology transfer of suitable treatment and effective resource recovery of integrated solid wastes to developing countries.

The typical recycled products derived from waste plastics are recycled resin and fuel. The separation of different types of resin by means of the electrostatic separation of mixed plastics from waste electrical and electronic equipment (E-wastes) and end-of-life vehicles (ELV) is currently commercialized, and the increasing amounts of waste plastics are recycled. Moreover, the technical reliability of converting waste into various solid, liquid and gaseous fuels has been demonstrated. In particular, solid fuel is widely used as a boiler fuel, as a substitute for coal, primarily in paper industry. However, due to the high processing cost of waste plastics, there are few economic advantages for waste management companies and recyclers. Consequently, only about 30% of waste plastics that generate in Japan are processed to produce recycled resin and waste-derived fuel.

In order to increase the recycling rate of waste plastic, it is important to recycle mixed waste plastics into the products with the higher market value, while lowering the processing costs. The new technologies, especially for precise separation and effective pyrolysis, are required for solving the tasks. In particular, petrochemical companies and resin manufacturers in the upstream sector of the plastics material flow, as well as various research institutions, have a certain responsibility to develop more sophisticated technologies, so that waste management sectors and recyclers could perform low-cost and environmentally effective recycling.

The resource recovery and recycling from wastes is a system technology that combines multiple elemental technologies, while it is also an effort to organize a social infrastructure surrounding multiple stakeholders. Considering the conditions of the business environments and the local societies, the effective initiative lead by the national government and local authorities are of importance in order to increase the recycling rates of wastes through supporting waste management sectors including recyclers. For example, in the case of underused resources that are difficult to recycle effectively in a market economy, such as waste plastics from containers and packaging, it is necessary for the government to play an active role in devising an effective plan for utilizing them, based on appropriate laws and systems.

(Original Japanese version: published in March 2011)

Energy

4 Promotion of Carbon Capture and Storage Technology Using Carbon Emissions Trading Systems

p.44

Japan is already a world leader in energy conservation, and further reductions in domestic CO_2 emissions will require substantial effort. Thus, in order for Japan to further reduce CO_2 emissions, it is essential that the country contributes to the reduction of overseas emissions by encouraging the use of Japanese technology abroad. The use of the Clean Development Mechanism (CDM) and other emissions trading systems is considered to be the key to further reducing CO_2 emissions.

The CDM is a mechanism defined in the Kyoto Protocol. Using the CDM, developed countries can acquire carbon credits by reducing CO_2 in developing countries and use the credits to meet their emission reduction commitments (caps). However, the scales of emission reduction projects based on the CDM have been small, and these projects have not been sufficient to achieve high reduction targets.

In order to prevent CO_2 arising due to combustion and the extraction of fossil fuels from diffusing into the air, carbon capture and storage (CCS) technology separates and captures CO_2, and sequesters captured CO_2 in deep geological formations for very long time spans. The technology is considered to have great potential for reducing CO_2, and many countries, including Japan, have been conducting demonstration tests. There are some issues involved, including ensuring appropriate safety in each country, the sophistication of monitoring technology, high cost, and securing appropriate storage locations. However, CCS was internationally recognized as eligible on a conditional basis for the CDM at the 16th session of the Conference of the Parties (COP 16) to the United Nations Framework Convention on Climate Change (UNFCCC) held in Cancun, Mexico.

It is unclear whether there are suitable large-scale storage locations in Japan, but it is estimated that there are many high-potential storage locations overseas. Therefore, from the perspectives of international contribution and national interest, it is important for Japan to promote CCS demonstration tests to make international standards (with a view toward smoothly developing CDM based projects in the future), and build favorable relations with countries that have potential storage locations.

(Original Japanese version: published in March 2011)

Science & Technology Policy

5 ICT Use and Increasing Openness in Higher Education — Advanced e-learning and Open Educational Resources —

p.58

Progress in Information and Communications Technology (ICT) has released space and temporal constraints from the traditional higher education system, providing the foundation for bringing a new kind of higher education. Radio and television programs have long been tools for distance learning. Due to the wide use of the Internet, the boundary between e-learning and distance learning has blurred, and these have become integrated in recent years. OpenCourseWare which publishes lecture materials and videos on the web, open e-learning content, and online laboratories have emerged to promote openness in higher education.

Taking ICT use in higher education in the United States as an example, we see that scalable education platforms have been created. The ICT use does not significantly increase the resources necessary for large scale education. Advanced e-learning not only improves learning effectiveness in knowledge acquisition, but also enhances cost effectiveness in education. In addition, open educational resources including OpenCourseWare greatly contribute to social education by providing equal opportunity in higher education all over the world. Open educational resources may even replace part of the traditional higher education system based on the accreditation of degrees and credits. These are important changes when we consider the higher education systems in the future.

In Japan, discussions on higher education and ICT tend to be conducted only among specialists in educational technology. However, technology advances may lead to substantial changes institutions of higher education, and therefore, it is essential to share and discuss this issue from various points of views.

(Original Japanese version: published in February 2011)

Others

6 Electronic Journals as Research Infrastructure *Aiming to Maintain Access to Electronic Journals*

p.70

Securing communalism for the knowledge that results from scientific research, and universalism, disinterestedness and skepticism across the entire scientific community encourage progress and are what makes science, science. Papers are a medium for this, and should be acknowledged as research infrastructure (facility).

The growth in the number of papers that can be accessed universally as a result of their publication as electronic journals signifies their growing importance as a research infrastructure, but if the cost of purchasing electronic journals increases too much, it will put pressure on research expenditure. Therefore, it will be necessary to take steps to make the costs rationally suppressed.

If electronic journals are a part of the research infrastructure, their value should, primarily, be evaluated (and thus priced) in terms of their contribution to research outcomes; at the very least, it is necessary to evaluate whether or not they are utilized in research. But in reality they are sold as a package, which is called a "Big Deal," thus are evaluated on the basis of the number of titles included in a package. The publication of electronic journals is becoming an oligopoly and the price is rising, because there are no escape routes for consumers, so apparent demand is being pushed up through bundling as a result of supply-side initiatives.

By purchasing electronic journals in the form of a package, research institutes themselves become the only points of contact for negotiations and contracts with publishing companies. As well as the sources of funding that they have had to date, after coordinating with their researchers, research institutes also appropriate money from the overhead of research grants to purchase electronic journals as a form of research infrastructure development common to all researchers. However, researchers do not adequately understand the current situation, whereby titles cost a considerable amount of money. In the future, it will be necessary for researchers to indicate what sort of negotiations they wish to pursue with publishing companies via the research institute, and to fulfill a certain level of responsibility themselves in terms of the financial burden.

First and foremost, it is necessary for members of the research institute to discuss and establish a consensus regarding what kind of investment in what kind of form they will make in purchasing electronic journals, with the aim of generating utmost research outcomes. Based on that consensus, the research institutes, which are the users, and the publishers, which are the suppliers, should engage in negotiation and should avoid price negotiation on a sly zero-sum basis.

An effective means of increasing the bargaining power of research institutes and researchers is to diversify access methods to other papers that will result in publishing companies' competition, such as open access and Inter-Library Loans (ILL). By working in partnership with the overseas research communities and introducing mechanisms such as basic charges in tandem with a "pay-per-view" system of access in excess of the basic rate, research institutes should give consideration to breaking a spell of the Big Deal contracts.

(Original Japanese version: published in February 2011)

1

A New Movement in Drug Development Technology — Microdosing and its challenges —

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1 Introduction

The use of pharmaceuticals, whether these are cold medicines sold at drugs stores or cancer drugs that cost hundreds of thousands of yen per ampule, provides us with great benefits, such as the treatment of sickness and the alleviation of symptoms. Though to the people who use them, it seems to be a given that such medicines are effective and without serious side effects, for the developers, it is difficult to develop such compounds, even with the latest scientific technology.

Figure 1 (a) shows the simplified process of normal drug development. Drug development starts with compound synthesis and optimization using knowledge from basic research, following which a few candidate compounds are selected by repeated test tube and animal experiments in the nonclinical test stages. Out of these candidate compounds, the ones that are estimated to possess the best qualities proceed to clinical trials, which is the stage in which the safety and efficacy of the compound on humans is verified. More than a few of them, however, cause unexpected side effects or show no effect on humans. As if to tease, “pharmaceutical companies have more than enough drugs, if you want to treat a lab rat,” it is very difficult to narrow down the results obtained in nonclinical studies to compounds that are safe and effective for humans, and more solid methods for doing this have been needed for a long time.

Microdosing trials were proposed as an effective technique at the beginning of this century (Figure 1(b)). Microdosing is a technique to narrow down the candidate compounds with the highest viability for clinical trials by administering them to humans at extremely low doses to examine their metabolism and tissue distribution when multiple candidate compounds remain after nonclinical trials. At these extremely low doses, there is a low risk of side effects, and therefore, this method enables the performance of candidate compounds in humans to be evaluated safely and in a short period of time.

This report introduces the trend of the microdosing technique in Japan and around the world in the context of recent drug development, and discusses the challenges facing the actual application of microdosing in the future.

2 Problems with Drug Development and the Significance of Microdosing

The development of a new drug generally takes about 15 years and costs tens to hundreds of billion yen. Commonly sold and used drugs are created through an overwhelming process in which a single compound is selected from among hundreds of thousands of candidate compounds. Pharmaceutical companies usually take the main role in drug development, but currently, they rarely undertake all of the processes. In many cases, the evaluation of candidate compounds and clinical trials are referred to contract research organizations (CROs). CROs verify the safety and efficacy of candidate compounds by tests done in test tubes and with animals as nonclinical tests.

Animal experimentation is essential to today’s drug development. From the past to the present, a large number of animal studies have been conducted to obtain important data at the organism level that cannot be revealed by molecular and cellular tests. However, it is not a versatile method, since results vary due to species-specific differences between animals and humans. Figure 2 shows a comparison of bioavailability—the fraction of an orally administered dose of a drug that reaches systemic circulation and circulates in the body after the compound is absorbed

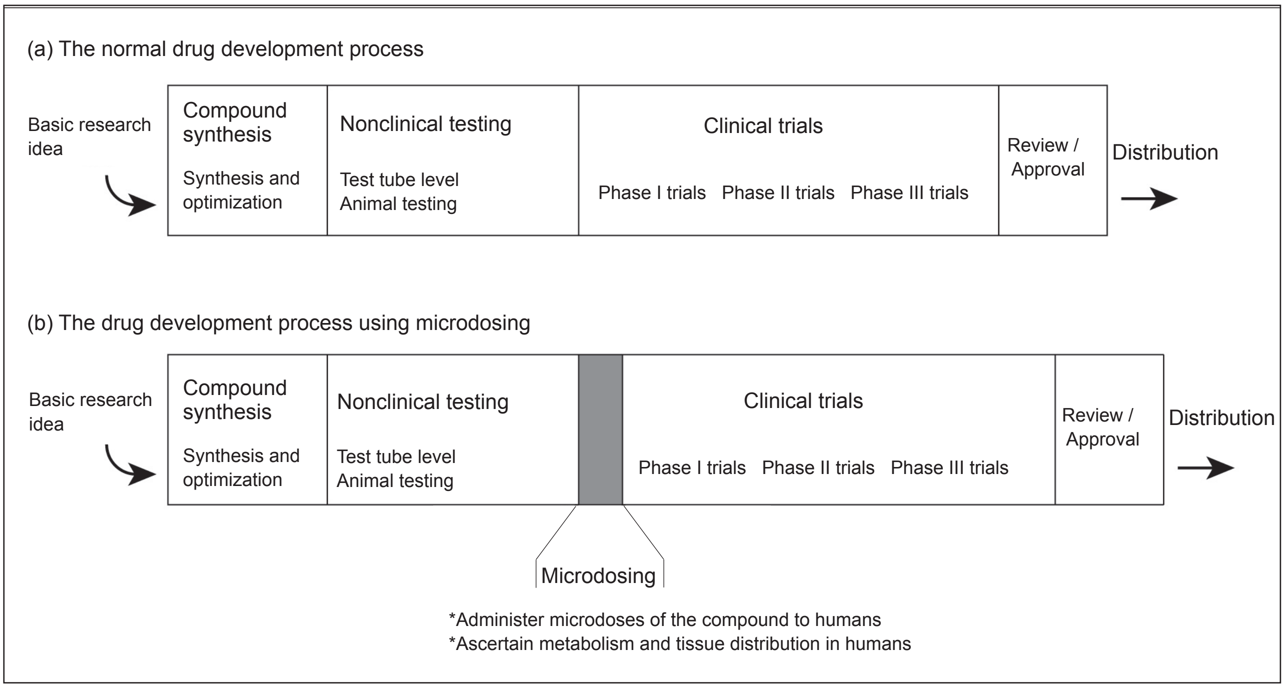

Figure 1 : The Drug Development Process

Prepared by the STFC

by the digestive tract—between humans and animals. Various drugs were tested in this experiment, and the results of each drug are plotted for comparison between humans and monkeys, humans and rodents, and humans and dogs. If the bioavailability of humans and the animals are proportional to each other, the results should plot along a linearly increasing line, whereas in reality, the plot points are scattered randomly. This means that there is little correlation between the bioavailability of humans and that of each animal, clarifying the difficulty of estimating human bioavailability from animal experiments.[1]

In drug development, several candidate compounds are selected in the nonclinical stage of the development and proceed to the clinical trials. As mentioned earlier, it is extremely difficult to select compounds in the nonclinical stages of development that will be safe and effective in humans, and the reality is that the probability of the compounds selected for clinical trials being approved as drugs in the end is low. Reasons for their disqualification vary; for example, the compound cannot be absorbed after oral administration and therefore does not reach circulation, it produces toxic metabolites when metabolized in the liver, it does not reach the target organ or tissue, it gets transferred to organs and tissues that trigger side effects, or it does not get metabolized in the body and actually exhibits toxicity. These are problems related to the pharmacokinetics, in other words, absorption, distribution, metabolism, and excretion, and take up a large proportion of the reasons for disqualification. Other factors contributing to disqualification include unwanted interactions with other drugs, as well as pharmacokinetics that vary from person to person or symptom to symptom.

Figure 3 shows the proportion of the compounds that make it to distribution out of the candidate compounds entering Phase I, the first stage, of clinical trials. Approximately 11% actually make it onto the market. When development is terminated at the level of clinical trials, various actions need to be taken, such as another set of clinical trials using other candidate compounds, and this is extremely inefficient, extending the development period and boosting up the costs.[2]

If candidate compounds are disqualified for pharmacokinetic reasons, the success rate in clinical trials can be increased by selecting candidates based on their good pharmacokinetic properties in humans. This is how microdosing came along. Microdosing can reveal whether the candidate compounds' metabolic rate is too fast or too slow, or if they reach the target organs or tissues in humans. If candidate compounds are selected with these data in mind, their viability will increase dramatically. In other words, improved viability means reducing losses from costs and time wasted on testing non-viable compounds, and as a result, reducing the development time. Of course, microdosing also requires a certain amount of time and costs. However, both the costs and the time needed are slight compared to normal clinical trials, and considering the current viability of 11%, the overall time and cost for getting the drug onto the market can be drastically reduced (Figure 4). As shown here, microdosing has drawn attention as a technique to improve the efficiency of drug development. In addition, it is believed to be useful in allowing a company to find which of their drugs are candidates for having the highest sales among those with the same mechanisms of action (Best-in-Class drugs), by comparing them with drugs that other companies have already come out with, and it is also said to be effective in allowing a company to re-evaluate its own candidate compounds.

3 The State of the Japanese Pharmaceutical Industry

Japan has contributed to a significant proportion of global drug development as one of the few countries that can develop new drugs domestically. At the same time, the country continues to move toward a "super-aging" society, and with the most common cause of death being cancer, and with neuropsychiatric diseases such as dementia increasing rapidly, development of drugs to treat these illnesses is an urgent task. In addition, unmet medical needs, meaning medical needs with no existing effective treatments, must also

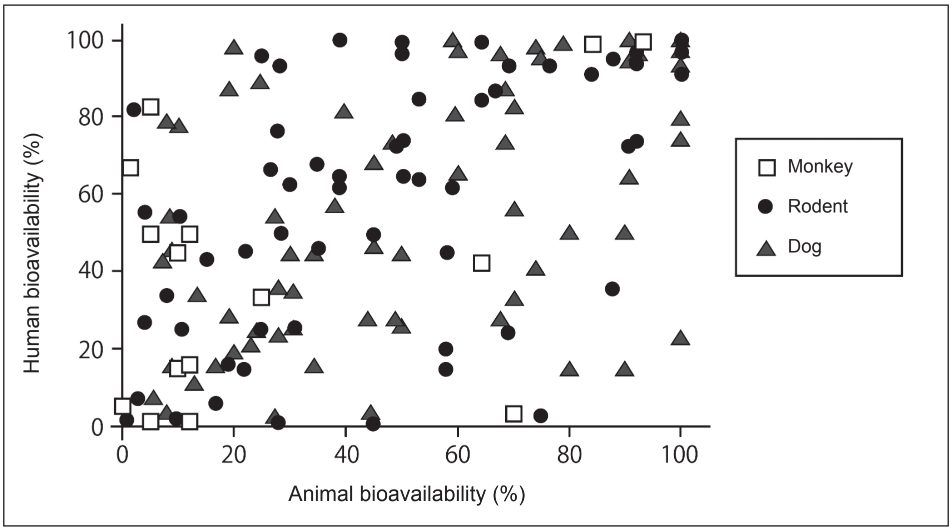

Figure 2 : Comparison of bioavailability between human and animals

Produced at the STFC based on Reference[1]

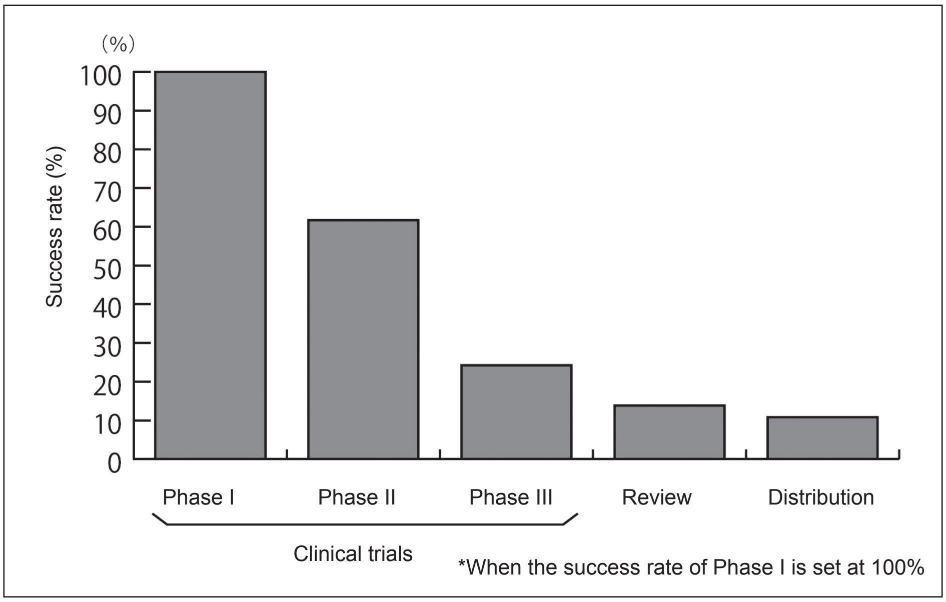

Figure 3 : Success rate of drug development in the top 10 U.S. pharmaceutical companies (1991–2000)

Produced at the STFC based on Reference[2]

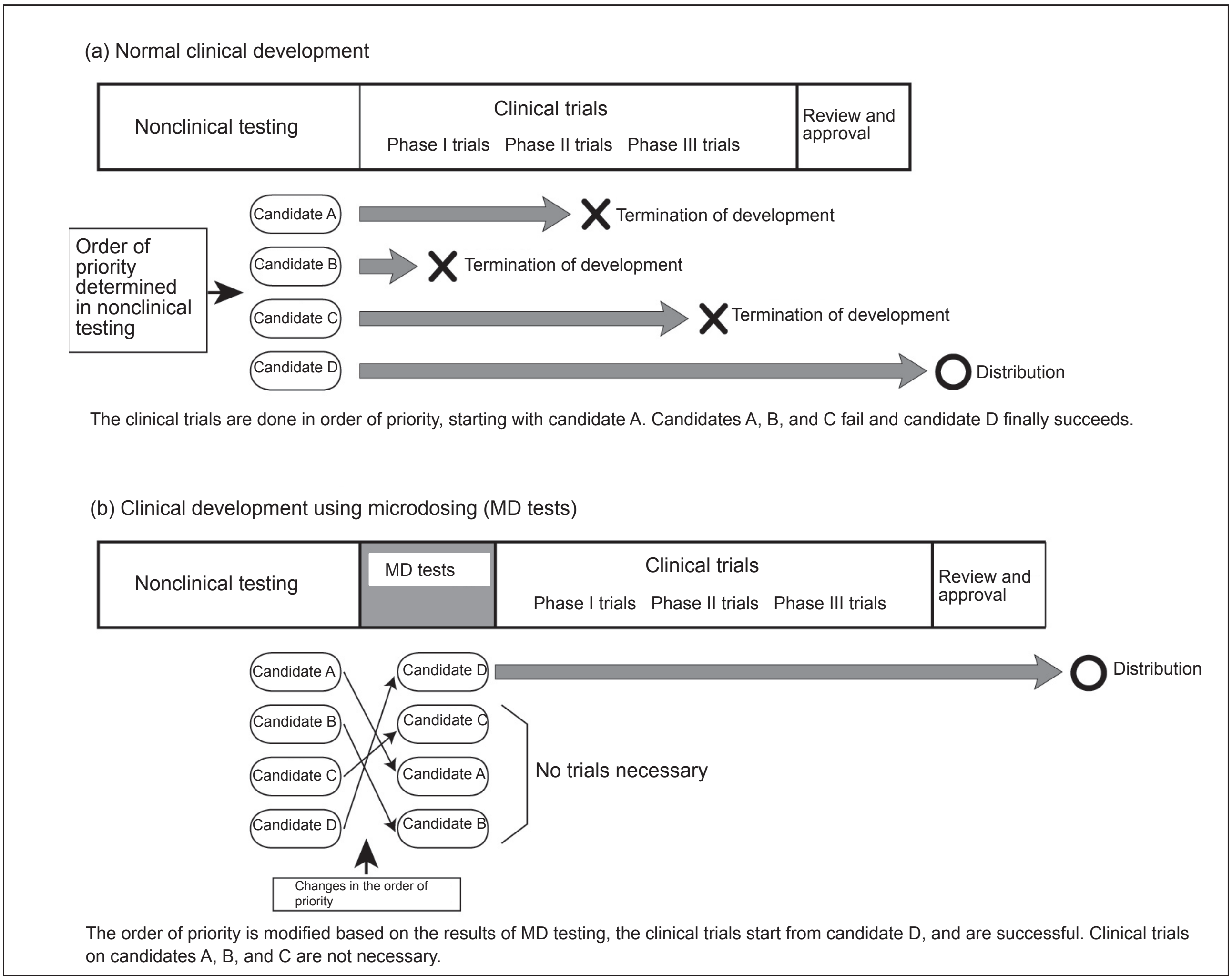

Figure 4 : Normal clinical development and clinical development using microdosing

Prepared at the STFC

be dealt with.

New drugs need to be developed; however, the number of new drugs developed in Japan has a decreasing tendency. Figure 5 shows the changes in the number of manufacturing approvals for new drugs, including those with new active ingredients, in Japan. This number starts to decrease in the later half of the 1990s, and it has notably not exceeded 10 per year after 2001.[3] A similar decrease can be observed in the U.S., albeit to a milder extent than in Japan.[4] In addition, the U.S. has increased its proportion of development of innovative drugs, meaning the first drug to be discovered that uses a certain mechanism (a new class of drug), whereas Japan has decreased here also.[5]

The decrease in the number of newly approved drugs causes the increase of development costs as a result. The average annual cost of research and development among 10 major pharmaceutical companies in Japan was 43.3 billion yen in 1999, whereas in 2008, it increased more than 3 times to 133 billion yen (Figure 6). This caused development costs to exceed 20% of sales in 2008, and caused net profits to drop to 5%.[3] One of the biggest factors in these increasing costs is the low viability of compounds in clinical trials, as mentioned earlier. When development is terminated at the half way point, most of the costs invested up to that point are wasted, and the loss gets bigger as the termination occurs later on in the development. Consequently, it starts to appear as an increase in development costs for the company as a whole.

The United States is one of the biggest markets for Japanese pharmaceutical companies, and the country's safety review of new drugs became stricter with the Food and Drug Administration (FDA) reform bill in 2009. With this, development costs are expected to increase further with the increase that this has caused in the number of subjects and extended period that will be necessary in future clinical trials.[4]

Japan is one of the few countries that develop drugs domestically, as mentioned earlier, however, in the balance of trade, Japan has an excess of imports

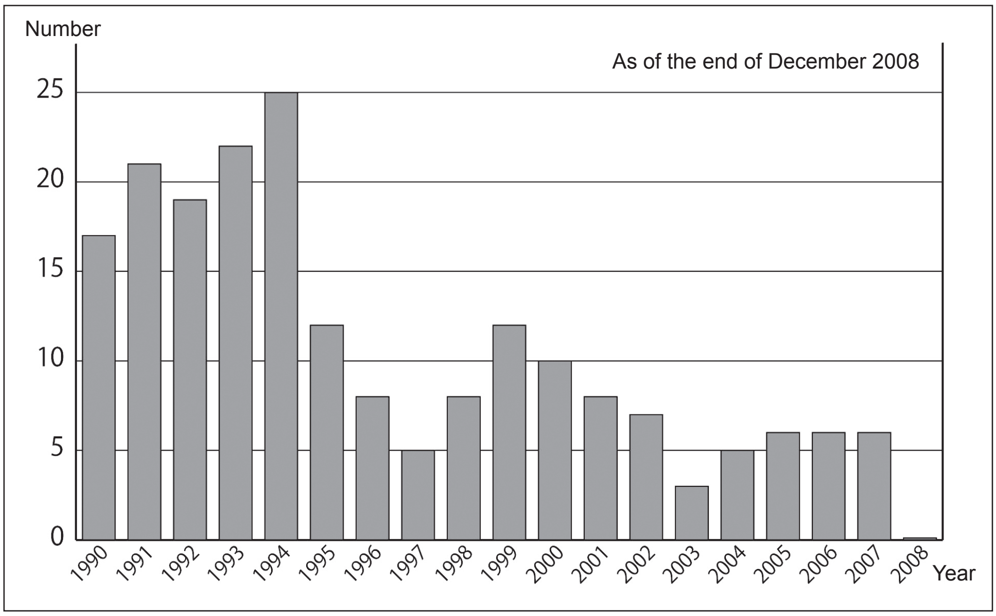

Figure 5 : Number of manufacturing approvals of drugs with new effective contents in Japan

Prepared at the STFC based on Reference[3]

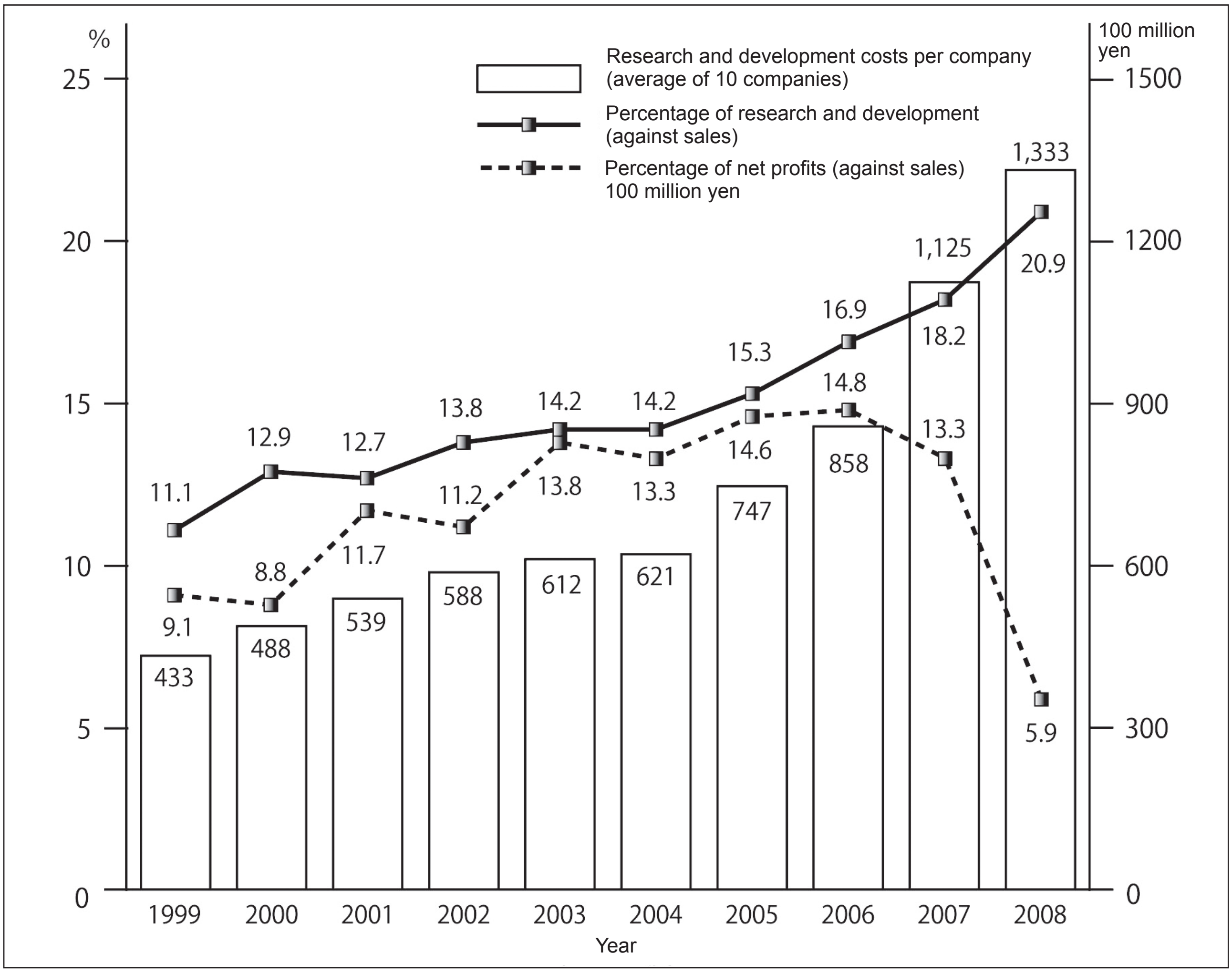

Figure 6 : Changes in research and development costs and the proportion of profit over sales at 10 major pharmaceutical companies in Japan

Prepared at the STFC based on Reference[3] over exports on the pharmaceutical industry. When comparing 2000 and 2008, exports increased slightly, whereas imports almost doubled, making imports more than triple of exports in 2008, and creating a deficit of 780 billion yen in the 2008 balance.[6] Japan is moving toward a super-aging society, and further increases in medical costs are expected. Developing drugs in Japan not only benefits its citizens, but also helps the trade balance by increasing proportion of purely domestic drugs. However, Japanese companies are at a disadvantage in innovating new drugs. They are relatively small companies by global standards, as evidenced by Takeda Pharmaceutical, which has the highest domestic drug sales, and is ranked only 17th in the world.[7] Mega-pharmaceutical companies in the U.S. and Europe may be able to run clinical trials one after another with their abundant financial resources. Small-scale pharmaceutical companies in Japan, therefore, should be more efficient in drug development, such as through the use of microdosing, to compete with these mega companies.

4 Advocacy of Microdosing and International Guidelines

Low viability and increases in development costs are not unique to drug development by Japanese pharmaceutical companies, but are, in fact, a global problem. One of the methods to solve this problem is microdosing.

The concept of microdosing first appeared in the position paper of the European Medicines Agency (EMEA) in 2003. In addition, the FDA issued a Critical Path Report in 2004, indicating the importance of conducting exploratory clinical trials before normal clinical trials, and further developing this idea later on. In response, though delayed, the MHLW (Ministry of Health, Labour and Welfare) in Japan released its Guidance on Microdosing in June 2008. Guidelines on drug development allow for more efficient development when standardized internationally. Therefore, the Non-clinical Safety Studies for the Conduct of Human Clinical Trials guideline of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), was revised and agreed upon among the EU, the U.S., and Japan, and publicized domestically in February 2010.[8] This has provided a way for microdosing to be conducted based on internationally standardized guidelines.

The Guidance on Microdosing, in addition to prescribing technical guidelines such as the administering dose of the compound, toxicity tests on the compound, the compound quality, measurement methods, and evaluation of internal exposure, also prescribes the formation of protocol for the clinical trials, formation of a review board, and the notification of the relevant government agencies, and requires that microdosing studies actually being conducted adhere to all of these guidelines, as well as the ethical aspects of such testing.

5 Implementation of Microdosing Studies and Measurement Technology

Microdosing studies are trials where less than 1/100 of an effective dose totaling less than 100ug of a candidate compound is administered once or multiple times (up to 5 times) to humans. Since the dosage is so small, there is little risk of side effects even when studies are done on humans. In addition, the toxicity testing that is carried out on animals before these studies can be completed more easily and in a shorter time than before normal clinical trials. In actuality, CROs commissioned by pharmaceutical companies conduct these studies, by administering microdoses of candidate compounds to several healthy male subjects and taking measurements. For measurement, one method is usually selected from 3 major methods (Table 1).

5-1 Accelerator Mass Spectrometry (AMS)

Accelerator mass spectrometry (AMS) is a method used for dating, and has a characteristic high sensitivity. In microdosing, candidate compounds are labeled with ^{14}C. After administering a microdose of labeled compound to a human subject, samples such as blood, urine, and feces are analyzed using AMS. Since ^{14}C-labeled compounds are administered, a small amount of radiation is released. The amount, however, is much less than the annual exposure to natural radiation, thus the radiation from the study is believed to have no effect on the subjects' health, and the labeled compounds are not legally regarded as radioactive isotopes due to their small doses. It is useful for investigating how the compound is

Table 1 : Measuring techniques used for microdosing

Measuring method	Labeling of testing material	Characteristics
Accelerator Mass Spectrometry (AMS)	Radioactive isotopes with a long half life, such as ^{14}C	*Extremely high sensitivity *Capable of constructive analysis of the metabolites of the compound *Requires large facilities and equipment
Liquid Chromatograh Mass Spectrometer (LC/MS/MS)	No labeling required	*Capacity for profile prediction of the medicinal properties of a compound *Suitable for cassette dose test
Positron Emission Tomography (PET)	Positron-emitting nuclide with a short half life, such as ^{11}C, ^{13}N, ^{18}F, ^{15}O	*Capacity to measure distribution and concentration of the compound in the body *Requires large facilities and equipment

Prepared at the STFC

absorbed, metabolized and excreted as a whole. In other words, by measuring the concentration of the administered candidate compound in the blood, urine, and feces chronologically, the pharmacokinetics of the candidate compound, as well as its metabolites in the human body, can be found. Since drugs become active and consequently act as drugs after becoming metabolized in the body in many cases, a low concentration of active metabolite in the measurement causes the compound to be given a low evaluation. In addition, the use of ^{14}C labeled compound enables the discovery and/or identification of new metabolites, allowing for a separate toxicity test of the metabolite later. Since there is a difference between some metabolic enzymes in humans and in animals, there is a possibility that a metabolite that is toxic specifically in humans may form. If the strong toxicity is revealed beforehand, the candidate compound can be eliminated from the list, and wasteful clinical trials can be prevented.

Highly sensitive AMS analytic methods are already being used in the U.S. and Europe, and are applied to many microdosing trials. There are also private analytical companies that are equipped with AMS and possess high analytical techniques in Japan.

5-2 Liquid Chromatograh Mass Spectrometers (LC/MS/MS)

A liquid chromatograph mass spectrometer (LC/MS/MS) is a device that combines a high-performance liquid chromatograph (HPLC) and a mass spectrometer (MS), and is able to quantify materials in a highly sensitive manner, as well as to detect blood concentrations of a drug at the order of pg/ml. As for its use in microdosing, it does not require labeling since it does not use radioactive isotopes. In addition, since it does not require a large facility, it can be used at a small scale organization or company.

One characteristic of LC/MS/MS is its effectiveness for cassette dose tests. The cassette dose test is a method to test multiple compounds simultaneously on one subject, enabling the comparison of the compounds under the same conditions, which provides valuable information that can not be obtained from the test of each compound. This means that it enables the compound with the best drug properties to be selected from multiple candidate compounds with similar expected effects, and also cuts costs by reducing the number of subjects required.

5-3 Positron Emission Tomography (PET)

Positron emission tomography (PET) is a method that is commonly used for cancer diagnosis in medical institutions. It measures the distribution and chronological changes of gamma waves emitted by a radioactive tracer labeled with a positron emitting nuclide with a short half-life (^{11}C, ^{13}N, ^{18}F, ^{15}O, etc). In microdosing studies, the distribution and the concentration of the compound can be detected chronologically as imaging data by labeling the testing compound with a positron emitting nuclide and using it as the radioactive tracer. This is a superior characteristic particular to PET. The two methods introduced earlier can measure the time and concentration from the time of administration until its collection, however, they can not reveal the course the compound took. PET can show important information about whether a compound is transferred to the target organs or not. For example, there are more than a few examples of compounds targeting the brain that could not reach the human brain in clinical trials. This is due to the blood-brain barrier in the human brain, which blocks the unnecessary components of the blood from entering the brain. The use of PET enables it to be clearly seen whether a candidate compound reaches the brain, providing important information for the evaluation of the compound. In addition, PET enables the measurement of the occupancy of receptors (how much of the compound is bound to a particular receptor) that are involved in treatment or in side effects.

As seen up to this point, PET has big advantages; however, it comes with disadvantages as well. Since PET uses radioactive isotopes, it requires strict management of the labeled compounds, necessitates assessments on the safety of the subjects' exposure. In addition, it requires a large facility and equipment including cyclotron, automatic synthesizing apparatus, and PET scanner, requiring a big investment of several billion yen for its construction. In addition, there are some technical problems remaining, especially the existing difficulties with the efficient labeling techniques of candidate compounds with positron-emitting nuclides in extremely short periods of time. In addition, since it is necessary to develop a synthetic method for labeling each individual compound, it is hoped that a universal synthetic method will be developed that can be applied to almost all compounds.

6 Research Trends of Microdosing

Microdosing is a relatively new method in the history of drug development, and its effectiveness had not been confirmed when it was first proposed. In particular, since the method involves taking measurements after very small doses of drugs are administered, there was no proof that measurements would be correlated (linear) to these when a therapeutic dose was administered, and this needed to be confirmed. In addition, many aspects of the measuring techniques were underdeveloped, and the establishment of a methodology, including the management of the overall study was necessary. Because of this, validation projects have been conducted to evaluate the effectiveness and problems of microdosing studies, using existing drugs whose safety and dosages have been confirmed in normal clinical trials, with England playing the central role.

One of the projects was the Consortium for Resourcing and Evaluation AMS Microdosing (CREAM) test conducted by four pharmaceutical companies led by a British CRO, Excelleron Corporation, in collaboration with Eli Lilly, Roche, and others, and its results were reported in 2006.[9] In this study, five existing drugs were used, out of which three maintained linearity, and two did not show enough linearity. However, it was determined that it was possible to predict the causes for disrupted linearity in the two samples using other information.[10]

Another project was the European Union Microdosing AMS Partnership Programme (EUMAPP), which began in January 2006 with the EU's public support. In this study, the aforementioned Excelleron Corporation took charge of coordination, and nine EU private companies and members of academia participated in evaluating seven major compounds that had caused problems in animal studies. As a result, in a study in which microdoses of the target compounds were injected intravenously, the microdoses were confirmed to maintain linearity with the therapeutic doses. On the other hand, the data from oral administration did not maintain linearity to the same extent as it did with intravenous administration, however, they concluded that most of the causes for the disruption could be predicted by the compounds' chemical properties.[11]

These two research projects were groundbreaking in the sense that they clarified the effectiveness and problems of microdosing studies. In addition, by moving forward with these studies, the know-how for conducting microdosing was accumulated and human resources were trained in European CROs such as Excelleron Corporation.

A validation project for microdosing is being conducted in Japan also, namely, the NEDO project, which started in October 2008, entitled Development of Innovative Drugs Using Microdosing Studies: Based on the Quantificational Prediction Technology of Drug Properties and Efficacy. This project is more ambitious than those conducted in the UK or in Europe, as it aims to develop innovative technology that will support drug development, by fusing microdosing studies that use various measurement techniques, including molecular imaging by PET, with kinetic analysis methods related to the prediction of a compound's dynamics in the body, dramatically improving the effectiveness and applicability of microdosing.[12] The abovementioned projects in the UK and the EU used only AMS, but this project values measurements by PET, as well as high-performance LC/MS/MS. In addition, it is attempting to enable wider predictions to be made from the data obtained in microdosing studies, by combining test tube and animal experiment data, such as data on the drug transporters and metabolic enzymes that are involved in transporting a drug in and out of the cell, and the influence of polymorphism on the genes related to them, and by constructing mathematical models from this combined data. The final results of the project are scheduled to be published in 2011, and they are expected to surpass those of the projects in Europe.[13]

7 Use of Microdosing Studies and the Status of CROs

Corporate activity, particularly information on drug development by pharmaceutical companies, is rarely publicized, making it extremely difficult to grasp the overall picture of the microdosing studies being implemented. An investigation by the Pharmaceutical Research and Manufacturers of America (PhRMA) reported that in the nine participating U.S. pharmaceutical companies they had surveyed, a total of 16 such studies had been implemented from 2006 to 2007 and another 16 had taken place from 2008 to 2009. However, it is noted that a larger number of such studies were actually being implemented.[14] In the UK, at first, many microdosing studies were being implemented for candidate compounds developed by startup companies, however, with the improvement of the measurement technology with PET and LC/MS/MS, major pharmaceutical companies such as GlaxoSmithKline, Servier, Merck, Sanofi-Aventis, and Amgen, started to conduct these studies as well. Especially from 2009 to 2010, conditions changed dramatically, with some reporting that the number of commissioned microdosing studies had almost doubled.[14]

PET is one of the most powerful tools in microdosing, and with the recognition that imaging technology provides valuable information on the direction of drug development, GlaxoSmithKline founded a research institution, the Clinical Imaging Center, at Imperial College London's Hammersmith Hospital in the UK, in 2008. This institution has two PET scanners and two MRI scanners, and has announced its use of imaging technology in approximately 40% of the drugs developed by the end of 2010.[15] As seen here, major pharmaceutical companies in the U.S. and Europe seem to be incorporating microdosing studies as a part of drug development. This is backed by the fact that the previously-mentioned validation studies on microdosing have provided training to the CROs, which makes it easier for the pharmaceutical companies to commission them.

On the other hand, operational experience with microdosing in Japanese pharmaceutical companies is comparatively scarce, with few reports on this topic. Mid-sized Ono Pharmaceutical has reported to have commissioned a British CRO to implement microdosing studies, and decided to continue with development using the results it obtained on bioavailability. Astellas Pharma has applied the accumulated knowledge of many years of PET studies to found their own facility and research institution (Bioimaging Institute) with PET and MRI, and it is believed that it will start running microdosing trials.

There are various CROs for different stages of drug development in Japan, creating a market of over 200 billion yen, and their ability and quality are regarded as extremely high compared to CROs in the U.S. and Europe. They have traditionally evaluated the safety and properties of candidate compounds using animal experiments, however, in recent years, there is a movement to actively incorporate procedures that connect the animals and humans, with an increasing number of CROs conducting tests using human cells. Some of these CROs are participating in the abovementioned NEDO project, and though it is a validation project using existing drugs, it provides the opportunity to advance the know-how and training of human resources for running microdosing studies. In the future, when the use of microdosing gains momentum, the techniques for handling microdose compounds and metabolites will improve, and the CROs will mature to the level of Western CROs. Microdosing studies using PET are harder to tackle than those that use AMS and LC/MS/MS from the perspective of the facilities involved, meaning that only a portion of incorporated administrative agencies, universities, and corporations are able to use PET in reality. Because of this, those that cannot will need to collaborate with CROs to conduct studies using PET in the future.

8 Problems with Microdosing Studies in Japan and Their Solutions

We have discussed microdosing and its techniques, the state of drug development, and domestic and international companies and research trends. As a result of validation studies on micordosing in Europe, microdosing is believed to be a useful technique that will be used more in the future. In the U.S. and Europe, this technique has been taken on by both startup companies and major pharmaceutical companies, and is already being used for drug development.

On the other hand, though delayed from the European projects, the NEDO project has started in Japan. Pharmaceutical companies and CROs are participating in this project, learning measuring and analytical techniques and training personnel by actually conducting microdosing studies. However, Japanese pharmaceutical companies have yet to commission domestic CROs to conduct microdosing studies, and tend to commission CROs abroad for this. Though microdosing is not necessary for all drugs being developed, persistence of the current state will create a large gap in the efficiency of Japan's drug development compared to the U.S. and Europe, causing a decline in the Japanese pharmaceutical industry.

To solve this, policies should be developed to construct a system for carrying out microdosing studies domestically based on the NEDO project results. Considering the validation projects that have already been implemented and the existence of experienced CROs in the U.S. and Europe, it is necessary to train human resources in domestic CROs with even higher techniques for microdosing studies to be conducted in Japan. Fortunately, domestic CROs are participating in the NEDO project, and higher levels of predictive techniques are starting to take shape under its ambitious goals. In order for Japanese pharmaceutical companies to commission domestic CROs rather than those abroad, these CROs need to accumulate experience. To do this, microdosing should be primed by the government (such as Ministry of Economy, Trade and Industry) by providing financial support to pharmaceutical companies to conduct microdosing studies, creating a virtuous circle in which pharmaceutical companies repeatedly commission CROs. Participating companies can be recruited publically, giving the opportunity for bioventures, universities, and incorporated administrative agencies, in addition to mid-sized pharmaceutical companies, to participate. Through this, pharmaceutical companies and CROs will receive actual experience with microdosing studies, resulting in the development of technology, personnel training, and upgrades in management ability, as well as the construction of a system for developing new drugs using microdosing within pharmaceutical companies.

In addition to the construction of a domestic system, it is also important to develop foundational technology, led by MEXT (Ministry of Education, Culture, Sports, Science and Technology). Microdosing is a barely 10-year old method, and upgrading is needed in all areas, such as sampling and sample processing. Testing by PET, in particular, has extremely high potential as a molecular imaging technique for distinguishing tissue distribution as well as for determining the efficacy of future treatments. Since compound labeling is important in microdosing studies using PET, efficient labeling methods should be established in order to construct a domestic system that can respond to a large volume of demand. Since PET studies are more difficult in terms of the facilities required, it is desirable for NIRS (National Institute of Radiological Sciences) and RIKEN, which promote molecular imaging research, to provide the technology and facilities, and collaborate with CROs in implementing microdosing studies.

In recent years, many biomedicines such as antibody drugs, peptides, and nucleic acid drugs have appeared and increased in significance. The technology for testing these biomedicines by microdosing still needs to be established.

As mentioned earlier, drug development requires knowledge in various academic fields, and this has been one of Japan's strong suits. In recent years, however, drugs in Japan are often introduced after their development abroad, creating concerns of the loss of substance in drug development in the country. If microdosing studies can be conducted outside of the country, more information on drug development will flow overseas, possibly worsening this situation. On the other hand, if a system through which microdosing studies can be conducted is established in Japan and uses better techniques than the U.S. and

Europe, pharmaceutical companies inside and outside of Japan will want to conduct their studies in Japan. Microdosing is a desirable tool for Japan to lead global drug development, and will allow many drugs to be developed efficiently to save people suffering from illness all over the world.

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Profile

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2

Research on Health Effects of Environmental Chemicals — New Developments through Introduction of Epigenetics —

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1 Introduction

In the last several decades, the physical constitution of people in advanced countries has changed apparently, and drastic increases in some kinds of disorders have been reported. For instance, the number of people having allergies, such as pollen allergies or bronchial asthma, has increased 10 times in 50 years since the end of World War II. One in every three people has some sort of allergy in Japan. Such a rapid change cannot be brought by a genetic variation. We believe it can be attributed to a recent change in living environment and lifestyle.

The Chemical Abstracts Service (CAS), which started chemical database services in 1965, reported that the number of chemicals registered with CAS topped 50 million in 2009. CAS reported that it took only nine months for the number of registered chemicals to increase from 40 million to 50 million, indicating that the number of chemicals discovered or synthesized by human beings has been increasing at a rapid pace. Japan and other advanced countries have been benefiting tremendously from such chemicals. Meanwhile, the number of chemicals taken in by human beings as medicines, cosmetics or foods has also been increasing, making it necessary to ensure the safety of such chemicals. In fact, safety evaluations, including adverse effects, have been performed.

However, in line with the development of new scientific technologies and the increased use of chemicals, a wide variety of chemicals, including non-regulated chemicals and unintentionally-generated chemicals, have been released into the environment, raising concerns about their adverse effects on human health. Particles and chemicals discharged by automobiles are suggested to be involved in the increase in the number of people having an allergy of some sort These chemicals in the living environment (i.e., environmental chemicals) are thought to be behind the recent change in human physical constitution.

When considering ways to reduce or prevent adverse effects of chemicals on health, it is essential to have scientific knowledge about the effect of each chemical on health and its mechanism. In this report, with regard to the mechanism of the health effect of chemicals, we would like to discuss the current state and problems involved in “epigenetics,” which has recently been drawing attention as one of the new approaches in life science. “Epigenetics” is expected to hold the key to elucidating the mechanism of “late-onset effects” of environmental chemicals, that is to say, the effect of exposure to environmental chemicals during the fetal period and childhood emerging in adulthood.

This report introduces epigenetic effects of environmental chemicals. The Science & Technology Trends Quarterly Review has already introduced epigenetics as a new research area in the field of cancer research in its May 2003 edition.[1] Epigenetic research has been progressing at an accelerated pace in a wide sphere in life science and its overall picture has been presented in the June 2009 edition of the Quarterly Review.[2] Please refer to the edition for better understanding.

2 Epigenetic Regulation of Genetic Information

2-1 Regulation of genetic information by epigenetic modification

Epi- is a prefix meaning “above” or “over.” The birth of an organism and all life phenomena are based on genetic information written in genes. Genetic information is also associated with maintenance, improvement and disturbances of human health. In molecular genetics, the mechanism for regulating

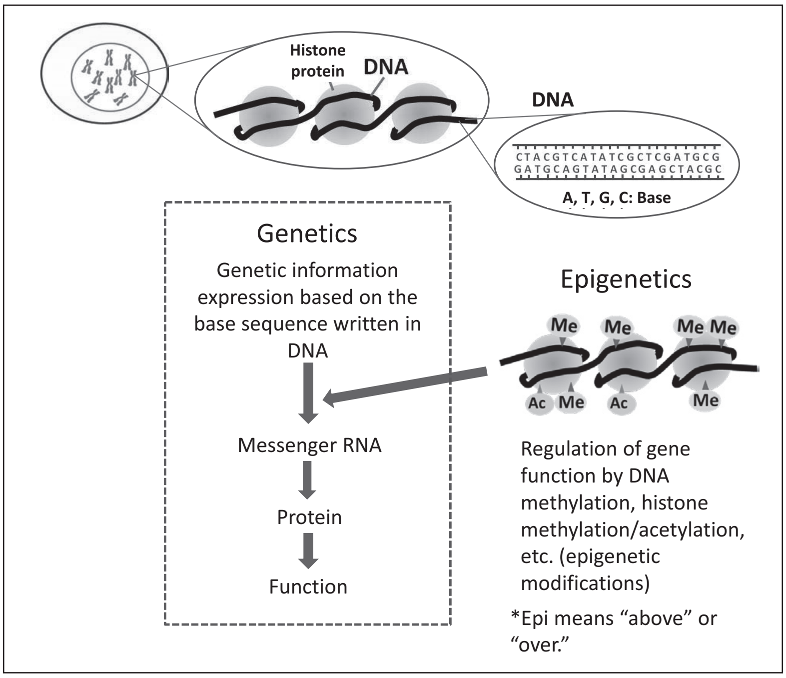

Figure 1 : Regulation of Genetic Information by Genetics and Epigenetics
In genetics, messenger RNA is created based on DNA sequence information, and the messenger RNA creates protein. On the other hand, epigenetics is a mechanism to regulate gene functions not dependent on DNA sequence. Gene function is regulated by mechanisms of both genetics and epigenetics.

Source: Prepared by the STFC

genetic information, such as the genetic ON/OFF switch, has been studied based on DNA sequences. On the other hand, “epigenetics” focuses on “the mechanism for regulating gene functions not dependent on changes in DNA sequence.” Specifically, it is a mechanism to regulate the ON/OFF switch of genes not by DNA sequence but by “epigenetic modifications,” such as DNA base methylation and histone protein methylation and acetylation (Figure 1).

2-2 Characteristics of epigenetics

Among the characteristics of epigenetic modifications are that they are, first of all, susceptible to environmental factors and that, secondly, they occur more frequently than mutation (change in DNA sequence). These characteristics have drawn attention to the possibility that environmental factors may change genetic information via epigenetics and thus affect human health and physical constitution.

As an example showing the relationship between epigenetics and environment, there is a study on monozygotic twins.[3] Monozygotic twins share common genetic information. However, it is reported that differences between the twins in epigenetic modifications, such as DNA methylation and histone acetylation widen as they grow. These results suggest that environmental factors affect the patterns of epigenetic modifications, which leads to phenotypic discordance, such as differences in susceptibilities to disease.

The third characteristic of epigenetics is the accumulative nature of epigenetic modifications. This accumulative nature is suggested to be closely associated with late-onset effects. In the mechanism based on genetics, if mutation occurs as a result of DNA sequence alteration, it could directly cause a change in protein alignment and cripple the function of the protein. On the other hand, in the case of epigenetic modification, its effect appears when cumulative modifications, such as histone modifications and DNA methylation, reach a certain level (Figure 2).

The fourth characteristic is that epigenetic alteration is reversible. By taking advantage of this reversible nature and by undoing DNA methylation change, drugs to prevent the progression of cancer have been developed.

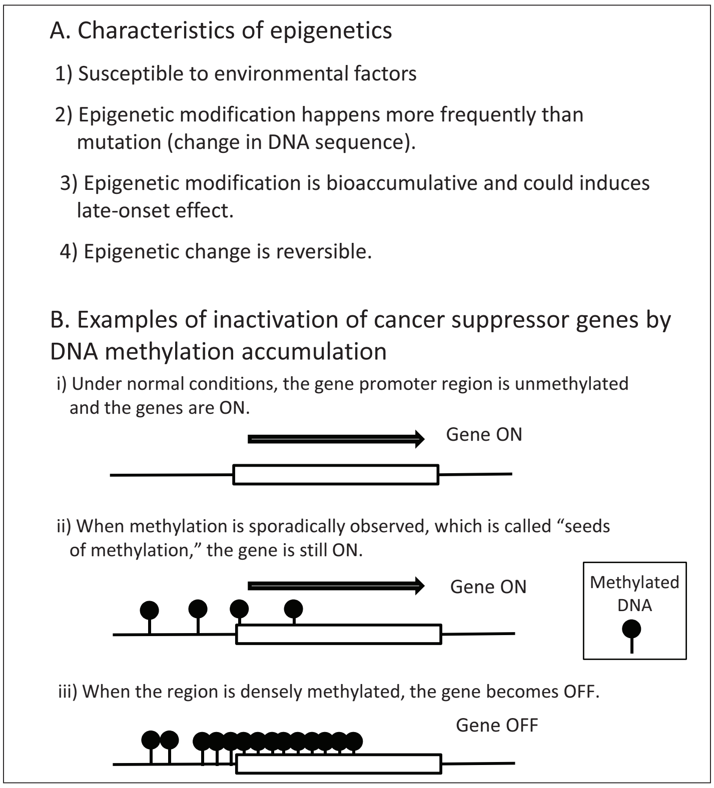

Figure 2 : Figure 2 Characteristics of Epigenetics (B is modified version based on Reference[4])

Source: Prepared by the STFC

3 Biological/Health Effects and Mechanisms of Environmental Chemicals

3-1 Health effect of environmental chemicals

Minamata Disease (Kumamoto Minamata Disease) in the 1950s was a disease caused by methyl mercury discharged by a chemical plant near Minamata Bay in Kumamoto Prefecture. People who had ingested methyl mercury-contaminated fish and shellfish developed neurological symptoms, such as numbness and pains in the hands and feet, impairment of language and ataxia. Moreover, methyl mercury ingested by mothers is transmitted across the placenta from mother to fetus and is accumulated there, resulting in serious damage to the development of fetus' cerebral nervous system.[5] After it was recognized that diseases like Minamata disease had been caused by human-induced environmental pollution, a concept of "*kogai* (public nuisance)" gained currency and prompted the establishment of the Ministry of the Environment and systematic implementation of pollution control and environment protection measures as national efforts.

Many countries, mainly advanced countries, have implemented measures to regulate and control the release of large quantities of poisonous chemicals into the environment. In 1973, Japan led the world in establishing the "Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances" to control and regulate manufacture and import of chemicals. In reality, however, a survey conducted under the PRTR (Pollutant Release and Transfer Register) system[6] shows that a large variety of poisonous chemicals have been released into the environment. We do not have enough knowledge about the harmfulness of not only new chemicals that are produced one after another but also many existing chemicals. The problem of environmental pollution caused by residual chemicals remains unsolved.

Polychlorinated biphenyls (PCBs), which began to be produced in around 1930, were once widely used as insulating material, cooling mediums and plasticizing agents. Meanwhile, the manufacture and use of PCBs have been banned by many countries in the world since the early 1970s, as the outbreak of so-called "*yusho* disease" in Japan and Taiwan revealed that PCBs have strong harmful effects. However, PCBs that were released into the environment as waste still remain in the environment, raising concerns about their adverse effects on immunity and the learning function of humans and wild animals.

With regard to highly poisonous persistent organic pollutants (POPs), such as PCBs, the Stockholm Convention on Persistent Organic Pollutants (POPs Convention) was adopted in 2001 with the aim of eliminating or reducing the release of POPs into the environment under international cooperation. The convention was later signed by more than 150 countries and entered into force in 2004. Among POPs are those that are manufactured for intended use, such as aldrin, chlordane, dieldrin and DDT, and those that are generated in the process of production of agricultural chemicals or released in the process of garbage incineration, such as dioxin and dibenzofuran.

In recent years, there are concerns about "endocrine-disrupting chemicals," such as chemicals having the same action as the female hormone estrogen or interfering with the reproductive function by disrupting hormone action. Bisphenol A, which is widely used as a material for synthetic resin, as well as the abovementioned PCBs and dioxin, are also reported to act as endocrine disruptors.

Meanwhile, the hazardous property of naturally occurring chemicals or elements that exist in the environment also poses a problem. A typical example is inorganic arsenic.[7] The intake of arsenic-contaminated well water has been causing disorders including skin disorders and cancers in such countries as China, Taiwan, India, Bangladesh and Argentina. It is reported that over several thousands of people are suffering from such symptoms in the world. A new technology is being developed to remove inorganic arsenic from well water. However, as it has yet to be put to practical use due to costs and technical problems, exposure to inorganic arsenic is going on around the world.

3-2 Functional mechanism of environment chemicals and epigenetics

Thanks to the progress of genomics technology, it has become clear that environmental chemicals cause various biological effects by affecting "on-off" switching of gene expression (Figure 3). A group of proteins called transcription factors plays a pivotal role in switching or regulating gene expression. It has been revealed that various types of chemicals alter gene expression by acting on specific transcription factors, resulting in causing various biological effects.[8] For instance, dioxin activates the transcription factor, Aryl hydrocarbon receptors (AhR) binds to it, and alters the expression of target genes, which is believed to lead to adverse biological effects.

In addition to these findings, there is a growing number of reports that chemicals exert biological effect by inducing epigenetic changes. One famous example showing that environmental chemicals alter DNA methylation is a study on the agouti mouse.[9] The coat color of the agouti mouse changes from yellow to brown depending on the methylation status in the DNA region that regulates the expression of the agouti gene. It is reported that if exposed to bisphenol A, an environmental hormone, during the fetal or prenatal period, the coat color of the mouse turns yellow, and that if the mouse is given foods associated with DNA methylation metabolism, such as folic acid, the color turns back. The research has revealed the gene that becomes the target of epigenetic action and that it is linked to expression of coat color. This is one of a few examples showing a clear causal relationship wherein chemical substances change phenotype via epigenetic modification.

As for inorganic arsenic actions, it was found that if pregnant mice are freely given water containing inorganic arsenic for only 10 days, the incidence of liver cancer is increased in their male offspring.[10] DNA methylation in the promoter region of ERα gene,,, which is associated with cell proliferation and carcinogenesis, was found to decrease in the liver of those male offspring. .Lower level of DNA methylation is favorable for genes to work. In fact, gene expression was found to be increasing, suggesting that inorganic arsenic increased cancer by enhancing the expression of carcinogenic ERα gene via epigenetic modification[10] (Figure 4). Another study reported that when a strain of mice which are prone to develop lung cancer are fed with water containing inorganic arsenic for a long time, it caused DNA methylation changes of tumor suppressor genes in the lung, inhibited the expression of these genes, and increased lung cancer.[11]

There is also a report that administration of vinclozolin (insecticide) to pregnant rats for one week decreased the spermatogenic capacity of their male descendants down to the 4th generation and increased the incidence of male infertility. These male rats inherited the DNA methylation change of reproductive cells. These results suggest that exposure to chemicals in fetal life causes changes in programming via epigenetic change of reproduction cells and that its effect is transgenerational.[12]

Epigenetic effects are reported in many other chemicals, including diethylstilbestrol (DES), a synthesized hormone, phenobarbital, a hypnotic, anxiolytic and anti-epileptic drug, dibromoacetic acid, a byproduct in the process of drinking-water disinfection, and benzopyrene, a highly-carcinogenic combustion product. Nickel, some other metals, cigarette smoke and diesel particulate are also reported to have epigenetic effects. However, the causal relationship between the biological effect of these chemicals and epigenetic changes remains mostly unexplained.

Figure 5 shows the concept of the causal relationship between DNA methylation change and cancer. When a cancer and epigenetic change are observed as a result of exposure to a chemical, there are two cases. One is that the epigenetic change caused the cancer and the other is that the cancer is caused by some actions of the chemical induced epigenetic change closely related to carcinogenesis. Further studies are necessary to clarify if and how deeply the chemical-induced epigenetic changes are related to the alteration of biological and physiological functions.

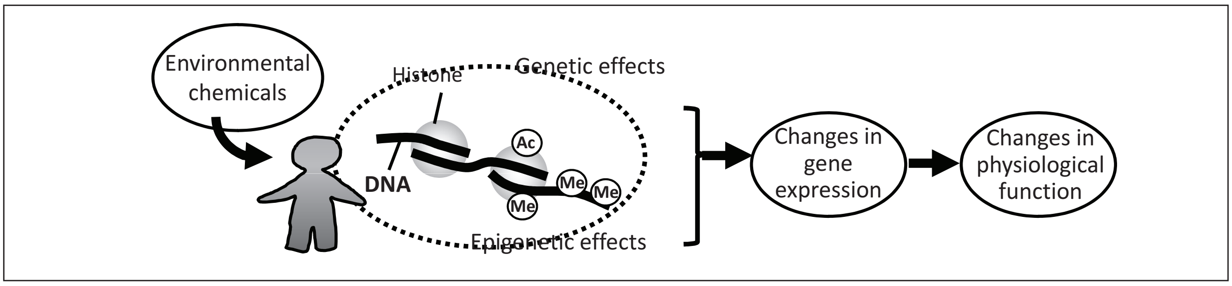

Figure 3 : Mechanism of Action of Environmental Chemicals via Alteration of Gene Function
In recent years, a variety of environmental chemicals are reported to be influencing biological functions by altering gene expression.

Source: Prepared by the STFC

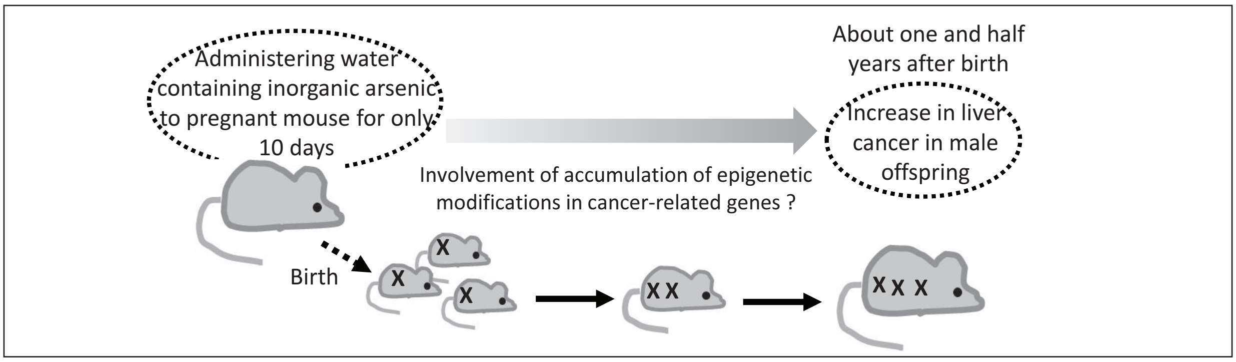

Figure 4 : Example of Late-Onset Transgenerational Effect of Environment Chemicals
The epigenetic effect is suggested in the experimental system in which giving inorganic arsenic to the pregnant mice increased the cancer in their male offspring in adulthood (Reference[9]).

Source: Prepared by the STFC

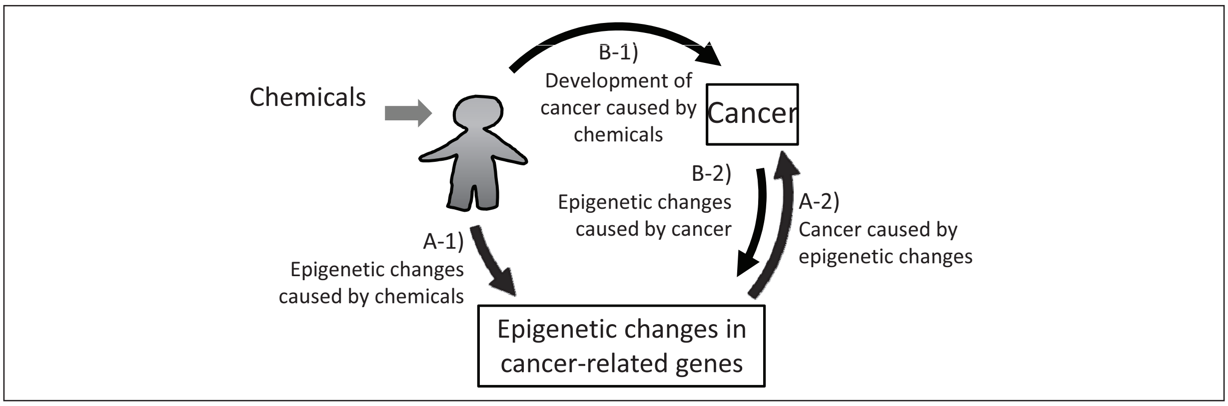

Figure 5 : Relationship among Exposure to Chemicals, Biological Effects, and Epigenetic Changes

Source: Prepared by the STFC

4 Effect of Exposure to Environmental Chemicals during Developmental Stage and Epigenetics

4-1 DOHaD hypothesis and epigenetics

In epidemiology study, the "DOHaD (developmental origins of health and disease) hypothesis" has recently come to draw attention. This hypothesis holds that the nutritional environment in the fetal and infant periods affects the risk of lifestyle-related diseases in adulthood. These periods have plasticity and are believed to be highly sensitive to chemicals. Epigenetics is suggested to play an important role in maintaining the changes in gene function caused by chemical exposure during perinatal periods, and the changes may exert adverse effects in later life. Thus, epigenetics is thought to be associated with DOHaD as a plausible molecular mechanism.

4-2 Japan Children's study

In conjunction with the DOHaD hypothesis, there has been growing international concern about environmental risks on children's health. With regard to the world research trend on children's health and the environment, please refer to the March 2009 edition of the Science and Technology Trends.[14] Under these circumstances, the Ministry of Environment started the "Japan Environment & Children's Study," an unprecedentedly large-scale national survey in FY2010. The survey is designed to elucidate the effects of exposure to chemicals and living environment on children's health. The ministry plans to recruit about 100,000 pregnant women from across the country in three years starting in FY2010 in order to survey and track children continuously from birth to around age 13 by conducting questionnaire surveys and performing physical measurement as well as environment survey, including chemical measurement.[15]

In such epidemiological research, biomarkers that are informative of the relationship between environmental influences and health effects would become powerful tools in analyzing research results. Changes in epigenetic modification can cause health effects, where some of the modifications would begin to change before their effects appear. In this regard, such epigenetic modifications would become biomarkers, or "epigenetic markers," that can detect the environmental effects at early stages. Since DNA is relatively stable, epigenetic markers such as DNA methylation are thought to be useful for retrospective study.

An epidemiological survey was conducted on umbilical cord blood DNA of about 700 children in New York City. The study reported that DNA methylation of the upstream region of gene ACSL3 is associated with transplacental exposure to polycyclic aromatic hydrocarbons derived from car exhaust emission and childhood asthma, suggesting that the change in DNA methylation in ACSL3 upstream may become an epigenetic marker.[16] Further study needs to prove the usefulness of the epigenetic marker proposed in the epidemiological survey in New York, including if the marker can be used for the Japanese, who have different genetic backgrounds.

5 Ways to Advance Future Research

Epigenetic modifications are thought to be influenced by environmental factors and alter the function of genes, and thus have an impact on human health. For this reason, environmental deterioration may have transgenerational adverse effects on human health. In fact, some of the epigenetic modifications of genes are reported to be inherited in the next generation. At the same time, it would be possible to maintain and enhance health condition via epigenetics by establishing a sound living environment. Therefore, research on biological effects that takes into account the epigenetic effects of chemicals in the environment is important for establishing a healthy life environment. Such research is growing in the United States and other countries. As of now, however, there are some discrepancies among the results on the epigenetic effects of environmental chemicals. The research is still in an early stage and needs to be further promoted.

Since epigenetics is closely related to developmental biology, epigenetic research has made progress in this field. Significant progress has also been made in the field of cancer research. The genetics technology and knowledge that have made dramatic progress since the 1990s have also been effectively utilized in epigenetics research. The research in these fields in Japan has made a great contribution to the progress of epigenetic study. However, with regard to epigenetics research on environmental chemicals, Japan's contribution would be limited compared with the United States and European countries. Since Japan experienced a number of pollution issues, such as Minamata disease caused by methyl mercury, Itai-itai disease caused by cadmium and Yokkaichi asthma caused by air contamination, the country has led the world in the research on biological effects of these heavy metals and hazardous chemicals in the air and environment.[17] In recent years, however, the number of young researchers has been decreasing in these research areas, raising concern that the research in these fields may taper off in Japan. At a time when environmental health research requires the epigenetic point of view, Japan is facing a challenge of securing and fostering human resources in the area.

The National Institute of Health (NIH) of the United States has been implementing "the Epigenome Roadmap Project" (total budget: $190 million) since 2009, which is one of the largest epigenetics projects in the world. Recently, the NIH released an epigenome map charting epigenetic modifications of various cells and tissues.[18] Last year, the International Human Epigenome Consortium (IHEC) was inaugurated in Paris. The IHEC is set to start a "1,000 Epigenome" project (total budget: $130 million) designed to map 1,000 reference epigenomes.[19] Japan is looking into taking part in the project.

These projects are mainly focused on basic epigenomes in normal cells and do not sufficiently deal with epigenetic modifications induced by exposure to chemicals. International collaboration and exchange of knowledge would be useful to establish a common view of epigenetic effects of chemicals. In order to nurture an environment to protect human health and make a significant contribution to the international community, it would be necessary for Japan to play an active role in establishing a global research system. .

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Profile

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3

Progress in the Technical Development and Dissemination of the Recycling of Waste Plastics

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1 Introduction

The recycling of solid wastes is the core challenge in establishing a sustainable society. Waste plastics, almost 10 million tons of which generates in Japan every year, decrease landfill capacity, and impose a burden on the environment, such as the emission of carbon dioxide as a result of incineration.

In response to this, over the 10 years since the Basic Act on Establishing a Sound Material-Cycle Society entered into force in 2000, a great deal of effort has been put in various fields such as containers and packaging, household electrical appliances, and motor vehicles to increase the recycling rates , based on the recycling law for each products. The Ministry of the Environment introduced resource recycling initiatives and outcomes in its White Paper, *"Annual Report on the Environment, the Sound Material-Cycle Society and the Biodiversity in Japan 2010,"* which involves a new chapter entitled "The Socioeconomic System Driven by the Environmental Industry." The White Paper shows that the Japanese technologies for "solid waste treatment" leads the developed world, this chapter describes Japan's new policy on the transfer of environmental technologies to other Asian countries facing solid wastes problems due to solid wastes to the rapid economic growth. Moreover, at the Asian 3R Promotion Forum, which was established in 2009, the overseas expansion of "venous industries" is being promoted.[1,2] In discussions by the Industrial Structure Council of the Ministry of Economy, Trade and Industry (METI), the advanced resource recycling systems of solid wastes in Japan was highlighted as one of the promising social infrastructures of worth exporting to developing countries because of the comparative advantages.[3] Those Japanese technologies have reached the stage at which we aim to expand "resource recycling industry" to overseas through the technology innovations in some fields such as resource recycling of E-wastes and ELV.

Amidst the growth in the recycling of various waste materials, the recycling of the most waste plastics is not economically feasible due to the complex composition and the high processing costs in comparison with those of metal and glass wastes. However, in the last 2 or 3 years, a upsurge in crude oil and material prices drives us to have the interest in waste plastics recycling. In particular, many companies focus on waste plastics as an important recycling business, similar to rare metals and scrap iron.

In *Science and Technology Trends*, the topics of the current status of recycling being undertaken by the materials industry[4] and technology for the recycling of resources from solid wastes[5] have been reviewed before. This article focuses on the recycling of waste plastics, which draw increasing interests in particular, due to the rise in material prices in recent years, and discusses the current situation, challenges and measures for achieving technical and social improvements.

2 The Current Status of Waste Plastics

2-1 The Current Status of Waste Treatment and Recycling of Plastics

Around 10 million tons of waste plastics generate each year. About half of them is general waste arising from households and small-scale business sectors, and the other half is industrial waste. Based on the polluter pays principle, local governments are responsible for the treatment of general waste, while each company or facility has responsibility for the suitable treatment of the industrial waste by itself or a waste management

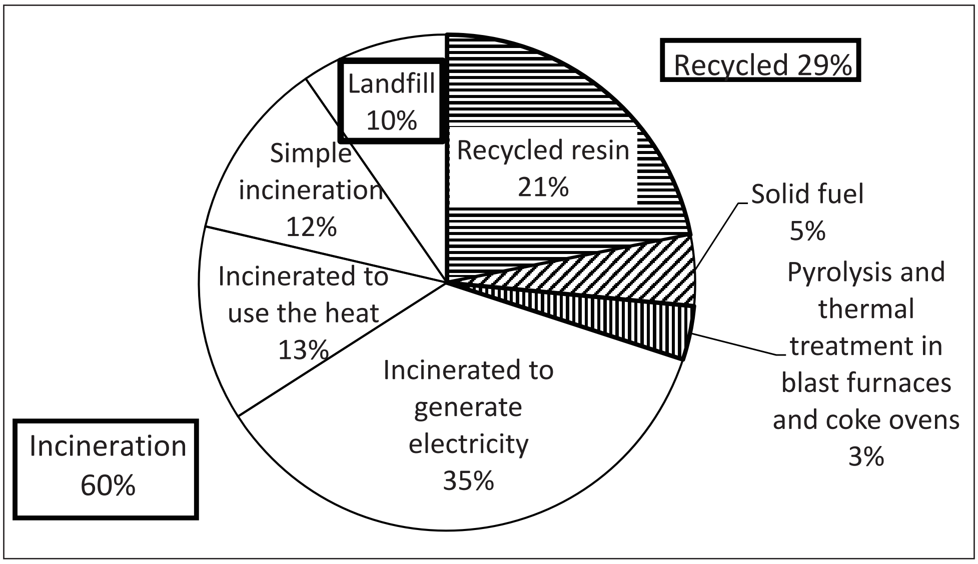

Figure 1: The Proportion of Waste Plastics Disposed and Recycled Using Each Method (2009)

Source: Plastic Waste Management Institute

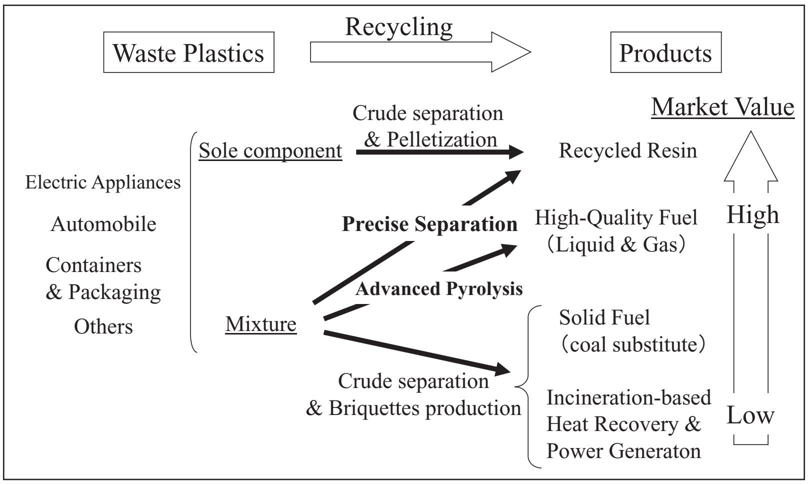

Figure 2: The Selection of Waste Plastic Recycling Methods

Depicted by the STFC

company under contract. Figure 1 summarizes the proportions of waste plastic disposed or recycled using each method.[6] In this diagram, pyrolysis refers to gasification or conversion into oil.

The types of plastic and content of rejects, which are the substances unsuited to recycling, in the solid wastes vary greatly depending on the types of wastes such as Electrical and Electic Waste (E-wastes), End of Life Vehicles Directive (ELV), and other wastes from factories, logistics and consumers. The recycled plastics are used as inexpensive household commodities, industrial materials, and textile goods such as bedding. Moreover, solid fuel called RPF, which is a substitute for coal, can be prepared from waste plastics mixed with wood or paper, solidified. This is mainly used in coal boilers as a heat source in paper factories. In addition, waste plastics are also recycled by means of pyrolysis, which is generally called feedstock recycling, or chemical recycling in Japan. Pyrolysis is thermal conversion of waste plastics into other types of compounds. Depending on the chemical properties and combustibility, the products are utilized as coal substitutes in coke ovens and blast furnaces at steel plants, synthetic gas production, and fuel oil production as petroleum substitutes.

In order to improve the recycling rate of waste plastics only around 30% at present, it is vital to adopt a new technological approach to mixed waste plastics. Moreover, with regard to the recycled products that currently manufactured, new technologies are also required to increase their market values.

2-2 The Selection of Waste Plastic Recycling Methods

Figure 2 summarizes the approach to the selection of processing and recycling methods for solid wastes containing plastics. The typical products derived from waste plastics are recycled resin and fuel. As long as there are no legal constraints on the wastes, the recycling method is selected on the basis of the properties of the waste plastic to be processed, the degree of difficulty of the recycling operation and the market value of the product (number of users or sale price). Even if there are legal constraints, the recycling method must be chosen carefully, with the aim of achieving a low environmental impact and a high recycling rate.

Recycling is feasible only when a solid waste contains enough amounts of valuable components, which can be converted into a suitable recycled product that has a market value. When the wastes contain different types of plastics that have low compatibility, the manufacturers of recycled products cannot accept those plastics as raw materials for recycling. In this case, fuel production can be the main option.

Recently, precise separation techniques for some types of plastics have been developed for commercial use, using electrostatic separation of mixed waste plastics, such as those in wastes of household electrical appliances, and the more waste plastic can be used as high-quality recycled resin by the new technique. The technological reliability of converting waste plastics into fuels in solid, liquid and gaseous forms has also been verified; in particular, the solid fuel is now popular as a boiler fuel, as a substitute for coal, primarily in the paper industry.

2-3 Problems in Recycling

2-3-1 The High Recycling Cost of Waste Plastics

Only 30% of waste plastics is recycled as shown in Figure 1. The typical reasons is no economic advantages in recycling for waste generators and waste management sectors. The other reason is higher recycling cost, while incineration and landfill are still conducted by local authorities and industrial waste processing businesses at the lower costs.

The Containers and Packaging Law prescribes the recycling of containers and packaging materials in household wastes, including PET plastic bottles, plastics other than PET (mixed plastics), glass bottles and paper packaging. Of the 1,800 local authorities across Japan, 1,308 local authorities engage in the separated collection of plastic containers and packaging; of these, 1,017 have entrusted recycling to the Japan Containers and Packaging Recycling Association (JCPRA), a designated corporation stipulated in the Containers and Packaging Law, and the total quantity of mixed plastics has reached 600,000 tons (fiscal 2008). This means that a commensurate degree of resource and energy conservation has been steadily taking place each year.

The cost of the recycling consigned to recycling businesses by the JCPRA is as much as ¥41 billion annually (fiscal 2009), which is the total for mixed plastics, PET plastic bottles, glass bottles and paper packaging. Based on the principle of extended producer responsibility, as well as the polluter pays principle, these costs are borne by the companies involved with commercial products that use those materials, in other words, the various businesses involved in the manufacture of containers and packaging, and those involved in the manufacture and sale of commercial products that use containers and packaging, so ultimately the consumer bears those costs. In the total recycling costs of the JCPRA, mixed plastics accounts for 94%.Thus, the cost reduction of, especially, mixed plastics recycling is the major challenge and concerning the recycling law. Consumers and businesses involved with plastic goods have a strong desire for low-cost recycling techniques.

Figure 3 summarizes the quantity of waste plastics disposed and recycled by the cost required for each method in two categories: plastics in general waste and industrial waste. The average gate fee of industrial waste plastics is ¥40,000/ton.[7] In the case of plastics in general waste, the cost of incineration is generally low, due in part to the subsidies of the central government to incineration facilities of the local authorities. In contrast, recycled resin production from mixed plastics collected separately from households costs ¥74,500/ton, which is significantly higher than the production of recycled resin from industrial waste plastics, which uses waste plastics of the better quality as raw materials, and higher than other disposal and recycling methods.

In the consideration of the environmental effects and costs, intense debate has developed involving businesses of plastic-related products, recyclers, consumer groups, those associated with local

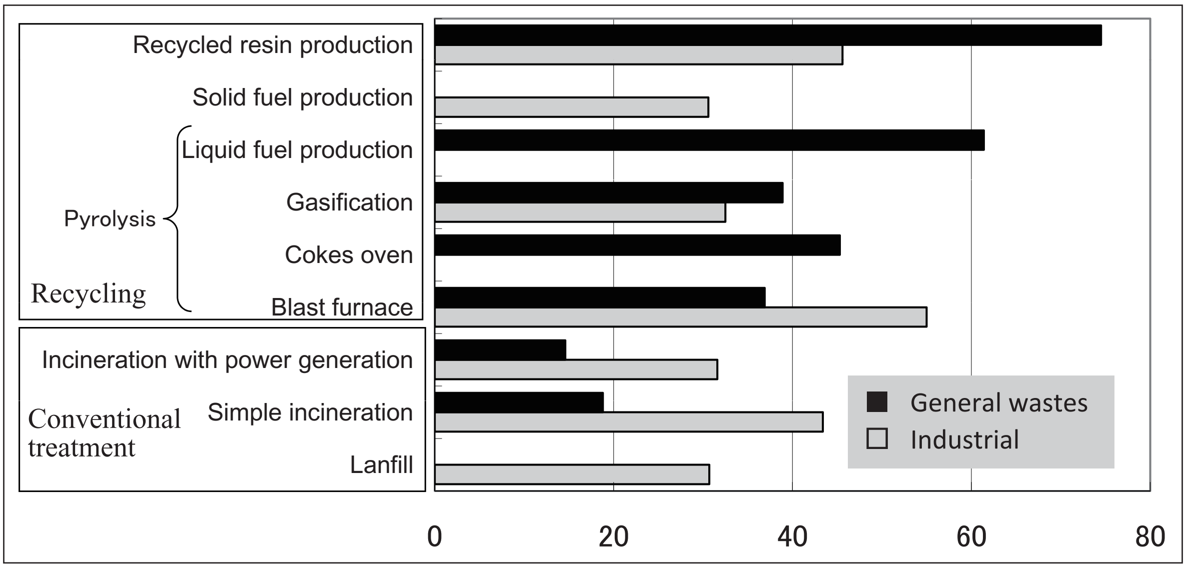

Figure 3: The Cost of Disposal and Recycling Waste Plastics According to Each Method
No cost is shown in case of any appropriate data are not available.
(¥1,000/ton)

Source: Prepared by the STFC based on the following sources: Recycling methods for mixed waste plastics of containers and packaging in general wastes, the Japan Containers and Packaging Recycling Association[8]; power generation from incineration and simple incineration, the Ministry of the Environment[9]; disposal and recycling methods of industrial waste, the Plastic Waste Management Institute[7]

governments and academics, concerning whether the prioritization of recycled resin production is an appropriate system, or whether it is acceptable to select a recycling method that prioritizes the cost: This debate also encompasses approaches to producer responsibility, the perspective of reducing social cost, and the expansion of business projects by companies adopting other low-cost recycling techniques.[10]

In the case of solid wastes arising from household electrical appliances and ELV, nobody is criticizing the high recycling cost comparing to that of mixed waste plastics from household containers and packaging. Waste treatment of household electrical appliances and ELV is conducted for suitable disposal of hazardous substances, processing of waste plastics, and resource recovery of valuable metal, which are relatively easy a technical and business perspective. These recyclers differ from the recyclers of containers and packaging in the cost-charging system for recycling. For the wastes of household electrical appliances and ELV, the manufacturers had been supported recycling companies and facilities equipped with suitable technologies for them. The social systems for waste collection and charging recycling fee were also implemented under the law. The limited numbers of the recycling companies in collaboration with the manufacturing companies were deployed appropriately according to the region or the generation amounts of wastes. This mechanism leads to reduce the burden on local authorities and ensure a stable recycling business of the wastes. Moreover, the manufacturers can obtain the knowledge on the effective design of their products for resource recovery, based on the recycling experience in action under the cooperation with recycling companies.

2-3-2 The Difficulty of Selecting a Recycling Method

Waste plastics recycling aims to reduce the total amounts of waste plastics that are disposed by simple incineration and landfill, to utilize plastic components for the effective purposes, and to save the consumption of resources. In selecting a recycling method, rational judgments are required not only on the part of frontline waste management businesses, but also on the part of those prescribing methods in legislation, such as in the case of the recycling of plastic containers and packaging.

The relative merits of recycling methods can be judged on the basis of the quantity of recycled plastics that can be replaced as the resources consumed in society. Moreover, it is necessary to take into consideration the total energy input in the manufacturing process of those recycled products. Conventionally, this has been evaluated by means of the LCA (Life Cycle Assessment) or LCC (Life Cycle Costing) techniques.

For example, a plastic article by of virgin resin is compared with that of recycled resin. It is easy to compare the relative merits of each manufacturing technique on the basis of the production efficiency of the manufacturing equipment, and the economic and environmental burdens of the electricity or fuel required for the production of the plastic article. However, apart from recycled plastic articles, products can be solid and liquid fuels, synthetic gas, and reducing agents for a steel manufacture. In order to compare the resource conservation effect of these different products, it is necessary to establish various calculation rules, and evaluation of each recycling method is not simple. Thus, various evaluation methods have been proposed to integrate a variety of criteria for each purpose.[11-13]

Table 1 shows the typical criteria for selecting a recycling method.[14,15] The table summarizes the ranges of the types of polymers that can be recycled, the recycling cost, the carbon dioxide emission reduction effect, and the types and prices of resources that these can replace.

In the case of the production of recycled resin, the raw materials are thermoplastics that do not contain any impurities or compounds that will spoil the color or physical strength of the resulting resin product. With regard to mixed waste plastics, it is essential to carry out high-speed, high-precision separation of foreign objects, which presents an obstacle in terms of the production efficiency and cost of recycling. In the case of waste plastics collected from specific production processes at factories, which have few impurities, the recycling cost is reduced because the process of separating foreign objects can be abbreviated. Furthermore, they have a high value, as they can be used as a substitute for expensive virgin resins.

Mixed waste plastics from household containers and packaging contain large amounts of foreign materials that cannot be separated. The recycling cost increases and the commercial value of the recycled resin lowers as the result of the process of separating the foreign materials and generation of a large amount of the residue as a byproduct. Under the containers and packaging recycling law, the production of recycled resin from mixed waste plastics is carried out as an operational priority. Moreover, this law allows the recycling methods of processing waste plastics in coke ovens or blast furnaces, manufacturing solid fuels, gasification, and fuel oil production. The production of recycled resin and fuel oil both conserve petroleum, which are more exhaustible than coal, so one can envisage the relative merits of recycling methods that take this fact into consideration.

Solid fuel production is the recycling method to make use of the high calorific value of waste plastic with biomass of low calorific values. The calorific value of the resulting fuel is equivalent to that of coal. The recycling cost is about ¥25,000/ton. Wooden biomass has a limited end-user application because of the low calorific value. Solid fuel of waste plastics with biomass meets the demands from the more fuel consumers. Biomass combustion is not included in carbon dioxide emissions, so there is a big carbon dioxide emission reduction effect if the solid fuel users increase. The solid fuel has an economic effect as a substitute for coal. A current price of the solid fuel is about ¥3,000/ton, which is cheaper than the average coal price of ¥10,000/ton.

Using pyrolysis, it is possible to obtain a liquid fuel that can be used as a substitute for heavy or light oil, as well as a gaseous fuel that can be used as a substitute for natural gas and LPG. Liquid and gaseous fuels are widely used in local communities, and their prices are subject to sharp fluctuations. Fuel production through pyrolysis accepts the broader range of raw materials containing dirties and impurities than recycled resin production. But because of the higher investment of system installation, as well as the need to ensure

Table 1: Examples of Criteria for Determining the Relative Merits of Recycling Methods

Recycling Technique	Good availability of recyclable raw materials	Recycling cost	Carbon dioxide emission reduction effect	Economic advantage as a substitute (examples of prices of substitutes,yen/kg)
Manufacture of recycled resin	△	△ (Separated wastes from factories) × (Recyclable plastic containers)	○ △	◎ ○ (Polyethylene and polypropylene 100 - 150)
Manufacture of solid fuel	◎	○	◎	△ (Ordinary coal 10)
Manufacture of oil via pyrolysis	○	△	○	○ (Heavy oil and light oil 70)

Prepared by the STFC

safety, the recycling cost is high (around ¥80,000/ton). With regard to pyrolysis plant for liquid fuel, small-scale plants were developed some 30 years ago, with a capacity of around one ton a day. Large-scale plants (with a capacity of up to 40 tons/day) were also developed and went into commercial operation. But the recycling business using large-scale plants struggle to secure the requisite amounts of waste plastic as a raw material, while the small-scale plants have poor profitability. The development of inexpensive and feasible techniques of effective de-chlorination and low-energy-consuming equipment with high heat-transfer performance are crucial challenges under about 5 tons/day capacity, which is estimated as a profitable line of business.

The next chapter provides a technical overview of advanced processes of recycled resin production and new pyrolysis processes.

3 The Progress of Waste Plastic Recycling Technology

3-1 Recycled Resin Production Technology That Facilitates Horizontal Recycling

Wastes of household electrical appliances are collected and recycled on the basis of the home appliances recycling law. The recycling rate is stipulated for each item category – for example, in the case of air conditioning units, it is prescribed as at least 70% of the weight of the item – and, based on these provisions, the appliance manufacturer selects a product design and materials that make the product easy to recycle. Figure 4 provides an overview of the process for producing recycled resin from waste plastics obtained from wastes of household electrical appliances.

In the conventional recycling process of the wastes of household electrical appliances, the recycling rate prescribed by the law was achieved by means of recycling metals of a high product value and manual dismantling of waste plastics. Clean waste plastics on visual examination were then used to produce recycled resin. Moreover, the plastics that were generated in a mixed form could not be recycled, so they were disposed of by such methods as incineration. The recycling rate prescribed in the home appliances recycling law is increased as required, so in order to achieve the stipulated recycling rate, recycling companies have been engaging in ongoing efforts to achieve high-precision material collection and to expand the applications of the items collected.

To date, electrical equipment manufacturers – irrespective of whether they are manufacturers of household electrical appliances or electronic and

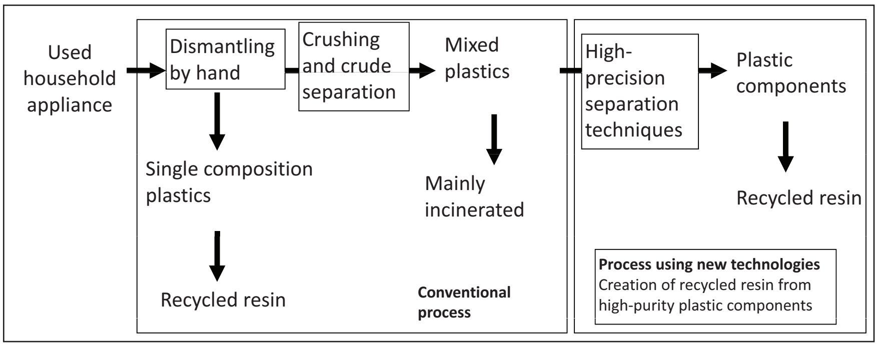

Figure 4: Schematic Processes for Producing Recycled Resin from Waste Plastics Obtained from the Wastes of Household Electrical Appliances

Prepared by the STFC

Table 2: Typical Separation Techniques for Waste Plastics[16,17]

Technique	Major type of equipment	Principle
Size separation	Trommel separator and vibrating screen	Crude separation by the size of wastes.
Specific gravity	Air classifier, fluidized-bed separator, and specific gravity separator	By the function of separation media such as water, sand and air, waste separation is performed by its specific gravity.
Spectroscopy	Optical separator	Waste separation by optical detection of spectroscopic difference followed by air-jet sorting.
Static electricity	Electrostatic separator	Depending on the types of plastics, positive or negative charged particles are obtained. These charged particles fly differently in an electric field to be sorted in the different storage chambers.

Prepared by the STFC

electrical instruments – have constantly striven to achieve stringent cost reductions in regard to each and every component. In particular, they are actively working on the use of waste plastics, which are not easily impacted by fluctuations in oil prices. A number of household electrical appliance manufacturers have collaborated with plant manufacturers and various recycling companies in order to develop new separation and sorting techniques for the various kinds of plastics of which mixed waste plastics are composed, and the commercial use of finely-separated recovered plastics by recycling businesses has begun to spread. Not only can the recovered plastics be used as low-performance components, where it does not matter if there are issues with their physical properties or external appearance (cascade use), but they have also opened up the way to so-called horizontal recycling, where they are used in crucial components and exterior materials where a high level of performance, such as strength, is required.

Mixed waste plastics conventionally had few applications other than heat recovery by incineration. Electric appliance manufacturers have the information on the types and amounts of materials in the wastes, and recycling companies know the effective processes of dismantling and resource recovery. Consequently, a substantial quantity of recycled resin of a certain quality level will be secured if a new separation techniques appropriate to the composition of the mixed waste plastics is developed instead of the conventional separation processes, .

Table 2 shows the typical separation techniques for waste plastics. Air classification is an effective crude separation technique for separating waste plastics from mixed waste of different sizes and shapes. By separating and recovering specific types of plastics from the mixed wastes, it is possible to obtain high-value recycled resin. And wet specific gravity separation and spectroscopy have been used.

A new technique using electrostatic separation for powdered plastics has now been developed. This makes it possible to separate some types of plastic materials more precisely.

When a charged plastic powder is put into an electrical field, it flies to different directions depending on the type of plastics, thereby making it possible to separate them. The electrostatic separator was developed using this principle (Figure 5).
This equipment consists of the following three functional areas:

1. Area I: Plastics were crushed less than 10mm and separated into up to two types using specific gravity separation. The resulting plastic power undergoes triboelectric charging followed by a constant feeding to the rotating drum.
2. Area II: In an electrostatic field charged with high-voltage direct current, the electrically charged plastic particles are separated by type.
3. Area III: The separated plastic particles enter separate containers.

Separation of polystyrene and ABS is a typical example of this technique. Waste plastic from household electrical appliances firstly undergoes air classification and specific gravity separation; then, the polystyrene separated from the mixture of ABS resin and polystyrene with a recovery rate of 88% and a purity level of 99%. Moreover, with regard to the recovery of ABS from more complex waste plastic mixtures, combining the conventional specific gravity separation with electrostatic separation leads to give ABS with a purity level of around 99%. This result means that the recovered resin can be used for the similar applications as virgin ABS resin.[18]

From 2011, Mitsubishi Electric Co. has announced that will increase the consumption of recycled resins for their products from the current level of 6% to 70% of annual generation amounts, 10,000 tons, of the waste plastics.The company introduced this technology in a new recycling factory, and it opened in June 2010, with a primary focus on recycling plastics from the wastes of household electrical appliances.[19,20]

3-2 Conversion into Solid Fuel

Converting waste plastics into fuel is a recycling technique that can be used with mixtures that cannot be used as recycled resin. The key properties required of the fuel are a high calorific value and clean exhaust gas. Solid fuel is easy to produce from combustibles such as wood and plastics that does not contain chlorine or nitrogen. In order to reduce carbon dioxide emissions, the use of biomass as fuel is being promoted. However, wood-based biomass only has about half of the calorific value of plastic by weight. By mixing it with waste plastics and solidifying the resulting mixture, it is possible to create a solid fuel that has a calorific value equivalent to that of coal, so its use has become popular among large-scale fuel users, such as paper factories that require a large quantity of low-priced fuel. Unlike heat recovery by incineration, fuel production provides the convenience to heat users in the points of transportation and heat supply at any time. However, depending on the composition of the raw material, boilers undergo corrosion or the exhaust gas at combustion contains hazardous substances. Consequently, at present, its use is limited to coal boilers equipped with exhaust gas cleaning systems.

3-3 Pyrolysis for Manufacturing High-Quality Fuel

In terms of their calorific value by weight, liquid or gaseous fuels obtained through the pyrolysis of waste plastic are of the higher value than solid fuels. The typical important task in the development of new pyrolysis technologies is the removal of the waste components yielding hazardous exhaust gas, such as chlorine, during the pyrolysis process with respects to the production of high-quality fuels. In particular, in the case of the waste plastics generated by households, plastics containing chlorine are often mixed in with other plastics. The technical measures to remove it is a typical reason for the rise in the cost of fuel oil production. Chlorine contamination in the feedstock in fuel oil production causes the formation of hydrogen chloride when heated, which corrodes equipment, and they combine with coexistent olefinic hydrocarbons yielding organochlorine compounds. Dioxins will be generated upon combustion of such fuel. Rigid articles of polyvinyl chloride can be separated comparatively easily by means of specific gravity separation or optical sorting (spectroscopic method). However, in practical terms, it is difficult to remove chlorine-containing plastics because of the cost problems like introducing separation equipment, and difficulty in the effective separation of wrapping film containing chlorine (mainly polyvinylidene chloride).

In October 2010, a waste management company in Fukuoka Prefecture began the commercial operation of a small-scale pyrolytic oil production plant focused on separated waste plastics from households; the system has a capacity of 5 tons a day and can simultaneously dechlorinate the plastics and convert it into oil. Figure 6 provides schematic flow of the

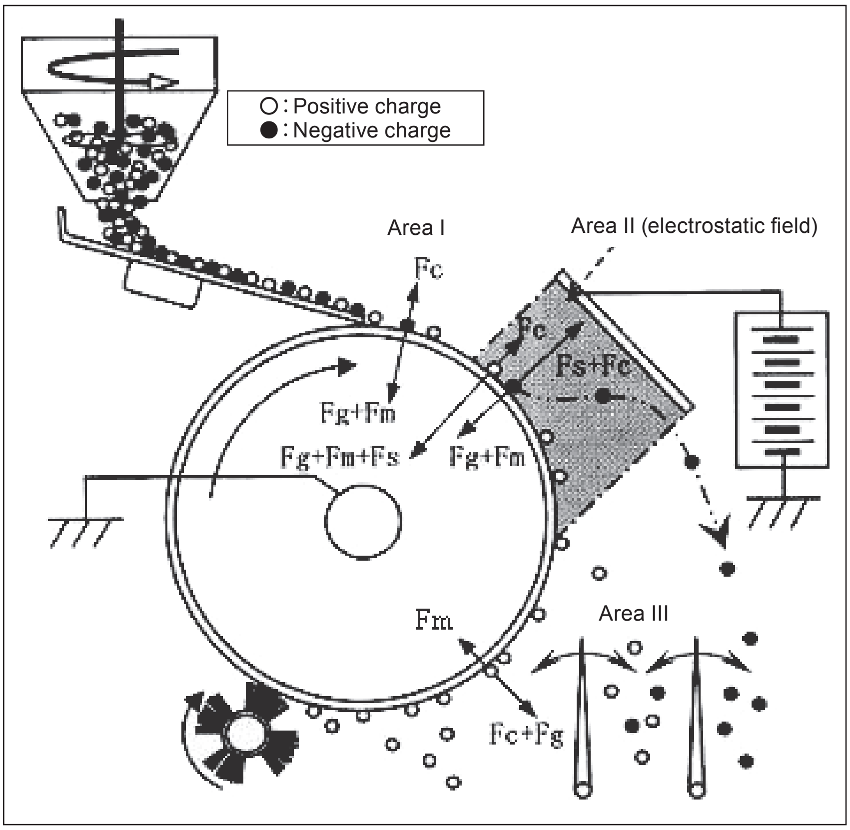

Figure 5: The Principle of Electrostatic Separation Devices
The forces working on the plastic particles, Fc, Fg, Fm, and Fs indicate centrifugal force, gravity, image force and electrostatic force, respectively.

Source: Reprinted with permission from materials published by Hitachi Zosen Corporation[18] commercial plant. The thermal process was basically developed by the University of Kitakyushu. It involves the treatment of plastics in the presence of calcium hydroxide and waste FCC catalysts, which was used in oil refining.[21] Whereas typical pyrolysis takes place at 500 – 550ºC, plastics undergo catalytic decomposition in the process at the comparatively low temperature of around 400ºC. Moreover, it reduced the residual chlorine in the pyrolytic oil to 120ppm, which is less than 1/5.

For the efficient decomposition, FCC catalyst was used in this plant. This plant is the first commercial oil production facility to use a paddle mixer system, which has excellent mixing efficiency, comparing with a tank-shaped reactor in the conventional commercial oil production.

Moreover, by using this type of device, it has become possible to achieve the effective reaction of the hydrogen chloride generated from plastic containing chlorine with calcium hydroxide, thereby preventing the generation of organochlorine compounds in the hydrocarbon oil. In tests using a processing capacity of 10kg/h bench plant, it was possible to maintain the dechlorination rate at more than 99% where plastic used as the raw material had a chlorine content of 20%, which is far in excess of the chlorine content of plastic in separated general waste (1 – 3%). The more analytical data concerning the residual chlorine in pyrolytic oil in long-term operations are awaited.

Pyrolytic gas obtained from waste plastic is considered as a high-quality fuel comparing with solid and liquid fuels because it gives highly clean exhaust gas upon combustion. In the project of developing technologies for the detoxification of asbestos, gasification of polyethylene containing asbestos was demonstrated, and the resulting gaseous fuel was used as a fuel to melt asbestos in the demolition wastes containing asbestos. The demonstration research was carried out by using a plant of 1 ton per day capacity on the premise of commercial gasification plant with a capacity of 10 tons per day. By combining it with a melting accelerant, it was possible to melt asbestos at 750ºC, which usually requires a temperature of at least 1500ºC to melt.

As shown in Figure 7, the plant used in this study was an external-heating rotary kiln with a circulating bed. In this plant, asbestos in demolition wastes and the plastic sheets that generate in large quantities from asbestos removal work undergo melting treatment, and waste plastics of mainly polyethylene are gasified effectively. Furthermore, this system uses the resulting pyrolytic gas as a fuel for melting asbestos and the gasification of plastics.

The wastes processed in this method are mixed briquettes of demolition waste containing asbestos (50% by weight), waste polyethylene (47.5% by weight) and melting accelerant (2.5% by weight). By heating the briquettes in an external-heating rotary kiln at approximately 750ºC, pyrolytic gas generated from the polyethylene. This was then supplied to the rotary kiln and used as a fuel. LPG was supplied at the initial heating stage, then, after the generation of pyrolytic gas was confirmed, LPG supply was stopped.

No asbestos was detected in the solid residue, pyrolytic gas, the exhaust gas from combustion, and the pyrolytic oil that generated in small quantities as a byproduct. The combustion heat of the pyrolytic gas was in excess of the calorific value required to heat the demolition wastes and generate pyrolytic gas from waste plastic. It was clear that this system is self-sufficient in energy.

The composition of the pyrolytic gas was as follows: hydrogen 26.0, methane 25.4, ethylene 21.4, carbon monoxide 5.7, and carbon dioxide 4.7 (% per unit volume). The remaining gas that is not used to heat the plant can be stored and be used for other purposes, such as for power generation using a gas engine.

The conversion technology for producing chemical feedstock focuses on using waste plastic as a source of hydrogen or a hydrocarbon resource, rather than as a liquid or gaseous fuel.[24] The new gasification system using a rotary kiln has an advantage in the operation at the lower temperature range 700 – 800ºC, compared with examples of the conventional gasification technologies, such as the production of hydrogen or methane using a gasification melting furnace,[25] and the conversion of waste plastic to a synthetic gas with hydrogen and carbon monoxide as its main constituents using a two-stage gasification furnace[26] (both of which have a reaction temperature of 1300 – 1500ºC).

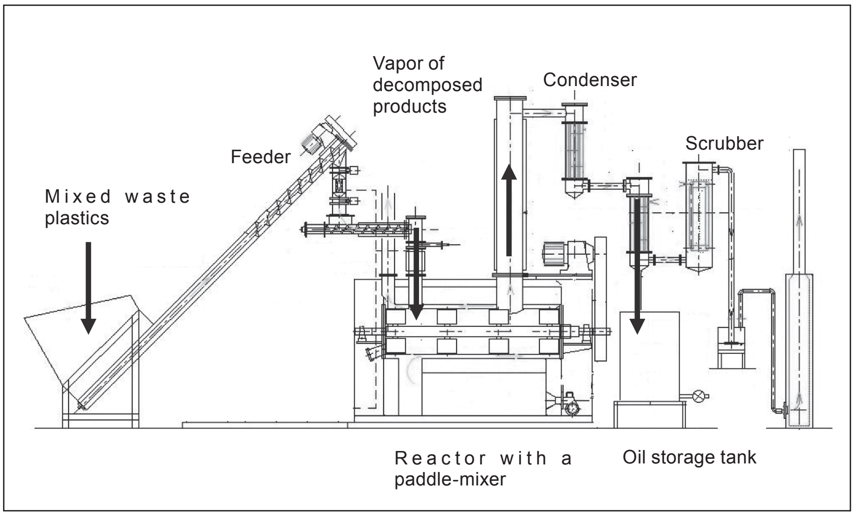

Figure 6: Schematic Diagram of the High-Efficiency Pyrolytic Oil Production System Using Waste FCC

Source: Edited from materials provided by ECR Co., Ltd.

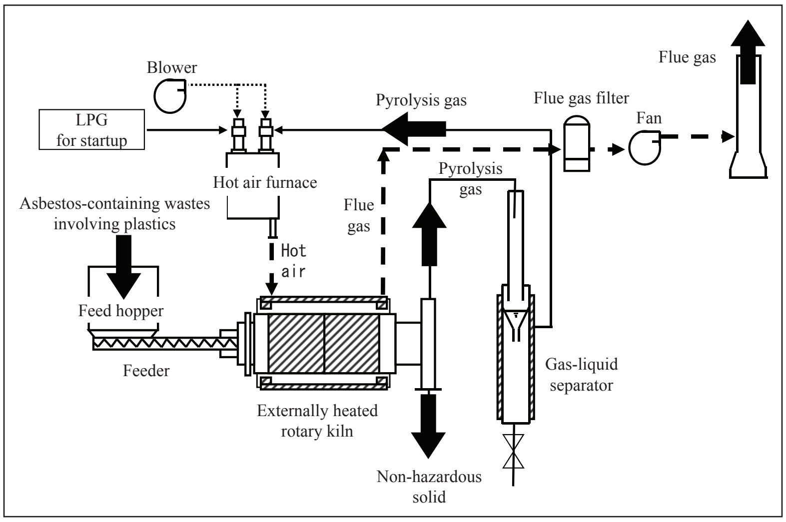

Figure 7: Schematic Diagram of an Asbestos Melting Plant Using Gas Fuel from Waste Plastics

Source: Edited from materials provided by Street Design Corporation

4 Towards the Dissemination of Waste Plastic Recycling

4-1 A Technology Strategy Aimed at Expanding Recycling

The Technology Strategy Map (2010 edition)[27] details the research and development strategy of the METI. It lists a wide range of technologies, as 3R technologies for the future, including the recycling of waste plastics, environmental-friendly product designing for re-use and reduction of wastes, and the development of materials that place little impact on the environment. Figure 8 provides a summary of the development strategies for the leading recycling technologies listed in that publication. Based on the Technology Strategy Map, the future prospects of the technologies for recycling waste plastics can be summarized as follows.

1) Recycling using advanced separation processes and equipment

In the case of E-wastes and ELV, product design allowing easy dismantling and material separation should be implemented with a view to horizontal recycling, while mixed waste plastics that cannot be separated in conventional sepataion processes will undergo precise separation technologies to fulfill advanced resource recovery.

2) Recycling using compounding technologies, such as adding an antioxidant and compatibilizing agent to improve polymer materials

Some additives are effective to increase their strength and durability, depending on the types of polymer and the degree of degradation, before undergoing horizontal recycling into high-quality components or cascade recycling into low-grade components, according to their physical properties.

3) **Recycling using efficient pyrolysis processes and equipment**

When mixed waste plastics are not suitable to produce recycled resin, they are to be converted into liquid or gaseous products that can be used as a clean fuel or utilized as chemical feedstock.

4-2 Innovation of Recycling Technologies According to the Properties of Waste Plastics

Compared with other solid wastes such as paper, glass and metals, waste plastics have more differences in properties and composition depending on waste generation sources and types of applications of plastic products. Technological innovation should be oriented to recycle the wider types and compositions of waste plastics and improve the market values of recycled products. Moreover, in processing and recycling waste plastics, it is necessary to combine the reduction of the environmental impact with a decrease in the social and business costs.

In order to increase the recycling rate of waste plastics, it is important to recycle mixed waste plastics at a low cost and create products with a high market value. The high-precision separation and high-efficiency pyrolysis described in the previous chapter are effective technologies. In the case that a market value of the product commensurate with their cost cannot be obtained even if these technologies are applied, then it is appropriate to select the option of solid fuel production or incineration for heat recovery or power generation. Mixed waste plastics from household containers and packaging are wastes containing a large amount of impurities and foreign components that are not suited to recycled resin production, such as chlorine, nitrogen or metal foil. Accordingly, new technologies that will lead to their effective use are required.

4-2-1 Developing Advanced Separation Technologies

As a domestic resource, recycling waste plastics will assist corporate activity by enabling it to resist soaring prices for fuel or materials, by improving the market value of recycled products and expanding the range of solid wastes that can be recycled. A great deal of high-performance plastics such as ABS and POM are contained in E-wastes and ELV, so it is important, when designing products, for manufacturing companies to give consideration on the easy separation at disposal; in addition, it is necessary for recycling companies to improve the recycling rate and to establish a closed recycling system for recovered plastics. This is a common challenge for recycling companies and manufacturing companies. Consequently, more advanced separation technology for mixed waste should be developed, and separation technology for plated items and lacquered and coated items are also important.

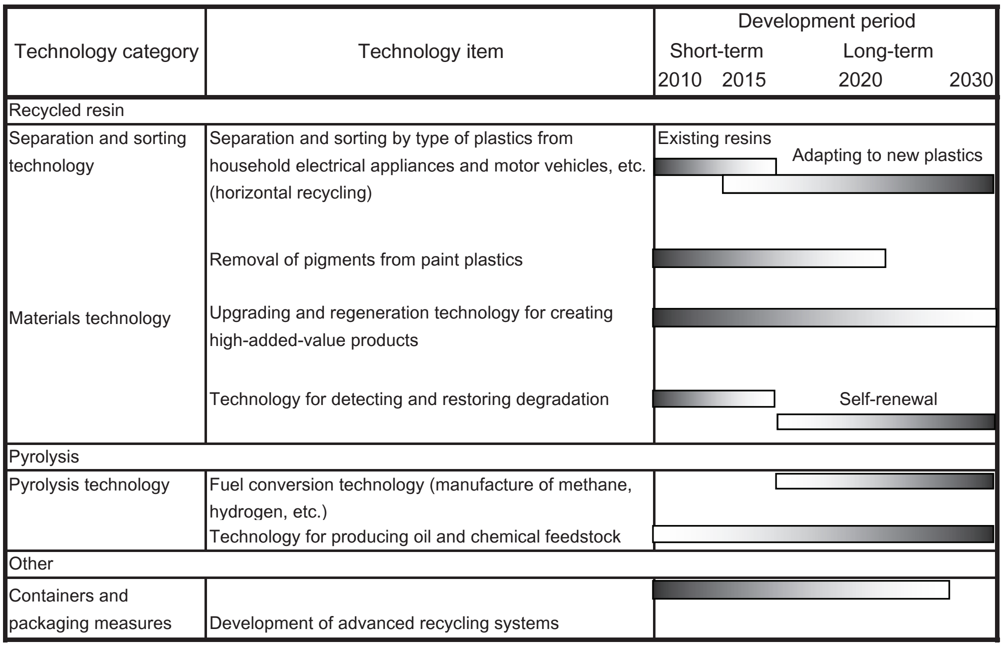

Figure 8: Development Strategies for Vital Recycling Technology for Waste Plastics
Source: Compiled on the basis of the *Ministry of Economy, Trade and Industry Technology Strategy Map 2010*[27]

4-2-2 Establishing Compatibilization Techniques

In contrast to precise separation techniques to obtain a sole component of polymer with the better physical properties from mixed waste plastics, compatibilization techniques is also effective. Suitable compatibilizing reagents promote to homogenize different types of polymers. If the polymers in waste plastics available cannot separate each other, adding a compatibilizing agent may satisfy the strength or other properties of the resulting recycled plastics.

It is important to develop compatibilization techniques for polystyrene and PET components from plastic containers and packaging, which are not soluble to polyethylene and polypropylene. There are many types of laminated plastic films used for packaging and some industrial purposes. It is necessary for plastic processing manufacturers such as compound manufacturers and converters to develop even more sophisticated compatibilization technologies.

4-2-3 Developing Advanced Technologies of Pyrolysis for Producing Fuels and Chemical Feedstock

Pyrolysis is the basic technology for converting waste plastics into fuels or chemical feedstock. In the production of fuels and chemical feedstock of high quality that meet to the users' demands, a new technology for controlling plastic pyrolysis should be developed. In the previous chapter, new pyrolysis techniques were mentioned; fuel oil production under the catalytic decomposition using the reactor with a paddle mixer and the fuel gas production using the external-heating rotary kiln. The thermal conversion techniques of these two types of reactors use small-scale, low-cost equipment that handle just a few tons each day, which means that they have the prospect of being commercialized on a scale commensurate with the business scale of waste collection. Compared with pyrolysis using the conventional tank reactor, those reactors allow using a solid catalyst in structural terms. The advanced pyrolysis technology will enable the boiling range control of pyrolytic oil and the composition control of pyrogas, of which the fuel properties meet to the burners and engines of fuel users.

The production of liquid and gaseous fuels from waste plastics has been added as an accreditation category under the Japanese J-Ver credit system,[NOTE] which aims to reduce carbon dioxide emissions.[28,29] The accreditation, will acceralate the use of high-grade fuel from waste plastics, and promote the progress of pyrolysis technologies for producing substituted fuels for petroleum, LPG and natural gas.

For chemical feedstock production from waste plastics, it is believed that waste plastics are not suited to purposes that involve the use of large quantities in mass production, such as the petrochemical industry because the amounts of generation and collection of waste plastics in local communities are limited. However, it is worth considering applications where they are used in small quantities as feedstock for functional chemicals, including paints and additives.

4-3 Creating Systems for Supporting Recycling Business

Each of the central government, local authorities, and the companies involved in the manufacture and use of plastics has a responsibility and an important role to develop new technologies and expand the scope and limitation of recycling, such as high-precision separation and pyrolysis, which aims at improving recycling rates, as well as minimizing social costs of recycling through optimization of legislations and social systems considering the actual status of waste generation, technologies, the user applications of recycled products, and the economics.

For example, mixed waste plastics from household containers and packaging had been a underutilized resource, which was not recycled in the market economy. The Central government has to establish legislation and systems to implement the policy of the effective utilization of the waste resources. Selecting a recycling method involves complex issues, such as the trade-off between reducing the environmental impact and conserving resources and energy, and the social costs thereof. The promotion of the development of a resource recycling industry is also involved.

The MOE and the METI hold deliberations by stakeholders and experts, and is conducting various studies concerning the latest developments overseas, soliciting public comment from a wide range of

[NOTE]
The offset credit (J-VER) system was enacted in November 2008 in order to provide accreditation for the quantity of domestic greenhouse gas emissions reduced or absorbed that can be used as carbon offset credits.

people, including individuals and citizen groups to build social consensus.

The resource recovery and recycling from wastes is a system technology that combines multiple elemental technologies, while it is also an effort to organize a social infrastructure surrounding multiple stakeholders. Individual companies or local authorities have limited ability to the utilization of waste resources. The generation of waste spans all sectors, including ordinary civic life, commerce and industry, distribution, construction and demolition, and agriculture and fisheries. It is necessary for the central government to take the initiative while further promoting recycling projects in which companies, the government and local citizens collaborate. Resource recycling will progress only when the effective utilization of recycled products is encouraged across industry sectors. The authors propose that the central government, research sectors, and industry supporting organizations cultivate and support new technologies in the field of waste treatment and recycling, in the same way as they do for manufacturing technology. Furthermore, in order to promote technology dissemination of waste treatment and recycling and improve the efficiency, the government and local authorities should provide the appropriate support linked to the frontline of waste processing and recycling businesses and the communities concerned.

The processing and recycling of the waste of household electrical appliance and ELV has been established by the intensive efforts of the manufacturers, which are generally large companies and have financial ability to fulfill their social responsibilities. But there are many small and medium-sized enterprises in containers and packaging, and miscellaneous daily goods sectors, as well as overseas companies. Moreover, the waste generators and stakeholders, who is responsible for wastes recycling, are widely distributed in many business sectors and distribution and retail businesses, and also general consumers. Unlike in large manufacturers and the associated companies in electric and electronic, and automobile industries, the development of waste processing and recycling technology for plastic containers and packaging, dairy goods, and other plastic articles is beyond the reach of the abilities of waste management businesses and recycling companies, due to the scale and financial power of the companies concerned. It is necessary for local governments and public testing laboratories to develop highly practical technologies through collaboration with plant manufacturers and waste management businesses.

Technologies for the processing and recycling of wastes of household electrical appliances and ELV were already in practical use. The related manufacturing companies readily fulfill their social responsibilities. Some technologies are even at the stage at overseas technology transfer. Many useful polymer materials have been developed in conjunction with progress in the field of organic chemistry and materials engineering, but we still rely on incineration and landfill once they become waste. Hazard data concerning new compounds are reported using material safety data sheets (MSDS). The authors would like to propose that, when developing new materials, plastic material manufacturers also devise appropriate, low-cost processing and recycling techniques that have a low environmental impact. These technologies have the potential to give rise to new business opportunities. The authors also suggest that petrochemical and plastics manufacturing companies in the upstream of the material flow of plastics, as well as academic and research institutions will take the initiatives at developing advanced technologies that will enable local authorities and companies within Japan and overseas to implement low-cost, environmentally effective recycling and utilization of the recycled products.

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4

Promotion of Carbon Capture and Storage Technology Using Carbon Emissions Trading Systems

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1 Introduction

In order to mitigate global warming, it is necessary to consider the reduction of CO_2 emissions as a global issue. The 4th Assessment Report (AR4)[1] of the Intergovernmental Panel on Climate Change (IPCC) illustrates that global greenhouse gas emissions need to be reduced by 50 to 85% by 2050 compared to the level of emissions produced in 2000 in order to ensure that global temperature does not rise by more than around 2 degree-C compared to when the Industrial Revolution began. In Japan, the Basic Act on Global Warming Countermeasures sets high emissions reduction targets of 25% by 2020 and 80% by 2050 based on 1990. Japan has been rigorously improving energy efficiency since the oil crisis in the 1970s, and as a global leader in energy efficiency, Japan's CO_2 emission factors are lower than those of other developed countries. This means, however, that Japan will not be able to reduce domestic CO_2 emissions further by only using the conventional method of improving energy efficiency. To reduce CO_2 emissions further, it is not sufficient for Japan to merely continue to innovate technology; it is necessary to use such systems as emissions trading. Therefore, it is essential to encourage the use of Japanese technology worldwide and contribute to emissions reduction overseas.

Japan has been using the Clean Development Mechanism (CDM), an emissions trading system, to meet the emissions reduction commitment by reducing CO_2 overseas. The CDM is a mechanism defined in the Kyoto Protocol. Using the CDM, developed countries can conduct projects to reduce greenhouse gas emissions in developing countries, acquire carbon credits by reducing CO_2 in those countries, and use the credits to meet their emissions reduction commitments (caps). Generally speaking, production and electricity supply in developing countries are not efficient in making use of energy, and as such, Japan can contribute to substantial CO_2 emissions reduction in developing countries just by transferring Japan's existing technology. Since Japan cannot expect to reduce domestic CO_2 emissions further to a great extent, this is a very useful system for Japan to receive credits as its own by transferring technology and reducing CO_2 overseas.

Japanese companies have been using the CDM; however, CDM-related emissions reduction has not been as great as originally anticipated. This is because many of the projects conducted so far have been small, and even though there have been many projects, the total reduction has not been significant. Therefore, it is necessary to combine technology and a CO_2 reduction mechianism in order to reduce CO_2 overseas more efficiently. The problem of the limited amount of emission reductions by CDM can be solved by using Carbon Capture and Storage (CCS) technology.

To prevent CO_2 arising due to combustion and the extraction of fossil fuels from diffusing into the air, CCS separates and captures CO_2, and sequesters captured CO_2 in deep geological formations for very long time spans. It is possible to store a substantial amount of CO_2 (as much as one million tons per year) by using this technology. Such reduction would be ten times larger compared to an average CDM project.

Securing storage locations is always an issue when conducting CCS. It is not clear how much geological formation suitable for a large amount of CO_2 storage exists in Japan. This issue can be solved if Japan can use its CCS technology, combined with the CDM, in countries with great potential in terms of storage capacity, such as India, China, Indonesia, and Brazil.

Companies trying to put CCS into practical use aspire to use the CDM. CCS requires a lot of new equipment and additional energy in the process of separating and capturing CO_2 in the atmosphere and sequestrating it. This may lead to a great rise in cost for energy supply and industrial products. It is difficult to promote CCS widely just by addressing technology development issues. CCS can be widely used only when there is an emissions trading system like the CDM, where carbon credits can be earned.

The inclusion of CCS projects under the CDM had long been discussed but had not been agreed upon. This was due to some concerns about the effects on the environment and safety, as well as some technological and procedural issues where monitoring, recording, and demonstration framework was not yet established. There were also concerns among CDM host countries that there might be a decrease in investment in existing projects if CCS were recognized as suitable for the CDM. However, the participants of COP16 in Cancun, Mexico agreed that CCS was eligible , on a conditional base, for the CDM and have begun creating an appropriate environment. Once technological and practical issues are resolved, it is expected that CCS will be fully implemented as CDM projects.

This article analyzes the current state of and issues facing CCS (which is just on the way to be implemented under the CDM) and makes some proposals for the future realization of CCS under the CDM.

2 Current State and Issues of CCS

2-1 Significance of promoting CCS Technology

(1) Expectation for CCS

CO_2 reduction technology can be roughly categorized into two approaches: 1) to reduce CO_2 emissions by reducing fossil energy use, for example, by promoting nuclear or renewable energy and introducing energy conservation technology, and, 2) to prevent CO_2 from diffusing into the atmosphere by isolating it. In order to isolate CO_2 arising due to combustion and the extraction of fossil fuels keeping it off from diffusing into the air, the carbon capture and storage (CCS) technology selectively extracts CO_2 and injects captured CO_2 into deep aquifer to store CO_2 in it for very long time spans. This technology is considered to have the highest potential for reducing CO_2[2] and is regarded as important technology internationally. According to "Technology Roadmap Carbon Capture and Storage" (Figure 1) compiled by the International Energy Agency (IEA),[3] as the global energy demand skyrockets, it will be very difficult to halve CO_2 emissions by 2050. In fact, it will be impossible to achieve the target only by transferring Japan's excellent energy conservation technology and introducing nuclear and renewable energy. As such, the IEA anticipates that CCS should contribute approximately 20 percent of CO_2 emissions reduction.

In recent years, CCS has been considered important technology owing to the two major factors below.

Firstly, global warming has become a more urgent problem, and and a technology has been required that can quickly and substantially reduce CO_2. CCS used to be conducted mostly in the form of enhanced oil recovery (EOR), where CO_2 is injected into unproductive oilfields in order to increase the production of oil by reducing the viscosity of the crude oil and making it flow more easily, and, at the same time, to sequester CO_2. Nowadays, however, CCS is becoming mainly for the purpose of reducing CO_2 emissions.

Secondly, ocean sequestration technology (where CO_2 is transformed into hydrates or dry ice and stored on the ocean floor or under the seabed or where CO_2 gas is injected into seawater) used to be considered to have a high potential for reducing CO_2. However, the London Convention (Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972) was revised in 2006, and as a result, ocean storage is regarded as ocean dumping. Due to international law, it is now difficult to store CO_2 in the ocean.[4] The London Convention also clearly stipulates that the injection of CO_2 gas into seabed layers for the purpose of CCS should not be banned.[5] Therefore, CCS is virtually the only applicable technology to isolate a substantial amount of CO_2 from the air.

(2) Effectiveness of CCS

CCS enables us to act against global warming while continuing to use coal,[6] which is the most abundant energy source, is not concentrated in certain regions, and is therefore reliable in terms of supply.

Among fossil fuels, coal is abundant and inexpensive, and is produced worldwide without being concentrated in certain regions, and as such, it is the most stable source of energy in terms of supply for both developed and developing countries. However, coal's major drawbacks are that its CO_2 emission

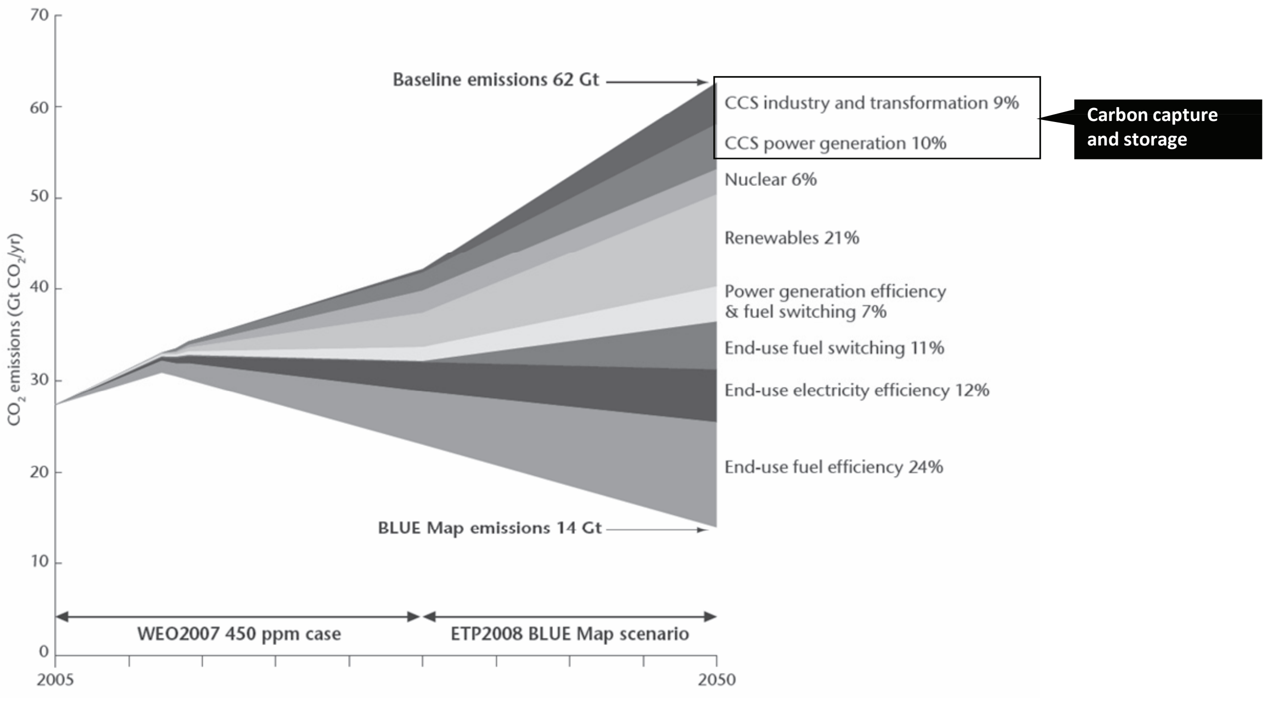

Figure 1: Roadmap for Global Warming Mitigation by IEA

Source: Reference[5]

factors are large and it has a high environmental impact. Technologies to make use of coal cleanly and highly efficiently are collectively referred to as Clean Coal Technology (CCT). CCT has been actively developed around the world. Past editions of this journal have covered, in detail, general CCT,[7] the Integrated coal Gasification Fuel Cell combined cycle (IGFC),[8] and CO_2 emission reduction efforts from the steel industry.[9] These articles suggest that appropriately isolating and storing CO_2 is an issue common to all these technologies.

Gasified coal, after going through a steam-reforming catalyst reaction, becomes gas containing high-density CO_2 and hydrogen. The same reaction can be used to separate and capture CO_2 and, at the same time, to produce fuel gas composed mostly of hydrogen. Supplying product hydrogen to Fuel Cell Vehicles (FCV) can contribute to lower CO_2 emissions in the transportation sector. In addition, compared to the process of separating and capturing CO_2 from combustion exhaust gas, it is more efficient to separate and capture CO_2 from coal-derived gas due to the high partial pressure of CO_2.

CCS simultaneously accomplishes the “3 E’s” (Economy, Environmental Protection, and Energy Security), and is therefore considered to be critical strategic technology both in developed and emerging countries.

2-2 Japan’s Efforts

In March 2008, the Ministry of Economy, Trade and Industry (METI) announced the Cool Earth Energy Innovative Technology Plan[10] and set a target to halve global greenhouse gas by 2050 compared to the current level. According to the plan, CCS is one of twenty-one innovative technologies that should be given higher priority.

The New Growth Strategy (determined by the Cabinet in June 2010) also sets CCS (in its strategy for becoming an environment and energy power) as one of the innovative technological developments that should be prioritized.[11]

In Japan, the Research Institute of Innovative Technology for the Earth (RITE) (established in 1990) has been conducting research on the technology of CCS and other related studies. In particular, one of the largest demonstration tests was conducted at the Iwanohara test site (in Nagaoka city in Niigata prefecture), where 10,000 tons of CO_2 was stored between fiscal 2000 and 2004. CO_2 stored underground has been monitored, and it is in a good condition even after two major earthquakes (the 2004 Mid-Niigata Chuetsu Earthquake and the 2007 Chuetsu-oki Earthquake in Niigata prefecture).[12]

In response to the government’s promotion of CCS technology development, some major companies that have CCS related technology (in fields such as power, oil refinery, oil field development) established

Japan CCS Co., Ltd. This is the world's first privately incorporated CCS organization. Japan CCS is conducting detailed research on the sub-seabed aquifers at the candidate sites for demonstration tests (Tomakomai offshore and northern Kyushu). The company is also conducting CCS feasibility studies (FS) at a depleted natural gas reservoir in the Iwaki offshore site.

In addition, J-Power and other companies are involved in a joint Japan-Australia CCS demonstration project in Australia.[13] Some research institutes and other companies are also developing technology to capture CO_2.

In August 2009, the METI released a guideline titled, "For safe operation of a CCS demonstration project," for large-scale CCS demonstrations.[14] The guideline lays out related laws and regulations, as well as action to be taken before and after starting CO_2 injection for the safe implementation of a demonstration test.

2-3 Overseas Trends

One of the world's largest and most notable CCS projects is the Sleipner project, which began in Norway in 1995. The project stores CO_2 separated during the refining process of extracted natural gas rather than CO_2 from combustion. The CO_2 is compressed and injected into an aquifer formation from an offshore platform in the central North Sea, about midway between Norway and the United Kingdom. One million tons of CO_2 are stored in the sub-surface annually, and 11 million tons of CO_2 has been stored so far over an area stretching several kilometers.[15]

In April 2009, the European Union issued the CCS Directive, stipulating a CCS-related legal framework. The European Union also issued a directive that a new fossil power station with a rated power output of 300 MW or more must ensure space availability for a CO_2 capture facility. In November 2009, the United Kingdom enacted a domestic law based on the directives.[16] The European Union has also been conducting six CCS projects based on the European Energy Recovery Programme (EERP).

In the United States, there are abundant coal resources. In August 2010, the Department of Energy (DOE) announced that the government and the industry would jointly conduct a project called "FutureGen 2.0" and conduct demonstration tests.[17] The project will add CO_2 separation and capture units and a pipeline to the 200 megawatt pulverized coal boiler in a power plant in Illinois, aiming to store one million tons of captured CO_2 underground annually. In addition, several CCS demonstration projects are being prepared. President Obama established an interagency task force to smoothly introduce a CCS project, and in August 2010, the task force submitted a policy report that laid out action required to start CCS commercial demonstration projects. The Environment Protection Agency (EPA) has been making legislative preparations to promote CCS, for example, by clarifying regulations concerning the conservation of drinking water in the surrounding areas as well as monitoring, recording, and verification.

China also has been developing CCS technology at several locations. In recent years, China has been conducting joint projects with other countries, and the European Union, the United Kingdom, the United States, and the IEA have begun joint development efforts and financial cooperation.[18] There is a movement to introduce low-cost CCS technology developed in China to the United States. In Korea, with a view to future global business, related governmental offices are working together, aiming to conduct a demonstration test by 2016 and to realize commercialization by 2020.[19]

2-4 Technological Issues for the Commercialization of CCS

Many elemental technologies are required for CCS, including separation and capture technology to extract CO_2 from combustion exhaust gas, civil engineering to excavate wells, and exploration technology to find suitable storage locations. CCS is involved in a wide range of industries, such as chemical engineering, mining, and civil engineering. It is also an integrated technology, deeply related to power generation, steel production, and other industries. Some technologies for CCS are in practical use or have similar results. However, there are four major issues to be addressed as shown below to promote the commercialization of CCS.

(1) Securing safety and establishing preliminary assessment technology

The potential risk of CCS is that underground CO_2 might leak in substantial quantities and reach the surface, causing health problems such as anoxia and toxicosis. Even if CO_2 does not reach the surface, it might affect the quality and the level of underground water.

CO_2 behaves as a supercritical fluid (indistinguishable between a gas and a liquid) above 31.1°C and 7.4 MPa. In CCS, CO_2 is compressed to a supercritical state and injected into an aquifer. An aquifer is an underground layer of water-bearing permeable rock (such as sandstone), sandwiched between two shielding layers (caprock). CO_2 expands under high pressure and spreads into the surrounding area. However, a CO_2-filled area only gradually expands due to resistance factors. Such resistance mechanisms include structural trapping (where caprock prevents CO_2 from spreading), solubility trapping (where CO_2 dissolves into underground water, increasing density), and mineral trapping (where CO_2 chemically reacts with minerals to become carbonic acid compounds).

CCS assessment simulation is to, in the short term, estimate such gradual diffusion during an injection period, and in the long term, estimate the diffusion over thousands of years based on the existing characteristic data. However, it is necessary to conduct monitoring for at least several years after a CO_2 injection in order to find whether such assessment simulation is accurate.

It is of course necessary to preliminarily conduct every risk assessment one can think of when assessing environmental impact and safety assurance; however, things beyond our estimation may happen. To gain trust from society, there is no other way but to steadfastly accumulate accident-free results just like when aeronautical, nuclear power, and other new technologies were introduced. It is also important to engage in efforts to avoid major accidents by accumulating countermeasure technology against smaller problems that will be experienced during the process. In particular, it is necessary to conduct demonstrations at a utility scale at locations with different geological conditions and gradually scale up the efforts.

Securing safety and establishing preliminary assessment methods are still in the demonstration phase.

(2) Establishing monitoring, recording, and verification framework

CCS is technology to store CO_2 in deep geological formations for very long time spans, and as such, it is very important to monitor changes in CO_2 stored underground during and after an injection, as well as whether there is any CO_2 leakage to the surface. CO_2 measurement methods include remote nondestructive measurements (such as the seismic prospecting method and the gravitational method, which are conducted at the surface level and elsewhere) and, using many monitoring wells surrounding the injection well, electric resistance measurement (of temperature, pressure, and underground water) or elastic wave tomography and electromagnetic wave tomography. Such results from various methods have been analyzed and compared. In addition, two-dimensional and three-dimensional CO_2 maps have been created to conduct follow-up studies on the changes.

Monitoring technology can only be developed and verified at an actual CO_2 storage site, and as such, it is still in the phase of being developed through demonstrations conducted in Japan and overseas. It is necessary to verify the characteristics of monitoring technologies at least in several representative geological conditions.. To realize commercialization, it is essential to conduct demonstrations at many locations and establish monitoring technologies.

At the same time, to calculate the total greenhouse gas emissions by a country, it is necessary to internationally identify the amount of captured and stored CO_2 in a fair manner. Since the CDM is involved with emissions trading, it is important to accurately determine the amount of stored CO_2. To appropriately identify CO_2 emissions reduction as a result of CCS, monitoring, recording, and verification (MRV) framework is required.

The Sleipner project in Norway reports that CO_2 distribution maps (based on the seismic prospecting method) and predictive simulations are relatively consistent from the perspective of monitoring CO_2 behavior to thoroughly grasp signs of CO_2 leakage. However, as to the amount of CO_2 stored underground, the figures from the CO_2 maps and the actual amount of CO_2 injected are different (over 20 percent).[20] It is necessary to improve accuracy.

(3) Economic issues

CCS requires additional large-scale facilities and also additional energy input in order to prevent CO_2 from diffusing into the atmosphere, and as such, economic efficiency has always been an issue.

According to a RITE estimate, it costs about 7,300 yen per ton of CO_2 to separate and capture one million tons of CO_2 annually at a newly established large coal-fired power plant (870 MW) and store it in an aquifer, 20 km apart.[21] This is much higher than 10 to 15 euros per ton (about 1,100 to 1,700 yen), the CO_2 emissions trading price in Europe as of December 2010. Operating a coal-fired power plant costs about 6 yen per kWh, but the cost will double to about 12 yen per kWh if the CCS cost is added.[22]

The RITE roadmap aims to reduce the cost of the separation and capture process (over half of the entire process) to the 1,000 yen level in order to have a more competitive CCS cost.[23]

The aforementioned economic estimate is based on the assumption that 20 percent of CO_2 from a new large-scale coal-fired power plant is separated and captured, and then stored at a location 20 km away from the plant. The assumption uses favorable conditions: the amount of CO_2 to be separated and captured is small, and the transport distance is short. In reality, even if a picked location has less favorable conditions, it is necessary to reduce the total CCS cost to a level equal to other technologies to counteract global warming.

(4) Uncertainty in storage locations in Japan

According to RITE, Japan's potential CO_2 storage capacity is about 146 billion tons, combining both the land and the sea (under the seabed).[24] The annual emissions were 1.34 billion tons in 2006, and the capacity has the potential to store 100 years worth of CO_2. However, the potential storage capacity is somewhat similar to resource storage and is an estimate of a physical capacity under certain assumptions. As such, it is different from something like recoverable reserves and is not economically viable storage capacity. Generally speaking, it is desirable that a single location can store a large amount of CO_2 and have geological conditions permitting a high injection rate (tons per year).

The New Energy and Industrial Technology Development Organization (NEDO) estimates that there are 29 promising structural aquifers (both in the land and the sea areas) with a total capacity of about 1.5 billion tons.[25] The average capacity in one location is about 50 million tons, but the actual storage capacity and acceptable injection rate for each location needs to be studied in detail.

Coal-fired plants are large sources of CO_2 emissions, and a 1,000MW plant produces about 5 million tons of CO_2 annually. Therefore, the CO_2 storage capacity of a location, as mentioned earlier, may store 10 years worth of CO_2 generated by a 1,000MW coal-fired plant. In Japan, there are 40 of 500–1050MW coal-fired power plants. Among them, 12 are either 1,000 or 1,050MW units. Therefore, if we try to achieve the goal (proposed in the mid- and long-term roadmap by the Ministry of Environment [MOE]) to capture most CO_2 emissions from fossil power plants (not limited to coal-fired ones)and to store it underground and elsewhere,[26] it is expected to use up all the capacities of the 29 promising locations in about 10 years only for coal-fired plants. Unless we find many other appropriate locations that have equal or larger capacities or economical injection rates, we will be left with locations that have less CO_2 storage capacities. However, considering the CO_2 storage capacity, the cost to excavate a well at these locations will not be economical.

The caprock at the Iwanohara test site in Nagaoka has a dome-like folded shape, and the anticline structure can hold CO_2. This is the most desirable geological formation to store CO_2. However, Japan has many disadvantages: for example, aforementioned desirable geological formations are rare,[27] and since Japan has many earthquakes, there are many faults that may cause leakage.

Many demonstrations need to be conducted at various geological formations to fully understand capacities and injection rates, so it is uncertain whether Japan has appropriate locations to store a large amount of CO_2.

2-5 Necessity of overseas development

As discussed earlier, it is uncertain whether Japan can secure appropriate large-scale locations to store CO_2, and as a result, the storage cost may increase. In contrast, it is estimated that there are many potential storage locations overseas (Figure 2).[28] RITE estimates that the world's potential underground CO_2 storage capacity is 26 trillion tons (7.1 trillion tons in carbon-equivalent terms).[29]

When considering promoting Japanese CCS technology, it may be necessary to transport CO_2 arising in Japan to overseas locations to store it. Currently, CO_2 is not regulated by the Basel Convention on the Control of Transboundary

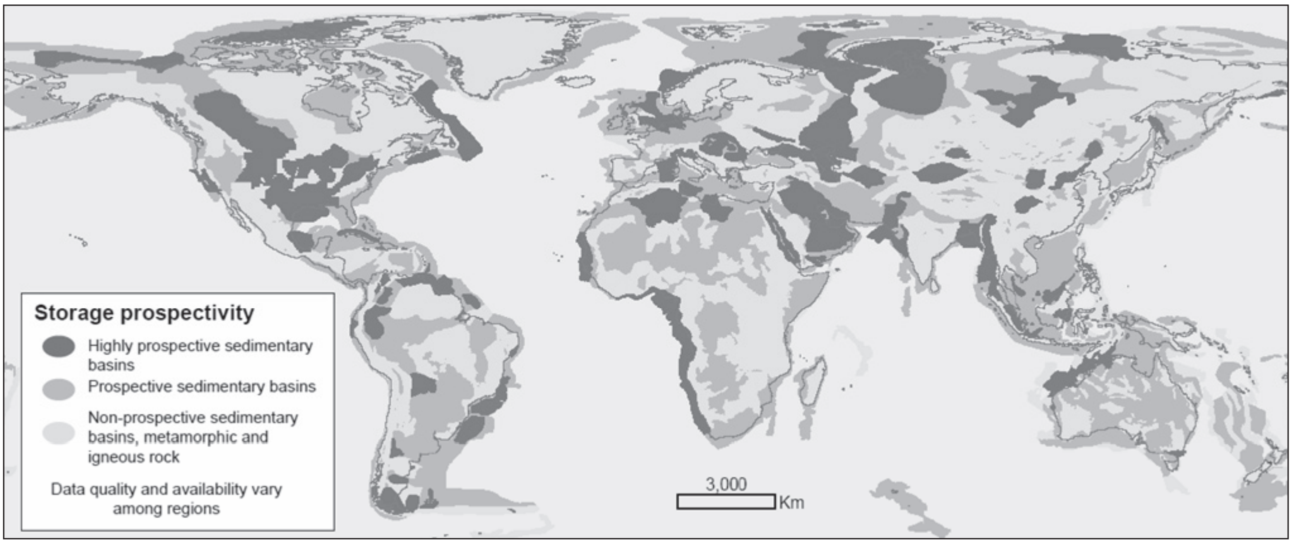

Figure 2: Estimated potential CO_2 storage capacity of the world

Source: Reference[28]

Movements of Hazardous Wastes and their Disposal. Therefore, transporting CO_2 generated in Japan to overseas locations is not a problem. However, it is apparent that such transport will generate more CO_2 emissions and increase costs.

Given that CO_2 emissions will affect global warming equally regardless of which country they originate from, it is more reasonable to use Japan's technology overseas to capture and store locally-generated CO_2 than to transport CO_2 produced in Japan to overseas locations for storage. Based on the CDM (an emissions trading system) specified in the Kyoto Protocol, contributing to the reduction of CO_2 emissions overseas using Japan's technology and acquiring emissions rights is one way to finance CCS costs. This is an advantageous method considering the aforementioned economical issue.

It is expected that conducting CCS projects under the CDM will overcome such issues as economical inefficiency and the uncertainty of securing appropriate storage locations. The current state of the CDM and some issues to be addressed to conduct CCS under the CDM are discussed below.

3 Current State of the Clean Development Mechanism (CDM)

3-1 What is the CDM?

The CDM is defined as a mechanism whereby Annex I countries (developed countries, such as Japan, which need to meet their caps under the Kyoto protocol) can, to reduce greenhouse gas emissions, invest in emissions reduction projects in non-Annex I countries (which do not have caps) while contributing to their sustainable development. Investors can earn carbon credits to meet their caps. Figure 3 illustrates the summary of the CDM.

3-2 Examining CDM methodologies

For greenhouse gas reduction projects to be recognized as CDM projects, methodologies for each type of projects need to be developed and approved. For example, when determining emissions reduction by a project, it is necessary to set a baseline amount of emissions that would be generated in the absence of the project. The difference between the baseline and the predicted emissions is considered the amount of reductions generated by the given project. The way a baseline is set depends on the type of project. Different types of projects will have different methodologies.

Once a methodology is established, it needs to be approved by the CDM Executive Board. A Designated Operational Entity then validates the case. The project is then registered as a project approved by the CDM Executive Board. Investors can then implement the project according to the methodology to earn carbon credits. After the onset of a project (not only after the construction of a facility but after actual operation for a certain period), a Designated Operational Entity will verify the project and, only if it approves the amount of CO_2 reduction will it issue credits (Figure 4). The MRV framework plays a critical role during this process, but the technology for CCS has not been fully established.

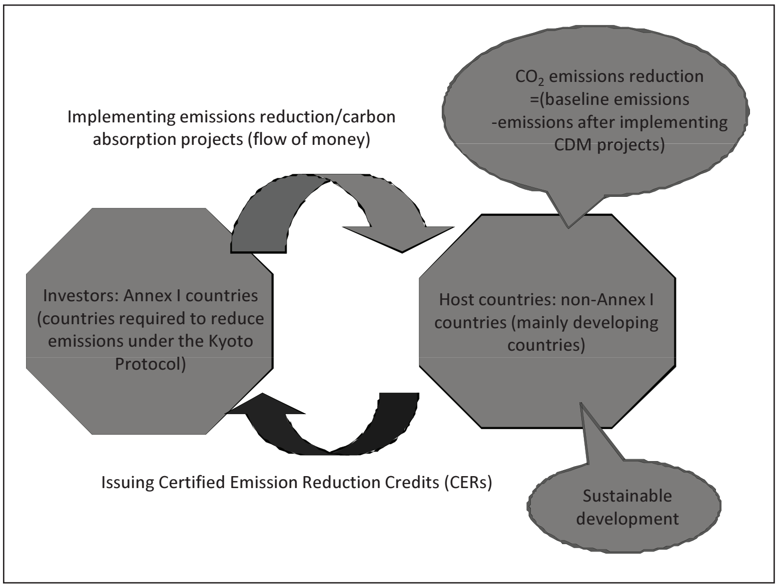

Figure 3: Summary of the CDM

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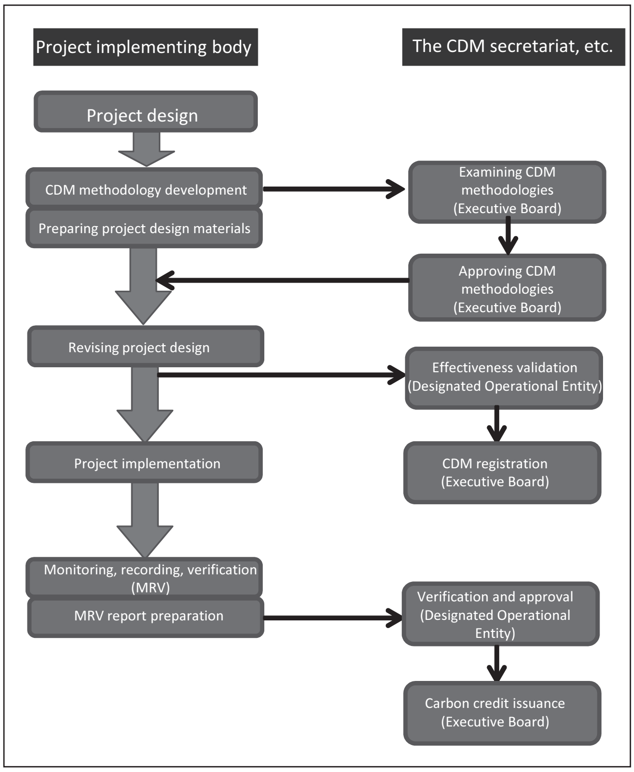

Figure 4: Approval process of CDM methodologies

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3-3 Registered projects

More than 100 methodologies have been developed for CDM projects. Based on these methodologies, renewable energy (wind power, hydropower, etc.), methane capture, and other projects have been implemented. Figure 5 illustrates the proportions of different kinds of projects registered as of January 2011. The figure shows that more than half the projects are relatively small (in terms of emissions reduction), such as wind power and hydropower generation projects (the proportions of six projects have been rounded to 0%).[30]

As of January 2011, 2712 projects have been registered, and a total of 1.97 billion tons of CO_2 has been credited (by the end of 2012). By 2030, a total of 7.7 billion tons of CO_2 will be credited. Moreover, as of January 2011, more than 200 projects are applying to be registered and more than 3,000 projects are applying to be validated.[30]

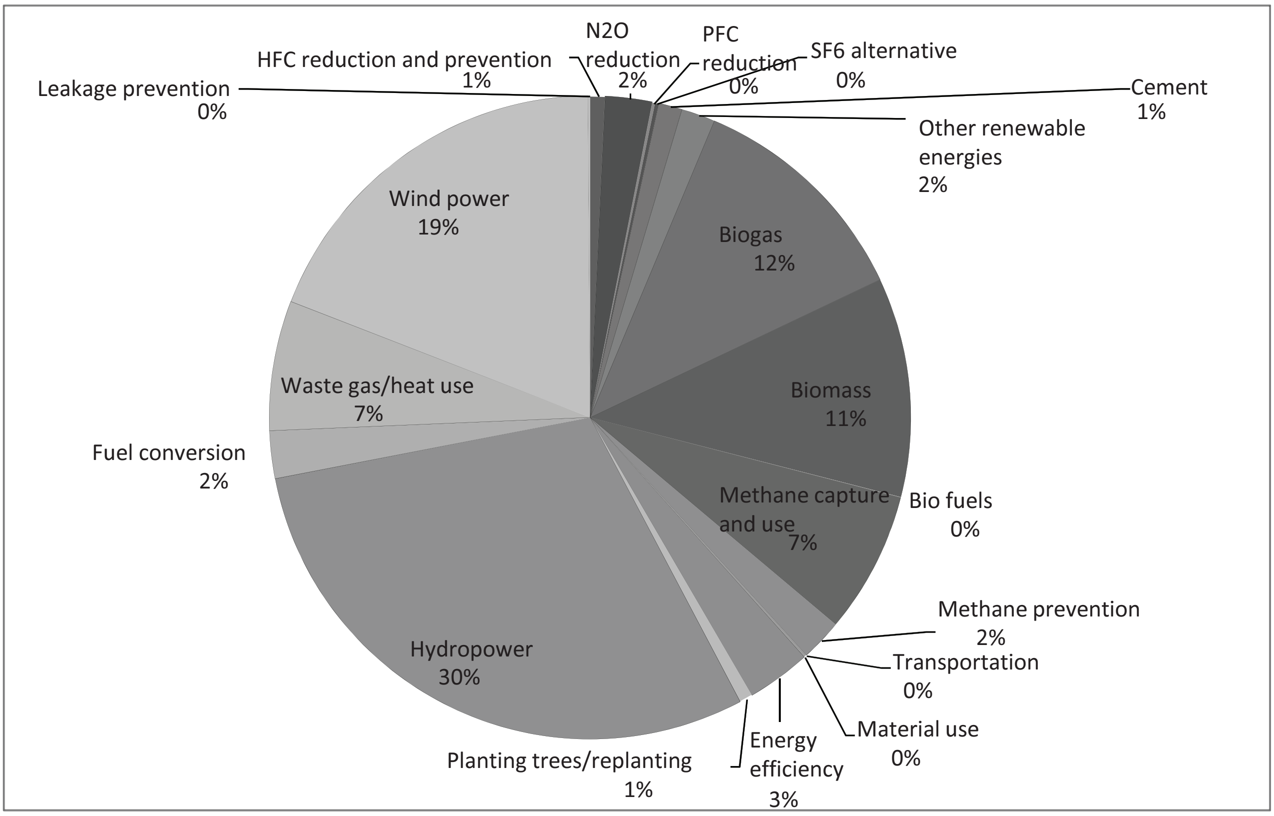

Figure 5: Registered CDM projects by type (as of January 2011)

Prepared by the STFC based on the IGES database[30]

4 Implementing CCS as CDM Projects

4-1 Current state of CCS as CDM Projects

Japan has submitted some CDM methodology applications for CCS projects. In September 2005, Mitsubishi UFJ Securities Co. submitted a methodology application for CCS projects to store CO_2 in spent oil/gas reservoirs. In January 2006, Mitsubishi Research Institute, Inc. and JGC Co. submitted a CDM methodology for CCS projects to separate and capture CO_2 from natural gas and store it in underground aquifers or spent oil/gas reservoirs.

These two applications are being examined by the CDM Executive Board and have not yet been approved. Before finalizing its decisions, the CDM Executive Board receives guidance from the Subsidiary Body for Scientific and Technological Advice (SBSTA), which was established based on the United Nations framework convention on climate change. As can be seen in the following section, the SBSTA clearly specified what issues to be addressed in order for CCS projects to be approved as appropriate CDM projects. The issues were discussed at COP15 in Copenhagen in December 2009, but there were both pros and cons. As such, it was determined that the issues would be discussed again at the next meeting.

The discussion on the inclusion of CCS projects under CDM did not easily reach an agreement. This was due to some practical issues discussed later as well as some concerns among the CDM host countries that CCS might lead to a reduction of investment in energy efficiency, renewable energy, and other existing projects.[31] However, at COP16 in Cancun, Mexico in December 2010, an agreement was reached that CCS technology was appropriate for CDM projects.[32] It was a great step forward. If the practical issues (discussed in the next section) are resolved, CDM methodologies for CCS technology may be established.

4-2 Practical issues

Before the Cancun agreements were made, the SBSTA suggested some practical issues that one can face in the implementation of CCS projects under CDM. The following two are the major issues.

(1) Environmental impact, safety, and attribution of responsibility

The CDM emphasizes sustainability, and as such, the SBSTA pointed out some environmental and safety issues to be addressed for CCS technology. These include securing safety in CO_2 transport and in establishing related facilities, the possible impact of CCS on the surrounding environment, and in the case of CO_2 leakage, the impact on humans, the eco system, and underground water. If there might occur leakage or if there happened an environmental damage or human suffering that might have been caused by leakage, claims for compensation for damage may arise. Even if an unexpected problem arises during the process of CO_2 injection, there will be arguments relating the CCS project and the problem. If a problem arises long after the injection, such causal arguments will be more intense.

In case of leakage, even if there is no human suffering, at least part of the carbon credits issued in the past will become invalid. How to handle such invalidation of carbon credits due to leakage is also an issue.

(2) Establishing and creating international standards of monitoring, recording, and verification framework

Another important issue presented by the SBSTA is the establishment of the aforementioned MRV framework. In order for CCS projects to be approved as CDM projects, it is necessary for MRV framework to be fully established and internationally accepted.

Even when a highly reliable MRV framework is established, it needs to be internationally accepted. It is necessary to make international standards for the total process of monitoring, recording, and verification, including some contract matters, such as how long the process should continue after the completion of CO_2 injection.

4-3 Future direction of CCS under the CDM

Technological issues of CCS (discussed in 2-4) and practical issues of CDM (discussed in 4-2) are correlated. Solutions to one will effectively work on the other, and as a result, it is expected that more CO_2 emissions will be reduced (Figure 6). Below, this article proposes what Japan, in particular, should do to solve the issues.

(1) Implementing demonstration tests

The safety of CCS technology and the validity of MRV framework can only be veryfied at a demonstration test site. There is no other way to earn the trust of society than conducting continuous demonstration tests. It is essential to conduct demonstrations at a practical scale in terms of storage capacities and injection rates, at several sites having some Japan's major geological formations.

(2) Standardizing monitoring, recording, and verification framework and safety assessment methods through international cooperation

In order to reduce CO_2 in a CDM project to be approved, the accuracy of the data needs to be acknowledged internationally. It is effective to work

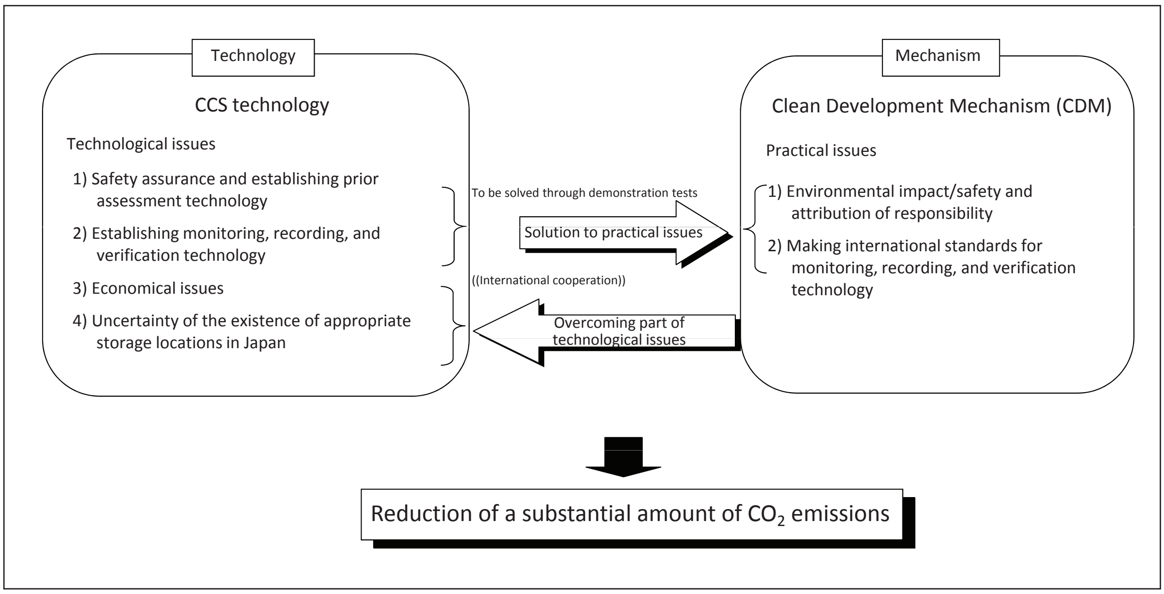

Figure 6: Resolving CCS technological issues and CDM practical issues

Prepared by the STFC

with other countries conducting CCS demonstration efforts and to efficiently implement verification research. It is expected that international cooperation will improve the level of the global efforts. If Japan continues to participate in such global efforts, global warming counteraction will speed up, and Japan's contribution to the world will be recognized.

At the same time, in order for Japan to conduct conduct CCS in a foreign country in the future smoothly, Japan needs to take the initiative in creating international standards for technological matters and frameworks (including safety assessment methods, monitoring/recording/verification methods, attribution of responsibility, and verification methods for reduction effectiveness). In the CDM, a private organization (Designated Operational Entity, certified by the United Nations CDM Executive Board) verifies the amount of CO_2 reduction. To establish MRV framework, this article proposes that the government should help set opportunities up where Designated Operational Entity's officials and Japanese engineers can team up to develop technology.

(3) Establishing favorable relations with counties with storage capabilities

To smoothly conduct CCS projects under the CDM in the future, it is essential to build good relations with the countries that have storage capabilities. It will be effective to conduct international exchange programs with the countries conducting or planning to conduct demonstration tests, for example, by having Japanese researchers and engineers participate in projects overseas, as well as by inviting foreign researchers and engineers to demonstration projects in Japan.

J-Power Co. and other Japanese companies have already started a joint project with Australia. Japan should, however, cooperate with not only developed countries but also countries that can become CDM hosts.

We would like to point out that some countries are potentially good partners where Japan may be able to conduct CCS under the CDM. These countries include India, China, Indonesia, Brazil, and other countries, with their high CO_2 storage potentials and growths and coal consumptions that are expected to increase. Other countries such as Southeast Asian and Middle East countries are also good candidates because of their high CO_2 storage potentials and high CO_2 emissions due to fossil fuel excavation. If these countries trust Japan through personnel exchange, searching for appropriate storage locations and starting to conduct projects will be done smoothly there in the future. In addition, such good relationships will work favorably for Japan during negotiation processes to determine international standards for monitoring, recording, and verification framework, etc.

5 Conclusion

Japan has already improved energy efficiency to a great extent, and as such, it will be difficult to further reduce domestic greenhouse gas emissions. A promising method for further contributing to greenhouse gas reduction efforts is to reduce emissions overseas. In particular, the use of an emissions trading scheme of the CDM will be the key. The internationally approved CDM projects in the past have been small-scale and have been insufficient to achieve high reduction targets. Therefore, it is desirable to implement CCS projects under the CDM to reduce CO_2 emissions.

The international community agrees that CCS is technology to simultaneously accomplish the 3 E's (Economy, Environmental protection, and Energy security). It is also a technology that the IEA is expecting the diffusion to a certain extent. There is still a lot of improvement in terms of performance and cost reduction, but the technology required to conduct demonstrations has mostly been established. Even so, there are no incentives for CCS investors, and as such, it will be difficult to commercialize CCS unless, for example, investors can earn carbon credits overseas using the CDM.

Previously, CCS had not been recognized as appropriate for CDM projects even though it had been discussed. However, at COP16 in December 2010, an agreement was reached that CCS was eligible for CDM projects, at least on a conditional basis. Creating an environment to put this into practice is under way, but there are still some technological and practical issues. In particular, it is essential to eliminate concerns over environmental impact and safety as well as to establish monitoring, recording, and verification framework. CCS projects under the CDM will soon be realized by accomplishing technological development through international cooperation and facilitating efforts to create international standards for the technology.

It is unclear whether Japan has appropriate storage locations in the country, and as such, realizing CCS projects under the CDM is more desirable. It would be beneficial to the international community and also in the country's interest if Japan could smoothly conduct CCS projects overseas and steadily earn carbon credits by developing technology through domestic demonstrations and creating international standards for monitoring, recording, and verification framework.

This proposal is also effective for the bilateral credit framework, which has been discussed by the Japanese government.

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5

ICT Use and Increasing Openness in Higher Education — Advanced e-learning and Open Educational Resources —

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1 Introduction

The environment surrounding higher education has been dramatically changing due to social changes such as globalization and aging, as well as to rapid technological advancement. In particular, progress in Information and Communications Technology (ICT) has released space and temporal constraints from the traditional higher education system, providing the foundation for bringing a new kind of higher education.

The Open University, United Kingdom, the Open University of Japan, and other distance learning have long been using radio and television programs as shown in Figure 1, mainly to provide lifelong educational opportunities to working people. In recent years, the widespread use of inexpensive personal computers has created a favorable environment for e-learning. Moreover, the boundary between e-learning and distance learning has blurred, and these have become integrated with the use of electronic content distribution and interactive communication systems on the Internet. It is highly probable that open movement in education such as OpenCourseWare which publishes lecture material and videos on the web will change not only the frameworks of distance learning and e-learning, but also the existing framework of higher education in general.

This article introduces novel higher education using ICT mainly in the United States, and describes increasing openness in higher education and the resulting global ripple effects.

2 Effects of ICT Use in Higher Education in the United States

2-1 Cost assessment

In the United States, the National Center for Academic Transformation (NCAT)[1] was established in April 1999. NCAT is an NPO aiming to improve learning effectiveness and reduce costs in higher education. With support from the Pew Charitable Trusts (an NGO) and the Department of Education

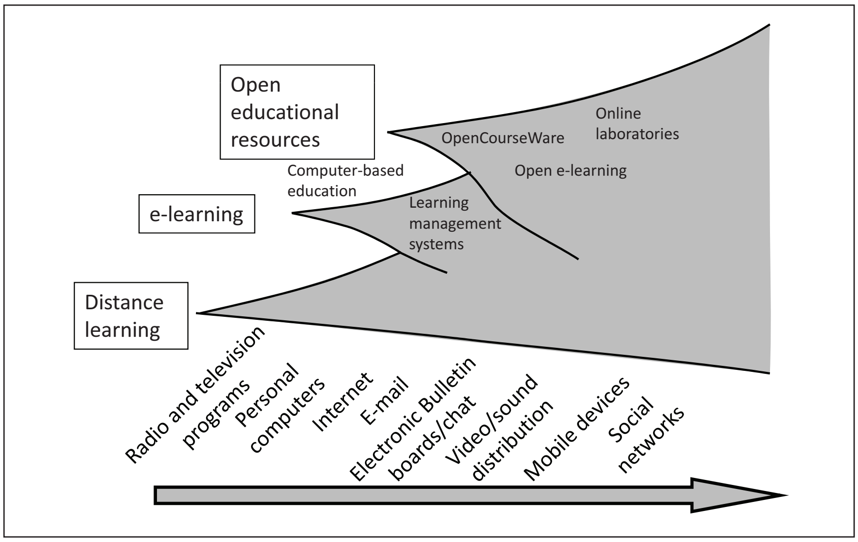


Figure 1: Changes of higher education using ICT
Prepared by the STFC

in the United States, NCAT conducted a project to introduce new educational courses using ICT and to assess the effect of the courses. Figure 2 illustrates the cost-reduction effect of the new educational courses using ICT, as indicated by NCAT. The chemistry course at Arizona State University reduced the cost per student from $439 to $351. The total number of students who took the course was 4,640, and the total cost reduction amounted to $408,320. The math course at Virginia Tech reduced the cost per student from $91 to $21, achieving a 77% cost reduction. The Spanish course at the University of Tennessee also cut the cost per student from $109 to $28. The courses that have shown significant cost reduction include math, chemistry, languages, and English composition. The common characteristic of these courses is that they are basic-level courses where students' achievements can be clearly determined.

The cost calculation and allocation methods considering common facilities need to be further examined. This project is very important, because it aims to objectively verify a portion of higher education courses from the perspective of cost effectiveness and, at the same time, to promote the use of ICT. The following sections introduce some specific cases.

2-1-1 e-learning centers with teaching assistants

Virginia Tech opened a learning center called the Math Emporium, which has 537 computers for math e-learning.[3] The center is open all day, and students can independently learn according to their own schedules. In addition, students have opportunities (80 hours per week) to get personal assistance from professors, lecturers, and teaching assistants. On weekdays, teaching assistants work until late at night, so that even after faculty office hours, students can get learning assistance. After the onset of this system, the GPA (Grade Point Average) increased from 2.39 to 2.42 on a four-point scale, and the percent of students who acquired credits raised from 80.50% to 87.25%.

Cost per student also decreased through independent e-learning and support from teaching assistants. One of the reasons was that the novel courses received more earnings from tuition due to the increased number of students compared to traditional courses. Another reason was that the active use of teaching assistants, who cost less than professors and lecturers, led to personnel cost cutting.

The University of Idaho and the University of Alabama also established similar e-learning centers (the Polya Mathematics Center and the Mathematics Technology Learning Center, respectively). After the introduction of e-learning at both universities, equal or better learning effects were observed, and the percentage of students who failed to acquire credits decreased.

2-1-2 Independent learning assistance through e-learning

The beginning Spanish courses at the University of Tennessee and Portland State University and the statistics courses at Pennsylvania State University

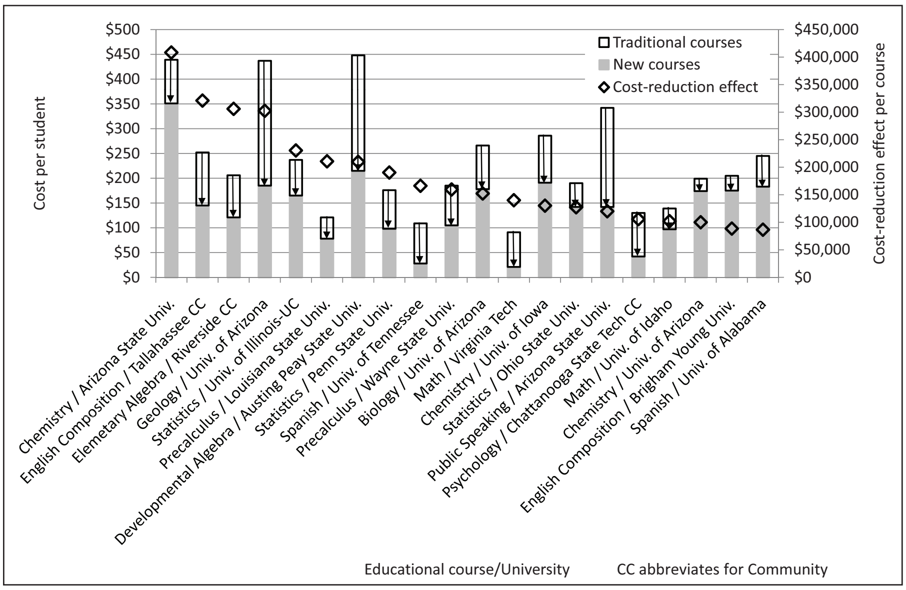


Figure 2: Cost reduction effects in novel courses using ICT

Prepared by the STFC based on Reference[2]

and the University of Illinois at Urbana-Champaign have introduced independent learning for their students using e-learning materials. The teaching staff receives feedback as the learning portfolio collecting learning records and including students' test results using the e-learning systems. The staff could adjust teaching speed in their classes according to students' understanding. This also contributes to improve the progress of the classes. A part of teaching contents explained in the usual classes was substituted by e-learning. Such independent learning assistance reduced the number of classes. As a result, it increased the number of students per teaching staff, and decreased the cost per student.

2-1-3 Online distance learning classes

Online classes can reduce physical constraints in higher education, such as the lack of classrooms. Art courses at Florida Gulf Coast University use an Internet phone and meeting system to conduct online distance classes, without using actual classrooms. This reduces the costs for keeping classrooms and other facilities, leading to cost reduction per student.

In Japan, a partnership between Bond University in Australia and Business Breakthrough, Inc. provides online distance classes in a MBA program.[4] Without studying abroad for a long period of time, it is possible for students to participate in a program offered by an overseas institution of higher education. In addition, RareJob, Inc., a language education company, uses free Internet phone services to have students and graduates from the University of the Philippines (living in the Philippines) teach English conversation classes.[5] This kind of transnational online distance education has led to the creation of new businesses that utilize highly skilled workers in developing countries.

2-2 Imroving efficiency through learning management systems based on ICT

Learning Management Systems (LMSs) and Course Management Systems (CMSs) enable information sharing between teaching staff and students, the centralized management of handouts and assignments, the management of students' progress, and achievement assessments. Digitized teaching materials used in e-learnig are also included in LMSs. By introducing LMSs into higher education, a smaller number of teaching staff are able to effectively teach classes for a larger number of students.

Blackboard[6] (commercial system), Moodle[7] (open source system), and Sakai[8] (open source system) are known as LMSs. The number of registered Moodle users has been increasing, and at the end of 2010, more than one million people were using Moodle around the world (Figure 3).

Figure 4 shows a screenshot of Sakai LMS and available functions. Sakai offers collaboration, teaching/learning, and portfolio tools. The collaboration tools provide functions for sharing information between teaching staff and students and for promoting communication among participants. The latest version of Sakai includes collaborative functions with cloud applications like Google Docs, Gmail, and SNS like facebook. The teaching/learning tools provide syllabuses, assignments, and tests. The portfolio tools offer feedback to students about their assignments as well as the management of their learning progress.

In addition, mobile learning (m-learnig) using smart phones and other portable devices based on the LMS have been tried.

Since various LMSs have been developed, the compatibility between different systems has also been examined. For example, the Advanced Distributed Learning (ADL) Initiative in the United States[NOTE 1] developed SCORM,[9] which integrates a set of standards, specifications, and guidelines. In addition, ISO/IEC JTC 1/SC 36[11] discusses technology standardization concerning LMSs.

2-3 Management systems for higher education

Kuali Foundation has developed and released (as an open source) a comprehensive management system that includes not only learning management tools, but also administrative and research management tools for universities.[12] Kuali's administrative management modules have been introduced at the University of Southern California, Cornell University, Indiana University, and Colorado State University. Colorado State University had estimated $5 to $7 million for the introduction of an administrative management system

[NOTE 1]
The Office of the Under Secretary of Defense for Personnel and Readiness (OUSD P&R) created the ADL Initiative in 1998 during the Clinton administration.[10]

on the market, but ended up paying only $2 million by adopting Kuali's administrative management modules.[12]

2-4 Cloud educational applications

Google offers Google Apps for Education free of charge for educational institutions. This is a cloud application that includes e-mail, group calendars, and Google Docs.[13] If an institution changes its email system to Gmail, it can continue to use same e-mail addresses with previous system, and so the transition is easy. By using such cloud services, educational institutions can provide ICT-based services to their teaching staff and students without having to set up and manage their own servers.

3 Globally influential open educational resources

Educational contents represented by OpenCourseWare, educational tools including learning management systems developed as an open source, and related intellectual properties, are called open educational resources (OERs). The following section introduces some of these globally influential open educational resources.

3-1 OpenCourseWare

OpenCourseWare (OCW) is "an open and a free publication of formal course materials of universities on the Internet."[14] OCW provides syllabuses, lecture notes, assignments, and exams and their answers. OCW also sometimes provides lecture videos and

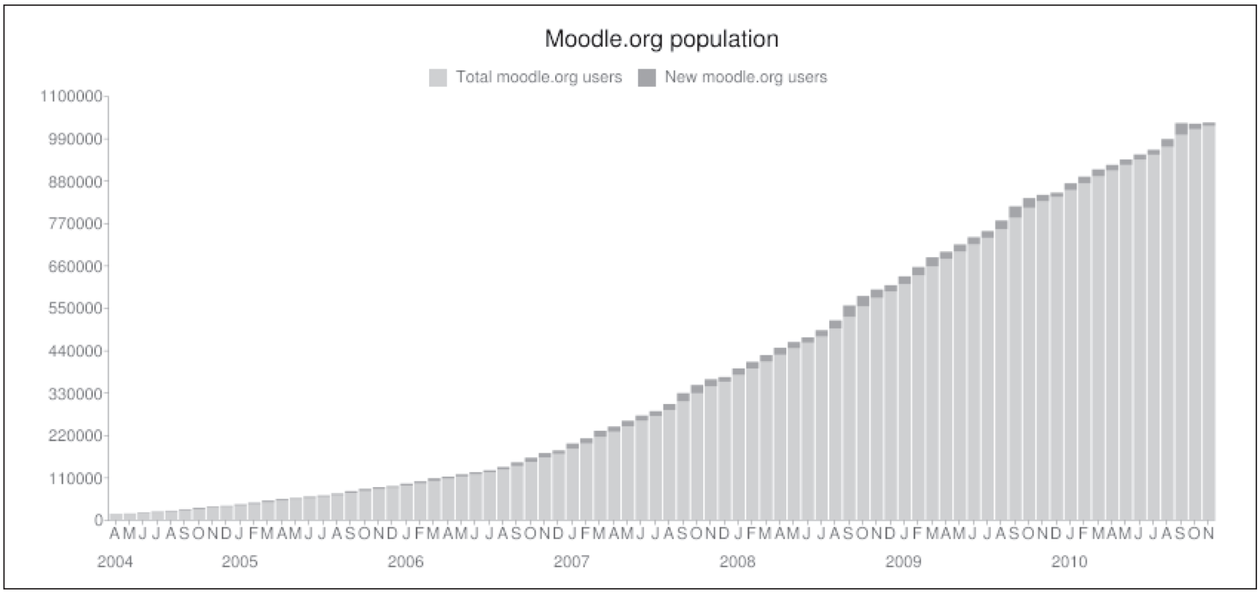
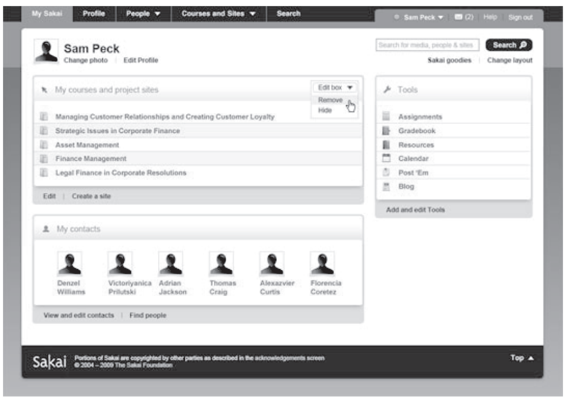


Figure 3: Changes in the number of Moodle's (open source provider's) registered users

Source: Reference[7]

(a) Screen shot



(b) Functions

Collaboration tools	Teaching/learning tools
- Announcements	- Syllabus
- Site-related information	- Timetable
- List of participants	- Assignments
- E-mail archive	- Tests & Quizzes
- Wiki	- Grade book
- Blog	- File sharing
- Calendar	**Portfolio tools**
- Chat	- Progress management
- Discussion forums	- Feedback
- Glossary	- Report management
- External link	- Templates
- News	

Figure 4: Sakai (open source provider's) LMS system

Prepared by the STFC based on Reference[8]

e-learning materials. Universities do not offer degrees or credits to OCW users who are not their students. Additionally, universities do not allow such outside OCW users to contact their teaching staff. Not all content in a class is included in OCW materials due to copyright issues that does not allow to open to the public.

As Figure 5 illustrates, Massachusetts Institute of Technology (MIT) has offered OCW courses since 2002, and published more than 2,000 courses in 2010.[15] 8.01 Physics: Classical Mechanics is a representative MIT OCW, for which all the class content is published, including lecture videos, notes, exams, and answers.

It is estimated that more than 100 million people have accessed MIT's OCW website, and about 60% of the visitors are from Asia and Europe. MIT has delivered audio and video using YouTube, iTunes U, Podcast, and flickr providing photo sharing services in addition to OCW since 2008. There are mirror sites of MIT OCW that provide translated and localized versions around the world. These contribute to the extension of opportunities for higher education in developing countries.

In addition to MIT, Tufts University and many other universities in the United States offer OCW courses. The Open University[16] in the United Kingdom and the Open University of Japan (which have been conducting distance education) have also provided OCW courses. According to the OpenCourseWare Consortium, 107 organizations in 208 countries conduct OCW activities.[17] In Japan, Japan OpenCourseWare Consortium (JOCW) established in 2005 is active to popularize OCW as well as offering OCW. As shown in Figure 6, the number of OCW courses offered in Japanese and English have been increasing. In French-speaking countries, UniversitySurf,[18] an OCW portal site, offers more than 1,500 courses. A similar portal site called Universia[19] exists in Spanish-speaking countries. In China, China Open Resources for Education (CORE) is conducting OCW-related activities.[20]

It is not easy to assess the overall trends in OCW offered by various web services around the world. Apple's iTunes U offers more than 350,000 lecture videos and materials from over 600 universities.[21] In the case of iTunes U, a university can limit access to its own students, so content is not necessarily open to the public. It is substantially estimated that an even greater number of higher educational resources have been used around the world.

3-2 Open Learning Initiatives

The Open Learning Initiative (OLI) at Carnegie Mellon University (CMU)[22] aims to make advanced e-learning content as an open educational resource. The OLI offers free e-learning content in physics, chemistry, biology, biochemistry, statistics, French, etc..

Figure 7 illustrates online materials and a virtual lab offered by the OLI at CMU. In the online materials in Figure 7(a), a computer-based tutor on the computer

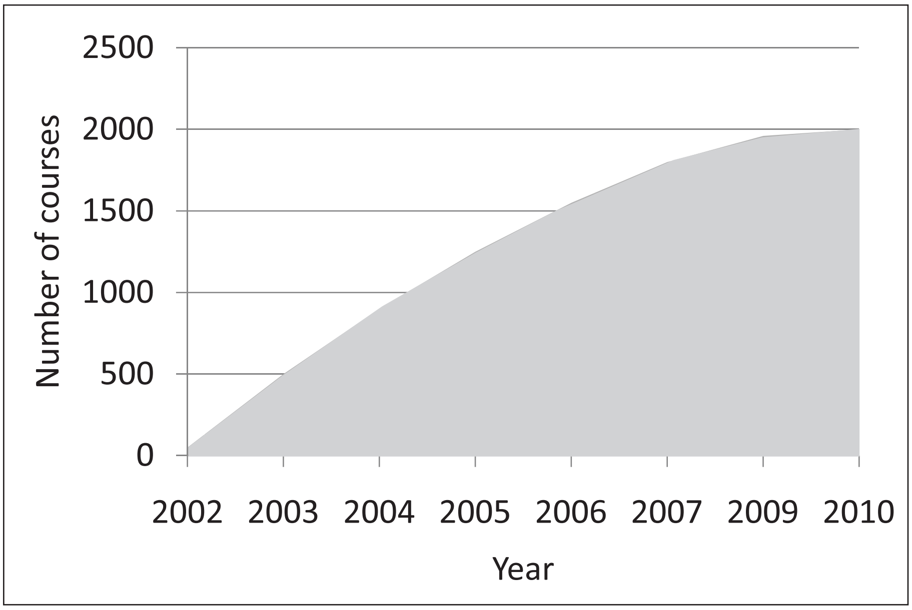


Figure 5: Changes in the number of OCW courses at MIT

Prepared by the STFC based on Reference[15]

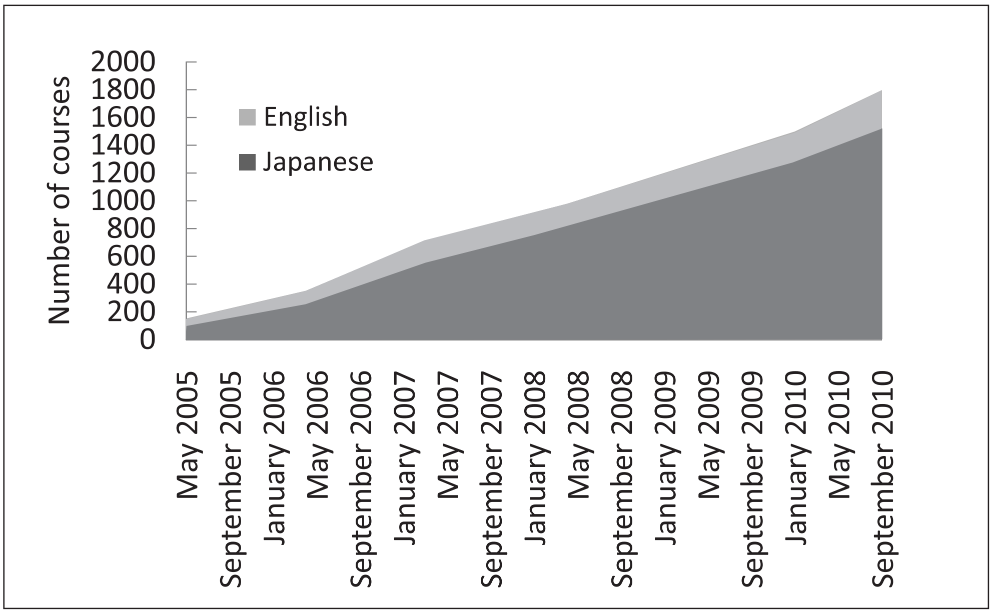


Figure 6: Changes in the number of OCW courses published in Japan

Source: Reference[14]

comments on a student's answers. When a student makes a mistake, the student can quickly check why he/she has made the mistake. It makes efficient independent learning possible. Figure 7(b) shows a virtual laboratory where a neutralization reaction is simulated and the result is visualized. This application allows a student to understand the changes in molar concentration, temperature, pH, etc. when the reaction has started by mixing the solutions. It is useful to better understand chemical phenomena.

The OLI at CMU consists of academic courses without limitation and open & free courses that limit available functions as shown in Table 1. Anybody can take the open & free courses, but the users are not allowed to contact teaching staff at CMU or to receive credits. Not only CMU students, but also students and teaching staff at other educational institutions can take the academic courses if they register. However, credit accredit to a student depends on the educational institution that the student belongs.

3-3 Khan Academy

Khan Academy,[23] a non-profit educational institution, uses YouTube to provide more than 1,800 lecture videos in math, physics, chemistry, and other subjects covering elementary, secondary, and tertiary education levels. Each lecture video in each topic is ten to twenty-minutes long. Instructor uses a computer pen tablet that replaces an ordinary lecture board, so that the lecture videos can be created inexpensively without using special equipments including movie camera and so on. Khan academy also offers some captioned lecture videos and web applications for exams. The content is regarded as high quality and suitable for independent learning, and is supported by Google Inc. and the Bill and Melinda Gates Foundation.

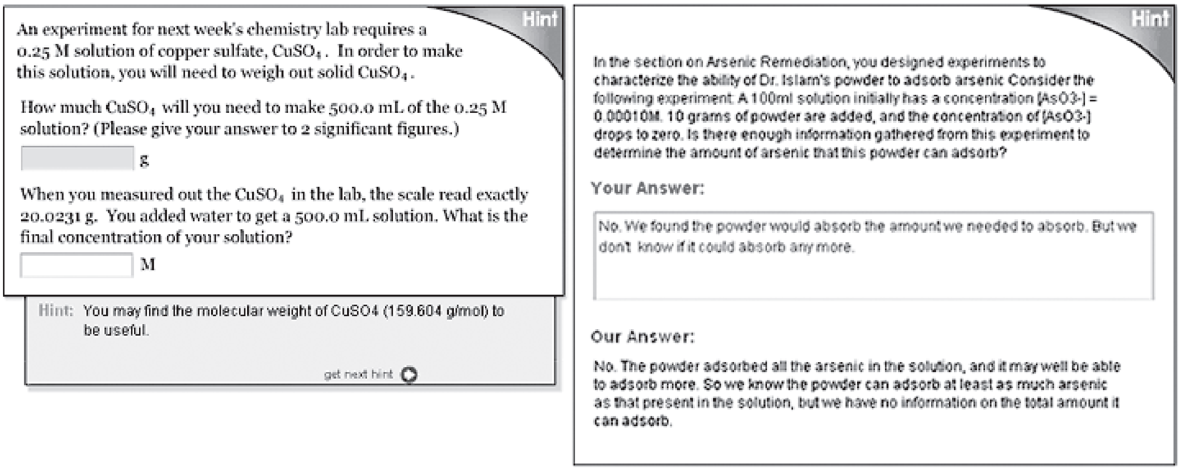
3-4 Online laboratories

Research equipments and computers connected to the Internet have been shared to a greater extent than previously in various research areas. This is an aspect of the changes in research called e-Science.[24] There is also a movement toward educational equipment and facilities being used more openly. For example, the iLab project offers online laboratories that can be operated using a web browser.[25] The iLab project provides opportunities of online experiments in physics, chemistry, electronic engineering, and other subjects. Not all experiments can be conducted online. However, interactive experiments can be done through the remote operation of measurement control tools connected to computers in many cases. The National Science Foundation (NSF) in the United States supports the iLab Network project that universities in the United States and Australia participate.[26]

One example of an online experiment in the iLab Network project is the use of inductively coupled plasma atomic emission spectrometry at Northwestern University in the United States (Figure 8). The device applies thermal excitation to a sample at 4,000K and then observes an emission spectrum when the sample

(This virtual laboratory simulates a neutralization reaction and shows the changes in molar concentration, temperature, pH, etc. when the reaction has started by mixing the solutions.)

(a) Online materials



(b) Virtual lab

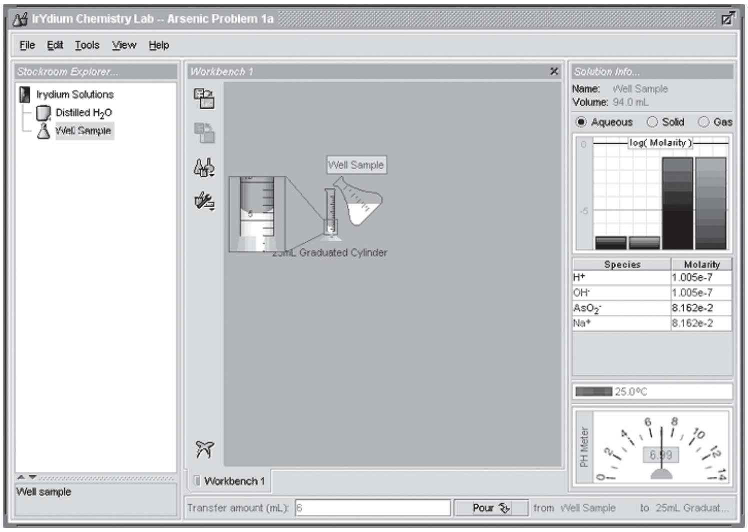


Figure 7: Online chemistry materials and a virtual lab offered by the Open Learning Initiative (OLI) at Carnegie Mellon University (CMU)

Source: Reference[22]

Table 1: Tools offered by the OLI at CMU

	Open & free courses	Academic courses
course materials	○	○
Simulations, Computer Based Tutors, Virtual Laboratories, and Self-Assessments	○	○
Formative Feedback for student	○	○
Access to an Instractor teacher	×	○
Graded Exams	×	○
Tracks Student-Learning as Feedback for Instructors	×	○
Credit / Verification of Course Completion	×	○

Prepared by the STFC based on Reference[22]

returns to the ground state. The device identifies the elements composing the sample and determines their quantities from the spectrum. For example, online environmental science experiments targeting college and high school students allow the study of metals contained in samples such as water, soil, plants, etc.. This online laboratory adopted a learning management system and automatically provides students registration, content and related OCW to be pre-learned.

As such, online laboratories allow teaching staff and students to share expensive equipments from anywhere in the world and conduct experiments without constraints of their own equipment. In particular, online laboratories are effective in the situation where special equipment is only owned by a limited number of organizations. Widely providing advanced science and technology programs will contribute to extend educational opportunities in these fields. Of course, it is also hoped that these online laboratories will be widely used not only in higher education but also in secondary education.

4 Prospects of Changes in Higher Education Using ICT

This chapter discusses changes in higher education using ICT mainly in Japan as well as the impact of increasing openness in higher education around the world from the three perspectives in the following sections.

4-1 Scalable educational infrastructure

In the traditional teaching style in which a teaching staff lectures to students in a classroom, the number of students is limited according to the size of the classroom. However, online lectures and e-learning can easily expand the number of students and the physical distance between a teaching staff and students. When an institution in higher education only has a small number of students, it can work together with several other institutions to gather many students and boost scale merit. If the number of students decrease in the future, the scale can be easily adjustable. In Japan, institutional collaboration based on e-learning have already been conducted in the framework of the Support Project for Strategic University Collaborations by the Ministry of Education, Culture, Sports, Science and Technology.[27,28] There is a possibility that institutional collaboration in higher education taking advantages of ICT will be important in Japan where birthrate continue to decline, compared with other countries.

In Japan, cram schools and companies have more introduced e-learning taking advantages of ICT than universities so far. If more universities adopt ICT, it will be possible for them to invest saved resources in new research or other educational improvements. If universities use the saved resources for reduction in tuition and scholarships, it will lead to expand equal educational opportunities in higher education.

4-2 Expanding use of advanced e-learning

e-learning, and mobile learning based on learning management systems enable students to access educational content from outside the university whenever they want. Moreover, social network systems may allow extended communication between

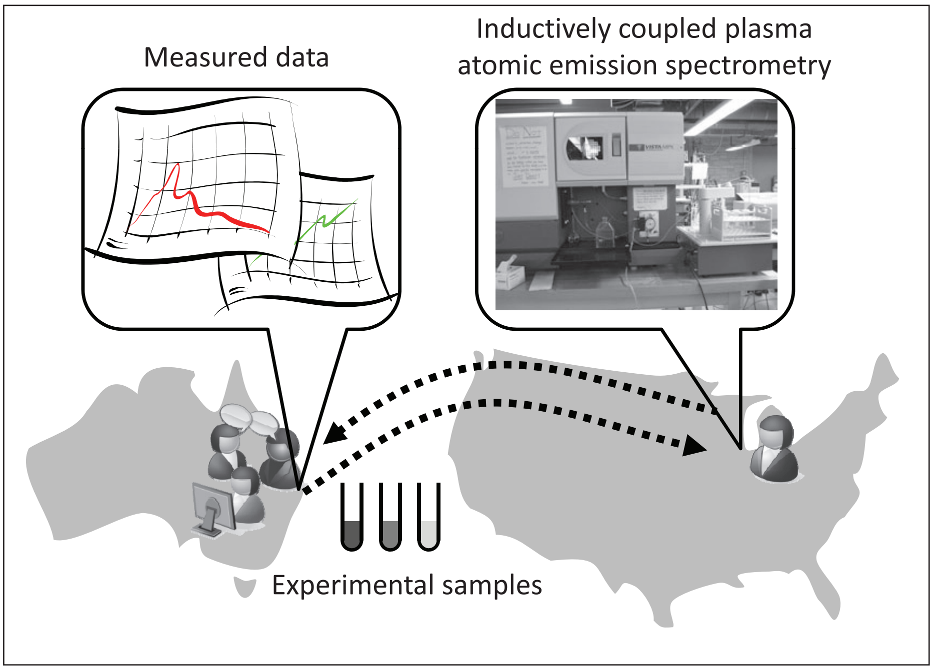


Figure 8: Online experiments of environmental science provided by Northwestern University in the United States through the iLab Network project

Prepared by the STFC based on Reference[26]

teaching staff and students who do not belong to the same institution. If advanced e-learning improves the effectiveness of independent learning, problem solving and experience based learning can be emphasized in actual classrooms. If e-learning is used more widely, the roles of tutors will be more important, and the balance between teaching staff and students in higher education will be changed in the future.

In Japan, e-learning-based outsourcing services have been provided for remedial education to students who lack academic capabilities required at universities. Remedial education using e-learning has been conducted for prospective students who have passed AO (Admission Office) exams or have been admitted based on recommendations.[29] It is expected that efficiency in higher education will be improved through outsourcing services using e-learning, not only in remedial education, but also in general and professional education. For example, such services can be used to teach students who have different professional education backgrounds in interdisciplinary research. In order for students with different academic backgrounds to quickly acquire the basic knowledge required for research, supplementing the curriculum with e-learning and other tools will be effective. In remedial education, teaching staff in universities do not have much psychological resistance to adopt e-learning, since they consider the remedial education outside the scope of education in universities. However, the introduction of e-learning into general and professional education will lead to reconsider the traditional educational system, including personnel organization at higher educational institutions. Professionals involved in higher education must pay more attention to the fact that global changes in technical trends require institutions of higher education to change.

4-3 Increasing open educational resources

OpenCourseWare (OCW) providing educational materials free of charge to prospective students and self-learners can be considered as ways for higher educational institutions to send information to society. For example, OCW provides lifelong study to self-learners who were not able to receive higher education due to their regional or cost issues. OCW plays role to restore accumulated intellectual resources in universities to society. On the other hand, OCW is an effective publicity tool for educational institutions to attract excellent students from around the world. This may increase gaps between educational institutions in the future.

If we consider higher education from the aspect of public goods shared in society, open educational resources can be regarded as common pool goods[NOTE 2] that anyone can learn independently without cost. Open educational resources that offer more open educational opportunities are different from club goods provided by the traditional educational system, where educational institutions exclusively accredit credits and award degrees to students who pay tuition. If some people wish to learn without needing to acquire degrees as signaling for guarantee their capabilities, part of the knowledge acquisition process in higher education can be easily and effectively replaced by open educational resources. Meanwhile, we emphasize the aspect of public goods in terms of open educational resources that is not limited to specified institutions, there will be new issues how we share social expense to develop and maintain such resources as well as the management of intellectual properties and copyrights. These imply important changes when we overlook the future of the higher education system.

It is estimated that MIT spends between $10,000 and $15,000 to make OCW content for each course,[15] which suggests OCW content of 2,000 courses costs $20 to $30 million. Since the content needs to be updated annually, the university must continuously share the cost for the maintenance of OCW. In the United States, the William and Flora Hewlett Foundation, the Andrew W. Mellon Foundation, the Bill & Melinda Gates Foundation, and other

[NOTE 2] : Classifications of goods

	Competitive	Non-competitive
Excludable	Private goods	Club goods
Non-excludable	Common-pool goods	Public goods

*If the consumption is non-competitive and the supply is non-exclusive, the goods or services are called public goods. Non-competitive means that a person can consume goods or services without paying any costs. Non-exclusive means that multiple people can equally consume the goods or services.

private foundations have been providing funds that greatly contribute to the expansion of open educational resources including OCW. The progress of ICT reduces the infrastructure costs for providing open educational resources, but the support for continuous maintenance and improvement of open educational resources still remains an issue. Currently, organizations and teaching staff who recognize the worth of open educational resources provide such resources. Although contribution to open educational resources is regarded as part of their educational activities for individual teaching staff, it will be necessary to provide incentives, e.g. performance evaluations for teaching staff, to keep their efforts to expand open educational resources.

To provide equal educational opportunities, the International Institute of Educational Planning in UNESCO[30] and the Open eLearning Content Observatory Services[31] funded under a project in the European Union have portal sites offering research, reports, and information on open educational resources. It can be considered as an effective way to develop public infrastructure to maintain this kind of portal site and other repositories that do not belong to a certain institution of higher education apart from direct funding support.

Licenses applied to open educational resource basically follow the Creative Commons licenses,[NOTE 3] however similar but original licenses have also been applied. Since Creative Commons licenses are composed of detailed articles, allowance and restriction can be flexibly set up either for commercial or non-commercial use as well as treatment for their derivatives. It is generally allowed to distribute copied materials for educational use in a class without a fee for publications including academic journals published from academic institutions as well as commercial publishers. However, similar allowance cannot be applied to the open content. Contribution from researchers are also required to enrich the open educational resources, for example, they actively open a part of research achievement to the public under the Creative Commons licenses through Wikimedia Commons or similar sites.

5 Conclusions

The introduction of advanced e-learning into higher education is expected to improve learning effectiveness and to reduce costs, which are conflicting problem to be solved in the traditional higher education system. Open educational resources will easily replace part of the knowledge acquisition process in higher education. The worth of institutions of higher education will be evaluated from the originality of their curricula and content appeared in their special programs such as problem solving and experience based education, rather than knowledge acquisition process where ICT can be used.

Open educational resources represented by OpenCourseWare have greatly contributed to social education by closing regional gaps in higher education and expanding lifelong educational opportunities for many people. At the same time, this increasing openness may require redefining the traditional higher educational system based on the degree accredit. The impact of ICT such as advanced e-learning and open educational resources should be regarded as a change of technological trends that presents issues to institutions in higher education. Such technological change may bring great transformation to institutions of higher education, so professionals involved in higher education must share a common awareness of the issues.

We guess the discussion on higher education and ICT in Japan has mostly been confined to specialists in educational engineering. According to the instances shown in the spontaneous activity of institutions of higher education and nonprofit organizations mentioned in this article, the discussion should be put into a broader context that includes the management of universities and globalization, which has the potential to develop further.

If higher education in Japan is required to respond to global changes, it will obviously be essential to steadily introduce technological innovation using ICT into education. It is necessary to consider the impacts of external environmental changes including advanced

[NOTE 3] : Creative Commons licenses[33]
It offers intermediate licenses that are different from protection or renunciation of all copyrights or. A licenses is defined by a combination of 1) attribution (the original work must be credited), 2) non-commercial use (the work must not be used for commercial purposes), 3) no derivative works (the original work must not be altered), and 4) share-alike (derivative works must be released only under a license identical to the license of the original work).

ICT in higher education from a broader perspective as well as labor saving tasks in education and research using ICT from a day-to-day perspective.

For each institution of higher education, it is required to expand current efforts from specialists engaged in teaching to the institutional administration. The first step to for the purpose would be to share understanding and discussion between teaching and administrative staffs beyond specialties and organizational boundaries.

It is also desirable for the government to assess in a certain standard and announce spontaneous activity of each institution from the perspectives of learning effectiveness and costs. To encourage the sustainable efforts in each institution, it would be effective to reflect the assessments to the distribution of funding.

ICT is expected to release physical and temporal constraints in the traditional higher educational system and to enable a scalable educational infrastructure, where a considerable increase of investment in educational resource is not required even if the scale expands. It has become increasingly clear that advanced e-learning and open educational resources have multifaceted impacts, such as expanding learning opportunities due to lower costs, improving the effectiveness of independent learning, and creating borderless learning environments (Figure 9). Of course, these are not effective in all aspects of higher education, though we guess that their impacts on education aimed at knowledge acquisition, in particular, are considerable.

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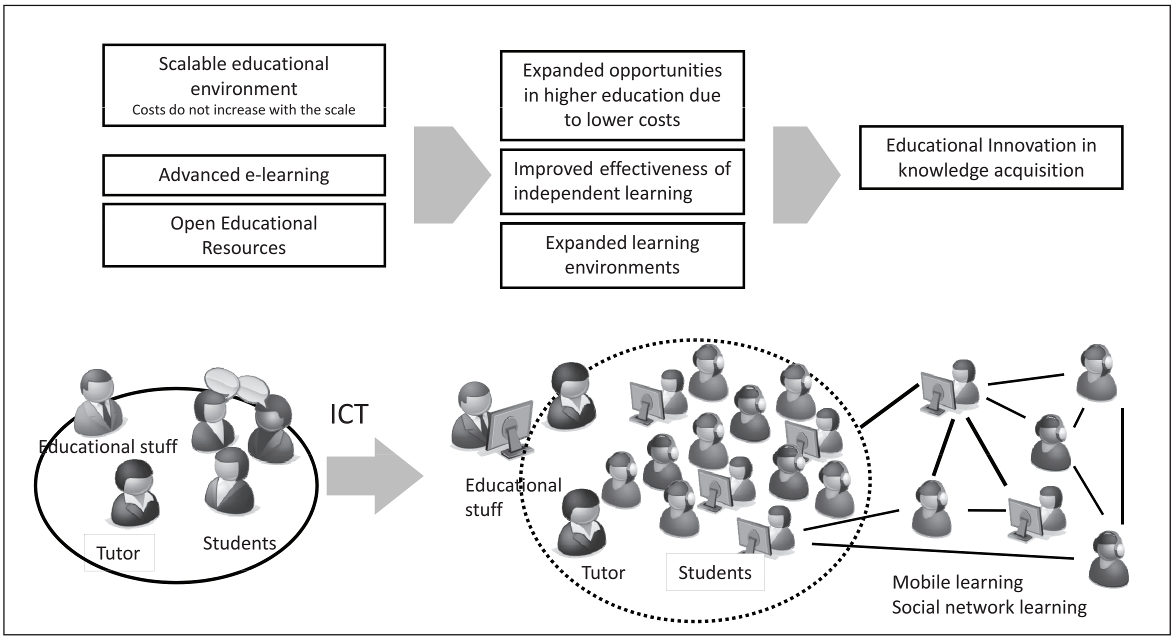

Figure 9: Prospects for changing higher education with the use of ICT

Prepared by STFC

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Profile

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(Original Japanese version: published in February 2011)

6

Electronic Journals as Research Infrastructure
Aiming to Maintain Access to Electronic Journals

Makoto FURUNISHI
Senior Research Manager

1 Introduction

Securing communalism for the knowledge that results from scientific research, and universalism, disinterestedness and skepticism across the entire scientific community encourage progress and are what makes science (at least academic science), science.[1] Papers are a medium for this; consequently, they are indispensible to science. Research interchange is important for generating excellent research outcomes, and papers provide a forum for undertaking indirect research interchange, so they should be acknowledged as an important research infrastructure (facility).

As a means of accessing papers, the importance of electronic journals is increasing and, in a survey by the Standing Committee for Research on Academic Libraries, the number of respondents who use electronic journals at least once a week was in excess of 80% in the fields of biology, chemistry, medicine, dentistry, pharmacology, mathematical and physical sciences, and agricultural studies, while it was approximately 70% in the field of engineering.[2] The increase in the number of titles (number of journals) that can be accessed as a result of their publication as electronic journals signifies their growing importance as the research infrastructure.

At the same time, the cost of purchasing electronic journals is rising and thus the proportion of research costs accounted for electronic journal purchase expenses increases, it will put pressure on research expenditure, it will be necessary to take steps to make the costs rationally suppressed. Looking at the situation from a macro perspective, at present, the cost of purchasing electronic journals per professor and associate professor is approximately 200,000 yen at national universities, and is just over 100,000 yen at public (prefectural and municipal) and private universities,[3,4] which appears to be a manageable level.

The modernization of research infrastructure through the development of electronic journals should be welcomed if the cost can be maintained at the current level.

If we say that electronic journals form a part of research infrastructure, then, as an indicator of research outcomes, primarily, it is necessary to ensure that the cost of purchasing electronic journals per a research outcome should be adequate. Unfortunately, in the same way as other elements of research infrastructure, in reality it is difficult to clarify the causal relationship between research outcomes and purchasing costs of electronic journals. There are case studies supported by publishers, concerning the impact of the use of libraries on grants.[6]

At present, electronic journals are treated as though the number of titles that can be accessed as a result of being sold in packages was an indicator of their value as research infrastructure, but at the very least, it is necessary to look at whether or not they are actually being used in research. In order to do so, it is necessary to make information on the number of times a title or paper is accessed or downloaded open, and make it possible to check whether purchasing a title is a waste of money or not. As in the case of citation index and impact factors, figures for the number of times a title or paper is accessed or downloaded can be used as indicators for evaluating them. No ambiguous relationship has been observed there. However, even though the fact that there was a certain level of access to titles with no impact factors in the field of economy, political science or education, the quantitative relationship between impact factors and the number of times a title or paper was accessed differ according to the field.

This article focuses on research in the fields of science, technology and medicine (referred to as STM). Differences in approach may exist within the

Table 1: Electronic Journal Purchase Expenditure at National Universities

Unit: 1 million yen

University A	University B	University C	University D	Average for national universities
5077	1377	1383	487	97

Source: References[5]

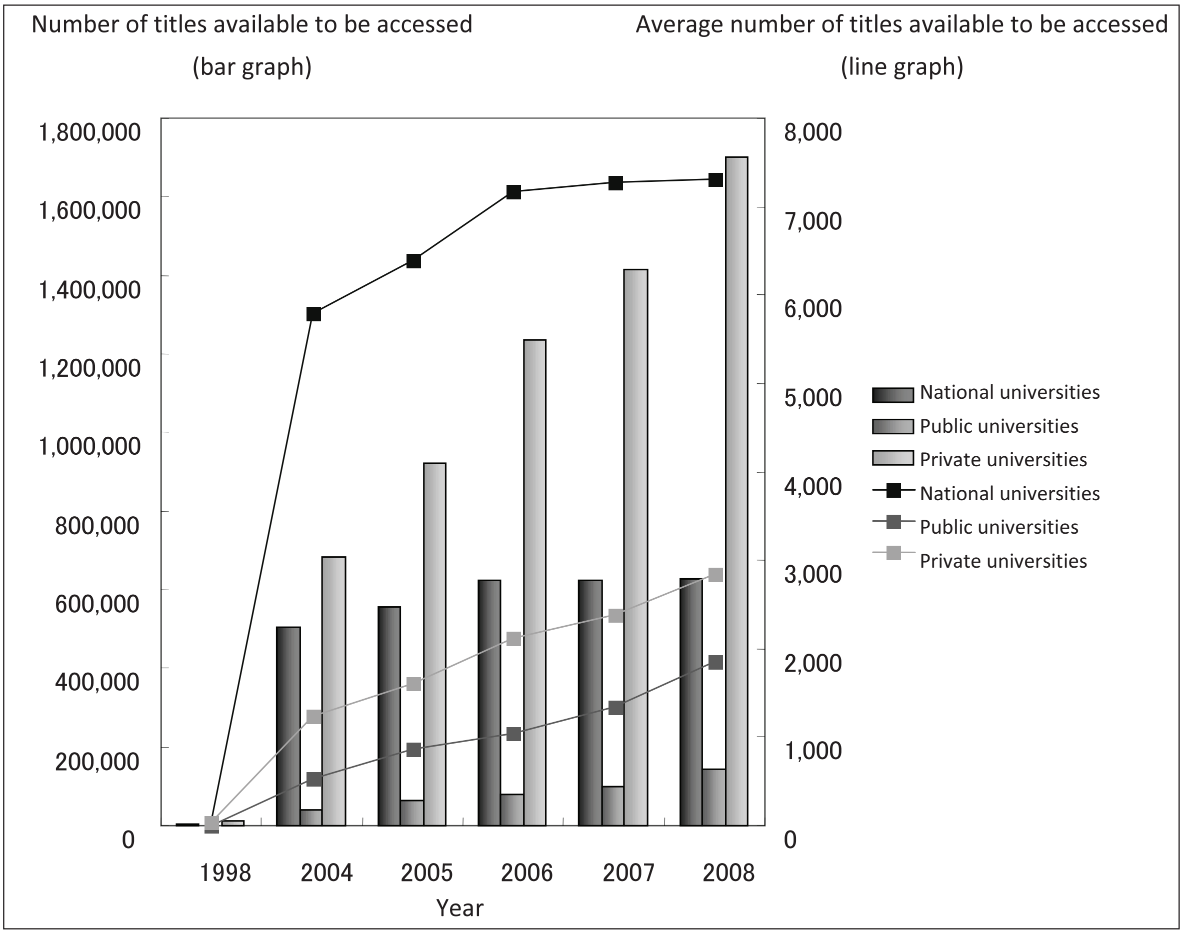

Figure 1: Number of Electronic Journal Titles available to be Accessed

Source: References[3]

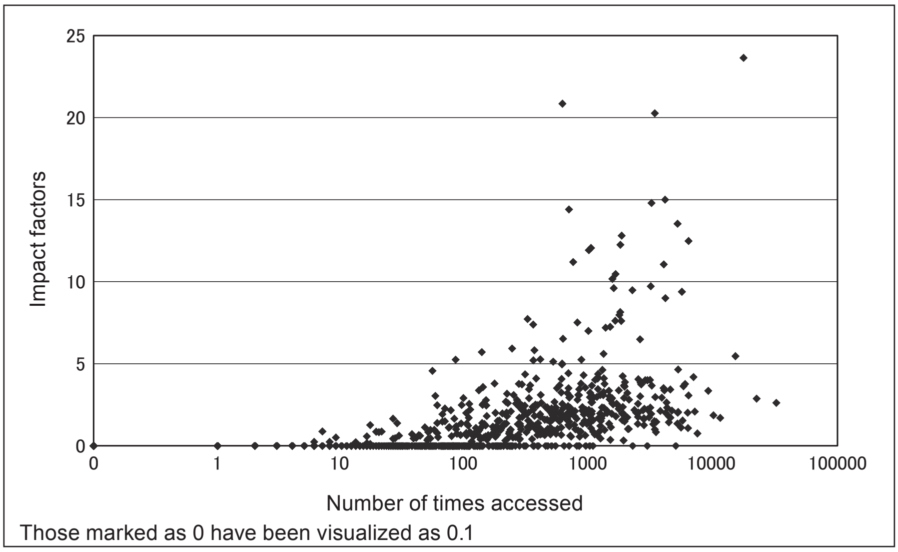

Figure 2: Impact Factors and Number of Times Accessed (Example of Elsevier at a Certain Large National University)

Prepared by the STFC

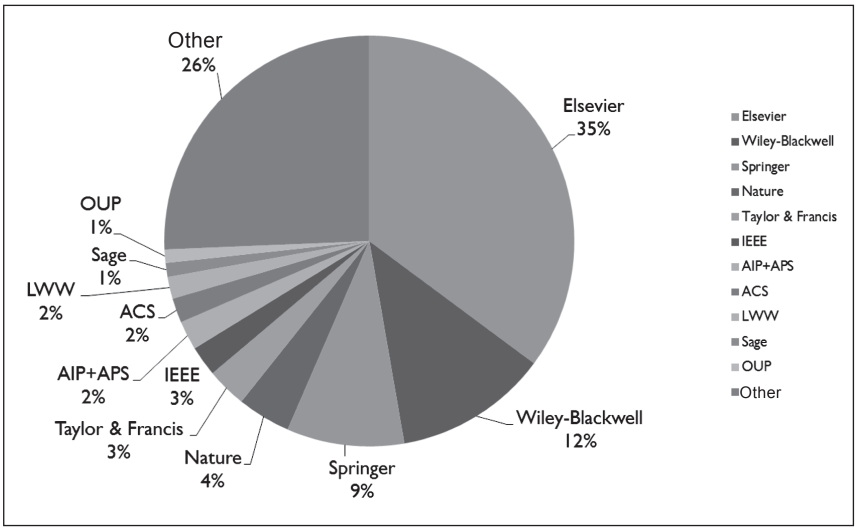

Figure 3: Share of Foreign Titles in Japan
Source: Japan Association of National University Libraries Survey of Contracts (fiscal 2009)

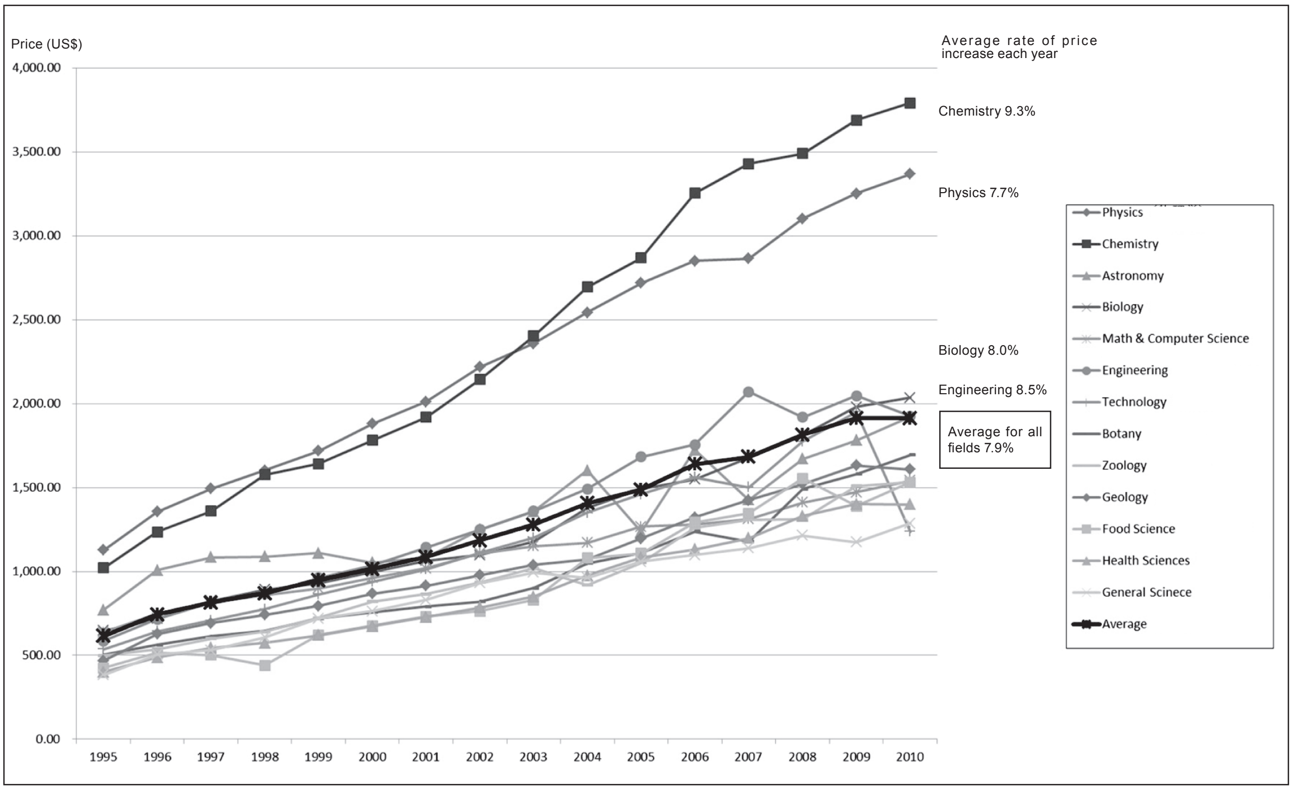

Figure 4: Trends in Average Price for Foreign Titles
Source: Source: Library Journal Periodical Price Survey. 1996 - 2010

STM fields; furthermore, in the social science and humanities, dependence on electronic journals as research infrastructure should also differ considerably. Moreover, we have not explicitly touched upon electronic journals as educational infrastructure, but the subject is discussed on the basis that education and research are indivisible at research universities.

2 Forms of Electronic Journal Purchase

At present, electronic journals are sold as a package, in a form which is called a “Big Deal.” More specifically, by paying an additional fee on top of the initial fee based on purchase history (current spend), it becomes possible for the users to access all of a publishing company’s titles, including titles other than

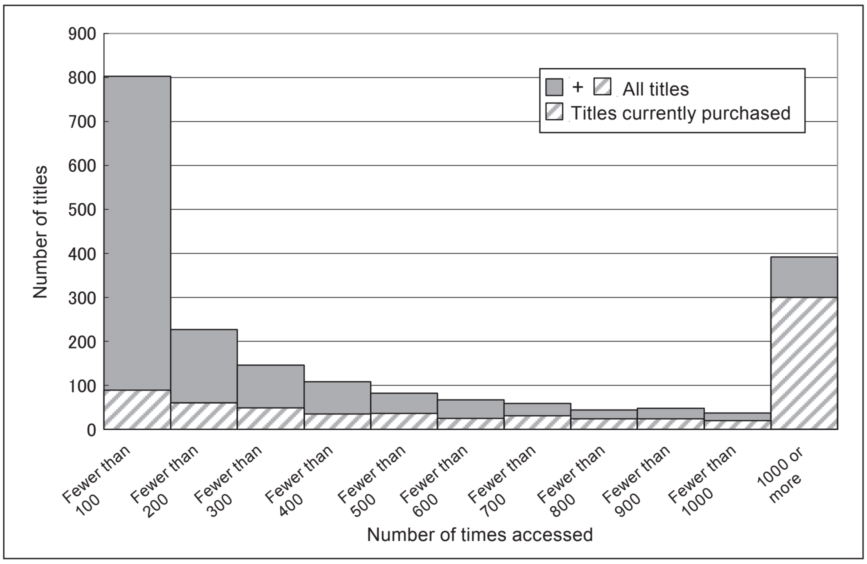

Figure 5: Share of all Titles by Number of Times Accessed Accounted for by Titles Currently (Example of Elsevier at a Certain Large National University)

Prepared by the STFC

those that one really needed. As a result of this form of contract, the contract cost for large universities, which have a high current spend, becomes higher than that for small universities. Even if the number of titles that can be accessed decreases, the price does not fall very much, and each university is compelled to adopt this form of contract.

Even in the case of usage pricing, where the price is determined according to the size of the purchasing institute and the actual number of times an article or title is accessed, rather than being based on purchasing history, publishing companies do propose the prices, but so far, no such agreement has been reached with a purchasing institute.

The publication of electronic journals is becoming an oligopoly, and, with no other escape route for the users, the price has been rising. The bundling of titles is being carried out as a supply-side initiative, and, as a result, there are problems in that it is driving up apparent demand.

It is true that Big Deal contracts are the right option from the perspective of minimizing the price per accessible title. However, terminating Big Deal contracts by means of additional payments in the event that the supplier (publishing company) will not compromise is perhaps something that will have to be considered in the future.

In promoting the publication of information, it is necessary to have publishing companies demonstrate that they are playing a vital role in bringing forth research outcomes. As a result, it is conceivable that this will give rise to competition among publishing companies in terms of the form of sale.

From the perspective of protecting personal information, at present, only publishing companies can reach the details of each access to each title. The research institutes, which are the purchasers, do not have an understanding of the current situation. It would be preferable for research institutes with responsibility for upgrading the research infrastructure to be notified by publishing companies of which papers were accessed, how many times and by researchers in which field; moreover, this may be inevitable, so that research institutes can decide upon rules concerning appropriate cost burdens.

There have already been cases in which research institutes have terminated their contracts with specific publishing companies in response to price increases. Although there is potential for this to encourage competition between publishing companies, this is the result of negotiations between publishing companies and research institutes from the perspective of price, so it could result in a deterioration of the research infrastructure at the research institute that has terminated the contract, which would not be welcomed by the publishing companies, nor, of course, by the research institutes themselves.

3 The Relationship of Researchers and Research Institutes to Electronic Journals

With regard to printed formats, there were those a research institute (primarily its library) was responsible for purchasing, and those the individual researcher was responsible for purchasing. With regard to the latter that were purchased successively based on responsibility for a major course or faculty, it is likely that it was rare for researchers to have a sense that they have developed the stock of titles on the basis of individual responsibility. However, as titles have been published in electronic form and sold as a package, they have exceeded the cost boundaries that would enable them to be purchased within the purchasing authority limits of a researcher, and a unified point of

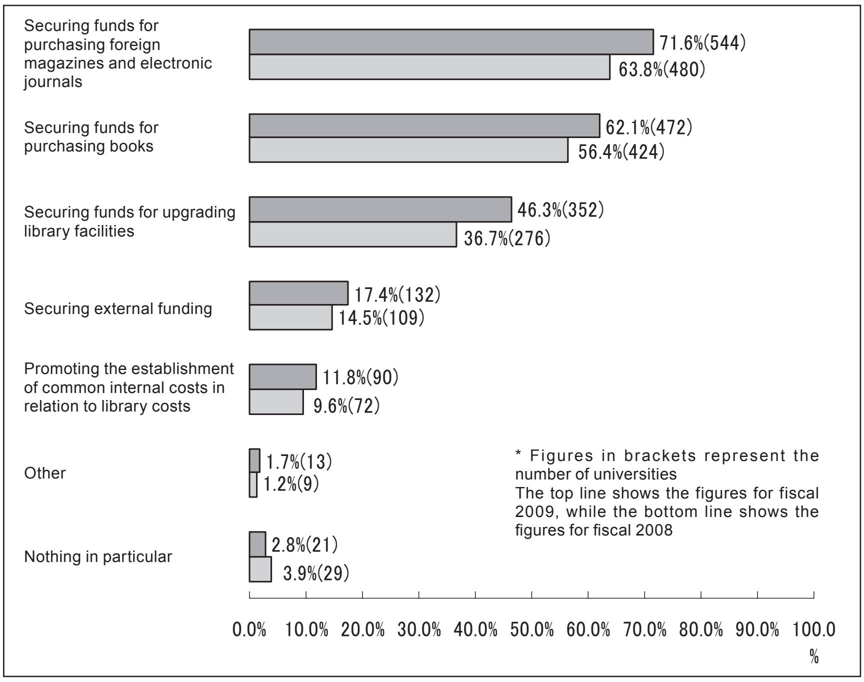

Figure 6: Financial Issues for Libraries

Source: References[3]

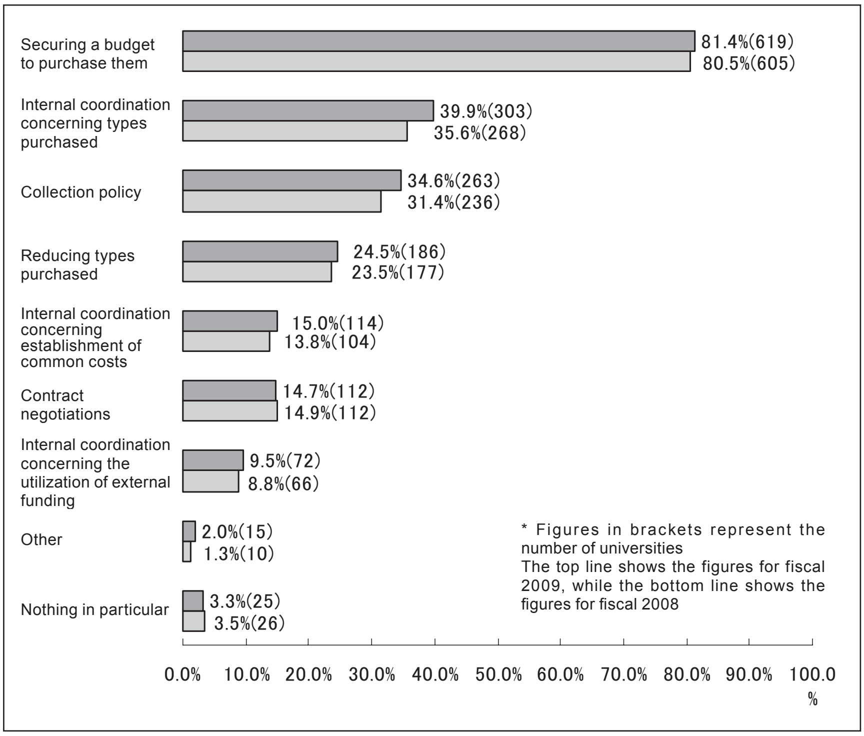

Figure 7: Challenges Relating to Electronic Journals

Source: References[3]

contact has become necessary, so research institutes have been compelled to shift to taking charge of negotiations and contracts with publishing companies.

At present, as well as the sources of revenue that existed hitherto, research institutes are appropriating the overhead[NOTE 1] of research grants and, after undertaking coordination with the researchers, they purchase electronic journals as a means of upgrading the research infrastructure common to all of the institute's researchers. In the same way as other high-cost equipment, electronic journals have reached the stage at which they have become research infrastructure that is developed by a research institute and used jointly by researchers. In the future, it might become necessary for researchers jointly using these titles to allocate part of their research grants as a source of funding.

One can say that there is a lull at present, but the cost of purchasing electronic journals is the biggest financial issue facing libraries, while securing a budget for the purchase of electronic journals is the biggest challenge that they face in relation to electronic journals. As this implies, it is conceivable that initiatives that differ from the approach taken hitherto will be required in the near future.

At universities, researchers exist as free agents within the research institutes. Researchers who have not purchased electronic journals at their own responsibility do not adequately understand the current situation, whereby it costs a considerable amount of money to purchase electronic journals in order to upgrade the research infrastructure. One can see that there are still few researchers who are aware that they need to indicate what kind of negotiations they would like their research institute to pursue with publishing companies and that they need to fulfill some responsibilities themselves in terms of the cost burden.

Small universities are forming joint negotiation bodies (consortia) with large universities at their core, thereby seeking to strengthen their bargaining power. These consortia are just for negotiation, and are not for joint purchasing. Irrespective of the scale of the university organization, and solely from the perspective of developing excellent research infrastructure that generates excellent research outcomes, it is necessary to ensure that it is possible to negotiate with publishing companies.

National universities and public (prefectural and municipal) and private universities have already formed their own consortia, named JANUL (Japan Association of National University Libraries) and PULC (Private and Public University Libraries Consortium) respectively. In October 2010, the two bodies concluded a comprehensive agreement and, as well as engaging in joint negotiations concerning electronic journals, they are undertaking such initiatives as the development of backfiles (archives of title content).

With regard to bulk purchase by the state (national site licenses), Japan has judged that, "Due to aspects such as the cost involved, this is not appropriate."[7] However, fundamentally speaking, rather than the cost aspect, it is not appropriate for an organization, in the form of the state, to develop a uniform research infrastructure; rather, individual research institutes should take responsibility for what kind of research infrastructure they will develop, and it could be desirable for there to be competition among research institutes from this perspective.

However, if the steep rise in the cost of purchasing titles continues in the future, establishing a joint purchasing body, like a mainframe computer center used jointly by universities across the country, enhancing public support and securing the funds for their purchase might be an unavoidable measure. In the same way as regional TLO(technology licensing office)s, it could be conceivably effective to establish a joint purchasing body around a core university.

Moreover, it is essential for a joint negotiation body to have personnel with the professional competence to be able to take charge of negotiations with publishing companies. As well as joint negotiation bodies, it is necessary for the libraries that function as a point of contact with the university to employ personnel capable of dealing with such matters; they should devise ways of providing technical expertise through such endeavors as formulating skill standards, as well as ensuring that decent work is provided on an ongoing basis. The formulation of skill standards

[NOTE 1]
Based on the 2nd Science and Technology Basic Plan (March 2001, Cabinet decision), 30% of research grant shall be allocated to overhead.

Table 2: Consortia in Japan

	JANUL (National Universities)	PULC (Public and Private Universities)
Year established	2000	2003
Operating & negotiating organization	Ad Hoc Committee on Reform of Scholarly Information Distribution (6 chief librarians, 8 divisional and departmental heads, others)	Meetings of leading universities (16) and plenary meetings
Number of participating institutes	91	375 (55 public, 319 private, 1 other)

Source: Extract from materials published by the NII

Table 3: Consortia Overseas

	Number of participating institutes (approximate)	Overview
Lyrasis (USA)	2000	Established in 2009. As well as electronic journal contract negotiations, it constructs union catalogs, undertakes ILL and implements research projects.
Joint Information Systems Committee (JISC) (UK)	200	Established in 1993. It constructs and develops digital materials.
Couperin (France)	200	Established in 1999. As well as electronic journal licensing contracts, it provides cooperation in state projects focused on digital materials.

Source: Extract from materials published by the NII

could be conceivably implemented as a project of a public body such as the National Institute of Informatics (NII), which has previously undertaken training courses aimed at university library staff. If it is difficult to employ staff with the relevant expertise on an ongoing basis, it might perhaps be a good idea to make use of retired teaching staff, utilize external personnel, or to give concurrent job assignments in this area to key personnel involved in industrial-academic cooperation.

In Germany, backfiles are purchased in bulk by the state. From the perspective of archives, it might be a good idea to consider the state taking responsibility for developing backfiles through an institute such as NII. If it were possible to set a short period for a current subscription, this would hold the potential to contribute to reducing purchasing costs, even if the Big Deal contracts were used.

From the perspective that electronic journals work as the research infrastructure specific to each university, the quality of access to electronic journals can become an incentive for people outside the institute to engage in joint research with that research institute.

4 Issues for Consideration

What is important is for each research institute to discuss what kind of investment it is going to make in purchasing electronic journals in which model, in light of its objective of generating research outcomes, and to build a consensus. Based on this, negotiations should take place between the research institute, which is the consumer, and the publishing company, which is the supplier. However, price negotiations on a sly zero-sum basis should be avoided.

At each research institute, someone with the responsibility and skill to develop the research environment should be involved in operating the library, including the purchase of electronic journals. In the same way as the establishment of CIOs to develop the information infrastructure, someone in a purely honorary position, who leaves everything to their staff, should not be appointed to this post.

4-1 Open Access[NOTE 2]

In order to increase the bargaining power of research institutes and researchers, it is effective to keep a means of access to other papers that ensures that publishing companies have to compete with each other. As well as being important for researchers who

[NOTE 2]
There is a form called the “golden road,” which enables the paper itself to be read as a result of payments by authors, and a form called the “green road,” which enables the paper to be read through registration with a institutional repository.

find it difficult to obtain support from the research institute to which they are affiliated, science has come to have to rely on commercialized titles, and it will be necessary to secure open access in order to ensure a certain level of communality of knowledge in the future.

In order to ensure that open access does not stop at the provision of the minimal level of information, in the form of matters relating to research trends, but rather plays a role in contributing to scientific progress, it is particularly important to ensure that open access to peer-reviewed papers that have been exposed to skepticism is possible.

Open access that facilitates access to research trends is also vital from a completely different perspective: that of accountability to the public.

With regard to the importance of open access, based on the Budapest Open Access Initiative undertaken in 2002 (http://www.soros.org/openaccess/read.shtml), the Japan Association of National University Libraries published a document entitled *Statement on Open Access – Pursuing New Scholarly Communication* in March 2009. Moreover, the number of academic papers and theses held at institutional repositories at Japanese universities is growing,[3] and this expansion of sources of access is to be welcomed.

Overseas, universities and research institutes have been at the heart of proposals for a mechanism called COPE (Compact for Open-Access Publishing Equity) (http://www.oacompact.org), which is a mechanism for securing open access with financial support from research institutes. Moreover, although the fields involved are limited, the US National Institutes of Health's PubMed Central and arXiv which is maintained by Cornell University with support from the US National Science Foundation, are functioning and have become important sources as open access repositories. Nine Japanese institutes are currently providing funds to arXiv on a voluntary basis. Moreover, CERN (European Organization for Nuclear Research) has been at the center of an attempt to realize the "golden road" (see footnote 2) through SCOAP3 (Sponsoring Consortium for Open Access Publishing in Particle Physics).

Open Access involves research institutes and researchers in developing material to be provided for the use of external parties, so it is an example of an external economy (a true externality), and there are many cases in which official support should be sought. In the case of activities in a limited field, it is desirable for joint usage and joint research hubs in Japan to cooperate. It is appropriate to provide official support for such activities as a part of a "large scale research project".[8]

The idea has been proposed for acquiring a competitive edge by developing a title that is not published by an oligopolistic publishing company, but this is rather a stale idea. This is because, in the first place, the problem is that, as a result of comprehensive contracts, research institutes even have to purchase titles that do not have a very large readership. Even if an excellent title emerged, it would be difficult to rely on this alone. If so, additional expenses would be required to purchase it. In order to secure access to excellent outcomes, it should be precisely open access and the development of institutional repositories for this that would seem to be desirable. It will be recognized that the cultivation of titles should be undertaken for the differing objectives of ensuring public ownership of Japan's excellent research outcomes and making an international contribution to qualitative improvements in the fields of science, technology and medicine.

4-2 Inter-Library Loans (ILL)

From the perspective of preventing the scope of bundling expanding unnecessarily, and responding to the needs of researchers who wish to access literature for which there is low demand as a result, inter-library loans (ILL), for which demand has fallen as a result of being outpaced by electronic journals, should be utilized. Under the existing electronic journal purchase contracts, the interchange of literature between libraries is limited to the paper medium, which is an obstacle from the perspectives of cost and providing a prompt response. In the future, it is conceivable that ILL will increase in significance through the revision of contracts to permit interchanges of electronic media between libraries and the provision of the material to researchers in the paper medium by the portal library.

4-3 Breaking Free of Big Deal Contracts

A consensus among researchers is yet to be required, but in the future, consideration should also be given to introducing beneficiary charges for researchers. This would lead to a rise in the unit cost of purchasing each paper, but consideration should also be given to the introduction into contracts with publishing companies of a mechanism that would combine a basic charge with a pay-per-view charge for access in excess of this basic rate. In doing so, it is hoped that a discussion would be initiated at each research institute, concerning how the overhead of research grants should be used in the first place.

In order to move from the concept of papers that can be accessed, to the concept of papers that need to be accessed, it may well be necessary to introduce a mechanism to research institutes for levying a charge on researchers for each view, irrespective of whether or not pay-per-view system is introduced to contracts with publishing companies.

4-4 Collaboration with the Overseas Research Community

Negotiations have taken place between domestic research institutes and publishing companies that have expanded internationally. At present, we are finally moving from the stage of this being a problem for individual research institutes to the stage at which it is emerging as a problem for the research community in Japan as a whole, as can be seen from the formation of joint negotiation bodies. The research community should also become more international, as in the case of COPE. It should cooperate with publishing companies that have expanded internationally and engage in discussions concerning the construction of a research infrastructure from which we can expect even better outcomes.

Moreover, it is conceivable that if Japanese researchers were to make a contribution not only as authors of excellent papers, but also as editors and reviewers, it would incidentally increase their bargaining power with publishing companies.

Acknowledgements

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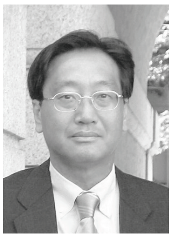
Profile



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