

The Group Management Philosophy

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

Editorial Policy

The Kyowa Hakko Kirin Group Corporate Social Responsibility (CSR) Report outlines the Group's efforts to make meaningful contributions to society through its corporate activities in line with its Group Management Philosophy. The CSR Report 2012 mainly focuses on activities undertaken during fiscal 2011.

The Management Commitment section features an interview with the Group's president, Nobuo Hanai, who assumed the position in March 2012. In this interview, Mr. Hanai shares his thoughts on efforts to apply the management philosophy to business activities and the importance of corporate social responsibility (CSR). In Special Feature 1, employees working in departments that are heavily involved in promoting CSR activities express their views. Special Feature 2 showcases business activities that were significantly progressed in fiscal 2011 along with comments from those who helped make them a success. The overall objective of this report is to describe the efforts of the Kyowa Hakko Kirin Group in terms of the 7 core subjects set out in ISO 26000, an international standard that provides guidelines for social responsibility activities. At the end of the report are comments from a third-party expert and our response to his comments. Detailed environmental data are provided in the "Environmental Data Book," which is available on our website. This CSR Report offers only minimal information concerning the financial performance of the Group. For detailed information on this, please refer to the Group's securities reports, annual report and other relevant documents.

Scope of the Report

The CSR Report 2012 provides information on Kyowa Hakko Kirin and its consolidated subsidiaries in Japan and abroad. Environmental data, including data contained in the "Environmental Data Book" (online version), were collected from domestic production and R&D sites of Kyowa Hakko Kirin and its consolidated subsidiaries. Some data included in the Material Balance were collected from overseas production sites while some included in the Green Office Plan were collected from sales offices in Japan. The Report does not include any information about Kyowa Hakko Chemical (presently KH Neochem Co., Ltd.), as all shares in this company were transferred to KJ Holdings Co., Ltd. in March 2011.

Period Reported

The CSR Report 2012 covers the period from January to December 2011, with some data from 2012 also included. The domestic environmental data included in this report were collected from April 2011 to March 2012 while environmental data from outside Japan were collected from January to December 2011.

Published in July 2012

Next issue scheduled to be published in July 2013

Environmental Data Book

The separately published Environmental Data Book containing detailed environmental data is only available online.



http://www.kyowa-kirin.com/responsibility/csr_report/index.html

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Our Group is United in its Goal to Become an "Indispensable Member of Society."



First of all, I would like to express my deepest sympathies to all those who were affected by the Great East Japan Earthquake of March 11, 2011. I wish for the early restoration of the affected areas. Immediately following the earthquake, due to shortages of some of our medical products we had to ask health care providers to write prescriptions sparingly. Let me take this opportunity to apologize for any inconvenience this may have caused. The disaster, however, served to strongly remind us of our responsibility as a pharmaceutical company to supply medical products to patients who rely on them. Based on what we have learned from our experience with the earthquake, our company has reviewed its systems and manuals throughout the supply chain, including in the areas of manufacturing, warehousing and logistics, in order to ensure appropriate risk management.

In addition to this, as part of the Kirin Kizuna Project, we have also organized programs for children in areas affected by the disaster, including table tennis lessons and science education programs. Hoping to see smiles return to the faces of all those living in the disaster-affected areas, we will continue to support the restoration of these communities.

As the public face of the company, I fully recognize the magnitude of our corporate responsibility to society.

Since assuming the role of president in March 2012, I have had more opportunities than I expected to meet with both employees and those outside the company. Just recently, for example, I met with a group of young employees for about two hours and discussed with them their various opinions and suggestions.

Through meetings with a variety of Kyowa Hakko Kirin employees, I have been strongly impressed by the marked difference in mindsets evident among those belonging to different age groups and departments, even though they all work for the same company. To bridge the gaps among these different groups and unite us all as a team that can pull in the same direction is one of my most important tasks as president. As such, I will be making effective use of employee opinions in developing business policies and improving the internal work environment.

The importance of corporate social responsibility is another major issue that I have re-familiarized myself with since assuming the role of president. As an individual, of course, and as the face of Kyowa Hakko Kirin, I strongly recognize the import of the social responsibilities that the company is expected to fulfill.

In addition to the development of innovative new drugs, the Kyowa Hakko Kirin Group contributes to public safety and comfort.

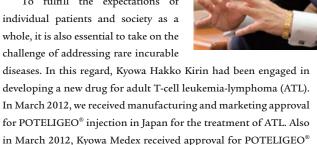
By what strategies can we effectively meet our corporate social responsibilities? Now, more than ever, the Kyowa Hakko Kirin Group must offer clear responses to this question.

A good example of where we have succeeded in this might be kidney disease. As society ages, the number of people reported to be suffering from kidney disease is rising. Both the increase in patients with kidney disease or chronic kidney failure and the associated increase in medical costs have become issues that affect society more broadly. Kidney disease has been a key therapeutic area of focus for Kyowa Hakko Kirin. We have already developed and marketed many effective new medications in this area and are ready to contribute to

the development of new drugs to treat hypertension and diabetes associated with kidney disease.

Our development strategy in this regard has been based on biotechnology. Under this strategy, we will focus future efforts on specific therapeutic areas including oncology and immunology/ allergy as well as kidney disease so as to meet the expectations of society.

To fulfill the expectations of individual patients and society as a whole, it is also essential to take on the challenge of addressing rare incurable



In addition to the development of innovative new drugs, it is also critical for Kyowa Hakko Kirin to supply drugs in such a way that patient safety and comfort is assured. With the hope of conveying this message clearly to employees, I have recently intentionally started to use the term "drug manufacturing" more frequently than before in addition to the term "drug discovery." What I mean by this is that our task does not end with the successful creation of a new drug. Rather, it is equally important that we focus our efforts on improving the quality and safety of the discovered drug as a commercial product. In this context, we need to improve the internal systems employed by the Reliability Assurance Department.

TEST, a companion diagnostic for the POTELIGEO® injection.

These efforts of Kyowa Hakko Kirin to ensure safety and security have sparked synergistic effects in other Group companies. An example of this can be seen in the efforts made by Kyowa Hakko Bio Co., Ltd. The level of quality management this Group company requires for amino acid infusions, one of their specialized fields, is as high as that required for medical products. To achieve this high level of quality management, they apply knowhow provided by Kyowa Hakko Kirin.



Efforts to provide a work environment that ensures employee satisfaction and allows all individuals that make up our diverse workforce to reach their full potential.

In seeking to fulfill our social responsibilities, I believe it is also important to provide a work environment that ensures employee satisfaction. In this respect, I would draw attention to our Diversity & Inclusion (D&I) Project.

During my four-year stint starting 2003 as president of one of our Group companies in the United States, I had the chance to work with a broad range of people in terms of personal characteristics and abilities. This proved a tremendously valuable experience for me. In particular, the energetic commitment of female executives I came into contact with was a source of great motivation.

In comparison with this experience in the United States, the D&I Project, which is ongoing at Kyowa Hakko Kirin, needs to be pushed forward. For example, the ratio of female-to-male sales staff needs to be improved.

Another important area requiring more attention is the development of staff who can work in global settings, which is essential for the Kyowa Hakko Kirin Group to become a global corporate group. By this I do not mean that all employees are equally required to be trained or equipped for global competition. My expectations concerning employee efforts toward globalization spring from the idea that Japan is part of the world and that the division between Japan and the rest of the international community must be transcended. As an example of steps we are already taking in this respect, Kyowa Hakko Kirin is working to strengthen its sales bases within Japan as one of its global strategies.

Sharing common values, we will implement CSR activities with an emphasis on complying with international standards.

In implementing global strategies, the Kyowa Hakko Kirin Group needs to promote CSR based on international standards. In this context, the Group has started adopting ISO 26000, an international standard providing guidelines for social responsibility efforts. Employees are now required to assess their CSR activities based on social issues described by ISO 26000 to identify which level their activities are at and what needs to be done to meet the requirements. They are then encouraged to share information on their findings internally so as to ensure proactive and ongoing improvements.

In order to respond to the international community's expectations, we must also collect feedback from various stakeholders and reflect it in our activities. In connection with this, we are currently considering how to increase opportunities for communicating with broader sections of the population including patients, with whom we have had few opportunities for direct



communication despite their being important stakeholders.

In promoting CSR, it is also important that we share the same values, aims and ideals, which is the concept behind the Group Management Philosophy and Commitment to Life. This principle should also form the basis of our CSR activities.

"Serving the needs of society"—this is our primary purpose.

Our ideal is very clear: "to be a corporate group that is an indispensable member of society." The primary reason for the existence of the Kyowa Hakko Kirin Group is to achieve this ideal.

The most essential task in becoming "a corporate group that is an indispensable member of society" is to provide safe and easy-to-use products and services that satisfy the needs of users. In seeking to achieve this, each Group company should draw upon its unique strengths. We are also expected to develop products that help cut medical expenses and, as members of local communities, to serve the surrounding areas in which each of our facilities is located. We can further contribute to society by taking initiatives to promote environmental conservation.

Through medical products, our core area of focus, we directly contribute to improving the health and well-being of innumerable people. Working in such a rewarding field, we are proud of what we do and it is our pride that drives our ongoing efforts to satisfy the needs of both patients and various other stakeholders. One of our greatest pleasures is to hear someone say, "Thank goodness for the Kyowa Hakko Kirin Group!"

By utilizing the strengths of the Kyowa Hakko Kirin Group, more efforts will be made to promote CSR in ways consistent with good management. In this, as always, our aim is to foster group employees that society trusts and Group companies that society needs.

Our mission statement Commitment to Life

Countless precious lives surround us.

Brought into this world, blessed, raised with loving care—full of dreams, happiness as the goal of life.

Deeply instill in us, and know that what we work for-the most precious presence of all on this planet.

Infinite possibilities for us, a pharmaceutical company.

Believe in ourselves, believe in our power, believe in what we have built together.

Not a large company, but with qualities like none other

History so unique we can be proud of, technology unmatched,

And superior human beings that cannot be found elsewhere.

Be brave; do not shy away from challenges. Have passion; break away from the norm.

Innovation is not just about growth—but instead a leap towards the future, a grand growth with wings.

Wings never to be given to those who settle for the status-quo.

Don't just make medicine. Make people smile, bring light to their lives.

How strongly one longs to live. How deeply one is loved by their loved ones.

How sincerely one desires to help the one life they dedicate themselves to in the field of medicine.

Stay receptive, sharpen your sensitivities.

Let us become the top company in the world who cares the most for life.

Strength is not what saves the world. A caring heart is what the world calls for.

Strive to become a superb team.

One human being, excellent or not, is ever so powerless, as a power of one, mistakes, even a possibility.

Show the world the excellence of coming together. Amazing results, when we become one.

Be driven. Think of those fighting for their lives every day.

Their strong devotion to life speaks to our hearts.

Hurry-do not scurry, but we must not stand still. Stay sincere, always-may that be our vow.

We make medicine. This is, our walk of life.

Work, can bring happiness. Remember this, always.

Born on this planet in various parts of the globe, passing through life in different ways,

And like a miracle we found one another—our jobs, our team, our company.

Know this, and be fulfilled, always.

Be thankful of what you have, pour your heart and soul into the mission you were given,

Be proud of your work, the work to save precious lives.

We are, each and everyone of us, Kyowa Hakko Kirin.

Taking the walk of life, one life at a time.

"Commitment to Life" is the mission statement of Kyowa Hakko Kirin, created when the company was established in October 2008. The statement expresses the strong determination of each employee to devote themselves to saving the lives of all who are suffering from disease, and save society through the development of new drugs.



Outline of the Kyowa Hakko Kirin Group

The Kyowa Hakko Kirin Group seeks to contribute to the health and well-being of people around the world through biotechnology. The Group's core company is Kyowa Hakko Kirin, which focuses on discovering innovative new drugs. The two other major companies in the Group are Kyowa Hakko Bio, which manufactures amino acids for use in bulk pharmaceuticals and infusions, and Kyowa Medex, a major player in the area of *in vitro* diagnostics.

Kyowa Hakko Kirin

Developing new drugs in the areas of oncology, nephrology and immunology/allergy

Following the merger of Kyowa Hakko and Kirin Pharma, two companies in possession of leading-edge biotechnology, Kyowa Hakko Kirin was established in October 2008 to produce and market pharmaceuticals. The company is currently working with more than 50 types of pharmaceuticals, including anemia drugs that stimulate erythrocyte production. In the area of therapeutic antibodies, Kyowa Hakko Kirin has developed a unique technology that boosts the activity of antibodies. With this technology, the company developed POTELIGEO®, a drug to treat adult T-cell leukemia-lymphoma (ATL), and received approval in March 2012 to manufacture and market the drug. The company's aim is to become a Japan-based global specialty pharmaceutical company and bring health and well-being to people around the world.

Major products: Pharmaceuticals

2009

History of the Kyowa Hakko Kirin Group

A history of the Kyowa Hakko Kirin Group focusing on CSR promotion activities by Group companies is shown on the right: 2008

The Kyowa Hakko Kirin Group was established.

January Kyowa Hakko Kirin:

"Commitment to Life" developed by gaining ideas from 1,000 people.

March Kyowa Hakko Kirin Group:

The "Kyowa Hakko Kirin Group Compliance Guidelines" were developed.

Kyowa Hakko Kirin:

Kyowa Hakko Kirin's "Human Resources (HR) Philosophy" was

developed.

May Kyowa Hakko Kirin:

The entire company earned ISO 14001 certification.

(including Kyowa Medex Fuji Plant)

Company Profile (as of April 1, 2012)

Company Name: Kyowa Hakko Kirin Co., Ltd.

Date of Foundation: July 1, 1949

(Trade name changed from "Kyowa Hakko Kogyo Co., Ltd." on October 1, 2008, upon the merger with Kirin Pharma Company,

Limited.)

Paid-in Capital: ¥26,745 million

Representative: Nobuo Hanai,

President and Chief Executive Officer

Head Office: Ohtemachi Bldg., 1-6-1 Ohtemachi,

Chiyoda-ku, Tokyo 100-8185, Japan

Phone: +81-3-3282-0007

Number of 7,229 (consolidated), Employees: 4,258 (parent company)

(as of December 31, 2011)

Major Consolidated Kyowa Hakko Bio Co., Ltd., Subsidiaries: Kyowa Medex Co., Ltd.

Main Businesses: Pharmaceuticals (manufacture and sale of

ethical drugs and *in vitro* diagnostics)

Bio-chemicals (manufacture and sale of pharmaceutical and industrial raw materials, health care products, and products for agriculture)

Other (wholesaling, transportation)

Kyowa Hakko Bio

Developing amino acids for use in health care

By exploiting its innovative fermentation production technologies, Kyowa Hakko Bio active substances, and other beneficial substances. The company is playing a key role in meeting increasing global demands for value-added amino acids for pharmaceuticals as well as the needs of the specialty generic pharmaceuticals market. It supplies raw materials for pharmaceuticals and cosmetics, health foods and their raw materials, and other products that contribute to human health and well-being.

Major products: Pharmaceutical raw materials, health care products

2012

2011

2010

Kyowa Hakko Kirin:

June

The "Declaration of Environmental Commitment" was developed.

August Kyowa Hakko Kirin Group:

CSR Report 2010 was published. (From Sustainability Report to CSR Report)



October Kyowa Hakko Kirin:

The "Diversity & Inclusion Project" was launched.

Kyowa Hakko Kirin Group: March

A monetary donation and daily necessities were provided to support victims of the Great East Japan Earthquake.

Kyowa Hakko Bio: May

The entire company earned ISO 14001 certification.

Kyowa Hakko Kirin Group: August

The "Kyowa Hakko Kirin Group CSR Policy" was developed (approved by the CSR Committee)

October Kyowa Hakko Kirin:

"Kyowa Hakko Kirin Table Tennis Lessons" were held as part of the Kirin Kizuna Project, a recovery support program, at 5 sites in Iwate, Miyagi and Fukushima prefectures.

Kyowa Hakko Kirin: March

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., a joint venture for the development, manufacturing and marketing of biosimilar products, was established.

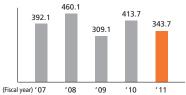
Kyowa Medex

Offering in vitro diagnostics and medical instruments for the prevention and treatment of diseases

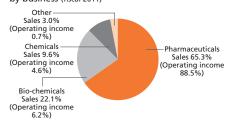
Financial Highlights (Kyowa Hakko Kirin's consolidated financial results)

- * Due to the change in the fiscal year end, fiscal 2009 data shown below cover a period of only nine months, from April 1 to December 31, 2009.
- * The data below include the business results of Kyowa Hakko Chemical for the three months from January to March.

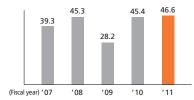
Net sales (Billions of ven)



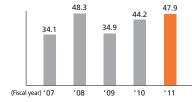
Sales and operating income composition by business (fiscal 2011)



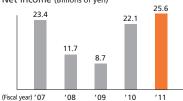
Operating income (Billions of yen)



R&D expenses (Billions of yen)



Net income (Billions of ven)



R&D expenses as percentage of net sales (%)



Kyowa Hakko Kirin Group CSR

Recognizing that to realize the Group Management Philosophy it is essential above all else to fulfill our CSR commitments, the Kyowa Hakko Kirin Group will focus more efforts on meeting social expectations in line with the ISO 26000 international guidelines on social responsibility so as to contribute to the sustainable development of society.

ISO 26000 -

ISO 26000 is an international standard providing guidelines to help organizations meet their social responsibilities. Launched in November 2010, this guidance document offers a range of advice and applies to all types of organizations, including corporations, governments, schools and NGOs. It was prepared with input from a variety of stakeholders, including governments, corporations, workers, consumers, NGOs

and experts from more than 40 organizations in over 90 countries, both in the developed and developing world. One of the reasons for undertaking such a large-scale project to establish this international standard for social responsibility is the increasing expectations held by stakeholders toward the international activities of various organizations.

• "7 core subjects"* of ISO 26000







Humar rights



Labor practices



Community involvement and development



The environment



Fair operatin practices



Organizationa governance

Management Philosophy and CSR of the Kyowa Hakko Kirin Group

In its Group Management Philosophy, the Kyowa Hakko Kirin Group promises "to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies." Based on this philosophy, all employees perform their daily tasks in accordance with the Group's Action Guidelines: "We will work together in a sincere and mutually respectful manner," "We will

take a forward-looking, energetic approach to change," "We will do our utmost to add value and contribute to a brighter future around the world" and "We will always act with integrity in everything that we do." We consider it part of our CSR to realize our management philosophy through activities consistent with these action guidelines.

CSR Promotion Policy

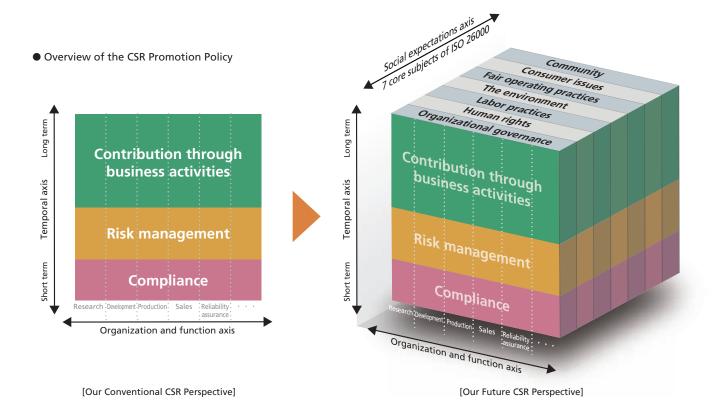
CSR activities have been reorganized from a global perspective as shown in the figure below according to the 7 core subjects defined in ISO 26000.

Before the reorganization, our top priorities were "compliance" and "risk management" in terms of temporal urgency and, from a mid- to long-term perspective, "contribution through business activities" in response to changes in the social

landscape in terms of organization and function.

In addition to these two axes, the temporal axis and the axis of organization/function, the new policy includes the 7 core subjects proposed by ISO 26000 as the axis of social expectation. Under this revised policy, more emphasis will be placed on dialogue with stakeholders as a means of strengthening our contribution to developing a sustainable society.

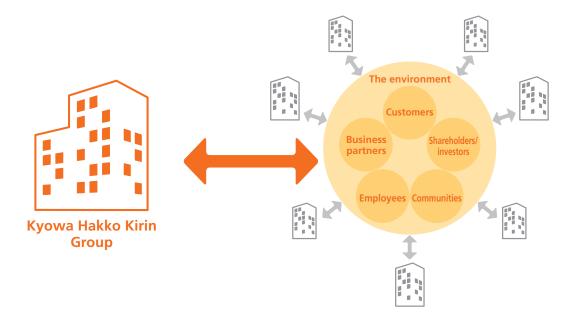
 $[\]mbox{\ensuremath{^{\star}}}$ The 7 core subjects are based on "ISO 26000: 2010" by the Japanese Standards Association.



Our commitment to stakeholders

Companies are expected to create and offer value that is useful to society. When companies meet social expectations, society rewards them with recognition, trust and support. The Kyowa Hakko Kirin Group seeks to determine what role it should play from society's rather than its own perspective. The Group believes that this approach will help it meet the expectations

of customers, shareholders, investors, business partners, local communities, employees and other stakeholders and build relationships based on trust. In this context, more emphasis will be placed on commitment to and dialogue with stakeholders in order to identify and meet their expectations of the Kyowa Hakko Kirin Group.



Promoting the CSR of Kyowa Hakko Kirin Group

The entire Kyowa Hakko Kirin Group promotes CSR in line with ISO 26000. This section provides information on how CSR is being implemented, with a focus on departments that have a particularly close involvement in CSR promotion.



Corporate Strategy & Planning Department



Niro Sakamoto
Managing Officer
Director
Corporate Strategy & Planning Department

Discussion is ongoing to fulfill our goal of creating new corporate value through CSR efforts.

CSR plays an important role in enhancing corporate value. The fundamental concept underpinning the Kyowa Hakko Kirin Group's CSR can be found within its Group Management Philosophy, "to contribute to the health and well-being of people around the world." To assess our daily activities, the ISO 26000 concept serves as a "useful measure." Through assessing how each department's activity relates to the seven core subjects of ISO 26000, department members can be confident in what they are doing and/or gain new viewpoints to move forward. "Commitment to Life," which expresses the universal value shared among Group members, is also closely related to the concept of CSR. It is therefore expected that new corporate value will be created through the fulfillment of this concept.

Through cooperation and discussion with the CSR Management Department, we will further promote CSR in a way that is unique to the Kyowa Hakko Kirin Group, thereby building higher corporate value.

Corporate Communications Department



Shigeru Morotomi **Managing Officer** Corporate Communications Department

Our focus is on creating a work environment that facilitates employees in their efforts to achieve "Commitment to Life" as part of their everyday business activities.

Since "Commitment to Life" was established, it has guickly spread among the employees. Now it is time for them to implement this concept by way of their own individual tasks and responsibilities. To support this important phase, our department has developed and adopted various special programs. For example,

we produced a DVD about recipients of the President's Prize, showcasing their efforts to implement "Commitment to Life". The DVD has been provided to each work site. In promoting CSR, I think it is important to assess our efforts from an external perspective. Overseas stakeholders in particular emphasize "social responsibility" in determining the value of a company. To meet such expectations, we should put more emphasis on compliance with ISO 26000.



President's Prize Award Ceremony

Human Resources Department

Now building up a system to make the best use of each employee's abilities.

I am keenly aware of many issues for which the Human Resources Department must take the initiative in promoting CSR, including work-life balance and diversity in the workplace. Whenever we interview students during recruitment drives, candidates express favorable opinions about our corporate value, namely, "Commitment to Life," which indicates that this concept has attracted considerable attention from people even outside of the company. In considering of such delightful acknowledgement, all individual employees should be aware of our responsibilities and how best we can perform our own "Commitment to Life." It's really therefore up to the leadership at each individual work site who routinely execute this concept. We would like to include programs designed to help personnel at the managerial level implement the "Commitment to Life" into management training sessions and other occasions.



Yutaka Ouchi **Executive Managing Officer** Human Resources Department

Sales & Marketing Division



Fumihiro Nishino Director of the Board **Executive Managing Officer** Vice President Head Sales & Marketing Division

A new sales approach where MR serve as "health care providers" is being developed.

The Sales & Marketing Division has launched a project to develop a new sales approach in order to better contribute to the health of individual patients and live up to the expectations of society

as a whole. In this project, we regard MR* as health care providers. Based on this definition, MR will not only provide information but also be engaged in the kinds of activities that add value to health care and ensure better outcomes for patients. With regard to CSR promotion, we are discussing how we can carry out "Commitment to Life" as part of our daily sales activities. Our goal is to demonstrate to medical professionals and other third parties just how serious we are about taking on the role of health care providers.

* MR: medical representative MR as a "health care



Contribution through pharmaceutical business

Providing high-quality drugs to as many patients as possible at the earliest possible date—
With the aim of becoming a global specialty pharmaceutical company, Kyowa Hakko Kirin contributes to the health and well-being of people around the world through its pharmaceutical business, which is supported by leading-edge biotechnology.

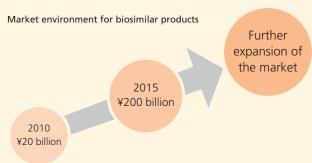
topics 1 Biosimilars

Providing effective biopharmaceuticals at reasonable prices

With the advent of the aging society, medical costs in Japan as a whole are increasing. Finding ways to reduce the cost of drugs, which make up part of these medical costs, has thus become a pressing issue. In response to this need, generic pharmaceuticals have become widely available. A generic drug is defined as a drug product that uses the same active ingredient as a brandname drug (original drug) whose patent has expired. The generic drug is manufactured by a different company to the original drug and sold at a lower price. Generics called "biosimilars" have emerged recently on the biopharmaceutical market and have slowly been drawing attention. However, it is not easy to manufacture biopharmaceuticals because doing so requires the use of biotechnology.

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., a joint venture between Kyowa Hakko Kirin and Fujifilm established in March 2012, specializes in developing, manufacturing and marketing biosimilar products. The new company integrates knowledge that has been uniquely accumulated by Kyowa Hakko Kirin through its development and manufacture of biopharmaceuticals

with the highly sophisticated manufacturing technology and quality control technology acquired by Fujifilm through its photographic film business. By doing so, the company has developed an innovative production process that ensures quality on a level comparable to the original drug but at a reduced cost. The company's first clinical trial is scheduled to start in 2013, with the first product launch planned for four to five years after that. The aim is to provide high-quality, inexpensive biosimilars that meet patient expectations while contributing to society by reducing medical costs.



- High growth of biopharmaceuticals market
- \bullet Expiration of patents for original biopharmaceuticals
- Clarification of guidelines for quality standards/clinical trials
- Concerns over financial collapses of insurers in some countries

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. VOICE

Hoping to help patients and contribute to society by reducing pharmaceutical costs

Our objective is to develop biosimilars so as to reduce the burdens on both patients and society as much as possible. To do this, we intend to bring down the prices of drugs without ever compromising product quality. Our focus is on ensuring that each product we offer can be used safely by patients without any concern. There is no doubt that drugs have an impact on the health and lives of patients. Our employees are well aware that at the end of the day, our product will be used by real people fighting real diseases. We want to prove worthy of the expectations of society and become a company that is viewed as an essential player in the field of health care.

The company has only just been established and it is still a small organization of about 30 employees. But we provide a dynamic and relaxed work environment and are united in our efforts to achieve our goals.



POTELIGEO® Injection • POTELIGEO® TEST

Concerted effort of the Group to combat rare disease

Adult T-cell leukemia-lymphoma (ATL) is a viral disease that is reported in the Japanese population with a higher incidence. Each year in Japan, around 1,000 people develop the disease, which has a very high mortality rate. The only established effective treatment for ATL is bone marrow transplant.

Having focused considerable efforts on developing a drug to treat ATL, in March 2012 Kyowa Hakko Kirin received approval to manufacture and market POTELIGEO® injection in

Japan. Kyowa Medex received approval also in March 2012 for POTELIGEO® TEST, a companion diagnostic used with the POTELIGEO® injection. Generally speaking, companion diagnostics are used to identify specific genetic and protein alterations in patients, enabling optimal personalized treatment. In developing these new drugs, researchers from Kyowa Hakko Kirin and Kyowa Medex worked together.

Kyowa Hakko Kirin is also engaged in other ongoing projects to develop new drugs for rare diseases. Our joint efforts with other group companies will continue to be focused on addressing intractable disease.



Kyowa Medex VOICE

Optimal treatment personalized to each patient combating intractable disease

I have been engaged in marketing in the POTELIGEO® TEST project, particularly in establishing a sales system. This project is jointly conducted between two companies belonging to the same group, which makes it easier for us to communicate with each other and, as a result, a strong cooperative relationship has been established. The diagnostic agents we are offering support treatment that is very important in the lives of ATL patients. The one I am involved with, POTELIGEO® TEST, is a companion diagnostic that enables optimal treatment personalized to individual patients' specific symptoms and therefore significantly contributes to the treatment of ATL patients.

topics 3 Multi-national clinical trials

Promptly developing new drugs in various countries around the world

A multi-national trial (MNT) is defined as a clinical trial that is concurrently conducted in more than one country and/or region using the same protocol. Conducting an MNT allows collection of patient data in a relatively short period of time. This means a new product can be on the market sooner and in more than one country simultaneously. Also, in countries where independent clinical trials cannot be conducted due to a lack of patients, this system makes it easier for pharmaceutical companies to

develop new drugs, thus achieving a positive effect in terms of eliminating drug lag*.

In August 2011, we started an MNT of ARQ 197 for lung cancer in Japan, Korea and Taiwan. ARQ 197 is a new drug candidate discovered by ArQule in the United States, for which Kyowa Hakko Kirin acquired development and sales rights in Japan, Korea, Taiwan and China.

Kyowa Hakko Kirin will continue focusing its efforts on conducting MNTs so that we can provide efficacious drugs to patients not only in Japan but also in other countries.

* **Drug lag:** the delay from the time a new drug is approved in one country until its approval in a different country

Kyowa Hakko Kirin VOICE

Hoping to conduct more MNTs in Asian countries

In the MNT of ARQ 197, I am mainly in charge of Taiwan. While working with this product, I have many opportunities to talk with investigators from local hospitals and I can feel their sincerity in treating their patients. Through my experience working overseas, my concept of medical treatment has changed. For example, Asian countries do not adopt the same treatments as other countries, and some diseases are specific to or are more commonly seen in Asia.

In the past, it was common practice to develop new drugs mainly in Europe, the United States and Japan. But I now firmly believe that it is important to focus on new drug development in Asia as well. Based on my experience with ARQ 197, I am hopeful that there will be more opportunities for new products to be entered in Asian MNTs.





Consumer issues

To provide safe and high-quality products, reliability is ensured at every step of the process from development through to post-marketing. Efforts have also been made to increase communication with patients and other consumers so that we can reflect their valuable opinions in our business activities.

Highlight

Supporting DOPPS

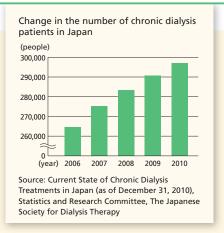
We are participating in a collaborative study conducted in more than 12 countries with the aim of advancing dialysis care.

Dialysis care plays an important role in treating patients with chronic renal failure. More than one million patients around the world are currently receiving dialysis. While the technology and devices used in dialysis care have recently undergone significant improvement, there are still many issues that need to be addressed, such as improvement in treatment methods to reduce burdens on patients.

An international study called DOPPS (Dialysis Outcomes and Practice Patterns Study) aimed at improving dialysis treatment is ongoing in more than 12 countries around the world. This is the first ever global joint survey in the dialysis field and Kyowa Hakko Kirin has been playing a supportive role in Japan since 1999.

Many valuable data that have been collected through

DOPPS have been used to improve treatment methods and reduce burdens on patients. In addition to its supportive role, Kyowa Hakko Kirin organized a joint symposium with



the Japanese Society for Dialysis Therapy. It has also been providing relevant information and been involved in other promotional activities to contribute to the progress of dialysis care.

Kyowa Hakko Kirin also provides support for research on treatment methods for chronic kidney disease and the influence of dialysis on bone and the parathyroid glands. In the future, in addition to the research and development of pharmaceuticals, more efforts will be focused on activities like these aimed at elucidating diseases.

Dedication to product safety and quality assurance

The Kyowa Hakko Kirin Group divides its business activities into two fields: Pharmaceuticals and Bio-chemicals.*¹ In each of these fields, sound operation of the quality assurance system is ensured by way of our three-layered system. The first layer is a quality assurance organization at each plant. Further up, we have quality assurance organizations overseeing each of the two fields of business. Finally, we have the Corporate Quality

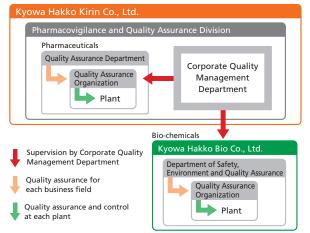
Quality Assurance Policy of the Kyowa Hakko Kirin Group

- We maintain a high level of quality and provide products and services that achieve customer satisfaction.
- Safety is our first priority. We provide products and services that gain the trust of customers through the reliable Quality Assurance System in compliance with applicable laws and regulations.

Management Department, which is responsible for supervising the quality assurance activities of the entire Group. In all of our quality assurance activities, we ensure regulatory compliance and make the safety of our customers our number one priority.

*1 See pages 7 and 8 for details.

The Kyowa Hakko Kirin Group's quality assurance organization

















Quality assurance in the development of pharmaceuticals

To ensure that its pharmaceuticals development complies with the principles of Good Laboratory Practice (GLP)*2, Good Clinical Practice (GCP)*3, and the Criteria for the Reliability of Application Data, Kyowa Hakko Kirin has established its own Pharmaceutical Development Guidelines and Standard Operating Procedures (SOP). Under these governing documents, the company focuses its efforts on assuring the reliability of application documents throughout the entire process from preclinical research to clinical trials in humans as well as the protection of the human rights and safety of people participating in clinical trials.

- *2 Good Laboratory Practice (GLP): Standard for the conduct of nonclinical laboratory studies for pharmaceuticals
- *3 Good Clinical Practice (GCP): Standard for the conduct of clinical trials for pharmaceuticals

Manufacturing control and quality control of pharmaceuticals

To ensure the high quality of our pharmaceuticals, we periodically audit plants operated by manufacturers in Japan and overseas that perform our outsourced production, as well as our own plants. Our auditors assess compliance with the Good Manufacturing

Practice (GMP) standard*4 in relation to manufacturing control and quality control as well as with the Quality Agreements entered into with the company and with the Pharmaceutical Affairs Law. Where improvements are needed, we issue appropriate instructions



Auditing the quality of operational management at a manufacturing plant from a third-party perspective

*4 Good Manufacturing Practice (GMP): International standard governing the manufacturing control and quality control of pharmaceuticals

Ensuring the safety of pharmaceuticals

To make sure that pharmaceuticals are used safely and effectively, we collect a range of safety information, including reports from health care professionals, research reports published both in Japan and abroad, and information provided by overseas regulatory authorities. In addition, reports from patients are also received as an important data source. All these collected data are assessed and analyzed, and important findings are provided to health care professionals via medical representatives (MR) and our website.

Quality assurance in bio-chemicals

Amino acids and other fermentation products offered by Kyowa Hakko Bio are used in a wide range of applications, such as pharmaceuticals, foods, food additives, health foods, cosmetics, and pharmaceutical synthetic intermediates. Our products are manufactured in plants in Japan, the United States, and China and supplied to markets around the world.

To ensure the safety of our products, production processes and quality are strictly controlled in accordance with Good Manufacturing Practice (GMP) for pharmaceuticals.

Communication with customers

Sharing useful information on the web

Kyowa Hakko Kirin's websites serve as an important source of information for the public, including patients. Our Antibody Technology site, for example, uses illustrations and video to explain what therapeutic antibodies are and how they differ from low molecular drugs.

In 2011, the "Parkinson's Disease Support Net" website was launched to provide information on Parkinson's disease in an

easy-to-understand way. The information provided ranges from basic general information to details on diagnosis and treatment as well as tips for improving daily life. (This website is in Japanese only.)



Parkinson's Disease Support Net

Therapeutic Antibody Technology site: http://www.kyowa-kirin.co.jp/antibody/english/

Medical Information Office

The Medical Information Office responds to inquiries about our products from medical doctors, pharmacists, patients and their families. The number of inquiries has been increasing every year and last year reached over 38,000. Information received by the Office is immediately provided to MR and shared with relevant departments. Through cooperative efforts with the Sales & Marketing Division and other departments, this information is effectively utilized in addressing safety management and quality issues.

A member of the Medical Information Office answering an inquiry





Human rights/Labor practices

Paying special attention to the human rights of workers, we strive to create a work environment that values diversity. Importance is also placed on ensuring fair labor conditions. In particular, our focus is on developing systems that deliver a good work-life balance and providing work environments where employees can work safely. Our goal as a corporate group is to develop a diverse workforce made up of broadminded and fully engaged individuals.

Highlight

Diversity and Inclusion Project

Efforts focused on creating workplaces where all employees, regardless of background, can reach their full potential.

To ensure good labor practices and the protection of human rights, it is important to provide systems that make it easy for employees of different backgrounds to get along with each other while achieving their full potential. Kyowa Hakko Kirin is committed to creating a work environment where diversity is respected and valued.

In October 2010, the Diversity & Inclusion (D&I) Project was launched to implement this concept. While the project's office is located within the Human Resources Department, its members consist of staff from different departments and divisions. Under the leadership of this cross-departmental organization, efforts are being made to create a corporate culture that motivates all employees regardless of background to perform to the best of their abilities. Since fiscal 2011, on-site supporters have joined the project activities to provide opportunities for



employees to improve their awareness of D&I and interact with each other more frequently. Through these efforts, D&I

activities have been expanding. Discussions are currently being held to determine new ways to help create a work environment where diversity is respected and valued.

The D&I Project is an essential component of Kyowa Hakko Kirin's plan to expand its business activities around the world as it pursues its vision to become a "global specialty pharmaceutical company." Looking forward, we will intensify our efforts to achieve a corporate culture where all employees can make a valuable contribution regardless of gender, nationality, career before joining Kyowa Hakko Kirin, life events, or disability.

Kyowa Hakko Kirin's Human Resources (HR) Philosophy

Kyowa Hakko Kirin has established an HR Philosophy, a set of basic principles concerning human resources that will help us develop a professional workforce capable of achieving the company's vision to become a "global specialty pharmaceutical company" and promoting and embodying the ideas set out in "Commitment to Life." *1

The main purpose of the HR Philosophy is to affirm that Kyowa Hakko Kirin values employees' self-initiative, encourages them to improve their abilities and creativeness, and will create a work environment in which they can pursue their own infinite possibilities and be fully motivated at work. It also serves as the foundation of our HR policies and the corporate culture of Kyowa Hakko Kirin. Based on its principles, personnel are expected to pursue our strategies.

*1 See page 6 for the full text.

Kyowa Hakko Kirin's HR Philosophy

We value employees' self-initiative, encourage them to improve their abilities and creativeness, and will create a work environment in which they can pursue their own infinite possibilities and be fully motivated at work.

Developing professionals

We will provide employees with opportunities where they can proactively seek new challenges to acquire high expertise and a broad vision.

Promoting diversity

We will provide employees with opportunities where diverse human resources can work well together by understanding and respecting different values.

• Clarification of mission and fair treatment

We will share the company's vision and goals with employees to continuously enrich the value of their work, and clarify their expected roles.

We will evaluate and reward employees fairly for their achievements and contributions to the company.

(Established in March 2009)















Efforts concerning human rights

The Kyowa Hakko Kirin Group respects the human rights and individuality of all people. We therefore focus considerable efforts on creating workplaces free from discrimination and harassment. We also comply with labor-related laws and thereby maintain a healthy environment that is comfortable for employees to work in.

Promotion of human rights

Kyowa Hakko Kirin conducts activities to promote human rights based on the policies and measures determined by the Kirin Group Human Rights Promotion Committee.*2 One such activity is the Human Rights Training Program launched in 2009 targeting all employees. This program has also been introduced to Kyowa Hakko Bio, Kyowa Medex, and other Kyowa Hakko Kirin Group companies to enhance employee awareness of the importance of human rights throughout the Group.

Other human rights promotion activities include conducting surveys on the human rights awareness of our employees in conjunction with other companies belonging to the Kirin Group; conveying a message from the President to employees during Harassment Elimination Month; and soliciting slogans from employees for Human Rights Week. We have also established hotlines that employees can call to report or seek advice on harassment and other human rights issues.

*2 Kirin Group Human Rights Promotion Committee: A committee chaired by the human resources director of Kirin Holdings and staffed by human resources department managers from the major companies within the Kirin Group.

Employment of people with disabilities

Kyowa Hakko Kirin is actively providing employment for people with disabilities. As of the end of December 2011, we employ 73 workers with disabilities. This constitutes 1.6% of our total workforce, which falls short of the statutory requirement of 1.8%. We are currently making every effort to increase the rate for the next fiscal year and thereafter. We are also working hard to help people with intellectual disabilities find jobs by offering work experience programs*3 to students of designated Tokyo Metropolitan Special Support Schools.*4 In April 2012, for the first time, we employed a person who had completed this program.

Similarly, the Kyowa Hakko Bio Yamaguchi Production Center

(Ube) received a request from Yamaguchi Prefecture to take part in its Mental Health, Welfare and Social Adjustment Training Project. Seeking to help promote the social rehabilitation of persons with disabilities, the



Work experience program

Yamaguchi Production Center responded to the request in fiscal 2011 by offering one man the opportunity to perform office work in its General Affairs Department for 6 months to prepare him for his integration back into society.

- *3 Work experience programs: On-the-job training that includes computerbased data entry, filing, collection and delivery of mail, and copier paper replenishing
- *4 Tokyo Metropolitan Special Support Schools: Schools that offer, as part of their high school program, a Shugyo Gijutsu-ka (vocational course) that prepares intellectually disabled students for work in the private sector

Ethical considerations in R&D

In its R&D on pharmaceuticals, Kyowa Hakko Kirin takes the following ethical considerations into account.

Bioethics: Kyowa Hakko Kirin sets internal rules with the aim of assuring ethical and scientific validity in human genome analysis and research using human tissue as well as preventing the loss of dignity and protecting the human rights of tissue donors.

Safeguarding human rights in clinical trials: When conducting a clinical trial involving human subjects, Kyowa Hakko Kirin observes the ethical principles contained in the Declaration of Helsinki, Good Clinical Practice (GCP: the standard to which clinical trials must conform), and related regulations (the Pharmaceutical Affairs Act, etc.). We have also established internal rules consistent with GCP and the relevant regulations to make utmost efforts to protect human rights and maintain the safety of trial subjects (patients and volunteers).

Work-life balance

Childcare Support Policy

To create a work environment where every employee can pursue their full range of career options regardless of their lifestyle or gender, Kyowa Hakko Kirin is promoting childcare support based on the following concepts in cooperation with the labor union.

Kyowa Hakko Kirin **Childcare Support Policy**

- We recognize that the creation of a society and companies that provide equal opportunities for men and women is an important matter to Kyowa Hakko Kirin and will support that effort.
- We support employees who require temporary leave or workload reduction for taking care of their children but wish to continue employment and grow with the company.
- We seek to develop a group-wide culture of supporting employees involved in childcare by instilling awareness that the reconciliation of work and childcare is beneficial to Kyowa Hakko Kirin, while encouraging employees who receive support to actively seek harmony with their fellow employees.

■ Childcare/Nursing care support measures

Kyowa Hakko Kirin has two systems to help employees continue working after the birth of a child and while raising children over the longer term. One is a childcare leave system under which employees can take a leave of absence until the child becomes two years old. The other is a reduced work hours childcare system that employees can take advantage of for a total of up to 48 months*¹ before the child enters the 4th grade of elementary school. We offer a further system for employees with a family member who needs nursing care. This system allows such employees to take a leave of absence or work shorter days for up to 12 months in total. In fiscal 2011, a total of 108 employees used the childcare leave system while the monthly average number of employees who made use of the reduced work hours childcare system was 66.

*1 The total number of months for which an employee is permitted to take childcare leave and work reduced hours.

Development of Human Resources

Independent career development

Kyowa Hakko Kirin offers various tools and training programs to encourage voluntary career development.

Career Development Sheet

All employees are required annually to fill out the Career Development Sheet, which is designed to help them develop their mid- to long-term career plan. Each employee meets with his or her immediate supervisor to seek advice and make sure that their career plans are aligned with the company's career development policy.

• Career Life Design seminar (CLDS)

The objective of this seminar is to encourage employees to look back over their career and life when they turn to 30, 40 and 50 years old and consider their future in the light of their personal values and goals. Upon completing the seminar, employees are given special leave to give careful thought to their future plans.

Optional training programs

To help employees who are willing to grow with the company fulfill their own needs, a variety of training programs that let them enhance their expertise and broaden their perspective are available. These programs, which employees can participate in at their choosing, are designed to improve employees' skill levels to meet the company's requirements. More than 600 employees voluntarily take part in these seminars annually.

Self-development support system

This is a system to support employees actively pursuing their own professional development along with that of the company by subsidizing fees and other expenses. In fiscal 2011, 498 employees used the system.

Development of a globalized workforce

Kyowa Hakko Kirin places emphasis on recruiting and developing adaptable employees who can play an active role in enhancing our global business. The Global Executive Program, one of the programs that develops globally competent employees, trains employees to be able to play a leading role in international business at overseas offices and at the Kyowa Hakko Kirin Head Office. The objective of the program is "to help employees better understand the corporate philosophy and acquire the mindset, knowledge and skills required of executives so that they can successfully lead the organization via managerial positions at Kyowa Hakko Kirin Group companies in various countries." The program is provided in English.

In fiscal 2012, 17 employees in total, consisting of 9 from Japan, 2 from China, and 1 each from the USA, the UK, Korea, Hong Kong, Singapore and Malaysia participated in the Global Executive Program. Collective training sessions conducted 4 times over a 10-month period provided the participants with business school executive level training as well as practical training to prepare them to become global executives. In addition, the program gives participants an opportunity to experience management simulations online and

take part in a team project. At the end of the program, the participants present the results of their team project to the Group's management team and receive valuable feedback during the subsequent Q&A.



A session of the Global Executive Program

Ensuring Workplace Safety

Efforts regarding mental health care

Kyowa Hakko Kirin believes that the active involvement of each employee is critical to continued corporate growth and that the sound development of a company depends upon the sound body and mind of its employees. To help maintain the physical and mental health of its employees, Kyowa Hakko Kirin places emphasis on enhancing industrial health through creating a comfortable work environment in compliance with the Guideline for the Maintenance and Promotion of Worker Health in the Workplace issued by the Ministry of Health, Labour and Welfare. To address mental health care issues in particular, we contract with industrial physicians specializing in psychiatry, psychosomatic medicine and other relevant areas to implement primary and secondary preventive measures. These include encouraging those with mental health issues and their supervisors to be more actively engaged in addressing the issues; conducting















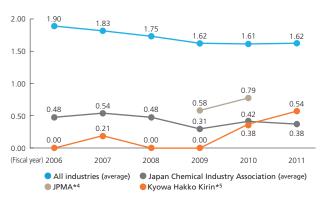
stress checks and training sessions using external employee assistance programs (EAP), and establishing centers for face-to-face, phone and online counseling services. Cooperative efforts with industrial physicians and other industrial health staff have also been undertaken to improve reinstatement programs and a follow-up system after reinstatement to prevent relapses and help affected employees to continue working.

Occupational safety and health

To prevent industrial accidents, the Kyowa Hakko Kirin Group conducts risk assessments at each business site as part of its daily production activities and prior to construction work. In 2011, we reviewed our industrial accident reporting criteria so as to enable all employees to quickly share information on industrial accidents. Safety training is provided annually to newly appointed executives and staff in charge of safety management in order to promote safety awareness. The progress of safety activities is checked in the annual safety audit, and the audit results are reported to management at a meeting of the Environment and Safety Committee and reflected in the action plan for the following year.

In 2011, the number of accidents resulting in lost work time at Kyowa Hakko Kirin, Kyowa Hakko Bio, Kyowa Medex and Daiichi Fine Chemical was three. The accident frequency rate*2 was 0.54 and the accident severity rate*3 was 0.028, both higher than the previous year. One accident resulting in lost work time was reported by one of our subsidiaries, which is in the transport business. Details of accidents and measures taken are shared throughout the Group to prevent recurrence.

Accident frequency rate



- *2 Accident frequency rate: The number of fatal and lost time accidents per million working hours
- *3 Accident severity rate: The number of lost days per 1,000 working hours
- *4 Accident frequency rate of manufacturing plants according to the Japan Pharmaceutical Manufacturers Association (JPMA)
- *5 Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio, Daiichi Fine Chemical

It was found that the accident frequency rate from the Japan Chemical Industry Association for FY 2009 included in our CSR Report 2011 was not correct. Accordingly, we corrected the value in the above graph.

Safe driving promotion

Kyowa Hakko Kirin has a fleet of approximately 1,600 vehicles for use by salespeople in the field. To maintain high safety awareness among our salespeople, we introduced a safe driving training program in fiscal 2008. For new employees, we perform a unique five-scale assessment of their driving skills to help them enhance their driving techniques and safety awareness. Driving recorders are installed in vehicles used by new employees and those with high risk of accidents. To further prevent accidents, hazard prediction training is conducted and safe driving levels are scored.

Group locomotion drill

The Kyowa Hakko Kirin Head Office has established a group ambulatory locomotion system in order to be prepared in case of disaster. This system is designed to assist employees who wish to return home on foot when public transport is disrupted following a disaster or for other reasons. During the drill to test the system on November 22, 2011, participants were divided into small groups and walked to predetermined destinations.

The drill helped participants raise awareness of disaster prevention, confirm a possible route home and the locations of support stations, and identify group members heading in the

same direction. The next steps will include determining means of communication to confirm the safety of employees' family members and preparing stores of emergency supplies at workplaces.



Participants in the group locomotion drill

Disaster drills at work sites

Work Sites	Drills	Details
Kyowa Hakko Kirin Head Office	Disaster drill	Otemachi Building general disaster drill
Kyowa Hakko Kirin Takasaki Plant and Bio Process Research and Development Laboratories	Disaster drill	Annual disaster drills joined by all employees. Drills conducted in 2011 included an evacuation drill joined by all employees, a fire-fighting drill by the fire-fighting unit, and a rescue drill.
Kyowa Hakko Kirin Fuji Plant and Fuji Research Park	Earthquake disaster drill	Annual earthquake disaster drill joined by all employees and others who are within the engineering works premises on the day of the drill.
Kyowa Hakko Kirin Sakai Plant	General fire drill	Twice annually: a disaster drill joined by all employees and held with the cooperation of the Sakai Fire Station in June and another conducted without the participation of the fire station in December.
Kyowa Hakko Kirin Tokyo Research Park	General disaster drill	Annual disaster drill joined by all employees. On March 2, 2011, a joint disaster drill was conducted with the Machida Fire Station.
Kyowa Iryo Kaihatsu Yamaguchi Plant	Disaster drill	Each year in December: a fire-fighting drill conducted with the participation of all employees. The drill includes: securing evacuation routes, securing objects or materials that have beer predetermined to be saved for an emergency, and operating fire extinguishers.
Kyowa Medex Fuji Plant	General disaster drill	On November 9 each year: a general disaster drill joined by the entire staff of the plant. In 2011, particular emphasis was placed on conducting a group locomotion drill. As part of the drill, the amount of food products and supplies kept for an emergency are checked.



Community involvement and development

To become an even more trusted company, we have worked to participate in community activities in Japan and abroad to respond to the expectations of society. We hope that through activities centered on exchange with local communities, we will strengthen our bonds with society. The Kirin Group is also united to continue its efforts to support post-disaster reconstruction in the Tohoku region.

Highlight

Kirin Kizuna Project for post-disaster reconstruction

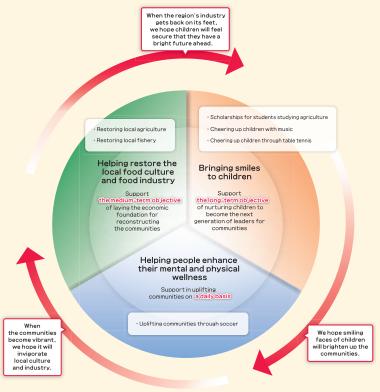
United efforts by the Kirin Group to provide post-disaster support, including table tennis lessons

The Kirin Group is promoting its Kirin Kizuna Project, a reconstruction efforts for communities affected by the Great East Japan Earthquake. Project comprises three pillars of activities: helping restore the local food culture and food industry, bringing smiles to children, and helping people enhance their mental and physical wellness.

Kyowa Hakko Kirin participates in the Kirin Group project by organizing the "Kyowa Hakko Kirin Table Tennis Lessons," a three-year project started in fiscal 2011 to provide fun and healthy activities for children living in disaster-affected areas. In fiscal 2011, students of local elementary and junior and senior high schools were invited to join lessons held in collaboration with a local table tennis association at 5 sites in Iwate, Miyagi and Fukushima prefectures. Members of our company's table tennis club, including top-level players from the Japan Table Tennis League, provided tips and skills training to local children and organized matches. Such equipment as table tennis tables and paddles used on the day of the event were all donated.

In addition to the table tennis project, the Kyowa Hakko Kirin promoted other reconstruction volunteer-based projects, such as science education programs. In fiscal 2011, 65 employees of Kyowa Hakko Kirin participated in volunteer activities to clean up the sea and help local fishermen with their recovery efforts. The Kirin Group will continue these concerted efforts for post-disaster reconstruction.

How the Three Pillars of Activities Work Together



Support for areas affected by the Great East Japan Earthquake

Kyowa Hakko Kirin gave a monetary donation of ¥100 million and donated drinking water and other supplies to support areas affected by the Great East Japan Earthquake.



Appreciation Certificate for support activities















Contribution to local communities

Responsible Care* Community Dialogue

Kyowa Hakko Bio participates in community dialogue activities promoted by the Japan Responsible Care Council (JRCC). This year, the Yamaguchi Production Center (Ube), in cooperation with 3 other JRCC member companies, hosted the 9th



The 9th Ube Region RC Community Dialogue meeting

Ube Region RC Community Dialogue meeting in February 2012. As part of the meeting, the 62 participants, who included local residents and representatives of local companies and government agencies, were given tours of the Kyowa Hakko Kirin Ube Plant and the Kyowa Hakko Bio Yamaguchi Production Center (Ube). After the tours, Kyowa Hakko Bio explained its efforts for the environment and safety. Participants later discussed such issues as the management of chemical substances and odor. Through discussion, they identified regional issues involving various companies, government agencies and universities and learned how they were addressed.

* See page 26 for "responsible care."

Co-sponsoring the Edinburgh **International Science Festival**

ProStrakan Group plc (a subsidiary in the UK) has programs to encourage students to study science. One of these is offering

grants as part of the Edinburgh International Science Festival, an educational charity focusing on science education. Grants go to schools where students engage in scientific experiments and are encouraged to take science classes.



Edinburgh International Science Festival

Donation and participation in the "Beautiful Gift" campaign

The "Beautiful Gift" campaign is a Korean event held on the Sunday before New Year, one of the major holidays in South Korea. On the day, people visit needy families and elderly people living alone to offer gifts. These include rice bought



"Beautiful Gift" campaign

with profits from the "Beautiful Shop," a largely volunteer-run second-hand charity shop, as well as daily necessities donated by supporters. In fiscal 2011, Kyowa Hakko Kirin Korea donated 1.5 million won and about 40 employees and their families joined the event.

Science classes for young students (Bio-adventure project)

We offer science experiment classes at our plants and laboratories to create opportunities to share the excitement of science experiments with large numbers of children. The Tokyo Research Park started the bio-adventure project in 2000, sending its research staff equipped with microscopes and other experimental equipment off to local elementary, junior and senior high schools to conduct science experiments related to genetics, microbiology and immunology. A total of 4 classes with

142 attending students were held in fiscal 2011. In the same year, the Research Park received a commendation from the local board of education for its contributions over the years.



Bio-adventure project

Internship program

In fiscal 2011, the Kyowa Hakko Bio Yamaguchi Production Center provided intern opportunities for a total of 17 high school and university students. The 2011 program newly included experience working in the Quality Control Section and the Engineering Section, in addition to the R&D Department. By interning in these departments, students learn how what they have learned at school is applied in industry. ProStrakan also provides an internship program called "You are the Future" in which 1 senior high school student and 5 university students participated in 2011. Over the roughly one-week program, participants learn about on-the-job attitudes and deepen their understanding of the work itself as well as the skills required for employment in the pharmaceutical industry. It is hoped that the program motivates students to enter the industry in the future.

Other activities in fiscal 2011

- Football class for children (Kyowa Hakko Kirin Takasaki Plant and Bio Process Research and Development Laboratories)
- Summer Holiday Junior Science Class (Kyowa Hakko Bio Yamaguchi
- Tennis School (Kvowa Hakko Kirin Tokyo Research Park)
- Kusuri-no Himitsu Tanken (Exploring the Secrets of Drugs) Lecture (Kvowa Hakko Kirin Ube Plant)

Research support

Supporting the La Jolla Institute for Allergy and Immunology

The La Jolla Institute for Allergy and Immunology (LIAI) is a nonprofit research institute established in La Jolla, California, the United States, in 1988, by Dr. Kimishige Ishizaka, an immunologist, to realize his aspiration of creating a world-leading

research institute specialized in allergy and immunology. Kyowa Hakko Kirin shares this aspiration and has been working with the institute as a sponsor and partner for drug discovery and development.



LIAI and KKC

VOICE

Mutual access to cutting-edge technology revolutionizing biomedical research

Lilia Koriazova

Associate Director Research Division, Biochemistry Group Kyowa Hakko Kirin California, Inc. (KKC)



The La Jolla Institute for Allergy and Immunology (LIAI) and Kyowa Hakko Kirin California, Inc. (KKC) share a new state-of-the-art facility located in UCSD (University of California, San Diego) Science Research Park. LIAI recently won an NIH award for developing San Diego's first center for RNAi screening, which opened last August. RNAi screening is a revolutionary technology in biomedical science that explores how genes work and affect disease processes. KKC's scientists have already established working relationships with members of the RNAi screening facility and look forward to initiation of RNAi screens to identify novel potential targets in critical pathways linked to autoimmunity, inflammation, and cancer, which will act as a catalyst for the development of future therapeutics.

■ The Kato Memorial Bioscience Foundation

The Kato Memorial Bioscience Foundation was established

in 1988 for the purpose of promoting bioscience research in Japan. The foundation offers grants to scientists who are conducting prominent creative research in the bioscience field, as well as financial aid to support international



Kato memorial research grant presentation ceremony

exchange and help scientists organize conferences. In fiscal 2011, the foundation provided grants for 25 research projects, 31 international exchanges, and 10 conferences in the medical science and biotechnology fields.

Contributing to health and well-being

Joining the Seoul Citizen Marathon to help pediatric patients with childhood cancer

"Run for others at least one day a year!"—this is the slogan of the Seoul Citizen Marathon, an event organized in Seoul (Korea) every year to help pediatric patients with cancer. The objective of the event is to become a beacon of hope for children whose days, through no fault of their own, are tainted by their suffering, rather than filled with dreams and hope. Kyowa Hakko Kirin Korea joins the event every year. The 2011 event, held on May 1,

was joined by 73 people, comprising employees and their family members. A total of 2.5 million won was raised, all of which was donated to support the care of socially and financially disadvantaged childhood cancer patients.



Seoul Citizen Marathon

Tours of plants and laboratories

We organize tours of the plants and laboratories belonging to the Kyowa Hakko Kirin Group for the purpose of promoting communication with local residents and enhancing their understanding of the Group's business.



Health Promotion Lecture

To improve understanding of pharmaceutical production, the Fuji Plant and Fuji Research Park hold a tour of their drug formulation site, including screening a video that explains plant operations. These sites also hold an annual Health Promotion Lecture to provide health care tips to local adults. In fiscal 2011, a lecture entitled "Eating for Health! Recommended Emergency Foods" given by sports nutritionist Terumi Kobata was attended by around 100 people.

The Tokyo Research Park organizes lectures on its research and development projects for students, Group companies, government agencies, and others.

The Kyowa Hakko Bio Yamaguchi Production Center invited 70 university students to tour the laboratory as part of an internship program.















Spend a day in a childcare center campaign

In Seoul, people are encouraged to work in a childcare center on the fourth Saturday of every month to take care of infants less than 6 months of age. The campaign also seeks financial support for the families of children with physical disabilities and premature babies needing surgery and long hospital stays. The same campaign also urges people to act as short-term foster parents to parentless infants until long-term arrangements

can be made. In fiscal 2011, a total of 88 staff from Kyowa Hakko Kirin Korea and their families participated in this campaign.



Spend a day in a childcare center campaign

Distribution of free braille calendars

Each year since 1994, we have produced braille calendars for people with visual impairments and distributed them free of charge to schools for the blind nationwide. In fiscal 2011, we delivered 3,863 copies of the 2012 calendar to 80 schools.



2012 braille calendar

Other activity in fiscal 2011

- Joint table tennis training session with the Yamaguchi Prefecture
 Disabled Table Tennis Team (Kyowa Hakko Bio Yamaguchi Production Center)
- Supporting the organization of "Oidemase! Yamaguchi Kokutai" (National Sports Festival) (Kyowa Hakko Bio Yamaguchi Production Center)
- Lectures on the pharmaceutical industry at senior high schools (Kyowa Hakko Kirin Fuji Research Park)
- Co-sponsoring the Childhood Cancer Eradication Campaign (Kyowa Hakko Kirin Head Office)
- Co-sponsoring the international friendship exchange special concert for Disabled Persons Week (Kyowa Hakko Kirin Head Office)
- Supporting "Iyashi-no Geijyutsu Feeling Arts" performances at health care, welfare and education facilities (Kyowa Hakko Kirin Head Office)

Awards

As in past years, we again received a number of awards in fiscal 2011 for our efforts relating to product safety, quality control, information disclosure, environmental protection, safety and health, and other matters. The table on the right shows the major awards received.

Practical training and drills to prepare for emergency situations

Nobuyuki Kishibayashi

Environment and Safety Office Fuji Plant, Kyowa Hakko Kirin Co., Ltd.



To strengthen the organization of its disaster prevention unit, Kyowa Hakko Kirin Fuji Plant conducts disaster prevention and other training and drills in preparation for various emergency situations. Programs include joint training sessions with the local fire station and training to improve the fire-fighting skills of the fire-fighting team, which is made up of residents of the corporate dormitory. The disaster prevention unit of Fuji Plant was recognized for these voluntary activities with a merit award (Governor's Incentive Award). We will continue our efforts to raise employee awareness and train ourselves to prepare for emergencies so that we can contribute to our local community in an emergency situation.

Awards presented to work sites

Work Sites	Awards	Details			
Kyowa Hakko Kirin Takasaki Plant	Gunma Prefecture Governor's Appreciation Certificate for promoting blood donation	Blood drives, held regularly at the plant for many years, were held twice in 2011. The plant received an appreciation certificate for its blood donation campaign called "Ai-no Ketsueki Tasukeai Undo." Received a merit award for their safe and proper handling of hazardous materials by Machida Fire Station of the Tokyo Fire Department			
Kyowa Hakko Kirin Tokyo Research Park	Merit award for hazardous material engineers				
Kyowa Hakko Kirin Tokyo Research Park	Appreciation Certificate for the bio-adventure project activities	Received an appreciation certificate from the Machida City Board of Education for its support over many years of the educational activity organized by the Machida City Science Education Center for Elementary and Junior High Schools			
Kyowa Hakko Kirin Fuji Plant and Fuji Research Park	Shizuoka Prefecture Governor's Award	Awarded by the Governor of Shizuoka Prefecture for its efforts to raise awareness of fire prevention and its fire prevention activities conducted in and outside of the company over many years			
Kyowa Hakko Bio Yamaguchi Production Center Curtain Contest"		Kyowa Hakko Bio Yamaguchi Production Center (Ube) received the Most Outstanding Award in the business category of the Green Curtain Contest.			
Kyowa Hakko Bio Yamaguchi Production Center	Outstanding Award in Hofu City's "Green Curtain Contest"	Kyowa Hakko Bio Yamaguchi Production Center (Hofu) received the Outstanding Award in the business category of the Green Curtain Contest.			
Kyowa Hakko Bio Yamaguchi Production Center	Most Outstanding Award in Ube City's "Green Curtain Contest"	Kyowa Hakko Bio Yamaguchi Production Center (Ube) received the Most Outstanding Award in the business category of the Green Curtain Contest.			
Kyowa Hakko Bio Yamaguchi Production Center	Received the Yamaguchi Prefecture's "Eiko Medal"	The employee who won the gold medal in the table tennis singles at the National Sports Games for the Disabled (Yamaguchi) received the "Eiko Medal" from the Governor of Yamaguchi Prefecture.			
Kyowa Iryo Kaihatsu Yamaguchi Plant Kyowa Iryo Yamaguchi Plant Yamaguchi Plant Hazardous Materials		Received the award for serving as a model of safety management of hazardous materials facilities.			



The environment

Efforts are made to protect the global environment and to achieve and maintain a sustainable society.

Consideration is paid to the environment, safety and health in every process of product development, manufacture and marketing.

An environmental safety management system has been established to identify any environmental impacts caused by our various activities, enabling us to make ongoing improvements.

Highlight

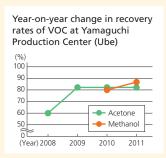
Reduction of volatile organic compounds (VOC)

Efforts to reduce VOC emissions by improving the manufacturing process

At the Kyowa Hakko Bio Yamaguchi Production Center (Ube), a proportion of the acetone, methanol and other VOC used during the manufacturing process is released into the atmosphere. Figures on the amount of these emissions are publicly disclosed. Furthermore, due to their tendency to vaporize and diffuse into the atmosphere, thereby creating photochemical oxidants, efforts have been made to reduce emissions of volatile organic compounds (VOC).

The Yamaguchi Production Center (Ube) has been promoting ongoing efforts to reduce VOC emissions, including by enhancing manufacturing processes and upgrading equipments, in order to achieve higher recovery rates of solvents used during manufacturing. For example, it has installed VOC removal equipment and refurbished acetone distillation columns. As a result, the recovery rate of acetone rose from 60% to 82%. The recovery rate of methanol, which accounts for a large portion of total VOC emissions, improved from 80% to 87%. We have also successfully reduced the use of formaldehyde to zero. Because the production volume (total volume of solvents used) differs every year, we cannot easily compare yearon-year figures for total VOC emissions. But total VOC emissions in fiscal 2011 were reduced by about 35% compared with fiscal 2008. In fiscal 2012, we are aiming to achieve a recovery rate of more than 90% for both

acetone and methanol by further improving the manufacturing process. Kyowa Hakko Bio will continue its efforts to reduce VOC emissions not only at the Yamaguchi Production Center (Ube) but also at all other sites.



Application of simulation resulting in successful improvement in the recovery rates of solvents

We used a chemical simulator*1 to create a basic design for both removal equipment and an acetone distillation column. For simple distillation recovery of the solvents (acetone, methanol), we invented a method whereby water is pumped into a vessel before simple distillation to raise the temperature of the generated vapor. This method has allowed us to improve the recovery rates of solvents using condensers. I am proud of having achieved reductions in both environmental impact and the purchase costs of solvents by improving the existing process without the need for any additional investment in facilities.

*1 Chemical simulator: A computer model designed to virtually assess various operating conditions

Takahiro Sugiyama

Production Strategy Office Yamaguchi Production Center Kyowa Hakko Bio

Environment and safety management

The Kyowa Hakko Kirin Group has in place both an ISO 14001-accredited environmental management system and an occupational safety and health management system centered on risk assessment, and continuously improves them through a systematic Plan-Do-Check-Act (PDCA) cycle. Our environmental and safety activities are based not only on the relevant laws and regulations but on additional, more rigorous targets that we have voluntarily imposed on ourselves. We will continue our environmental activities under the ISO 14001 management system to achieve our goal of low carbon corporate operations right across the supply chain.

Basic Policy on the Environment, Safety and Product Safety

Based on the Kyowa Hakko Kirin Group Management Philosophy, we will exert ourselves to realize an affluent society by conducting business activities with scientific consideration for health, safety, the environment, and product safety throughout the entire life cycle of each of our products, that extends from research and development through production, marketing, use, and disposal, at the same time, we are making efforts to ensure the quality and safety of our products, taking the safety of consumers as a matter of the greatest importance.

(Revised on March 22, 2012)







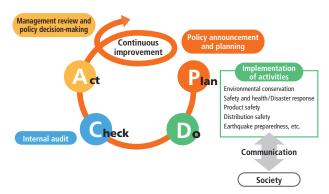








Environmental and safety management



Declaration of Environmental Commitment

As a member of the Kirin Group, which aspires to be a low carbon corporate group, Kyowa Hakko Kirin declared its commitment to protecting the global environment under the "Declaration of Environmental Commitment" in June 2010 and is making steady progress to meet the declared targets.

Kyowa Hakko Kirin Declaration of Environmental Commitment

We declare our active commitment to protecting the global environment for generations to come.

- We aspire to become a low carbon corporate group.
 - We will reduce CO₂ emissions of the Kyowa Hakko Kirin Group by 15% over the 2005 level by 2020.
 - We will promote the use of renewable energy.
 - We will reduce energy consumption in the administrative division by 1% annually.
 - We will introduce 1,000 hybrid vehicles for field salespeople by 2014 to encourage eco-driving.
- We will promote resource conservation.
- We will actively promote the procurement of raw materials, office supplies, equipment, and other items with a low environmental impact.
- We will promote the separation of garbage and reduction of waste to maintain zero emissions.
- We will actively work on environmental conservation and protection.
 - We will minimize the impact of our business activities on the environment, safety, and health throughout the life cycle of products from R&D to production, marketing, use, and disposal.
 - We will deliver environmentally friendly products and services.
- We will promote conservation of the environment and the ecological systems of local communities.
 - We will promote environmental conservation activities such as forest conservation projects.
 - We will work toward environmental beautification through activities such as keeping local communities clean.

Nobuo Hanai President & Chief Executive Officer Kyowa Hakko Kirin Co., Ltd. Progress made in our implementation of the Declaration of Environmental Commitment

Declaration	2011 results*2			
We aspire to become a low carbon corporate group.	Greenhouse gas emissions (CO ₂) in 2011 were 240,000 tons, a 9.7% reduction from the 2005 level. The use of renewable energies was promoted and photovoltaic power generators were put into regular operation at the Fuji Plant and Tokyc Research Park. Our goal is to increase the number of hybrid vehicles used for sales activities to 1,000 by 2014. As of 2011, a cumulative total of 585 hybrid vehicles has been added to the company's fleet.			
We will promote resource conservation.	Green procurement was promoted throughout the supply chain. In the industrial waste recycling project, we achieved zero waste emissions across the Group.*3			
We will actively work on environmental conservation and protection.	We have been planting trees since 2007 as part of the Kyowa Hakko Kirin Takasaki Water Source Forest Conservation Activities. As part of the Kirin Fuji-sanroku Water Source Forest Conservation Activities, we cleared overgrown trees and shrubs in cooperation with Kirin Distillery. We also participated in many other activities aimed at protecting water resources.			
We will promote conservation of the environment and the ecological systems of local communities.	We undertook conservation activities in cooperation with government agencies and local residents in several areas, namely, the area surrounding the upper reaches of Saba River (Yamaguchi) near Lake Ohara, the national forests to the east of Lake Shikotsu (Hokkaido), the area surrounding the upper reaches of Koto River (Yamaguchi) near Akiyoshidai, and around reservoirs in the district of Mito (Yamaguchi). We also collected trash and removed weeds from roads and cleaned up ports, harbors and rivers in the vicinity of our plants and laboratories in cooperation with local residents.			

- *2 Results between January and December 2011. (The zero emission results are from April 2010 to March 2011.)
- *3 "Zero emissions" generally means a reduction in the amount of generated waste to zero. The Kyowa Hakko Kirin Group uses the term to mean a reduction in the amount of waste disposed in landfills to no more than 0.1% of generated waste.

Environmental and safety audits

The Kyowa Hakko Kirin Group conducts environmental and safety audits annually to assess whether the environmental and safety system is functioning and being operated properly. In fiscal 2011, environmental and safety audits were conducted at 34 business sites of 11 companies. No legal violations in connection with the environment and safety subject to punitive measures were identified, nor were any environmental accidents. Items identified in these audits as requiring improvement will be regularly checked to confirm that improvement has been made so as to ensure to continuous enhancement.

Environmental, safety, and product safety assessments

Based on its own Basic Policy on the Environment, Safety, and Product Safety, as well as under the Responsible

Care*4 initiative for environmental protection and safety, the Kyowa Hakko Kirin Group operates rigorous assessments at each stage of the product life cycle, from R&D through to use and disposal.



Responsible Ca

*4 Responsible Care: A voluntary initiative under which companies handling chemicals continuously improve their health, safety, and environmental performance at every stage of the product life cycle from the development of chemical substances to production, distribution, use, final consumption, and disposal, publish the results of their activities, and promote dialogue and communication with other sectors of society.

Kyowa Hakko Kirin Group's environmental conservation activities

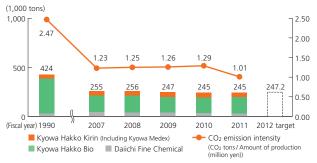
Our Activities for Reducing CO₂ Emissions

The Kyowa Hakko Kirin Group's goal is to reduce CO₂ emissions by 3% (247,200 tons) from the fiscal 2007 level by fiscal 2012, and by 15% from the fiscal 2005 level by fiscal 2020. Total CO₂ emissions of production sites in Japan in fiscal 2011 came to 245,000 tons, a 4.0% reduction compared with fiscal 2007. Despite the presence of some factors that resulted in increased CO₂ emissions, such as worsened CO₂ emission coefficients*¹ of Chugoku Electric Power Company and Hokuriku Electric Power Company and the temporary operation of heavy oil boilers due to a shortage of purchased steam, the CO₂ emission intensity*² improved to 1.01 compared with 1.29 in the previous year. The Group's energy consumption in fiscal 2011 was 108,000 kiloliters in oil equivalent, a 3.8% decrease from the previous year.

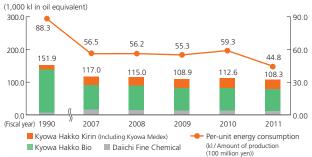
In fiscal 2011, we invested in energy-saving measures at our plants, such as switching to highly efficient freezers, improving facilities and replacing old lighting with LEDs. In addition, we also made process improvements, including optimizing operations. As a result, CO₂ emissions were reduced by 4,856 tons. In our efforts to promote renewable energies, a photovoltaic power generation system is used at the Fuji Plant and Tokyo Research Park. While it is expected in 2012 that the electric power CO₂ emission coefficient will worsen due to the suspension of nuclear power plant operations, our efforts to achieve the mid- to long-term goals will be continued.

- *1 A figure expressing how much CO_2 is emitted per kWh of supplied electricity.
- *2 CO₂ emission intensity = CO₂ emissions (tons)/Amount of production (million yen)

CO₂ emissions / CO₂ emission intensity



Energy consumption / Per-unit energy consumption



Waste governance

The Kyowa Hakko Kirin Group ensures that its waste contractors dispose of waste properly by conducting inspections prior to and regularly after contracting out waste disposal in order to help prevent illegal dumping. We are continuously reinforcing our governance system to make it even more effective and reliable through such measures as reviewing disposal outsourcing contracts.

Promotion of reuse and recycling

In October 2006, a facility to recover phosphoric acid from fermentation wastewater was built at the Kyowa Hakko Bio Yamaguchi Production Center (Hofu). The recovered calcium phosphate cake contains P2O5 at a rate of roughly 29%, which puts it almost level with phosphate ore. Although in the initial years recovered cake was treated as industrial waste, in 2008 the production center started to drying some of the cake to sell as fertilizer material. The amount slated for drying has since been increasing (see Table 1). The amount of phosphorus contained in total processed wastewater discharged by Yamaguchi Production Center (Hofu) has been dropping since the installation of the facility in 2006 (see Table 2). Our efforts therefore contribute to conserving the environment of the Seto Inland Sea. As the production volume of the Yamaguchi Production Center (Hofu) increases in the future, it is expected that the amount of phosphoric acid contained in wastewater will likewise go up. To address this expected increase, we will install new driers and take other measures to increase the amount of phosphoric acid recovered. Moreover, we will make additional efforts to promote the reuse of dehydrated cake as a valuable resource.

(Table 1) Output of dephosphorylated cake at Yamaguchi Production

Unit: t					
	2007	2008	2009	2010	2011
Industrial waste	95	79	25	26	36
Fertilizer material (amount sold)	0	23	75	63	96
Total	95	102	100	89	132

(Table 2) Total phosphorus emissions in total processed wastewater discharged by Yamaguchi Production Center (Hofu)

	UI				Unit: ton	It: ton	
	2006	2007	2008	2009	2010	2011	ı
Phosphorus emissions	10.2	3.5	3.5	4.2	5.1	5.6	

Emissions reduction at Kyowa Medex Fuji Plant

In December 2010, Kyowa Medex implemented a project to upgrade its obsolete boiler, including switching its fuel source from heavy oil to liquefied petroleum gas. In fiscal 2011, the outcome of these efforts was assessed. The findings showed a reduction in the following air contaminants: sulfur oxides (SOx) by 0.44 tons (100% reduction compared with the previous















year), nitrogen oxides (NOx) by 0.73 tons (72% reduction compared with the previous year), and dust by 0.02 tons (33% reduction compared with the previous year). CO2 emissions

were only reduced by 30 tons (3% reduction compared with the previous year) despite the fuel switch. We will continue our review of boiler operations with the goal of seeking further CO₂ emissions reductions.



Updated boilers

Other activities in fiscal 2011

- Operation of photovoltaic power generators (Kyowa Hakko Kirin Tokyo
- Electricity-saving measures (plants and offices of Kyowa Hakko Kirin Group)

Water-source protection project

To maintain ecosystems and biodiversity, it is necessary to protect the water resources that sustain natural living networks. Water is also an indispensable resource for the fermentation production process. The Takasaki Plant of Kyowa Hakko Kirin started to take part in the Kirin Group's water-source protection project in fiscal 2007, and Kyowa Hakko Kirin Fuji Plant, Kyowa Hakko Bio Yamaguchi Production Center and Kyowa Hakko Kirin Ube Plant also joined the project in fiscal 2009.

Activities at Kyowa Hakko Kirin Takasaki Plant

At the 5th Kirin Takasaki Water Source Forest Conservation Activities held on October 1, 2011, participants worked with NPOs such as Forest Gunma 21 to keep the forest in one of the water source areas of Takasaki City clean. Children who participated enjoyed creating group plantings using

bamboo pots. The project helped the 120 participants, including employees from the Kirin Group, to understand the importance of forest conservation and develop relationships good working together.



Other activities in fiscal 2011

- Kirin Chitose Water Source Forest Conservation (Kyowa Hakko Kirin
- Tree Planting for Water Conservation (Kyowa Hakko Kirin Ube Plant. Kyowa Hakko Bio Yamaguchi Production Center)
- Kirin Fuji-sanroku Water Source Forest Conservation Activities (Kyowa Hakko Kirin Fuji Plant and Fuji Research Park, Kyowa Medex Fuji Plant)

VOICE

Working with local people to preserve our rich natural heritage

Aoi Higuchi

Administration Department Takasaki Plant Kyowa Hakko Kirin



I am in charge of social contribution projects, including the "Kyowa Hakko Kirin Water Source Forest Conservation Activities." Our water source forest conservation efforts, which started in 2007, have been supported every year by many local people, including those at Forest Gunma 21, a local NPO. Kyowa Hakko Kirin, which performes manufacturing and research activities in Takasaki City, will continue such activities to protect the rich natural heritage of Gunma Prefecture.

Environmental conservation activities for local communities around our business sites

Each of our business sites conducts activities to show its commitment to protecting local ecosystems. Such activities include cleaning up Kise River in Shizuoka Prefecture, releasing young amago (red-spotted masu trout) into the Momozawa River in Shizuoka Prefecture, and protecting the grasslands in Akiyoshidai in Yamaguchi Prefecture. Each activity is conducted in cooperation with local communities. We also regularly take part in various events to clean up the areas around

our business sites, including the "Kannonyama Clean-up Volunteer Day" in Gunma Prefecture, "30 Million Persons Seto Inland Sea Clean-up Campaign" in Yamaguchi Prefecture, and "Clean-up Campaign Sakai" in Osaka Prefecture.



Seto Inland Sea Clean-up Campaign

Inappropriate management of transgenic mice

In response to an incident of inappropriate management of transgenic mice*3 in August 2010, Kyowa Hakko Kirin has taken all necessary measures to prevent a recurrence. In addition, a survey of wild mice conducted in the responsible laboratory's surrounding area found no abnormalities. The final report containing all findings from the relevant measures and surveys was submitted to and accepted by the Ministry of Education, Culture, Sports, Science and Technology in October 2011. We take this incident seriously and will continue our efforts to prevent any recurrence.

*3 In August 2010, it was discovered that the number of transgenic mice kept at the Tokyo Research Park did not match the recorded figure.





Fair operating practices

As well as promoting compliance with all relevant laws, rules and regulations, the Kyowa Hakko Kirin Group also makes tremendous efforts to maintain high ethical standards in the conduct of its entire operations. Moreover, it complies with the rules of fair competition at every stage of its corporate activities, including raw material procurement and product marketing, with the aim that all Group companies maintain their integrity and continue to enjoy the trust of society.

Highlight

Guidelines regarding transparency

Transparency guidelines have been established to ensure ethical behavior and enhance public trust in the Group.

Kyowa Hakko Kirin is engaged in developing innovative pharmaceuticals to contribute to the health and wellbeing of people all over the world. In developing pharmaceuticals, collaboration with medical institutions and/or universities in Japan and abroad is essential. As such collaboration has increased, conflicts of interests have arisen. Specifically, conflicts may occur relating to social responsibilities of research institutions, such as university medical departments, and the interests of medical professionals involved in joint research. To address these circumstances, the Japan Pharmaceutical Manufacturers Association (JPMA) developed a set of standards called the "Guidelines for Transparency in the Relationships between Corporate Activities and Medical Institutions." The guidelines propose that details of funding for industryuniversity joint projects be made public.

In agreement with the objective of the Guidelines, Kyowa Hakko Kirin October 2011 developed its own "Guidelines for Transparency in the Relationships between Corporate Activities and Medical Institutions." This document, which include codes of conduct that must be followed in daily activities, is freely available on our Guidelines for Transparency in the Relationships between Corporate Activities and Medical Institutions (excerpt)

Kyowa Hakko Kirin's approach

- As a company engaged in the pharmaceutical industry, which has a close bearing on the lives and health of the general population, Kyowa Hakko Kirin prioritizes human dignity above all else, acts with deference toward scientific achievement and adopts a set of rigorous and precise ethical standards.
- Kyowa Hakko Kirin respects basic human rights, complies with all relevant laws and regulations and adheres to both social norms and its own internal regulations in its activities pertaining to the research and development, manufacturing and marketing of pharmaceuticals. Furthermore, it conducts all of its activities in such a way as to gain and maintain a high level of public trust and support.
- Kyowa Hakko Kirin focuses its efforts on discovering innovative pharmaceuticals that contribute to the advancement of medicine while at the same time ensuring the safety, quality, stable supply, and proper use of pharmaceuticals. In this way, Kyowa Hakko Kirin helps individuals to overcome disease and achieve and maintain good health throughout their lives.
- In corporate activities conducted by Kyowa Hakko Kirin, its relationships with medical institutions are built based on the commitments described above. Efforts are also focused on making funding relationships with medical institutions transparent in line with the Guidelines for Transparency in the Relationships between Corporate Activities and Medical Institutions.

Japanese website. In creating these guidelines, our aim is to both enhance transparency and assure the public of the high ethical standards adhered to in the conduct of our corporate activities. In fiscal 2013, we will start providing information on monetary payments to medical institutions in Japan during the previous fiscal year via our Japanese website and other means.

Compliance

Promoting compliance in response to the demands of society is one of the fundamental requirements of CSR. At the Kyowa Hakko Kirin Group, compliance is promoted as a top priority issue in risk management. The Group Risk Management Committee determines the basic principles and policies regarding corporate ethics, and assists in the development of a "compliance mindset" throughout the Group.

Compliance education and awareness activities

To ensure that all Group members are familiar with the Kyowa Hakko Kirin Group's compliance policy, we formulated the Kyowa Hakko Kirin Group Compliance Guidelines in March

2009. At Kyowa Hakko Kirin, a handbook summarizing the compliance required in the pharmaceuticals business has been created and distributed to every employee. Furthermore, an education program comprising lectures, training,



The 14th Corporate Ethics Lecture















and e-learning is also provided annually to every employee to help them maintain high ethical standards at all times.

Corporate Ethics Lectures: Lectures given by invited outside experts. The lectures are recorded on DVDs, which are available for viewing at every business site.

Theme: Global Development of Companies and Impact of ISO 26000 on Corporate Management

Lecturer: Mr. Toshihiko Goto, Chief Executive of the NPO Sustainability Forum Japan

Human Rights and Compliance Training: Training organized jointly by the Human Resources Department and the CSR Management Department. The training consists mainly of group work, and is designed to encourage participants to take part in various activities. In fiscal 2011, programs to improve understanding of compliance and harassment through case studies and role-playing were provided.

E-learning Instruction: A program centered on case studies. Programs in fiscal 2011 included a compliance awareness survey and sessions on responsible alcohol consumption.

Set up and operation of hotlines

The Kyowa Hakko Kirin Group maintains hotlines in Japan that callers can use to make a report or seek advice in the event of discovering a legal or ethical violation or attempted violation. We are currently operating 4 hotlines, including an external one,

that can be used not only by officers and permanent employees but also by temporary, part-time, and dispatched workers. We have also distributed small booklets and cards containing the contact information to employees and regularly remind employees of the hotlines through the use of posters and during compliance training. The number of calls received during fiscal 2011 was 32 (29 in fiscal 2010).



A poster that reminds employees of the existence of the hotlines

Proper animal testing

Animal testing is essential to evaluate the effectiveness and safety of pharmaceuticals. Kyowa Hakko Kirin has established its own animal testing standards in line with relevant laws and regulations. Based on these standards, we care for laboratory animals and conduct animal testing in such a way as to promote animal welfare as well as scientific benefit. Guided by the 3R principle*1 and overseen by the President, the Animal Testing Committee inspects and supervises all animal testing plans from the perspectives of animal welfare and scientific rationality. We also provide animal researchers and breeders with training on animal welfare and handling.

In fiscal 2011, a self-evaluation of the conduct of animal testing concluded that testing had been properly performed. In addition, we took necessary measures to prevent recurrence of

the inappropriate management of transgenic mice*2. These efforts led to recognition that our animal testing is properly conducted according to the Fundamental Guidelines for Proper Conduct of Animal Experimentation and Related Activities issued by the Ministry of Health, Labour and Welfare. As a result, we received a certificate from the Center for Accreditation of Laboratory Animal Care and Use of Japan Health Science Foundation. Ongoing efforts will be made in the future to ensure the proper conduct of animal testing based on the 3R principle is continued.

- *1 3R principle: Reduce the number of animals used by avoiding unnecessary experimentation, Replace animal testing with methods that do not involve animals, and Refine experimental procedures to reduce pain and distress in animals.
- *2 For details, please see page 28.

Efforts to promote CSR procurement

Appropriate management throughout the entire supply chain is required to provide all customers with safe, easy-to-use and quality pharmaceuticals. To achieve this, Kyowa Hakko Kirin establishes and maintains collaborative relationships with its suppliers and promotes CSR activities in cooperation with them.

We have conducted questionnaire surveys for environmental activities of our suppliers. In fiscal 2012 survey, we will switch our focus from their environmental activities to their efforts to promote CSR activities. The survey will be given to around 100 suppliers of raw materials and packaging materials in Japan with the aim of gathering extensive information on their efforts to comply with laws and regulations, ensure occupational safety, protect human rights and conserve the environment. The findings will be fed back to participants as a reminder of the importance of their efforts and to encourage them to further promote their CSR activities.

Intellectual property

The Kyowa Hakko Kirin Group considers intellectual property to be an important asset. Particularly in relation to strategically important projects, we seek to secure extensive, strong and effective rights for ourselves while making every effort to respect and refrain from violating the rights of other companies. To ensure that all our employees are aware of the importance of these issues, we have designed and are providing educational programs on intellectual property tailored to different areas and job grades. We also support major affiliated companies in their intellectual-property-related activities in order to enhance risk management. In our pharmaceuticals business, efforts are focused on the selective licensing-out of products developed by our company and licensing-in of those developed by others. A particular emphasis is placed on acquiring multifaceted patent rights for fundamental technologies such as the POTELLIGENT® technology, which can produce significantly enhanced antibody activity.



Organizational governance

The Kyowa Hakko Kirin Group has been promoting efforts to improve corporate governance in order to ensure sound and transparent management.

The Group Risk Management System has also been developed to ensure risk management. Continuous efforts will be made to improve the organization and fulfill our social responsibilities.

Highlight

Business continuity plan (BCP)

Ongoing efforts to improve our BCP based on lessons learned from the disaster.

In the Great East Japan Earthquake, Kyowa Hakko Kirin suffered damage to some sales offices, including the Tohoku Branch, but escaped any direct damage to production sites. However, plants of our contracted manufacturers were affected by the disaster. As a result, we had to take emergency measures, such as switching production to Kyowa Hakko Kirin plants (Fuji and Ube) and conducting pre-planned power outages. As we addressed the emergency situation, a number of unexpected issues emerged. Based on this experience, we are currently improving our BCP, including by conducting a review of inventory levels, developing backup plans to serve in the event of operational failure at manufacturing sites and considering measures to address unexpected power outages. In addition, we

are developing measures to ensure a stable supply of pharmaceuticals, including adding new manufacturing sites, surveying and sharing information on alternative products both in Japan and



BCP review meeting using a teleconference system

abroad and improving internal systems.

Our ongoing efforts include the reorganization of documents that have been developed independently by each business site to make them consistent with the underlying concept of the BCP (the company-wide BCP Guidelines). We will further set and implement priority measures to address foreseeable risks and expand the application of the BCP throughout the Group. The Kyowa Hakko Kirin Group will pursue ongoing improvement of the BCP so as to continue to contribute to the health and well-being of people around the world.

Risk management

In order to ensure systematic risk control, a Group Risk Management System is in place to identify risks that may affect our business activities and prevent serious ones from materializing. The situation is followed up every quarter or half-term. The system allows us to consistently work on preventing damage to customers and our business, and to take appropriate measures swiftly if any incident should occur.

Corporate governance

We conduct our business under a management system and organization established to facilitate the realization of our Group Management Philosophy. We are also working hard to maintain the highest standards of corporate governance to ensure increased transparency and effective management oversight.

Strengthening corporate governance and internal control

Kyowa Hakko Kirin's management structure is centered on the Board of Directors and the Board of Auditors, organs required by the Companies Act for stock companies (classified under the act as a "Company with Auditors"). The Board of Directors consists of 8 directors, 3 of whom are external directors, and the Board of Auditors consists of four corporate auditors, 3 of whom are external corporate auditors (as of the end of March 2012). In accordance with the audit policies determined by the Board of Auditors, the corporate auditors attend important meetings, including meetings of the Board of Directors. They also audit the performance of the directors' duties by investigating the company's operations and finances. As advisory groups to the Board of Directors, the Remuneration Consultative Committee and the Nominating Consultative Committee, each composed of 4 directors including external directors, provide objective and fair advice and recommendations regarding the remuneration and nomination of directors and auditors to the Board of Directors. The Corporate Strategy Meeting has also been established to make strategic management decisions in an efficient manner.

To maintain the appropriateness of our business operations, the Board of Directors periodically reviews its policies on, and the current status of, the development of the Group's internal control system to assure continuous improvement of the system. The Internal Audit Department, which oversees internal auditing, works with the corporate auditors to conduct audits of business operations across the















Kyowa Hakko Kirin Group and monitor compliance with laws, regulations and the Articles of Incorporation, with a view to also enhancing management efficiency.

Risk management through in-house committees

Kyowa Hakko Kirin has various in-house committees (CSR Committee, Group Risk Management Committee, Group Environment and Safety Committee, Group Quality Assurance Committee, Information Disclosure Committee, Financial Management Committee) in place to deal with a variety of risks inherent in management decisions as well as issues of corporate governance. The committees regularly report on their activities to the Board of Directors.

Basic policy regarding information disclosure

The Kyowa Hakko Kirin Group regards investor relations (IR) as an important management issue and endeavors to provide shareholders and investors with information in a manner that is timely, appropriate, and fair. We have formulated our own disclosure policy to help shareholders and other investors understand the Group and to ensure the integrity and transparency of management.

Basic Disclosure Policy

Based on the principles of transparency, fairness, and consistency, Kyowa Hakko Kirin strives to provide timely, accurate disclosure of information to shareholders and other investors in accordance with the Financial Instruments and Exchange Act and the timely disclosure rules of the Tokyo Stock Exchange (TSE). In addition, Kyowa Hakko Kirin is committed to the timely, active disclosure of other information that, in the judgment of the company, will be effective in helping shareholders and other investors to understand Kyowa Hakko Kirin.

Communication with shareholders and investors

Results presentation meetings

Twice a year, following the announcements of interim and year-

end financial results, Kyowa Hakko Kirin holds meetings at which the President and other senior management members explain its business results and management policies to institutional investors and securities analysts.



Results presentation meeting

Publication of "To Our Shareholders" and annual report

We publish a business report, "To Our Shareholders," twice a year, and send it directly to shareholders. We also distribute printed English-language annual reports to overseas investors. These two publications, as well as our Japanese-language annual reports, are also available on our IR website.



English Investor Relations website: http://www.kyowa-kirin.com/investors/index.html

Listing on socially responsible investment (SRI) index

Recognized by the international community for its management approach and active environmental efforts, Kyowa Hakko Kirin is included on the world's major socially responsible investment indexes, including the FTSE4Good Index Series and the MS-SRI. (As of January 2012)





Morning Star Socially Responsible Investment Index

Corporate governance organization

As of April 1, 2012



Third-party Review

The Kyowa Hakko Kirin Group has sought advice since 2010 from Mr. Hideto Kawakita, a CSR specialist who has consistently reviewed the reports of our Group companies with an expert eye. We asked him again this year to provide his views on the contents of our CSR Report 2012 and our efforts in general. We will seek to reflect his opinions and advice in our future activities and next year's report.

Mr. Hideto Kawakita

CEO, International Institute for Human Organization and the Earth (IIHOE)



profile

IIHOE: A nonprofit organization founded in 1994 for the purpose of promoting "democratic and balanced development of all the lives on the Earth." While its main mission is to provide management support to other NPOs and social entrepreneurs, IIHOE also offers CSR support to many major companies. http://blog.canpan.info/iihoe/ (Japanese only)

This review was written based on the contents of this CSR Report and interviews with employees responsible for environmental management, safety, procurement, human resources, and CSR. I confirm that Kyowa Hakko Kirin has effectively begun the PCDA management cycle with respect to fundamental issues in CSR.

Highly evaluated achievements

- To create workplaces where all employees, regardless of background, can reach their full potential (p. 17), Kyowa Hakko Kirin has established the Diversity & Inclusion Project with the stated objective of "achieving a corporate culture where all employees can make a valuable contribution regardless of gender, nationality, career before joining Kyowa Hakko Kirin, life events, or disability by fiscal 2015," and has focused considerable efforts on promoting the project. It is particularly noteworthy that the company is ready to discuss proposals presented by 6 cross-disciplinary teams. It is strongly hoped that the objective will be achieved at the earliest possible time through exchange and cooperation with external organizations, particularly with other companies and local groups.
- The percentage of Kyowa Hakko Kirin employees who took leave or availed themselves of the shorter working hours system to participate in childcare, long-term care, or nursing duties reached 4.39% (pp. 18-20). I recommend that the company increase opportunities to provide its employees with information on those who have experience caring for a family member at home. It would also do well to consider helping to expand the network of those who have continued to work after having a baby in order to facilitate the sharing of information, particularly within sales departments where there are currently few working mothers.
- Turning to the company's efforts to reduce environmental impacts (pp. 25-28), the sales volume of fertilizer material made from phosphoric acid recovered from fermentation wastewater has increased. It is my hope that the precision of recovery will be improved so as to decrease the total amount of phosphorus emitted into the sea and that increased cooperation with agricultural producers will be promoted so as to make more effective use of the recovered phosphorous.
- Kyowa Hakko Kirin has established the clear medium- to longterm goals of reducing greenhouse gas emissions by 3% from the 2007 level by 2012, and 15% from the 2005 level by 2020 (p. 27).
 More efforts, however, should be made to reduce CO₂ emissions,

energy consumption and per-unit energy consumption. I hope that such efforts will be made across the company and that they will not simply rest upon the introduction and replacement of equipment but on continuous and proactive innovation and improvement by employees at each business site.

Efforts that have shown progress but require more commitment

- Kyowa Hakko Kirin took proper measures after discovering the inappropriate management of transgenic mice at its Tokyo Research Park (p. 28). While this is commendable, I also hope that scenarios involving more than one accident occurring simultaneously will be incorporated into the business continuity plan (BCP) and that training based on those scenarios will be conducted. I would also like to see initial incident responses and disclosure of information implemented in a timelier manner, and that those involved in research activities have an accurate understanding of risks and their potential impacts to ensure appropriate and meaningful activities.
- In its efforts to improve mental health (pp. 19-20), the company has developed and implemented specific measures, including a new training program and face-to-face meeting for employees in their second year of continuous employment, which I found noteworthy. It is recommended that a system be established to effectively eliminate a variety of hindrances at an earlier stage, including the establishment of a counseling center where employees can seek help on any issue, including non-work-related issues.

Points where further efforts are expected

- Procurement of raw materials (p. 30): I am deeply concerned that the company is still yet to establish a plan to prompt raw material suppliers to fulfill their CSR. I welcome the decision by the company to conduct a basic survey in fiscal 2012 with the aim of reducing environmental impacts during collection, production, and refining processes, promoting the human rights of the people engaged in the processes and those living near the sites, and gaining an understanding of how its suppliers are implementing their CSR. It is strongly hoped that the scope of the survey and the individual survey items are as extensive as possible. I would also like to emphasize that, to preserve biodiversity at raw material/sample collection sites, it is important to give appropriate consideration to and take the necessary action for access and benefit-sharing (ABS) for local residents.
- Employment of people with disabilities (p. 18): I give the company credit for its efforts to achieve the statutory employment ratio for employees with disabilities. Through a wide and detailed study of the best practices of other companies, it is hoped that more efforts will be made to form a community in which employees with disabilities can advise and support each other so as to prolong their employment.
- "Commitment to Life," mission statement (p. 6): I understand that many employees have been involved in developing the mission statement and many have joined the company because of this statement. I therefore recommend that the company create more opportunities for all employees to participate in sharing information on how the statement has been implemented at each department.



Response to Third-party Review

Yoshiharu Furumoto
Executive Director of the Board
Executive Vice President



Based on the understanding that to fulfill the requirements of the ISO 26000 international guidance standard on social responsibility is to meet the expectations of society, the Kyowa Hakko Kirin Group has started preparations for incorporating the 7 core subjects of ISO 26000 into specific efforts implemented by each Group company and organization. Still in the initial stages, we need to ensure compliance and risk management in order to translate the issues first into actions and then tangible outcomes. At the same time, it is essential to develop a new system that helps us identify social expectations from the stakeholder perspective and apply the PDCA cycle effectively to address issues identified by each company and organization. In this context, it is very important to seek objective and expert advice from a third party. Let me take this opportunity, therefore, to express my appreciation to Mr. Kawakita for his valuable comments

Mr. Kawakita's remarks on issues related to human rights, labor practices and the environment included both favorable and unfavorable comments. His comments indicate that we need to focus more on the promotion of communication-both with external parties and within the company-and on the formation of networks to facilitate mutual cooperation and the sharing of information. With regard to fair operating practices, he expressed deep concern over our failure to establish a concrete plan to urge raw material suppliers to fulfill their CSR obligations. He reminded us not only of the key role of internal efforts but also of the importance of extensive involvement by outside groups, indicating that effective outcomes are impossible without such involvement. In relation to community involvement and development, he emphasized the importance of our participation on a daily basis and advised on how we can contribute to local communities. He also emphasized the importance and effectiveness of making information on our community involvement available to a wide audience. In response to his advice, we will place more emphasis on interactive communication with society at large in order to accurately identify public expectations and address them from the social perspective rather than our own.

He also recommended that we share information on specific examples of how the Kyowa Hakko Kirin's philosophy of "Commitment to Life" has been implemented. We will seek to reflect his comments in a concrete form in our future activities. Moreover, the Kyowa Hakko Kirin Group will continue in earnest its efforts to understand and meet social expectations as a socially oriented corporate group.

Kyowa Hakko Kirin Co., Ltd.

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