Scientific Instrument News
2023 Vol.19

INTERVIEW

20

Roles and Activities of CERI as Professionals in “Quantitation”

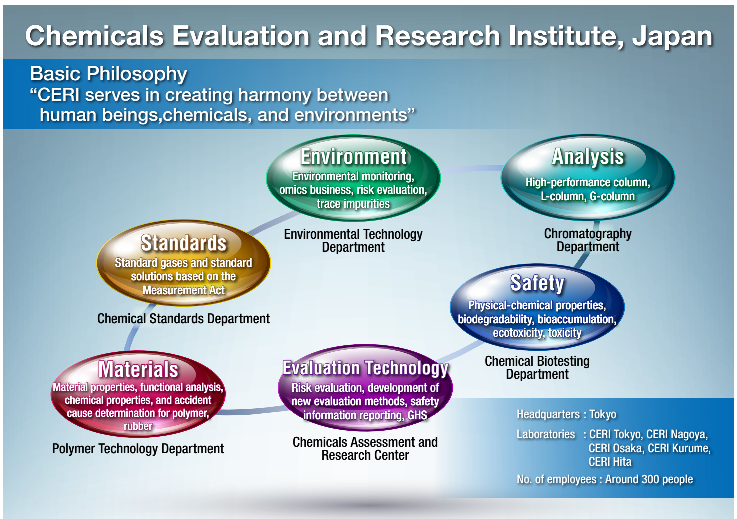
* CERI: Chemicals Evaluation and Research Institute, Japan

“If there was no value in the existence of CERI, then it would cease to exist. If we think about what is the value of our existence, then we must be useful for everyone”. These are the words of Mr. Kazuhiro Shikakume who serves as a managing director of CERI.

The work that CERI performs as an institute in the field of chemicals is to use chemical analysis methods that meet the needs of the client and submit reports to the client, as well as research and development related to this work. Although this makes it sound simple, CERI handles a wide range of chemical analyses. This extends from the environment including waterways and the atmosphere to the products around us, buildings, and infrastructure such as waterworks. This is a wide range that includes the field of polymeric materials including cellulose nanofibers and biodegradable plastics, work in omics in the life sciences, and extends to chromatography in what could simply be called the “fields of chemistry”, and is deeply rooted in our activities.

This broad range of fields is divided into the six departments of the Environmental Technology Department, Polymer Technology Department, Chemical Standards Department, Chromatography Department, Chemicals Assessment and Research Center, and Chemical Biotesting Department, which perform “chemical analysis” and “quantitative” analysis around-the-clock according to the goals of our clients, and which also explore experimental methods for these analyses.

In this article, we would like to present the worlds of “chemical analysis”, “substance evaluation”, and “quantitative” analysis performed at CERI by professionals in “(chemical) analysis” and professionals in “quantitative” analysis alongside interviews with those professionals.



1. Reference materials for "National Standards"

Kazuhiro SHIKAKUME

Dr. of Engineering, Managing Director
Chemicals Evaluation and Research Institute, Japan

"Any time we have something that we can 'measure' in the world, such as length, weight, and speed, we always have 'standards' "

When we think about "chemical analysis", this is almost always related to "standards". The Chemical Standards Department, which is one of the six departments of CERI, prepares, maintains, and manages the reference materials that are used as national standards (primary standards). As long as the quality of these reference materials has a universality such that they are able to function as "standards", the results of chemical analysis and quantitative values can act as universal "data". This means that reference materials are "essential" for chemical analysis.

Note that whereas the reference materials that are used such as in laboratories of various research institutes and private companies are reference materials that are subordinate to this national standard, CERI both develops the reference materials for the national standards and performs concentration determination of the subordinate reference materials. This ensures traceability from the widely used subordinate reference materials back to the national standards.

These national standards are for chemical reference materials that are measurement standards within the intellectual infrastructure*, which is public property of the nation. The reference materials connected to these national standards are supplied according to international standards such as ISO (International Organization for Standardization) and ensure the reliability of the reference materials. The system for ensuring the traceability of these is called the JCSS (Japan Calibration Service System), and certificates that bear the JCSS logo act as a guarantee proving that the materials were provided through this system. One of the major roles of CERI is to maintain and manage this JCSS.

*Intellectual infrastructure:
A concrete policy with aims such as maintaining and enhancing national competitiveness, promoting innovation, increasing the reliability of corporate activities, ensuring a manufacturing infrastructure for small and medium enterprises, and ensuring the safety and security of the lives of private citizens. The third stage of the "plan for establishing intellectual infrastructure", which lays out the plan covering the period up to 2030, was published by the Ministry of Economy, Trade, and Industry on 31st May 2021.

Building a system for “measurement”

Mr. Shikakume said that although there are “standards” wherever there is “measurement”, and JCSS is the system that allows these “standards” to function universally, it is difficult and takes a long time to get this system of “standards” embedded into society.

The Environmental Technology Department that Mr. Shikakume leads is involved in environmental measurements in response to the problem of pollution, measurement of controlled substances, and the omics business. Among the businesses which perform analysis work related to the environment, including not only CERI, many institutes perform measurements of controlled substances in tap water. When the quality of tap water is measured, the water quality standards are defined in terms of “controlled substances” such as lead, cadmium, and zinc. There are various measurement methods for detecting each of these substances, and there are also “standards” for the reagents that are used for this. Surprisingly, however, it was not until April 2015 that JCSS standard solutions were approved for use in water quality standards testing of tap water. “Up until then, only liquids prepared in-house by the stipulated methods were used, and it was not permitted to use purchased reagents. Although it was obvious in the past that you would create the reagents in-house, and everyone was able to prepare them because that is what we were taught at university, this is no longer the case”.

When it became possible to use purchased reagents, the need arose to focus on the importance of ensuring traceability. However, the path to understanding this was difficult.

Talking about the situation before 2015, he said “There was a time when we went to various government agencies asking them to use (JCSS standard solutions). No matter which agency we went to, we were rejected along the lines of ‘what on Earth are you talking about’ (laughs). They did not know of what other agencies are calling national standards, and so they said ‘we will not use such standards’ ”.

However, as times have changed with the trend toward globalization, attention has gradually turned to the traceability of reference materials. Although the decision for whether or not to grant the JCSS logo to a particular substance for use as a reagent is left up to the state, one of the main jobs of CERI is to research the basic data used for that decision. The job of CERI related to maintaining this JCSS in terms of tap water testing is “building a system so that reagent companies are able to securely supply reagents to society”. Thus, this system has the extremely large meaning of ensuring reliability by enabling tracing.

The dilemma between allowing tracing and social dissemination

Although it can be said that recognition of the importance of JCSS and traceability of reference materials is growing, the fact is that many problems remain. Although the JCSS standard solution was allowed to be used in tap water quality testing by the Ministry of Health, Labour and Welfare in 2015, this did not extend beyond “adding” the solution. In other words, from the perspective of ensuring traceability, sub-par conventional reagents (self-prepared) continued to be used in many sites. This was not only limited to tap water quality testing. There remained great room for the spread of chemical standards with assured traceability.

There is also the problem of the cost of reference materials. In order to maintain the JCSS system, which is responsible for standards with assured reliability, some amount of cost is required. There is also the difficulty of overcoming the barriers between agencies, and the difficulty of changing regulations. If the regulations are changed, there is a possibility that users will need completely new equipment. Furthermore, there is the question of how to ensure traceability in the case where reference materials are imported from overseas. There remain many problems.

Mr. Shikakume also noted that private measurer face the dilemma of balancing cost against data reliability in tests, and the system has not become widespread. However, this current situation is probably just one “step” in the process of people recognizing the importance of test data with assured traceability. There has been definite progress with the establishment of JCSS such as use among government agencies, and proof of this can be seen in the progress made in the “plan for establishing intellectual infrastructure” that spans government agencies against the background of further globalization.

Considering this, the current situation in which problems still remain can probably be thought of as a forward-looking "paradigm shift". This is a paradigm shift in the many important themes related to "chemical analysis" such as reference materials, universality of test data, and what are the reliable "quantities", as well as the "recognition" of these by people. This may change the "awareness" and "recognition" of those who support and promote technical innovation and establishment of regulations.

CERI will continue to move forward with this "paradigm shift" as reliable "professionals" without recoiling from adversity. The "value in the existence of CERI" as stated by Mr. Shikakume in the opening paragraph will undoubtedly grow in this period of change in chemical standards and also into the future.

2. Holding "Imaginativeness" for Phenomena and a "Broad Perspective" for the World

Takeshi KONDO

Managing Director and Head of Polymer Technology Center
Chemicals Evaluation and Research Institute, Japan

"Quantifying various phenomena is our job"
"Where do the things we use come from and where do they go"

These are the words of Mr. Takeshi Kondo who is a managing director and head of the Polymer Technology Center, Chemicals Evaluation and Research Institute, Japan. The Polymer Technology Department is a department working on various "polymeric materials" from quality inspection and certification of rubber, which was a state-controlled product before World War 2 to rubber, plastics, biodegradable plastics, carbon nanofiber, and cellulose nanofiber today. Among the work of developing and researching various polymeric materials in addition to the "business" of test screening, certification, and submitting reports of requested materials at the molecular level, what does Mr. Kondo mean by "quantifying phenomena"?

"Materials and products have things called properties. Hardness, slipperiness, susceptibility to wear, toughness, heat resistance, cold resistance, insulation, conductivity.... How can these properties be "quantified" and provided to the client. Thinking about this, selecting the method of testing these is one of our main jobs". All material and product properties are "understood" as "quantities", and are reported in an analysis report. This is the job of the Polymer Technology Department. The order from the client contains in advance the properties and items for which "quantification" is required. However, Mr. Kondo said that there are also many cases where the properties and items that are required need to be considered by our institute.

"All of the properties change depending on how the product is used by the end user. Sometimes there are requirements for unexpected properties. This leads to 'product accidents' ". Mr. Kondo gave "drain pipe packings" as an example.

"Product accidents" and imaginativeness

Drain pipe packings are a "seal" part made of rubber for connecting drain pipes. In most cases, the test items needed by the client are "hardness", "recovery rate", and "durability", and numerical quantities such as "compression set", "water resistance", and "water absorption" need to be determined and reported according to each of these required items. The reason that "water resistance" and "water absorption" are listed is because it is envisioned that "the product will be in contact with water since it is a drain pipe" when used by a typical end user.

However, consider the following use cases for a packing that has been commercialized based on this kind of analysis.

For example, let us assume that a user in a condominium has poured paint thinner or lacquer down a drain pipe. Due to the extremely high miscibility of rubber and solvent, the packing absorbs the solvent and expands, and a "water leak" occurs due to a gap opening up in the joint between the drain pipes as a result. A "product accident" has occurred.

A more familiar example is when cooking oil is poured down a drain and remains in a U-shaped pipe. The same expansion will occur in the packing and a water leak will occur.

"Accidents occur like this".

This is the explanation by Mr. Kondo. In other words, since "solvent resistance" and "oil resistance" were not included in the envisioned end user usage conditions, the product was not able to handle unexpected usage conditions, and this resulted in a "product accident".

"Can we propose anticipated items outside those anticipated by the client? I think this is connected to whether a laboratory or research institute is seen as exceptional or not. This is the same as taking the idea of considering the amenity for not only the clients but also their customers within the ISO standards".

Whether it is possible to use "imaginativeness" to consider how the product will be used outside the requested range is very important as a test for preventing accidents.

Mr. Kondo said "What I'm saying is that young researchers should not only look at the client request, but must always include in their planning of how the product will be used at its destination".

"Broad perspective" on the world

"I think that we need to consider 'where the things that we use come from and where they go' ". This was the reply of Mr. Kondo when asked about environmental problems. Mr. Kondo gives the example of "wear particles from tires". "For example, where do bicycle and vehicle tires come from? I think that most people have the impression that tires are rubber, and rubber is collected from rubber trees. So when the tires they purchase wear down through use, they replace them with new ones. At this point, I want you to think about 'where did the part of the tire that was worn down go?' ".

The part of the tire that was worn down is tire that was broken off through friction with the road surface. Although we could think of this as similar to "pencil eraser shavings", when we consider that all vehicles move by friction with the ground, how much "tire shavings" are generated every day around the world? This is thought to be one of the major factors in the problem of microplastics, and this is an unavoidable problem.

"If you think about it, it is clear that the broken off tire falls onto the road surface, is washed into rivers and flows into the ocean. If we don't think about it, then we simply get the impression that the 'tire wears down'. However, the tire cannot simply disappear. If we think about 'where does it ultimately go?' not only for tires, but for everything, it naturally leads to a discussion of environmental problems".

When Mr. Kondo says "thinking about where the worn-down tire goes", he means this from the broad perspective of thinking about everything in terms of the fact that they must come from somewhere and must go to somewhere, and not just limiting our thinking to within the range of awareness of how we ourselves use them. In other words, having this kind of perspective is probably the same as having an "environmental awareness" in terms of its truest meaning.

"The same applies when items are incinerated. They do not simply disappear. When something is burned, it normally emits water, carbon dioxide gas, and there is always ash. So, 'where does this ash go?' Some of it is reused by mixing into concrete, and some of it goes into landfill. What about after it goes to landfill? It is exposed to sea water and dissolves. So does this eventually go to the ocean? Yes. What to do with it then and how to act is another problem, but at least everyone can think about the future destination".

Come to think of it, once we have finished "using" something, it does not simply "disappear". However, once something is no longer within our awareness, we tend to think of it in "the same way as disappearing". This could be said to be one of the factors behind the occurrence of serious environmental problems.

If we think about it, the topic of the imaginativeness related to "the need to think about how a product is used at its destination", which came up repeatedly in the topic of "preventing product accidents" is similar to the broad perspective of "where does it ultimately go?" The common ground in the topics discussed by Mr. Kondo is the awareness and stance of having a wider and more outward looking imaginativeness and perspective. Considering that the job of the Polymer Technology Department is to "quantify" phenomena, this awareness is reasonable.

The concept of "quantifying" phenomena means to express a pure "phenomenon" in the form of numbers that can be understood by reducing it to a finite number of tangible properties. Like the example of the packing, outside these finite properties there are sometimes "unexpected" or "subconscious" ones. Always paying attention to this fact is always "approaching phenomena" with true humility. This attitude will therefore connect to the awareness of environmental problems.

"I think that polymers are going in various directions. We will potentially see the creation of various polymers including in a state close to a liquid, those that resemble the properties of timber, metals, and ceramics, and those that have properties that we cannot even imagine at the current time. If C and H fibrous resin can be fixed into a 'timber state', it may be possible to 'create timber'. Furthermore, if carbon nanotubes could be made usable in electrical transmission lines, they would have a weight that is one tenth of that for current materials and could be transported using mini trucks...".

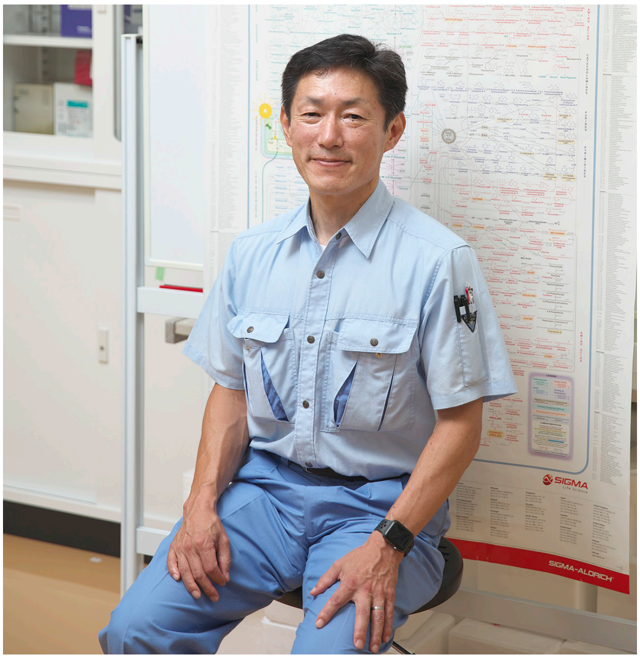
The future of the polymeric materials in which Mr. Kondo is immersed is endless. If we consider the "imaginativeness" and the "broad perspective" for the world of the Polymer Technology Department, there is no doubt that the future is approaching in a form that will be equally beneficial for all end users and the entire environment in which they exist.

Environmental Technology Department

The beginning of the Environmental Technology Department stretches back to 1972. At that time it started with performing "environmental measurements" to address the problem of pollution, and since then it has expanded into measurements related to "regulation" of hazardous substances in products. Today, this has advanced forward into life sciences fields related to the life and longevity of people, and they also participate in the "omics business" of genomics, proteomics, and metabolomics through measurements of all kinds of quantities within the human body.

We asked Mr. Hidenori Yamanaka who is a Chief Research Associate in the Technology Section of the Environmental Technology Department at CERI Tokyo Laboratory about the development of this "omics business".

3. Omics at CERI - Keeping up with Fast-moving Science



Hidenori YAMANAKA

Ph.D. of Engineering, Chief Research Associate, Technology Section Environmental Technology Department,CERI Tokyo Chemicals Evaluation and Research Institute, Japan

"Omics not only considers substances that are harmful, but also searches for good substances that are beneficial to people"

These are the words of Mr. Hidenori Yamanaka, Technology Section, Environmental Technology Department, CERI Tokyo, Chemicals Evaluation and Research Institute, Japan.

The history of the omics business at CERI began around 40 years ago when the Chemical Assessment and Research Center conducted business in environmental hormones, etc., in the field of bioscience. With the sudden rise in the omics field in around 2000, the omics business at CERI started in earnest through joining the NEDO project to use this omics technology to perform omics analysis of the safety of chemical substances and particularly evaluation of carcinogenicity.

"There was an awareness of the issue of performing evaluations of carcinogenicity in a shorter amount of time. At that time, the carcinogenicity of a substance was evaluated by administration to rodents, which both took a long time of around 2 years and had a cost of several hundred million yen per substance. By using omics analysis, this can be completed in 28 days. Furthermore, the data can also be determined down to the gene expression level." Mr. Yamanaka also explained that comprehensively treating data by using AI and deep learning is also important. "Genome, proteome, metabolome. Each of these includes the meanings of 'comprehensive' and 'overall'. The word genome is a combination of the words 'gene' and 'ome'. That is, it is 'genes overall'. Thus, these 'overall' and 'comprehensive' terms are important. This provides predictions of the properties of unknown substances by comprehensively obtaining and learning data. The prediction rate is over 90%. However, since there are many unknowns regarding what the predictions are based on, there is currently the problem that it is difficult to use the prediction results. 'How to use the comprehensively collected data' is very important."

The four areas of genomics, proteomics, metabolomics, and lipidomics, which are part of the omics business, perform analysis of genes, proteins, metabolism (products), and lipids, and the analysis of these is "comprehensive". Actually, it is correct to say that it has become possible to analyze "comprehensively" through significant advances in analysis technology in recent years. For example, although the analysis of the human genome, which contains 3 billion base pairs, was finished in 2000 in the field of genome analysis, when it was first started around 1990, it was said that the analysis would take from 1,500 to 2,000 years. The meaning of this is that comprehensive analysis is "virtually impossible". However, with the outstanding technical innovation in recent years, such as improved computer performance, it has become possible to analyze the human genome in 2 weeks by using next-generation sequencers.

"The processing speed of DNA sequencers has greatly increased. The 'electrophoresis method' has not changed in 40 years since the 1980s, and 'capillary electrophoresis' is currently used. Although the method is the same, the analysis is faster as the result of a great increase in computer processing speed and capacity."

Considering that it was "virtually impossible" a mere 30 years ago, the fact that we have entered the age where the unit cost of analysis has greatly decreased due to the increased processing speed and that genome analysis can now be performed at the individual level is amazing.

"The fact that genome analysis is completed comprehensively is extremely significant in proteomic analysis. This is because it can serve as a reference for interpreting proteins from the expressed genes. Although this has previously been a hurdle to analyzing proteins, it has now been overcome. However, after determining the amino acid sequence, the question becomes 'what does it mean?' This is where the use of gene analysis data as a reference has greatly advanced the analysis of proteins."

In addition to finishing comprehensive analysis, Mr. Yamanaka gives the example of "PCR testing" during the coronavirus pandemic in which genome analysis offers a "high-sensitivity" analysis. "The 'PCR testing' for COVID-19 is actually DNA analysis. This amplifies and analyzes the DNA of the coronavirus. This property of 'amplification' is what gives the high sensitivity of PCR testing. However, proteins 'cannot be amplified'. It was said that the reliability of 'antigen testing' for the coronavirus was low, and this was because it is a form of protein analysis. Because of this, the analysis sensitivity was low compared to PCR testing. However, if we want to comprehensively analyze proteins that cannot be amplified, "high-sensitivity" DNA analysis results are of great assistance as a reference."

Omics as a business

As a business in CERI, they accept outsourcing of exploratory testing for disease and drug efficacy markers, and safety analysis testing of chemical substances for the living bodies. Among the above four omics businesses, the Environmental Technology Department performs proteomics (proteome) analysis, metabolomics (metabolome) analysis, and lipidomics (lipidome) analysis. In all cases, since analysis is performed by microanalysis using mass analysis equipment, these are handled by the Environmental Technology Department, while genome analysis is handled by the Chemical Assessment and Research Center.

The business of "exploratory testing for disease markers" such as for cancer involves performing an analysis of the proteomes of cancer cells and regular cells. This makes it possible to identify the proteins that are expressed uniquely by cancer cells and the factors that can be used to analyze the relationship between the expression and the stage of cancer progression.

Analysis testing on the safety of chemical substances consists of analyzing the kinds of effects a substance has on the human body by administering that substance.

"The things that are used in all of the analyses are test animals and cell cultures. The reason is because 'inductive' analysis must be performed. Although samples such as blood taken from people have individual differences due to age, gender, race, and lifestyle, cell cultures are mostly homogeneous. This makes it possible to universally analyze the various phenomena that occur inside the cells. Since substances with unknown effects cannot be analyzed by using biology based on reductive methods, this means it is 'inductive' ".

In terms of the second aspect of the safety of chemical substances, they get a lot of requests not only for investigating safety, but also drug discovery and investigating efficacy of drugs.

"Clients include universities and research laboratories, and there are also many corporate customers from food companies and pharmaceutical companies. We also get requests to search for promising ingredients for health foods. We have comprehensive measurement technology and the ability to use it, but how it is used is determined by consultation with the client including proposals from our side.”

One of the business/research topics performed by Mr. Yamanaka is proteome analysis of impurities in pharmaceuticals. For this, omics analysis technology is used for analysis of the impurities.

“Although the word antibody has become more commonly heard in relation to the coronavirus, there are ‘antibody therapeutics’ which are created by using animal cells. Because of this, when the proteins of those animal cells become mixed in, it may invite unexpected side effects, and those impurities need to be analyzed. Since the impurities are thoroughly removed during the manufacturing process of ‘antibody therapeutics’ and the amount of animal-origin impurities contained in the product is extremely small, high-sensitivity proteome analysis technology is used if the impurity is a protein, and lipidome analysis is used if it is a lipid”.

Speed of progress in science and technology and CERI

We asked Mr. Yamanaka about the outlook for the future.

“I feel that the advances in the world are really accelerating. When I was a student, the idea of ordering outsourced tests when performing research was inconceivable. However, today there is outstanding progress around the world, testing and analysis are becoming more sophisticated and complex every day, and costs are also decreasing due to higher speeds. Analysis has become more sophisticated to the point of being difficult to perform with shared equipment like at a university, and the equipment itself is undergoing dramatic progress. Furthermore, outsourcing has become inexpensive. If we consider that progress will accelerate even more in the future, it will become necessary to skillfully use outsourced testing to make faster progress in high-productivity research, and the demand for outsourced testing is expected to increase.”

The continual rapid advancement in science and technology will undoubtedly expand the field of activities of CERI through outsourced testing. Against this background, Mr. Yamanaka said the following about the image that CERI will aim for in the future.

“Although we have always had methods for quantitative analysis of biomolecules related to some kind of particular target harmful substance or toxicity, the thing that omics now offers is untargeted comprehensive analysis. In other words, by performing inductive analysis of comprehensive analysis results without only considering substances that are bad and have some kind of significantly harmful effect, we are able to ‘explore’ substances that have a mild effect, i.e. that are good for the body and have a beneficial effect. I think that by skillfully fusing the natures of these two analyses (convergence), we can aim for a perspective unique to CERI.”

Polymer Technology Department

The history of the Polymer Technology Department extends back to the Taisho era (1912 to 1926). Starting as a control association that inspected and certified the quality and properties of rubber, which was a state-controlled product at the time, the department became the Rubber Goods Inspection Association, which performed inspection and certification of exported rubber products based on the Export Inspection Act after World War 2, and currently performs chemical analysis, analysis testing, quality management, quality inspection, and accident investigation for polymeric materials and products such as rubber and plastic. More specifically, the department performs business and research spanning fields such as biodegradable plastics, cellulose nanofiber, carbon nanofiber, and weathering tests.

We asked Ms. Takako Kikuchi, Head of Technology Section 2, Polymer Technology Department, CERI Tokyo Laboratory about the topic of biodegradable plastic, Mr. Hiroaki Kondo, Head of Technology Section 1, Polymer Technology Department, CERI Tokyo Laboratory about the topic of cellulose nanofiber and carbon nanofiber, and Mr. Hirobumi Ito Head of Technology Section 5, Polymer Technology Department, CERI Tokyo Laboratory about the topic of material and product weathering tests (accelerated weathering tests).

4. Ideology and Environmental Problems - The True Nature of the Plastics Problem

Takako KIKUCHI

Dr. of Engineering, Section Chief of Section 2, Chemical Analysis area Polymer Technology Department,CERI Tokyo Chemicals Evaluation and Research Institute, Japan

“Although there is an impression that ‘plastics = bad’, this is quite removed from the true nature of the problem. The marine plastic garbage problem and the microplastics problem are completely different problems”

These are the words of Ms. Takako Kikuchi, Head of Technology Section 2, Polymer Technology Department, Tokyo Laboratory, Chemicals Evaluation and Research Institute, Japan (CERI).

In recent years, we have been hearing the word “microplastics” even in casual conversation. This is because the number of research papers related to microplastics has increased dramatically in recent years, and it has become a focal topic that is frequently discussed in various specialist journals. In contrast, the topic of "marine plastics" includes photographs of the awful fate of marine birds that have become entangled in fishing lines and lost freedom of movement, and the discovery of large amounts of undigested bottle caps, plastic bags, etc. within the stomachs of dead marine animals such as sea turtles and whales.

However, how many people recognize that these are two separate themes? Ms. Kikuchi is sounding the alarm that the incorrect awareness of these as a single "plastics problem" is spreading amongst people. This article therefore addresses the true nature of the problem by clarifying the existence of the separate problems of microplastics and marine plastic garbage.

CERI and advances in biodegradable plastics

Biodegradable plastics are plastics that are broken down by microorganisms. These have the property of ultimately returning to the natural environment through breaking down into carbon dioxide and water at the molecular level, and this field has attracted growing interest at a time when the disposal of plastics into natural environments such as the ocean is becoming a problem.

The history of evaluating this kind of biodegradable plastic and CERI begins around 20 years ago. Ms. Kikuchi reflects on that time.

"The 2005 World Expo in Aichi was known as the 'environmentally friendly expo' and 'love the earth expo', and was a time when biodegradability had become a fad in industry. The 'Green Plastic' (now called Biodegradable Plastic) symbol appeared in labeling of biodegradable plastics. This made it necessary to distinguish between biodegradable plastics and non-biodegradable plastics when granting the symbol. We thus began to be involved as an institute for developing and performing an identification test (biodegradability test)."

However, although various institutes were initially involved in the field of biodegradable plastics, that gradually died down. At that time, although biodegradable plastics 'sounded good', the hurdles to market entry were high including the high cost and difficulty of forming and processing, and they were abandoned by many manufacturers.

At this point, Ms. Kikuchi said that there are "fads" and "economic feasibility" in all research.

"Although the economic feasibility was low, CERI continued to perform research as a third-party institute. We continued to perform evaluation testing of whether materials developed by manufacturers such as agricultural mulch film could biodegrade without problems when mixed with compost or soil."

Ms. Kikuchi said that the continuation of research related to the green plastic identification labeling system while other regular testing institutes were pulling out lead to the activity in recent years.

Ms. Kikuchi pointed out that we are in the middle of recent rapid changes in a domestic trend regarding the 'marine garbage problem' which is leading to biodegradable plastics.

"In terms of the marine garbage problem, Japan has fallen far behind the environmentally advanced countries such as Europe. At the G7 meeting that was held in Canada in 2018, the only countries that did not sign the Ocean Plastics Charter were the USA and Japan."

However, the trend greatly changed in 2019. Mr. Abe who was the prime minister at the time proposed the "G20 Osaka Blue Ocean Vision" for reducing marine garbage pollution to zero by 2050 at the Osaka Summit which was held that year. Ms. Kikuchi said that the trends greatly changed in June and July of that year with various institutes beginning work on the marine garbage problem and starting to enact various projects.

"In June 2019, the 'Roadmap for Developing and Introducing Marine Biodegradable Plastics' was established led by the Ministry of Economy, Trade and Industry and Ministry of the Environment, and work on this began in earnest. Furthermore, starting in 2020, the 'Moonshot Research and Development Program' was started by the Cabinet Office in order to take on challenges that are currently impossible, and the 'Development of marine biodegradable plastics which can control the timing and speed of their degradability' was incorporated as one of the goals of 'Realization of sustainable resource circulation to recover the global environment by 2050'. We were asked to participate in this."

Within the "Moonshot Research and Development Program", 19 institutes including The University of Tokyo, Kyushu University, and corporations are participating in research and development led by project leader Professor Kohzo Ito of The University of Tokyo who is an authority in the field of polymers, and Ms. Kikuchi and coworkers are participating as a subcontracting institute.

"More specifically, there are two items. The first is the development of bio-based polymers by using inedible raw materials. This is connected to the aim of contributing to carbon neutrality. The second is "multi-lock type" polymers which offer a resilience function during use and begin to degrade in the natural environment when exposed to multiple stimuli at the same time."

According to Ms. Kikuchi, this "multi-lock type" differs from previous "biodegradability" in that it provides an on-demand environmental degradation function.

"Biodegradable plastics are degraded by microorganisms. In the agricultural mulch films mentioned earlier, this means breaking down by microorganisms in the soil and compost. In contrast, the 'multi-lock type' differs from biodegradation in that the degradation starts triggered by two or more natural environment conditions being met at the same time, such as heat, light, and salt concentration, which is then followed by biodegradation into carbon dioxide and water. This development is extremely difficult and challenging, and involves a lot of trial and error regarding the conditions, and is termed 'moonshot type' for this reason."

Furthermore, Ms. Kikuchi also noted that although for previous research such as into biodegradable plastics, there was a strong awareness of creating something better, the viewpoint of "social implementation" of how well its use would actually be accepted by people was weak. However, the current "Moonshot Research and Development" also places emphasis on the social implementation side of 'is it actually usable' and 'can it be accepted by the market'. Ms. Kikuchi said that part of that idea was that the safety and biodegradability would be evaluated 'by an evaluation method that could be accepted by the market' during the creation of the new polymeric material "in order to gain social and market acceptance" of the created material, "and testing institutes such as ours are useful for this".

In addition to the "Moonshot Research and Development Program", Ms. Kikuchi and coworkers also participate in ISO standardization in the New Energy and Industrial Technology Development Organization (NEDO) project. Currently, ISO standardization in the field of marine biodegradability is progressing under the leadership of Europe, and although Japan is currently in a reactive position, this NEDO project was the start of our nation working on the ISO standardization. More specifically, Ms. Kikuchi said that the project is aiming at creating Japanese-based standards and fixing and improving problems with the existing standards, and CERI is currently looking at the existing problems and will work on supporting the creation and development of standards by creating standards to match developed materials in the future and finding testing methods that are suitable for them. Looking at the current active state in the field of biodegradable plastics, Ms. Kikuchi and CERI are extensively involved in this trend.

True nature of problems that is difficult to see

Both the microplastics problem and marine plastics garbage problem discussed in the opening paragraph are "ocean problems", and are worldwide problems that not only affect Japan. Currently, a trend of rejecting plastics due to treating these two problems as a single "plastics problem" is becoming widespread among people. Firstly, Ms. Kikuchi pointed out that these two problems have completely different characteristics, involve different features and difficulties, and therefore are "deeply rooted".

"When we talk about the problem of microplastics, since mankind lives completely surrounded by plastics everyday, the problem of microplastics is unavoidable. However, the "badness" that is brought about by microplastics and the effects that they have on the ecosystem have not yet been truly evaluated. However, it is also a fact that there is widespread discussion that only raises concerns, such as 'we did a survey and found microplastics' ".

In terms of microplastics, Ms. Kikuchi said that, for example in Europe, unrecoverable scrubbing materials that are contained in products such as facial wash and toothpaste are partially regulated as "intentional additives", and although these need to be classified separately from the problem of microplastics that occurs when incorrectly-disposed plastic bags, pet bottles, etc. are thrown into the natural environment and flow into the ocean, they are mixed together.

Ms. Kikuchi said that she has her own thoughts when considering the "risk" in this microplastics problem.

"When we think about 'risk', the requirements we must consider are 'hazardousness' and 'amount of exposure (dose)'. If either is missing, then we cannot consider the risk. When we speak of 'hazardousness', the problem is that the ecotoxicity (safety) of microplastics has not been evaluated rigorously, and there is a significant lack of scientific evidence. In terms of the problem of amount, since wastewater treatment is properly performed in Japan, the outflow of microplastics via the wastewater route is limited in some degree. Thus, although routes other than wastewater such as garbage discarded into the natural environment have been investigated, identification of the routes and understanding of the actual amount are not yet complete."

In terms of the marine plastic garbage problems, its "accidental" nature has been keenly noted. For the examples of sea birds entangled in fishing line and ingestion of plastics such as straws as described in the opening paragraph, Ms. Kikuchi explained "these are accidents due to failures in garbage handling".

"I feel uneasy about the current trend of saying that plastics should be banned because accidents have occurred. Although it may not be such a great example, it would be like saying that cars should be banned because car accidents occur. Accidents always have a cause, such as not adhering to legal regulations, and what we look at is the 'circumstances' that cause accidents. The latter can be handled by employing modern technology such as by fitting automatic brakes or sensors. I feel like that is one way.

In terms of the examples of sea birds and sea turtles, although this was meaningful in terms of the photographs raising social awareness of the plastics problem, from another perspective they caused everything to become mixed together, and gave rise to the equation 'plastics = bad'. The reason why this kind of 'accident' happened to sea birds and sea turtles is not 'because mankind used plastics', but 'because it was not used and collected correctly'. This can be addressed by setting up and building collection and recycling systems, and for the 'circumstances' that cause the accident, we can attempt to prevent the 'circumstances' that lead to accidents by giving the plastics 'new functions' such as degradability, for example by working on moonshot-type research and development. This is the same as making improvements to cars. I think that this is the approach that we should take to the plastics problem."

Ms. Kikuchi said that working on environmental problems without being unnecessarily patient or overdoing it is important in terms of actually considering feasibility and sustainability.

"Environmental problems become easily connected to ideologies such as 'plastics = bad'. Disposable chopsticks were also considered bad for a time, but that is no longer the case. I would like all of the consumers to look closely at the true nature of the problem without turning to this kind of ideology when looking toward the plastics problem and further sustainable development goals (SDGs)."

As a third-party institute

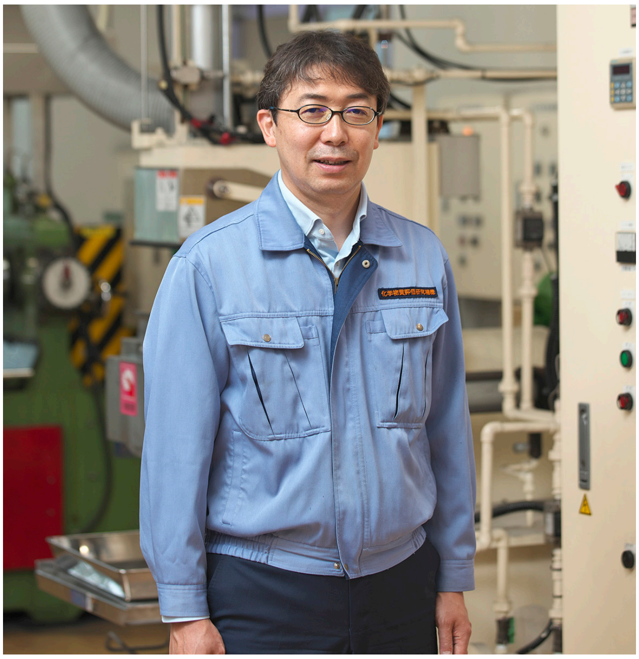
Ms. Kikuchi said that research and development has "fads" and "focus topics", and there is also the "economic feasibility" of the research to consider. Plastics also rode this kind of "fad". However, because of this kind of situation, the activities of CERI as a "third-party institute" are meaningful, and Ms. Kikuchi gave a vision for the future.

"As a third-party institute, I think that we are able to do the research that is really needed without looking at the 'productivity' or 'economic feasibility'. Regardless of whether there are many or few people who need that research in society, for fields that at least one person needs, we can face the data in a thoroughly scientific manner and help solve the problems."

Research into "environmental problems" has "fads" and "economic feasibility", and there is a tendency for the true nature to be difficult to find through the connections with all kinds of ideologies. This shows the difficulty of continuing to directly face the data without getting caught up in the times. However, as explained by Ms. Kikuchi, the "research that is really needed" definitively exists even today, and will continue to be created day by day.

First, we hope that the unfortunate stain on the name of plastics is wiped clean and the true nature of the problem can be clarified in society and discussed. It will not be long until the day that the true value of the various works at CERI is demonstrated including moonshot-type research and development.

5. The Fate of Materials - Development, Consumption, and Then What



Hiroaki KONDO

Ph. D. of Engineering, Head of Technology Section 1 Polymer Technology Department,CERI Tokyo Chemicals Evaluation and Research Institute, Japan

“Let us think about the ‘fate of material’. That is, consider the fate after goods have been created, consumed, and deteriorated. CERI is a place that allows us to consider this.”

These are the words of Mr. Hiroaki Kondo, Head of Technology Section 1, Polymer Technology Department, Tokyo Laboratory, Chemicals Evaluation and Research Institute, Japan. Mr. Kondo conducts research specializing in cellulose nanofibers (tubes) and carbon nanofibers (tubes) within polymer technology. Cellulose nanofibers and carbon nanofibers are both fibrous materials that have nano-size diameters as indicated by the word “nano”. Since they are lightweight and strong, they are used as fillers for various polymer materials, and are able to provide a variety of properties. Carbon nanofibers exhibit high mechanical strength and electrical conductivity. Cellulose nanofibers also have high mechanical strength, and are also connected to carbon neutrality since they are biologically based.

“Carbon nanofibers tend to agglomerate under normal temperatures and pressures. However, this reduces the strength and conductivity compared to individual nanofibers. The ‘unwinding’ process is therefore important for carbon nanofibers. However, the word ‘unwinding’ should not be interpreted as finely separating the agglomerated molecules, but as ‘controlling dispersion’. In other words, ‘appropriately controlling the dispersion state’ so that the required properties and dispersion level are fully obtained. This is the focus of my research.”

The idea of controlling the overall properties by controlling the “dispersion” of fiber molecules, which are the origin of the material properties, is extremely interesting. So then how is this related to the fields of “quantities” and “chemical analysis” at CERI? “The department that I am in charge of looks at ‘polymer processing’. Our work consists of accepting ingredients from customers, ‘creating prototypes” of rubber, plastic, etc., ‘analyzing’ the results as a test case, and reporting the analysis results including the completed product. The handling of actually ‘prototyping’ and ‘analyzing’ a material at the same time may be a unique aspect particular to CERI”. According to Mr. Kondo, performing “prototyping” and “analysis” together has a strong relationship with producing “quantities”.

“It is often the case that even when the same ingredients are used, there is some variation in the numerical quantities when the finished product is analyzed. This is because the conditions at the time of creation are different. If a material starts to be created using ‘stable processing’, it should have stable numerical quantities. Thus, the word “analysis” should not be thought of simply as analysis. It is difficult when the processing by which a material was created is not known. If we are asked to analyze some completed material, we should first consider how that material was made, how it is used, and what ingredients it is made of before we can produce ‘numerical quantities’.” This places the emphasis on “how a material is made” after the material has passed through the hands of the manufacturer who is our client. When a sample is simply analyzed, the numbers that are produced are nothing more than “an example”. It could also be said that “cause and effect” analysis is performed by considering the entire manufacturing process, in such a way that such numerical quantities were obtained from the product because it was produced in such a way.

“For example, heat and pressure may be applied during a processing. These will change the material. Given a material, the question is how it will change when some processing is applied. One of our strengths is that we have a database full of this kind of information, which I think other analysis institutes do not have. In other words, we have a stock of data on ‘materials where we know the answer’. Since we have a history of around 70 years, we have accumulated quite a lot of information. Since we know those manufacturing process, we can trace back a completed product through the previous stage processing. This is extremely useful for performing analysis.”

Although creating a prototype from the ingredients received from the client is important “work” as described above, CERI takes the stance of reporting everything down to the data during the prototype creation and the various methods used during fabrication in terms of conveying the tight cause and effect relationship between the “quantities” and “analysis results” for the completed product and the manufacturing stages.

“We are not manufacturers, and we perform work that we feel is useful for everyone from the public standpoint of a foundation. I feel that we want various information including the manufacturing process methods and numerical quantities to be used generously to create good products and obtain patents. That is our stance.”

Requests for development and analysis of materials are related to virtually all industries including chemical manufacturers, materials manufacturers, automotive manufacturers, and electronics manufacturers. Mr. Kondo pointed out that this comes against a background where it is difficult for typical private sector manufacturers to perform research and development. There are also issues with compliance, and it has become difficult to perform the various tests in an in-house laboratory.

Furthermore, there is also a lot of work related to standards utilizing their standing as a neutral institute making unbiased evaluations. Mr. Kondo has been involved in creating JIS standards and ISO standards for rubber. "Although standards and testing methods are often considered as a set, as an institute that performs testing from a neutral standpoint as neither a user nor a producer, we are involved in the creation of standards. There is a term international standards competition, and we cooperate and work together with the state and various industries to propose more standards from Japan."

Overcoming "valley of death" from nanofiber

We asked Mr. Kondo for his thoughts on the fibers that are the focus of his research as described in the opening paragraph in terms of the current state and future directions of materials.

"Carbon nanotubes are expected to find many applications including in batteries including fuel cells and capacitors, semiconductor devices, vehicles, and building materials. Furthermore, we also think that these materials will support the ever expanding electronics society.

In terms of cellulose nanofiber, this began as effective utilization of timber since there is a lot of timber obtained through thinning of forests in areas of Japan that have an abundance of timber. It was investigated as a replacement for metal in vehicles. Since it is also lightweight, it is expected to reduce the weight of vehicles and lead to reduced energy consumption."

However, as described above, due to it becoming stable by agglomeration, a lot of energy is needed for "unwinding" or "controlling dispersion", and this increases the manufacturing energy. Since this naturally increases the cost, its penetration rate as a material is currently not high. "There is a term '**valley of death**' in the industry, for example for technologies and materials that attracted a lot of attention at the research stage. However, there is a large chasm between this state and becoming commercialized and actually incorporated into a product. Many technologies and materials fall into this chasm. This is '**valley of death**'. It is large. I feel like carbon nanotubes are on the verge of crossing this chasm."

In the past, lead was used as a stabilizer in vinyl chloride resin, and asbestos and other materials were used in housing, but these have all become controlled materials. Mr. Kondo explained that although the effects on the environment and the human body cannot be ignored, "cost" can also not be ignored when considering materials to act as replacements for these inexpensive high-performance materials. "**valley of death**" represents a "dilemma" in the development and penetration of new materials.

What is the “fate of materials”?

“The long-established French global tire manufacturer Michelin has set a target and is working towards 100% sustainable tires by 2050. In the past, discarded tires were crushed into chips and used as pavement on pathways, and burned as a fuel. In contrast, now the materials that make up tires are returned to their raw material states.”

Mr. Kondo thus pointed out that this kind of trend of considering “what happens next” after all kinds of products are manufactured and consumed is currently becoming more active around the world.

“CERI also needs to consider how products are used, how they are consumed, and where they go as part of our basic philosophy. That is what I think. This is the ‘fate of materials’. If a new material is developed using the polymer processing that I am in charge of, CERI has technology to evaluate how that material will deteriorate in various environments, including the ‘weathering test’. We also have technology for evaluating the ‘biodegradability’ of how it will degrade. Furthermore, the Environmental Technology Department and Chemical Biotesting Department are able to investigate what kind of effect a material has on the ecosystem. By working together with other departments we can consider not only the development of the product, but also the subsequent ‘deterioration’ and ‘effect on the environment’ at the same time. I think that it is one of the wonderful aspects of CERI that it is able to offer multiple viewpoints and a broad perspective.”

This is probably because once some material or product is developed, the various departments have a “responsibility” for that development until the end through being in charge of performing analysis from start to finish. In any case, this idea is nothing more than downright serious and gentle “environmental awareness”. CERI, which has mechanisms for realizing this across the entire institute, plays a major role in society alongside this current global trend of “environmental awareness”.

6. Thinking together about the "Future Shape" of Materials - The Modern Era of Weathering Tests and Turning Points

Hirobumi
ITO

Head of Technology Section 5
Polymer Technology
Department,CERI Tokyo
Chemicals Evaluation and Research
Institute, Japan

All materials and products "change" or "deteriorate" as time passes. "Reproducing" this at a speed that is several times faster than reality is called a "weathering test". We now asked Mr. Hirobumi Ito, Head of Technology Section 5, Polymer Technology Department, Tokyo Laboratory, Chemicals Evaluation and Research Institute, Japan about this weathering test.

Mr. Ito said that the basic concept of the weathering test is originally to "have an answer". For example, if we assume that we have a car that has been running for 10 years in the real world, various changes and deteriorations such as discoloration of the paint and damage to the interior upholstery is expected to occur to the car. The basic idea of the weathering test is to provide an answer regarding "phenomena that occurs after 10 years" in a shorter time. However, Mr. Ito said that recently this has been increasingly misunderstood. "Recently, there have been a lot of people who think of the weathering test in terms of 'meaning future prediction'. For example, we get requests to know the state of deterioration after 10 years for a product when a new product is released. However, if you think about it deeply, nobody could possibly know what will happen to that new product after 10 years. Because of this, there is no 'answer' to this. This is 'predicting the unknown future' after 10 years."

Weathering tests consist of the following three elements. The first is acceleration. This is how quickly and in how short a time it can be reproduced. For example, 10 years of reality may be reproduced in as little as 1 week depending on the conditions.

The second is correlation. This is how much of a "correlation" there is between the real world results and the test results as the word suggests, and means "how accurately it is reproduced".

The third is reproducibility, which is whether the same results are obtained when the same experiment is performed. For example, if a weathering test is performed outdoors, then factors such as hours of sunlight, solar elevation (= amount of light), and amount of ultraviolet light will differ between the case of performing the test in Hokkaido and performing the test in Okinawa. Furthermore, even slight differences can have a large effect due to the "acceleration". This means that differences in conditions need to be considered.

However, Mr. Ito said that among these three factors, "acceleration" and "correlation" have a trade-off relationship. "If we are seeking more accurate results, it will take a longer time, and if we are seeking faster results, then we have to give up on high correlation. There are no weathering tests as yet that can guarantee all three factors to a high standard.

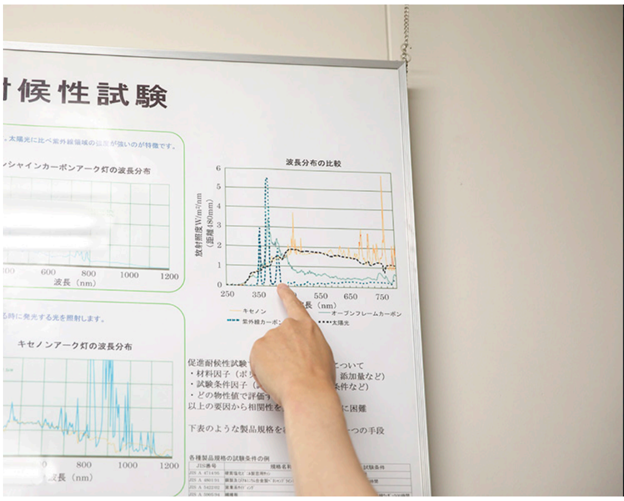
Therefore, we need to think about the needs of the client to achieve the best test and solution."

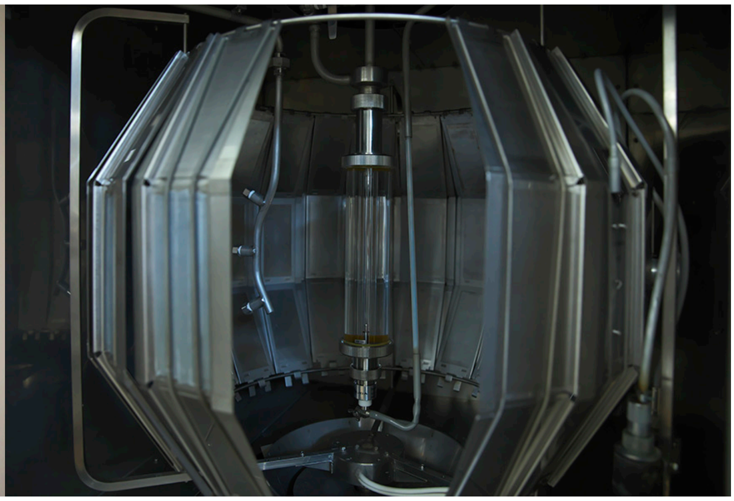
Mr. Ito said that although his job is to perform a weathering requested test, it is closer to proposing the appropriate test to suit the request. "We search for the weathering test that exactly fits the goal of the client from among our massive collection of previous test data. One of our main jobs is to think together about the best test to perform by cutting some of the three factors."

Even though the needs of the client can be put into a single word such as "degradation", this comes in a variety of forms. These are all kinds of changes, such as deterioration of physical properties, changes in colors, and surface appearance. Of course, they need to take into consideration which of these forms of deterioration the client most wants to know.

"Among various weathering tests, there are those in which the effect of rain is tested by spraying water. Recently, a method of acceleration by spraying hydrogen peroxide instead of water has appeared. This improves the acceleration by the photocatalytic action of white paint containing titanium oxide. While this can reproduce the equivalent of 5 years in Okinawa prefecture in around 1 week, although the reproducibility of the surface roughening by this method is high, the reproducibility of the color change is low. This is because of whitening by the bleaching action of hydrogen peroxide, which makes it difficult to reproduce the yellowing, etc. that occurs over many years. In other words, although this method is suitable for people who want to know about surface roughening, a different method needs to be proposed for people who want to know about the change in color."

Furthermore, although this method has data for white paint that contains titanium oxide, it does not have data for other materials such as polypropylene or polyethylene. They are also working on collecting that data.





Problem of differences in reproducibility

Furthermore, the problem of the test equipment for performing the weathering tests needs to be considered. Since there are differences in characteristics between test equipment made by various manufacturers, the results also vary. "This is the same as how the results of putting something in a 600 W microwave oven for 2 minutes vary to some degree between manufacturers." Although it is only 2 minutes in the case of a microwave oven, since it can take from several weeks to several years in the case of test equipment, the differences in results can become large.

Mr. Ito said that these differences between results, i.e. "reproducibility", have recently been a serious problem in Japan. "The needs for weathering tests in general differ between regions, such as America and Europe that have a demand for highly reproducible results even if it takes a longer time. In contrast, Japan has a tendency to demand results for a longer period in a much shorter time. For example, current building materials advertise warranties of as long as 50 years. When attempts are made to reproduce this using conventional weathering tests, the testing period takes around 10 years, which is too long to be feasible. In Japan, super-acceleration tests that give results for a 50-year period can be performed in 6 months to 1 year in some cases, and slight differences in reproducibility such as differences between positions and equipment becomes very large. The small difference in the case of 2 minutes in a microwave oven becomes a large difference in the case of 1 hour."

This is not the case when the test equipment is correct, and CERI collects data while performing comparisons with the results at standard testing sites with outdoor exposure in Choshi (Chiba prefecture), Asahikawa (Hokkaido), and Miyako-jima. "However, even in the case of outdoor exposure, since the weather differences over the entire year differed between 2019 and 2020, the results also differed. This is a very fuzzy field. We would like to propose the most beneficial methods for the customer including test equipment selection, testing method, and time period."

Paradigm shift and problem of differences in reproducibility at CERI in the future

"As an institute that handles organic materials, I think that we are tightly linked to the SDGs and the energy problems that are frequently mentioned recently. For example, the automotive industry and suppliers who frequently order services from us as customers consume a great deal of materials in Japan. If we think about the energy problem, as we transition to electric vehicles moving into the future, there will be virtually no need for hoses or belts, and this is expected to be a big turning point for the industry."

Mr. Ito said that they do not want to be "bystanders" at this turning point, but want to proactively search for ways to contribute to industry.

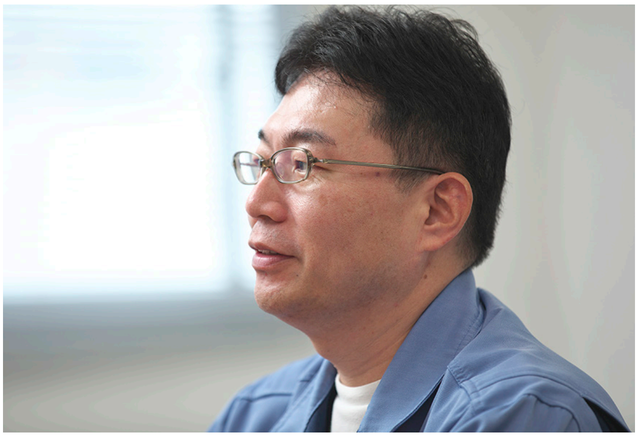
They have also seen an increase in the safety standards in weathering tests.

"Although I feel that the work we perform such as testing is simply outsourcing from the perspective of the manufacturers, I think that the range has been growing. The background is that the manufacturers are no longer able to perform tests that they previously did by themselves due to rising safety standards. I feel that the amount of requests from industries that we were not previously involved in is growing due to this situation."

The number of sections within the Polymer Technology Department has also increased alongside this trend. Mr. Ito said that the "niche range" that was previously handled by the department as a whole was now handled by individual sections, each having increasing specialization.

"In terms of weathering tests, there are sometimes cases where many outsourcing companies will not (cannot) accept work where there are 'special customers circumstances/conditions/needs'. However, I feel that CERI shines when it comes to these kinds of needs and special cases that could serve as case studies. Our job is not only to accept requests but also to think together about solutions and proposals."

Weathering tests need to reflect the individual needs of the client. The "nicheness" of CERI supports this individuality very well. In the current time that faces the two turning points of the energy problem and test compliance, CERI is broadening its field of activity.

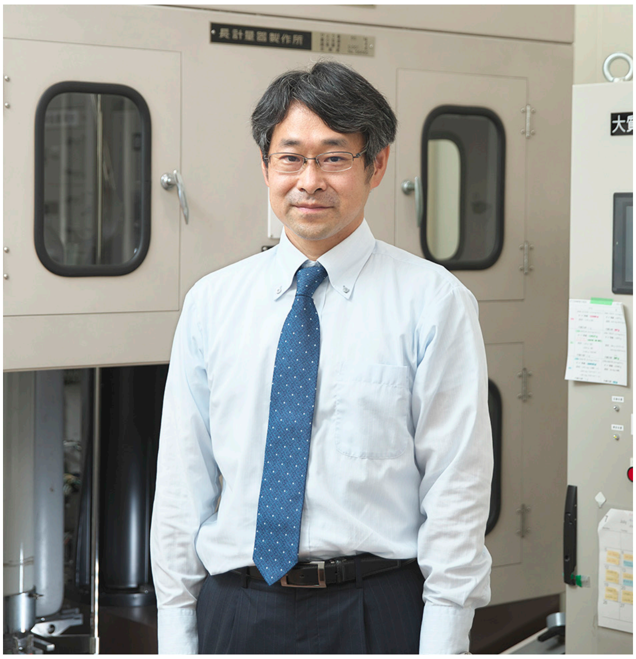


Chemical Standards Department

The Chemical Standards Department at CERI was deeply involved in the chemical standards within the measurement standards in the "intellectual infrastructure" established by the Ministry of Economy, Trade and Industry(METI) as a public property of the nation. They maintain and manage the national standards (primary standards) for the reference materials that are used in the field of chemical analysis. Although the reference materials that are normally used by the private sector are tertiary standards, they play an important role in terms of ensuring the traceability through higher level standards all the way back to the national standards.

We asked Mr. Shinji Uehara who is deputy head of the Chemical Standards Department, Tokyo Laboratory, CERI about the third stage of the plan for establishing intellectual infrastructure being promoted by the METI, including the relationship with future reference materials.

7. Disseminating JCSS Reference materials as a Third-party Institute - CERI and the Plan for Establishing Reference materials



Shinji UEHARA

Deputy Head
Chemical Standards Department,CERI Tokyo
Chemicals Evaluation and Research Institute, Japan

"Maintaining and disseminating Japan Calibration Service System(JCSS) is one of our main missions." These are the words of Mr. Shinji Uehara, Deputy Head, Chemical Standards Department, CERI Tokyo, Chemicals Evaluation and Research Institute, Japan. The reference materials that are handled by the Chemical Standards Department are standard solutions and standard gases. These are called "specified reference materials" (primary reference materials of JCSS), and the Chemical Standards Department prepares these, and maintains and manages their quality. However, it is difficult for the Chemical Standards Department to produce and supply working standards for users.

Because of this, accredited calibration laboratories maintenance and management of the quality of “specified secondary reference materials” (secondary reference materials of JCSS) whose property values are certified using quality-assured specified reference materials, and are responsible for the quality of working standards. Because of this, working standards are traceable to the highest level specified reference materials, and quality is assured. This system and framework is called JCSS.

Furthermore, the reference materials developed by CERI were decided in the Intellectual Infrastructure Development Plan. CERI contributed to decide participated on the plan. The plan for is currently entering its third stage. We will look back on the first and second stages of the plan and look at the progress made by CERI in terms of developing reference materials.

Intellectual Infrastructure Development Plan

The first stage of the plan for developing reference materials was led by the (later) METI from 1996 to 2010. At that time, Japan was in a situation of having very few types of reference materials compared to Europe and America, and the first stage of the plan was started in order to increase the number of types. The “Intellectual Infrastructure Development Plan” which contained a fixed numerical target of increasing the number to around 250 types on par with Europe and America by 2010 was published, and a number of different types of reference materials exceeding the target were established, so that the state of reference materials in Japan was pulled up to the level of Europe and America by the first stage of the plan. The second stage of the plan was to shift toward establishing reference materials that better suited user needs through interviews and exchanges of opinions with experts after the increase in the number of types of reference materials in the first stage of the plan. This was the “transition from quantity to quality” which was planned for 2012 to 2022 in the second stage of the plan and is still in progress.

The current third stage of the plan was started in advance with respect to the currently running second stage of the plan. A key point is how the previously developed reference materials can be used as efficiently as possible. “Although this plan is under the jurisdiction of the METI, at the time of the first stage JCSS had not penetrated at all to other agencies, etc. For example, in terms of the Waterworks Act, the barriers between agencies such as the Ministry of Health, Labour and Welfare were only overcome after the second stage had started. I hope that more of these barriers are crossed, and that JCSS becomes more widespread and used in a wider range of fields.”

According to Mr. Uehara, the fact that JCSS is becoming widespread in all kinds of fields has great significance in terms of industrial efficiency. “Before JCSS became widespread, companies needed to prepare standard solutions by themselves before performing analyses. Today, we are in a transitional period where although JCSS traceable reference materials can be used in some fields, they cannot be used in other fields. Since many businesses perform work that crosses all kinds of fields, improving the current situation where there is a mixture of whether or not JCSS can be used between different fields and creating uniformity using JCSS is highly meaningful in terms of increasing the efficiency of work. We are conducting awareness-raising activities through training sessions, etc. with related institutes such as the National Institute of Advanced Industrial Science and Technology, the National Institute of Technology and Evaluation, and the Japan Quality Assurance Organization.”

Reference materials as a business

"The importance business of CERI is the management work for the JCSS system. The clients in this case are accredited calibration laboratories. CERI carries out 'characterization' of secondary reference materials and issues certificates as requested by the accredited calibration laboratories. For reference materials, the property values of the specified reference materials always take precedence. For example, for a given gas standard, there are several different methods for determining property values (concentration), a representative example of which is 'gravimetric method'. A gas cylinder is sequentially filled with a component gas and a diluent gas, and the property value for the specified gas standard is found by measuring the mass of each using large precision scales. Next, a property value of the specified secondary reference gases is characterized with an analyzer calibrated using the specified gas standards. 'Certified value' of the tertiary gas standards for end users is then carried out by the accredited calibration laboratories using the secondary gas standards. The accredited calibration laboratories have also passed inspection based on the ISO/IEC 17025 standard, which ensures complete traceability from primary to secondary, and from secondary to tertiary." Furthermore, Mr. Uehara said that although the development and preparation of specified reference materials is performed by the Chemical Standards Department in addition to JCSS maintenance and management, unlike "standards" such as weights, for standard solutions and gas standards which are "standards that are consumed when used", "we need to continually create uniform substances". "In terms of manufacturing, we continually create specified reference materials periodically. In terms of maintenance and management, it is necessary to continually have precise reference materials by comparing and checking values against the immediately previous reference material."

Disseminating reference materials as a third-party institute

CERI has a great responsibility to handle reference materials as a third-party institute at the top of JCSS. With the recent spread of globalization, they have also participated in "international comparisons" as a designated institute nominated by the National Institute of Advanced Industrial Science and Technology, and have also participated in discussions about the types and concentrations of materials that are handled. Mr. Uehara was asked about the future prospects for this Chemical Standards Department. "Of course, I think that the role of the Chemical Standards Department of CERI is to overcome the barriers between agencies and promote the widespread use of reference materials. I think that we need to cooperate with the National Institute of Advanced Industrial Science and Technology to understand the on-site needs of users and reflect these in JCSS, the same as the third stage of the establishment plan."

Furthermore, while there have been some difficulties with the aforementioned "awareness-raising activities" and "training sessions" during the current coronavirus pandemic, they are also taking on new meaning. "I think that we need to aggressively promote awareness-raising activities to give more people a 'correct understanding' of measurement standards and chemical reference materials. In particular, although I have heard that a lot of training sessions, etc. have been conducted over the web during the current coronavirus pandemic, there has also been circulation of an 'understanding of standards' that is not particularly correct. Although this coronavirus pandemic has become one of the barriers to awareness-raising activities, I think that information about reference materials should be actively disseminated to more people such as by information over the web. Making JCSS more widespread is one of our main missions."

Chromatography Department

This department manufactures and supplies the columns that are used in gas and liquid chromatography, and is the only department of CERI that sells products. Because of this, they perform research and development of chromatography and columns as products.

Chemical Assessment and Research Center

This department is positioned as a kind of "general research center" within CERI, and mainly performs research over business. They contribute in the form of research for operations such as measurement and analysis that is performed by the other business departments. More specifically, they perform measurements and develop testing methods mainly in fields of bioscience such as genes, proteins, metabolites, and carcinogenicity, focusing on safety evaluation of chemical substances, and are also establishing mechanisms for outsourcing to the private sector.

(Interviews/text: Shinnosuke Niii)