

# Expectations of the expanding role of regulatory science for chemical substances

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## Introduction

The term “chemistry” seems to be regaining a positive image, Prof. Shinji Murai observed in the Guest Editorial of Chemistry and Chemical Industry, January 2008 issue. Last year also saw Prof. Osamu Shimomura being crowned a chemistry Nobel laureate, which might have helped in raising the image of chemistry. This makes me very happy. However, Prof. Murai also commented on the negative image that the paradoxical term “chemical substances” carries, near the end of the same article.

In contrast to the increasingly positive public view of chemistry, there still seems to be confusion surrounding the term “chemical substances”. “Chemical substances” continues to have a negative connotation, as seen in the use of terms “harmful chemical substances”, “chemical hypersensitivity” and such like. Bookshops stock many books that stir up public fear of chemical substances. However, recent publications of such books attempt to communicate the true nature of chemical substances with scientific evidence to show why a certain chemical substance is hated or whether it is really to be feared. Especially books written by those with a pharmacological background, using the poison and/or medicine paradigm, have been historically good publications that communicate the nature of substances well. The nature of substances is, as Paracelsus puts it, “*Alle Ding sind Gift, und nichts ohn Gift; allein die Dosis macht, daß ein Ding kein Gift ist.* (All things are poison and nothing is without poison, only the dose permits something not to be poisonous.)” or even medicinal.

## Chemical substances

The first recorded use of the word “chemistry” in Japan was said to be by a late Edo era Western scholar, Komin Kawamoto, from the Sanda domain (the Sanda han) in the Settsu province (the Settsu no kuni) (“Western Scholar Kawamoto Komin”, Yasutoshi Kita). Though who first used the term “chemical substance” is unknown, the general public now uses the term freely and widely.

The question of delineating the difference between a substance and a chemical substance is a difficult one to answer. Let us see how the dictionaries define the term “chemical substances”: In *Kojien*, editions four (1991) and five (1998), it is defined as, “A term to describe a substance, especially one of the substances that are subject to the study of chemistry, almost of the same as ‘pure substance’”. However, in the sixth edition, published in 2008, it was revised to, “A term to describe a substance, especially one of the substances that are subject to the study of chemistry. Often used to mean a chemically synthesized substance or an artificial substance, though this is not the original meaning.” This version omitted the previous definition of it being a synonym of ‘pure substance’ and added a new clarification stating that although the term is often used to mean a chemically synthesized substance or an artificial substance, that is not the original meaning. This is a very accurate explanation.

I attempted a search for the keyword, “chemical substance”, in six newspapers: the four major newspapers plus the Nikkei Sangyo Shinbun and the Chemical Daily, using the Nikkei Telecom search service. In publications from the

last three years, the Nikkei had 335 hits, Asahi 622 hits, Mainichi 707 hits, Yomiuri 1,312 hits, Nikkei Sangyo 532 hits and Chemical Daily 1,155 hits. Despite inconsistencies between the papers, this result shows how large the number of articles about chemical substances is. The content of the articles varies considerably. In many cases, the term used in the articles concerns various accidents and incidents as a prefix for the particular substance in question, such as, “the chemical substance melamine”; “strong cancer causing chemical substance benzene”; “harmful chemical substance tetrachloroethylene” and “the chemical substances found in cannabis, cannabinoids”, although there were some general newspaper articles that used the correct term, “organic chemical compound melamine”.

One could even hazard a guess that the recent tendency of opportunistic, uninformed and ad hoc use of the term “chemical substances” might have prompted the revision in the *Kojien* sixth edition.

## Statutory regulation of chemical substances

There was a time when I was involved in the safety evaluation of chemical substances. As an operational manager licensed under the GLP (Good Laboratory Practice; the criteria for a laboratory of the highest standard) provision in Chemical Substance Control Law, I was, on several occasions, at the receiving end of on-site inspections and audits by METI, the governing authority. The substances handled in business activities are under regulation by various laws concerning chemical substances including the Chemical Substance Control Law/CSCL (Act on the Evaluation of

Chemical Substances and Regulation of Their Manufacture, etc.); Law concerning Pollutant Release and Transfer Register/PRTR (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof); Occupational Safety and Health Act; and others. Each piece of legislation has its own definition of the chemical substances it regulates. It is prudent to be cautious, as the definition of such a chemical substance may vary slightly according to the relevant legislation. These statutes designate the Ministry of Economics, Trade and Industry, the Ministry of the Environment and the Ministry of Health, Labour and Welfare the governing authorities, and make the units such as department of or office for chemical substance management at the respective ministry the actual agency that implements the regulation. From this situation one cannot help but get the impression that chemical substances are substances that are regulated and managed. (Hereinafter, the term “chemical substance” is used for the substances that are subject to statutory regulation.)

The safety of chemical substances is controlled by a range of statutory regulations according to purpose and form of use and type of exposure of each substance. Among such laws, the Chemical Substance Control Law is especially important to a chemical technologist involved in the research, development and manufacturing of novel chemical products in the chemical industry. This law was established in 1973, in response to a chemical product-related accident that was completely different to any previous chemical pollution incident. Detailed background of the establishment of the law, history to date, content of the regulation and status of implementation are available at METI and the National Institute of Technology and Evaluation (NITE) websites, and I will not go into it further here. Currently, there is an ongoing discussion about the revision of the Chemical Substance Control Law in response to international trends in the safety regulations of chemical substances. The highest priority of which would be, as it has been said, the effort to shift from the hazard-assessment approach to the risk-assessment approach.

However, risk assessment requires expertise related to exposure assessment in addition to the hazard assessment. To achieve this, cooperation, understanding and collaboration are essential throughout the entire supply chain from the upstream end where the chemical substances are manufactured to the downstream where such substances are used by the manufacturers to produce automobiles, electronic appliances, construction materials, etc., and the consumers.

### Regulatory sciences

Although yet to be recognized widely, there is an academic scope, called regulatory science, covering scientific research related to various statutory regulations and risks. An American Physicist, Weinberg, first used this term in 1972 to raise awareness in this area. In Japan, Dr. Mitsuru Uchiyama (then of the National Institute of Hygienic Sciences) has developed this concept in drugs and foods since 1987<sup>1)</sup>. He defined it as, “...a science to create the methodology to understand a substance or phenomenon that is around us, including the knowledge about its origin, mechanism, quantitative and qualitative properties, and its impact in terms of efficacy and harm. Outcomes of this science will then be used to predict and help citizens’ health through administrative measures.” It is a science to regulate (and adjust) science and technology to the most desirable form, in harmony with people. Its application and discussion have been ongoing in areas such as drugs, agricultural chemicals, food products, atomic energy and so on.

Dr. Uchiyama went further by saying that regulatory science uses basic sciences as the means, with additional purpose to perform projections based on empirical data. In other words, it is the science of evaluation. Projection is an essential factor in rule making.

Applying the concept of regulatory science to safety assessment, projection, regulation and adjustment in chemical substances has significance. In The Chemical Society of Japan, Professor Isao Shimizu (of Waseda University) convened a symposium titled “Roles of The Chemical Society of Japan in Regu-

latory Science” at the 84th conference for spring, held in March, 2004. Participants from industry, government and academia shared their insights and information related to the comprehensive management of chemical substances. It was followed by vigorous panel discussions involving many participants on the floor.

In terms of statutory regulations, the regulator and the regulated are, in principle, on an equal footing. In other words, the law equally restricts the regulator as well as the regulated. The law makers representing us, the citizens, establish or abolish the laws. It is necessary for all four parties, industry, government, academia and the public, to have equal footings in implementing rational risk control of chemical substances backed with scientific evidence for the benefit of society. We chemists and chemical technologists, who carry out the mission to research new technology and novel substances, and to provide society with useful new chemical products, also have to regulate ourselves strictly and maintain our awareness for a harmonious society. Regulatory science includes the skills to design a system for society.

I hope the debate on regulatory science for chemical substances continues, and more energy in tertiary education will, in addition to ethical education, be directed into legal education related to science, technology, safety and society.

- 1) M. Uchiyama (editorial supervisor) “Development of Regulatory Science— for the Forum of Government, Academia and Industry”, Elsevier Japan, 2004.

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