Development of a risk assessment system for soil contamination and the application to the social system

— Processes in *Synthesiology* for practicing an advanced environmental risk management —

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In developing risk assessment technology for soil contamination, it is essential to carry out a wide range of fundamental research and to synthesize the results into a single system. We have carried out an integrated research project for a comprehensive risk assessment system; this project includes fundamental knowledge, database formulation, commercialization of technology, and the introduction of the research results to a social system. In this paper, we present a scenario in *Synthesiology*, the integration of each part of the research results, and discuss the spiral processes involved in the implementation of risk assessment.

Keywords **:** Soil contamination, groundwater pollution, risk assessment system, risk management

1 Introduction

The paradigm to manage soil environmental regulations in Japan has been shifted from governmental management into a self-governance framework, which is a risk-based approach on the basis of site-specific situations and environmental conditions at contaminated sites. The advanced paradigm for the governance framework was oriented from the methodology of exposure and risk assessment. Environmental media, such as soil and groundwater, compared with other media of air and water, exhibit the features of the limitation of exposure of contaminants from soils and the ease of controlling exposure to humans. Thus the risk assessment should include the mechanism of the exposure scenario specified at each site and under various geological conditions. In developing the risk assessment system for soil contamination, it is important to consider the variation of soil properties and groundwater flow characteristics relevant to the geo-environment.

This study focuses on the development of a comprehensive risk assessment system for the geo-environment that includes various parts of soil, groundwater and sediments. In this research, we designed a program of full and integrated research of geology and environmental sciences in order to combine various technologies, because only conducting individually each research work is inefficient for the completion of risk assessment system. This approach has yielded great success in research and development, and the paradigm has changed to solving the problems of soil contamination by means of the spiral process of risk analysis and management.

In this paper, we present the development of the geo-environment risk assessment system, an outcome of the full research comprising of combination of various research areas, the components of integrated research, disclosure and widespread utilization of the developed system in industrial and social applications, and the trials of applying the output for environmental management and the social system. Furthermore, the advanced scenario in *Synthesiology*, from *Type 2 Basic Research*[Term1] to *Product Realization Research*[Term2], is also discussed to allow for the integration of various technology components.

2 Current situations of soil remedial action and research objective

The number of soil contamination surveys and remediation in Japan has increased very rapidly since the enforcement of the soil contamination countermeasures act in 2003. According to the current record published by the Japanese Ministry of

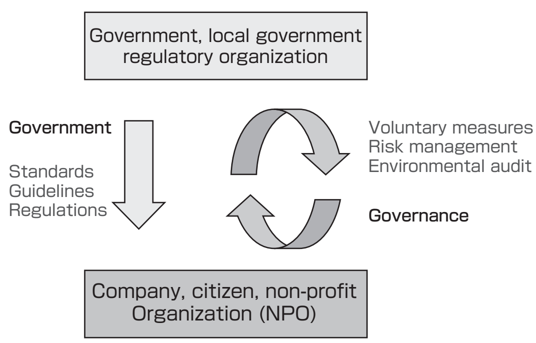

Fig.1 Structure of governance and contribution to environmental improvement.
This shows the difference of social system and approach of environmental management between legal system (government) and voluntary management (governance). The methodology of risk assessment and management is mainly applied in the approach of self-governance.

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the Environment, the official number of registrations by local governments for soil and groundwater remedial action was approximately 1200 in 2006, although the number of self-governance actions at industrial factories was much higher than the official value[1]. As the social background behind this trend, there are some typical situations of increasing environmental awareness and the active land transactions in recent years. Fig.1 illustrates the paradigms of environmental management; one of them is merely governmental action, such as environmental regulation, and the other is the governance approach by a loop-like various stakeholders including industry, citizens and non-governmental organizations. The spiral approach of the participation of all stakeholders is very important for achieving the successful management with multilayered governance[2]. The amendment of the soil contamination countermeasures act has come under review, because a new framework of cooperation between government and self-governance should be made applicable for comprehensive environmental management[3].

According to a survey by the Ministry of Economy, Trade and Industry of Japan, more than 90 percent of soil remedial actions were based on self-governance framework instead of the soil contamination countermeasures act. Those activities have been implemented by land or industrial plant owners in environmental management system, by means of voluntary measures[4]. However, there are no unified requirements on the methodologies of exposure and risk assessment and remediation actions, particularly for voluntary measures. Because of the lack of scientific information on exposure and risk, it is necessary to develop the risk assessment system that can be adopted for Japanese situations of soil and groundwater, from which we might be commonly exposed by environmental contaminants[5].

In taking such social and regulatory situations into account, integrated research work with various technology components has been carried out to complete the geo-environment risk assessment system. The role of governmental contribution in environmental policy and management is very important and is requested by local government and industries. This series of research include all related studies, such as the development of the risk assessment system, geological survey and data acquisition on site, and numerical simulation, as well as the disclosure and widespread utilization of the developed system. One of the significant outcomes is the introduction into social system for industrial location utilization, on the basis of product planning of the risk assessment system, and the development of databases necessary for such assessment. The final goal of this research is to establish the standardization of this risk assessment system for reasonable measures of soil remediation action in Japan. In addition, this system has some advantages, compared with other published risk assessment systems worldwide, such as the consideration of land use classifications, and the types of soil and geological media inherent in Japanese situations[6]. Thus we focus on widespread acceptance and utilization in many countries worldwide, particularly to Asian countries facing serious environmental pollution. Risk mitigation and cost reduction are the great contribution to any sector that uses the developed risk assessment system.

3 Significance in *Synthesiology* and research perspective

Fig.2 shows the processes of risk assessment in this research and spiral architectures based on the system development and user feedback. The research project is aimed at completing the risk assessment system, on the basis on of not only the accumulation of technology components, but also the integration with relevant analyses of each technology components. The original concept of introducing processes in *Synthesiology* to obtain the final goal is described below.

The existing environmental laws in Japan normally involve a uniform system of environmental criteria classified under concept of government action. On the other hand, in the current process of risk management, the regulations

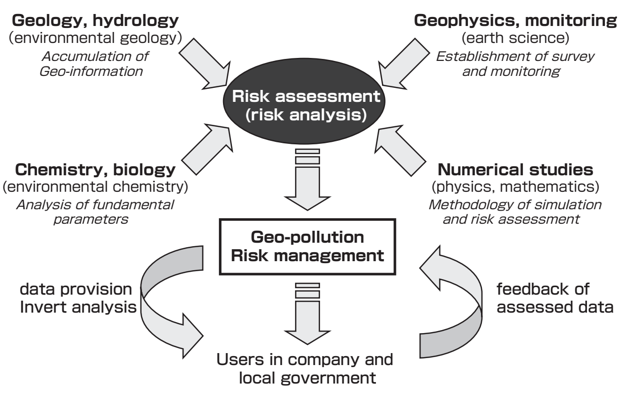

Fig. 2 Features of structure and approach in *Synthesiology* in this research.
This shows the scenario on the integration of technology components needed for competing the development, where a spiral structure is well characterized in developing the system and databases.

Table 1 Basic study areas and technology parts relevant to this research.

Exposure and risk analysis	Risk science (information science)	Risk analysis, Exposure analysis
Exposure scenario and factors	Safety science (toxicology)	
Geological structure database	Geology (urban geology)	Geological survey, Groundwater flow analysis
Soil and groundwater properties database	Environmental geology (hydrology)	
Flow and transport database	Earth and geo-sciences	Geophysical exploration, Environmental monitoring, Chemical analysis on site
Parameters of interaction with soil and organism	Environmental chemistry (chemical, physical analysis)	
Chemical substance database	Physical chemistry (equilibrium and kinetics)	Chemical partitioning, Biology/ecology
Datasets for environmental pollution	Environmental sciences	
Numerical simulation method	Fluid and computational sciences	Numerical analysis, Visualization of results
Formulation and visualization	System engineering	

have shifted to the system of self-governance, as shown in Fig.1. Since the process of self-governance is based on the participation of multiple stakeholders, it would be an effective measure in the environmental management system in the near future, considering the possible industrial structure with sustainability[7]. Thus this research adopted the original scenario of the integration of technology components and the interactive communication, on the basis of a unified index of environmental risk, to obtain the change in the paradigm of environmental policy.

The integration of fundamental studies, such as those in geology, environmental and earth sciences, is essential to achieve the landmark of system development, as listed in the table. In particular, information on soil properties, groundwater aquifers, and geological structure at sites is essential to obtain reliable assessment results. The characteristics of chemical and existence forms of pollutants and the parameters of exposure are also very important in realistic risk assessment. These research parts have features with complementary relationships that should be integrated to a uniform system by means of a common criterion. In the research program we intended to make up of a scientific consistency for data and parameters needed in the risk assessment. Thus we conducted the uniformity of methodologies and research management.

Some basic research, such as the formulation of equations for exposure assessment and the numerical simulation, are principal areas in the development of the risk assessment system. In addition applied research areas, such as the technological parts on geophysical exploration and groundwater hydrology at contaminated sites, are also quite important for the integration. Therefore, we have made some efforts to correlate these research results into the product of geo-resources risk assessment system, synthesized with a unified index of “environmental risk”. The verification of methodologies and parameters used in the system is essential to complete its development. Thus the assessment data is validated with the monitoring results to be obtained through feedback from the users, and experts and professors finally examine the system to validate it for public application.

4 Study on technology components and methodologies

The technologies needed for the development of the geo-environmental risk assessment system cover a broad range of components. There are various elemental sciences and technologies, such as geological survey, contamination assessment, analytical and simulation methods, monitoring, and risk analysis. Then we designed a comprehensive research program including those parts of technologies and integrated it into the risk assessment system for soil and groundwater contamination.

4.1 Development of methodologies for exposure and risk assessment

The principal concept for identifying hazards and quantifying risks from contaminants in soil and groundwater environment was proposed in the first step. The major exposure pathways are direct intake from soil and subsoil, indirect intake from groundwater, indirect intake from dust and vapor in air, and bioaccumulation through food intake[8]. Almost all exposure pathways and scenarios are considered in the concept of risk assessment (Fig.3). Two types of cancer (oral and inhalation) and non-cancer risks are assumed to be the endpoints[Term3] for risk assessment. In considering exposure scenarios, health and social investigations were conducted to define Japanese default values, such as exposure factors (mean weight of person, rates of water and air intake, average rate of soil injection), and other factors of frequency and chance of exposure. In the step of exposure assessment, the rate of exposure in each pathway, and the distributions were calculated for both cancer and non-cancer endpoints. In order to define risk level, hazard information, such as the dose-response effect and the characteristic equations, was included in the system. Multi dimensional numerical models for transport analysis in subsurface media have been developed to quantify the exposure concentration.

4.2 Properties of contaminants of concern and unregulated chemicals

The accumulation of data on the fundamental properties of chemicals and the correlation between soil and pollutant is essential for completing the risk assessment. Chemical substances intended to be assessed with this system are heavy metals, volatile organic compounds, pesticides, as regulated in the soil environmental law in Japan, and other pollutants,

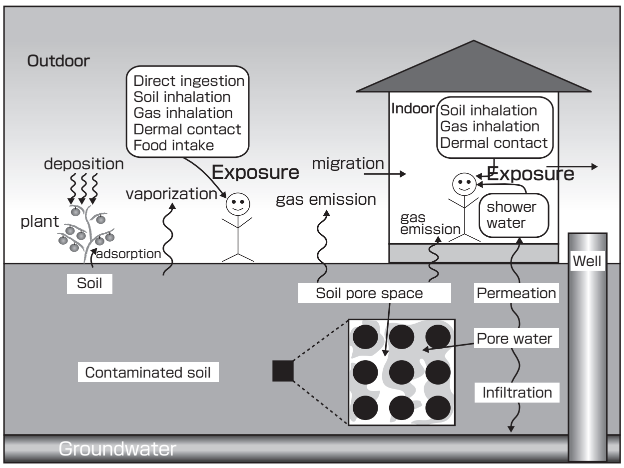

Fig.3 Exposure scenario and exposure pathways in risk assessment.

This illustrates the concept of exposure scenario in risk assessment for soil contamination. The assumption of exposure pathways, such as direct ingestion, and indirect intake from groundwater, air, and foods, is necessary for exposure assessment.

including dioxin and PCB compounds. Unregulated contaminants such as zinc, antimony, and formaldehyde, and mineral oils (petroleum hydrocarbon) are also target substances in this system. The database of the properties of 120 chemical substances and various parameters (Henry's constant, partitioning coefficients for soil-water and water-octanol) have been developed and improved through detailed examination of existing research papers and documents[9]. Because of a lack of data for petroleum hydrocarbon and PAHs (polycyclic aromatic hydrocarbons), the environmental parameters and properties, rate of vaporization, sorption coefficient, and diffusion coefficients in soil and water, have been experimentally obtained by soil column tests and partitioning examinations. Furthermore the system can be applied for complex pollutants to expand the function of the risk assessment protocol to multi components[10].

4.3 Geological information and the establishment of analytical methods

The geological information, including physical and chemical properties of soils, geological structure from topsoil to aquifer, and the behavior of groundwater flow, is very important in realistic risk assessment. In order to analyze the properties of topsoil, the existing classification method of soil types was modified using by the data obtained from geological surveys in many areas. One of the outputs in this study is a publication of geochemical and risk assessment map of subsurface soils in Miyagi Prefecture. The methods of the chemical analysis of soil components, heavy metals and other toxic substances have been established to obtain the database for both total content and leaching content[11]. Regarding the chemical and existence forms in soils and rock elution, the original method of serial extraction was developed to enable the consideration of both the toxicity and exposure rate of pollutants.

Convenient and prompt methods of soil sampling have been introduced in geological surveys at contaminated sites. The application of geophysical technique to soil contamination survey has become easier, particularly for soil sampling and contamination survey, because this technique has the advantages of low cost and low impact on the environment. As a result, geological information on the three dimensional subsurface structure and the hydrological situation has been clarified in the form of visualized data by the methods of geophysical exploration using electromagnetic and specific resistance media[12].

4.4 Analysis of soil and groundwater characteristics

In order to obtain fundamental information on the transport and migration of pollutants in soil and groundwater, some pollution surveys and monitoring were carried out for model and actual contaminated sites. The environmental parameters, such as permeability and diffusion coefficient in unsaturated soil, have been identified and analyzed. Since there was very little data on mineral oils containing various kinds of hydrocarbon, the parameters for multiphase flow and transport in soil and groundwater were measured by column experiments[13].

The chemical and biological transformations and degradations of contaminants in soil and groundwater can affect the result of risk assessment. The practical data on sorption by soil and clay minerals, chemical reactions, and biological degradation rates have been obtained on site surveys and laboratory experiments[14]. The correlation between soil and contaminants, particularly for heavy metals and VOCs (volatile organic compounds), was examined at several selected sites in Japan. In the survey of topsoil, the physical properties of soils, the properties of sorption and desorption, and the kind and content of clay minerals have been investigated to prepare databases. In the survey of groundwater, the behavior of natural attenuation owing to biological processes was investigated by long term monitoring of the contaminated soil and aquifer.

4.5 Improvement of geo-environmental information

The obtainment of geological and hydrogeological information is imperative for conducting risk assessment for specific sites, such as industrial land and urban areas. AIST developed a series of geochemistry of rocks, sediments and soils with toxic elements originated from natural sources in the general environment. Because these maps are very effective for improving the precision of risk assessment, the data for chemical components in soils and sediments have been included in the information system. The system of geochemical and risk assessment maps for subsurface soils contain numerous analysis results of the risk assessment of heavy metals, obtained by exposure distribution analysis in several particular districts[15]. The development of risk maps for heavy metals is the first trial for wide range of applications, in risk management of soil contamination, and in environmental policies related to land use. In addition, AIST and Tohoku University have developed an innovative information system for the geo-environment, named "the geo-environment informatics system", that is coupled with geological maps and other available maps of soil and groundwater under a unified code of GIS system[16].

5 Development of risk assessment system

The development of the geo-environment risk assessment system, abbreviated *GERAS*, is the final goal and output of this research, in which technologies for risk assessment have been synthesized and integrated. In developing the system, basic research on the optimum framework of scientific studies, and product realization research on model formulation, programming and numerical simulation, have been implemented by the engineering approaches of visualization and integration[17].

5.1 Integration of technology components and systematic development

The synthetic concept of the integration of technology components was firstly proposed for the completion of the risk assessment system, considering the suitable methodology, exposure model and exposure analysis for risks induced by soil and groundwater contamination. The most important motivation in the sense of systematic development is the leadership as a producer of risk assessment system. On the basis of the preliminary study on the methodologies, the types of parameters and data were selected and correlated for optimization in the form of risk assessment. In accordance with the advanced investigation, basic databases and analytic works were performed to produce a suitable risk assessment system.

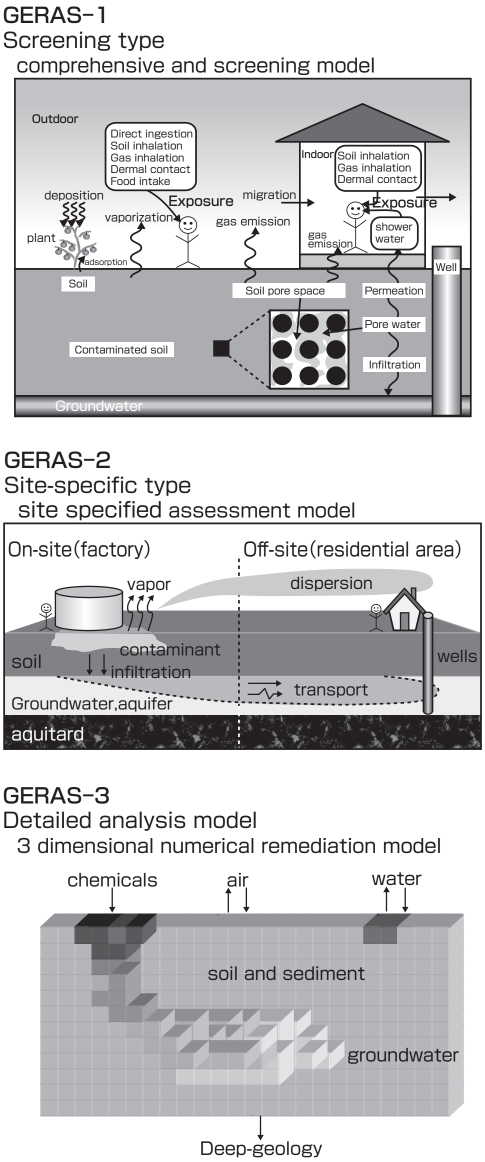

Fig.4 Layered structure of geo-environmental risk assessment system GERAS.
This illustrates three layered structures for GERAS. Depending on the risk level and purpose of risk and exposure assessment, screening type, site-specific type and detailed analytical models are installed in the system.

In the next step, the correlation and optimization of monitored and experimental data were examined to develop more reliable databases that can be utilized in the assessment. The databases have been verified using the monitoring and analytical data obtained at real contaminated sites. Default values for exposure factors and other parameters were determined and fixed for the system through modification and compensation with monitored real situations. There have been many practical cases in which monitored data and the results of risk assessment were provided in the process of feedback to the GERAS producer. Such data are very useful in improving the risk assessment system, particularly for the validation and the expansion of system functions. Several modifications of the system, such as easy input and visible output, were a result of requests from GERAS users. As shown in Fig.2, the integration of technology components and of research, characterized by a feedback process and spiral architecture, were conducted to obtain more a reliable risk assessment system.

5.2 Features of assessment system and basic functions

The features and basic functions of GERAS are illustrated in Fig.4. In consideration of the various situations of sites and purposes, the risk assessment system has three layers, screening type (GERAS-1), site-specific type (GERAS-2) and detailed analysis type (GERAS-3). On the basis of the results of basic research works, as mentioned in chapter 4, integration and coordination in technology components of risk assessment were conducted to introduce the newly designed concept in *Synthesiology*. Typical assessment cases for heavy metals and VOCs are shown to explain the features of components and technical breakthrough in developing the GERAS.

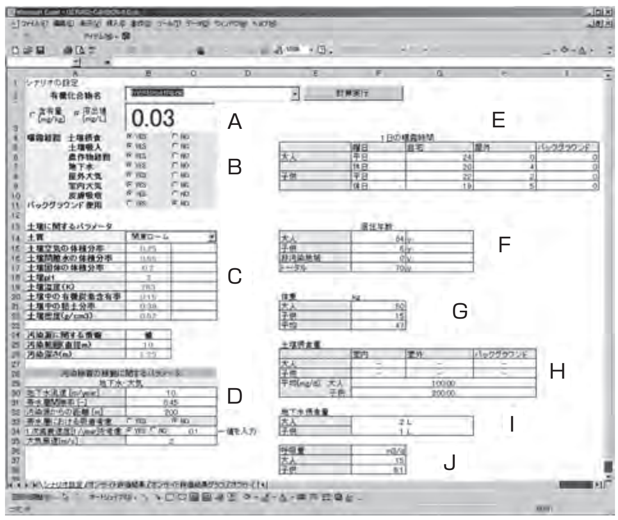

Fig.5 Configuration of input data and parameters in the risk assessment system.
This shows the configuration of computer system and input parameters needed for risk assessment system, GERAS-1,2. The properties of soil and groundwater, parameters for transport of pollutants, and exposure pathways and exposure factors are necessary.

GERAS is a system that operates on a Windows computer system, as described in Fig.5. This system has various functions of exposure and risk analysis, such as the correspondence with the types of soils inherent in Japan, exposure factors typical to the Japanese, and user input parameters such as soil leaching concentration and organic content in soil samples. In the actual operation of the system, user first inputs the kind of chemical substance as the target pollutant in soil (Fig.5, A), selects exposure pathways (Fig.5 B) that are possible to expose through them, and sets basic parameters. Then the user fills out some columns; soil parameters obtained from site-specific survey (Fig.5 C), groundwater parameters obtained from monitoring data (Fig.5 D), and other parameters for the receptor (Fig.5 E-G). The system has a default dataset of soil parameters and exposure factors, soil ingestion rate, water intake rate and inhalation rate for the average Japanese (Fig.5 H-I). The major exposure pathways considered in GERAS are direct intake from soil ingestion and indirect intake from drinking water, air and foods. The paths of inhalation from vaporized and particulate matters from contaminated soil, and dermal contact with contaminated soil and groundwater are also targets of risk assessment.

The calculation of exposure and risk analysis begins after the completion of data input. This system calculates the partitioning behavior and distributions of specified chemicals in soil, pore water, and vapor phases. By taking the initial condition of soil leaching value in contaminated sites, the concentration in soil vapor, and pore water can be estimated using pH, total organic content, and sorption factors of specified soil. In the next step, the exposure concentrations in soil, water and air are determined by transport analysis in every environmental medium, such as air, groundwater, crops and others. The rate of human exposure in each pathway is calculated for an exposure scenario in consideration of exposure factors and the properties of receptor. Finally, risks for endpoints are summed for all exposure pathways, on the basis of the toxicity data of chemicals. The calculation of risk is prescript with two categories; cancer risk and noncancer risk. The probability of cancer (10^{-6} or 10^{-5}) is assumed to be the criterion for chemicals related to cancer risk, and the rate of exposure compared with tolerable daily intake (TDI) is one of the criteria for noncancer risk.

5.3 Cases of risk assessment by GERAS

Practical risk assessments were carried out using GERAS, as described below for a heavy metal (arsenic compounds: As) and VOCs (trichloroethylene: TCE) [18]. These chemical substances are toxic to humans; As has the possibility of being carcinogenic, and TCE is the cause of hepatopathy.

In the risk assessment of these cases, the concentrations of the substances in contaminated soils were assumed to the standard values that are regulated in the soil contamination countermeasures act in Japan; total content of 150 mg/kg for As, and leaching value of 0.03 mg/l for TCE. The soil properties were obtained by the investigation of Kanto loam. The following exposure scenarios were assigned, type of land use: housing site, duration of exposure: 6 years for children and 64 years for adults, frequency of exposure: 24 hours per day. The exposure pathways were considered to be realistic worst cases; direct ingestion of soil, indirect inhalation (indoor and outdoor), dermal contact, groundwater intake, and ingestion of crops and foods grown in affected soil. The average exposure through a lifetime of 70 years was calculated for each chemical substance and pathway. World Health Organization (WHO) has defined the standard or tolerable amount of exposure for each chemical. According to the WHO reports, the tolerable daily intake (TDI) is 2.1 μg/kg/day for As, and 24 μg/kg/day for TCE. Taking the possibilities of exposure from the atmosphere and hydrosphere into account, 10 percents of the TDI was regarded to be the target value of the exposure baseline in this assessment; 0.21 μg/kg/day for As, and 2.4 μg/kg/day for TCE. The monitored and analyzed data were used to clarify the characteristics of soil and groundwater.

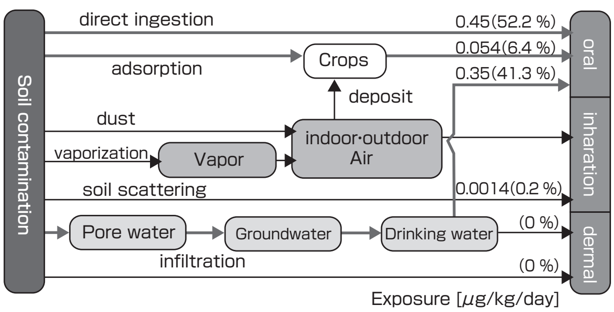

Fig.6 The result of exposure rate and partition from contaminated soil by arsenic.

As s result of exposure analysis using GERAS-1, this represents the rates of exposure and the partition for each pathway from As contaminated soil. The major pathways in case of arsenic are direct ingestion and groundwater intake.

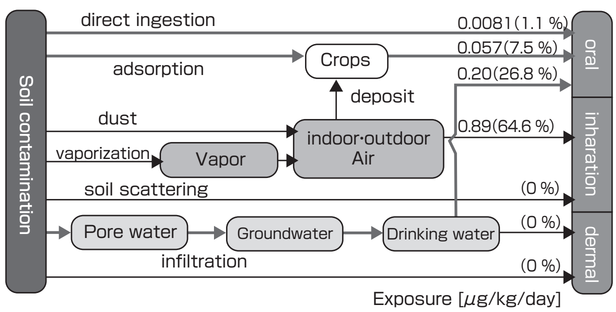

Fig.7 The result of exposure rate and partition from contaminated soil by TCE.

As s result of exposure analysis using GERAS-1, this represents the rates of exposure and the partition for each pathway from TCE contaminated soil. The major pathways in case of TCE are inhalation from indoor and outdoor air (atmosphere) and groundwater intake.

Fig. 6 and Fig.7 show the results of exposure assessment for As and TCE, respectively. In the case of As, the major pathways of exposure are direct ingestion and groundwater intake. However, inhalation from air indoors and outdoors is dominant for TCE. These results of exposure assessment show that the average exposure rate cumulated for all pathways is 0.85 μg/kg/day for As and 0.76 μg/kg/day for TCE. Compared with the target value of the exposure baseline, the exposure rate of As is about 4 times the exposure baseline, indicating that the risk level for this situation exceeds the baseline, which is the criterion in terms of human health. On the contrary, the risk level of TCE in this situation is considered to be acceptable for maintaining human health, because of much lower exposure rate compared with the baseline.

Although the rate of exposure and the risk level can be analyzed using GERAS, this system can also provide the target concentration for the remediation of soil and groundwater by inverse analysis. The case study on As-contaminated soil showed that the risk level was higher than the criterion. By the inverse analysis of that case, the target total content of As in soil can be estimated to be 37 mg/kg. In order to achieve this target, we should adopt measures of remediation or some form of risk management. The control of major exposure pathways is an effective measure in terms of risk mitigation. In the case of As, direct ingestion and groundwater intake are principal pathways, so that risks can be reduced by interrupting these exposure pathways, by adopting anti-scattering measure for soil and/or switching to a safe source of drinking water.

5.4 Disclosure and widespread utilization of developed assessment system

The development of the screening type model (GERAS-1) and site-specific type model (GERAS-2) was completed after a review by experts, and was disclosed to the public in February 2006. A CD-ROM with the software of the risk assessment system and databases has been distributed to users wishing to utilize the system, along with a user manual and confidential serial number. More than 800 units have been distributed and utilized by various users and industries, as illustrated in Fig.8, business sites, factories, companies for remediation and analysis, geological consultants, universities, and local governments. Major intended purposes are the self-governance of soil and groundwater contamination in industrial land and factories. The English version of GERAS is available for overseas use, particularly to Asian countries (China, Korea, Thailand and Vietnam), Europe and USA[19]. A special version of GERAS for mineral oils (gasoline, kerosene, and petroleum fuel) will be made available in 2009. Another system of detailed analysis, GERAS-3, for risk assessment and risk mitigation during the transport and transformation of environmental pollutants is under development, and will soon completed as a part of the whole GERAS.

The functions of GERAS have been improved and the databases have been renewed and modified using feedback data from users who applied GERAS to actual contaminated sites. Such risk assessment results are highly valuable in amending the system because the properties of soil and groundwater exhibit great variation and the results of risk assessment have great differences in time and space. The applicability of the developed risk assessment system is validated through the accumulation and amendment of data and the results of site assessments, and the system has been continually modified through version upgrades. So far, the modification of soil and groundwater databases, the addition of newly regulated chemicals (fluoride and boron), the application to unregulated pollutants (mineral oils, biofuels, MTBE, ETBE and PAHs), and the use the leaching value, have been implemented in several version upgrades in the continuing development of GERAS.

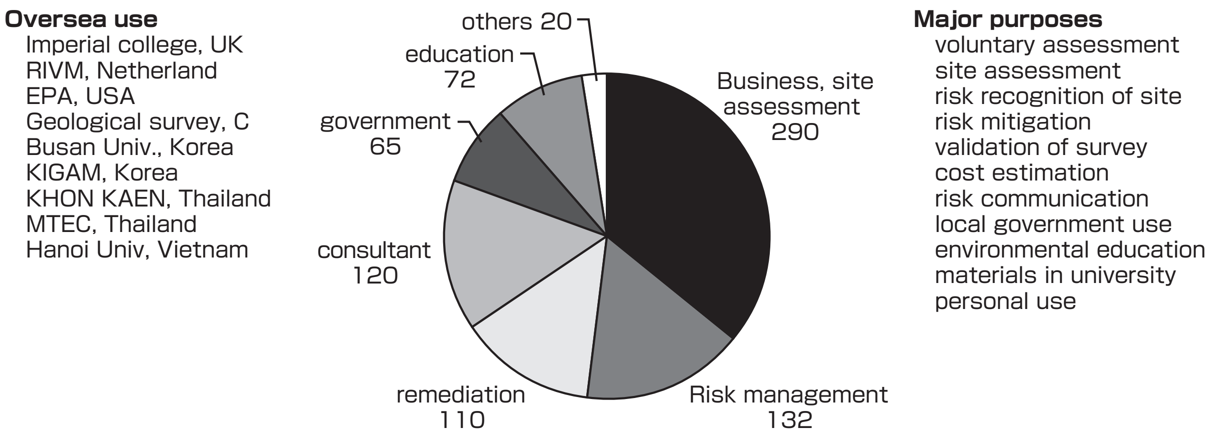

Fig.8 Category of business sectors and organizations where GERAS is distributed and utilized, and major purposes of application.

This diagram shows the number of business sectors and organizations where GERAS have been utilized. Among the whole of about 800 units, the most frequent users are business places and factories. It has been widely utilized for the purpose of remediation action and geological consulting.

6 Further technical tasks and application to society

The application of the development system to various types of environmental problems and the process of its establishment as a social system, including the contributions to industry and society, are described in this chapter.

6.1 Further technical tasks

As described in chapter 5, the developed GERAS comprises various technology components and databases. The optimum configuration of these parts and the reliability of databases have been verified in the previous research, but further improvement will be necessary, particularly for upgrading the risk assessment technology. For this purpose, further research will be continued for the advancement of basic studies on uncertainty of risk assessment and the advanced statistical computing method. These studies are essential for the public acceptance of risk assessment technology for environmental problems, which must be implemented to achieve more transparent risk communication. In order to advance social acceptance, the improvement of the reliability of the assessment results and databases is of grea+t importance, for example, by increasing cases of application at actual contaminated sites. The principal process of this research development involves a loop-type structure of improvement, as illustrated in Fig.9, in which fundamental databases of input side should be amended using the assessment result output. A couple of loops represent a scenario of both risk assessment and environmental improvement, including risk reduction, control, and management in each process. The accumulation and verification of data obtained through appropriate geological survey and analysis are most important to maintain the quality of risk assessment, as shown in the lower part of Fig.9. Through the introduction of these multilayered spiral structures in risk assessment, the benefits of both risk mitigation and cost reduction can be obtained.

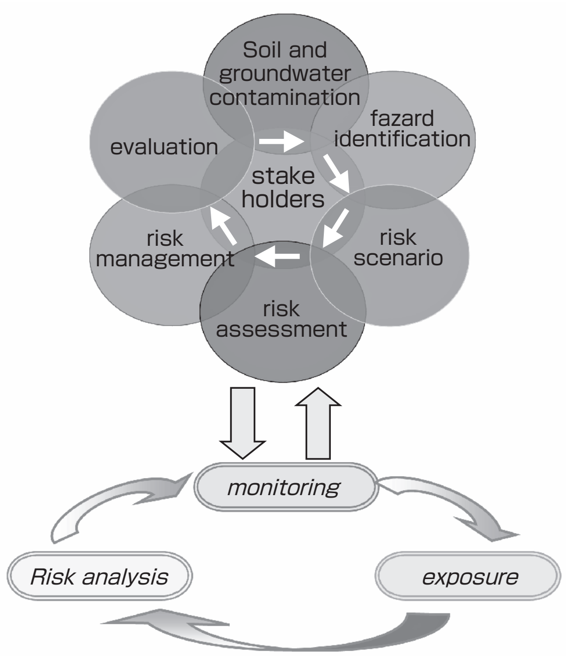

Fig.9 Looped scenario in risk management and multilayered spiral structures.
This illustrates a discriminative looped scenario in risk management for soil and groundwater contamination and a spiral process. In the implementation using GERAS, these multilayered structures are very important for risk mitigation.

GERAS has the possibility to be expanded to more generic environmental problems, such as ecological risk assessment and global environmental issues. The preliminary investigations on the application of GERAS to aquatic life and microorganisms have already been started, in order to assess risks for small amount of toxic elements. Most of the technology components can be utilized in the same manner as for geo-environmental problems. In addition, the risk assessments in the cases of geological CO_2 capture and storage and nuclear waste storage underground might be similar to the developed methodology of risk assessment. The trials of concrete investigation have been begun to clarify the above possibility.

6.2 Contribution to countermeasures for soil and groundwater contamination

The greatest benefit obtained by the application of the developed system is voluntary environmental improvement with a scientific understanding of risk assessment. The comparison of risk levels before and after the remediation provides important information for risk management and risk communication, on the basis of the scientific risk analysis for specified contaminated sites and various situations. Because GERAS can provide information on the exposure rate and risk for each pathway, it will be possible to control the exposure and to mitigate risk in any situation. The implementation of risk assessment contributes to a large cost reduction in risk management, for example, through the selection of an appropriate remediation method and the shutoff of the exposure pathway, compared with the conventional regulation of uniform environmental criteria.

Fig.10 represents the estimation results of risk mitigation and cost reduction upon the introduction of the risk assessment methodology. The reduction of environmental risk and cost of countermeasures is estimated to be 50 percent in the present situation, since the method of risk-based management has already been introduced in industrial sectors[20]. The application of the developed risk assessment technology can largely contribute to risk management, and ultimately reduce the cost as a result of its introduction into social and legal systems. The mitigation of environmental risk can also be expected by the exposure control and the development of low-cost remediation technologies such as an advanced method using geo-microbiology. In practical environmental management at industrial sites, GERAS has been widely used, particularly for voluntary risk management. Thus the risk assessment technology enables the realization of both environmental improvement and cost-effective countermeasures for soil contamination. Therefore, the establishment of a paradigm and the scientific methodology contribute to society and industry in terms of the economical aspect concerning cost benefit.

On the other hand, this system can contribute to alleviating the social issue of risk communication, transparent information recognition and reasonable decision-making. To clarify the real situations, the exposure and risk under specified conditions, the risks between before and after remediation, and the cost effectiveness as the relationship between cost and risk, more reasonable and scientific risk management can be expected. The smooth conversion of land use would be possible from unused industrial sites, named “brown fields”, as the basis of guidelines formulated from risk assessment.

6.3 Overview of the establishment of social system

In order to realize the establishment of the risk assessment technology in the social system, there are several technical and social tasks to be completed in future work. One of them is the technical methodology to ensure transparency and reliability of the risk assessment system. In the development of the system, efforts to realize the smooth application to industry and society have been taken by interactive communication between the producers and users. The introduction of this system into the environmental management system (EMS) is a favorable way to promote its widespread utilization. In the procedure of EMS, the methodology of site assessment is given for voluntary risk management at industrial sites. Since there is no prescription on how to conduct risk assessment in Japan, the developed GERAS has been widely used for the purposes of contamination assessment and evaluation of remediation action[21]. One of the important outcomes is the introduction of GERAS into the social recognition system of “Environmental Site Assessment”, operated by the Japan Environmental Management Association for Industry (JEMAI). The risk assessment technology and GERAS have been accepted for the risk assessment system of JEMAI, in order to promote its utilization of environmental business in industry[22].

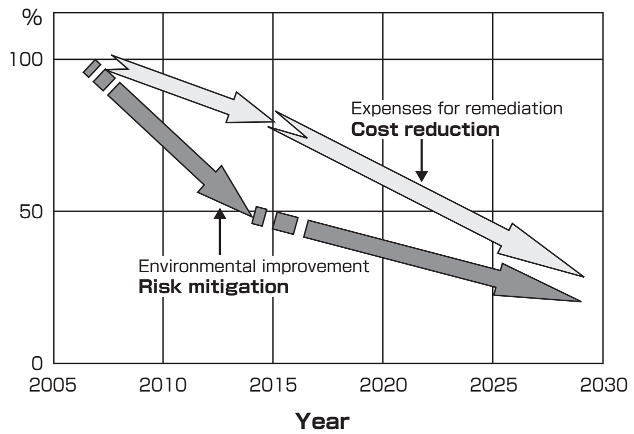

Fig.10 Estimation of risk mitigation and cost reduction caused by the practice of risk management.

This shows the estimated results and trends on the reduction of environmental risk and remediation cost, after the introduction of risk assessment technology. It is expected to mitigate risk and to reduce cost by more than 50 percent to the year of 2025 [20].

The investigation for the amendment of the soil contamination countermeasures act in Japan is under review by authorities. According to the official report, “Overview of the future soil environmental management by advisory body”, presented by the Ministry of the Environment of Japan in March 2008[23], the necessity of a reasonable and appropriate risk management regarding site-specific land utilization was stated to promote cooperation between the legal system and voluntary system in industry. The fundamentals in promoting the law amendment are risk assessment technology and the paradigm of risk governance, obtained in our research work. The importance of site- specific risk assessment and reasonable risk management has been accepted socially, and the methodologies will spread into the social system.

In April 2008 we demonstrated GERAS at the world industrial exhibition of “Hannover Messe”, where many researchers and industrial managers in Europe expressed interests in the application. Compared with the U.S. product[24], GERAS has some obvious advantages; the development as a user-specific system, the possibility of data feedback from users, and the abundance of databases for soil and groundwater[25]. Therefore, there were many responses from foreign countries wishing to utilize the system, as listed in Fig.8. As tasks in the near future, new functions of risk assessment will be installed in the continuing improvement of GERAS, to promote research output toward not only domestic but also the worldwide users.

7 Conclusions

The risk assessment technology for soil and groundwater contamination was established by the integration of technology components from various research areas. The risk assessment system, GERAS, was developed in this research program, on the basis of a unified methodology of risk assessment and databases. In this research, we introduced an advanced methodology of risk-based assessment and the paradigm of risk governance, in order to combine and integrate optimum technologies under the concept of a spiral process and architecture. As a result, the development of the first risk assessment system for soil and groundwater contamination in Japan was completed, and the product was widely distributed and utilized for use in voluntary management by industry and local governments. This system will soon be introduced into the social system, enabling the implementation of a reasonable risk management, and will contribute to the sustainable development of society and industry. The widespread utilization of the developed system will be promoted, since there are many advantages of this system compared with products from foreign countries. Moreover, the research work will proceed in order to develop a geo-information system for soil, groundwater and geology, as a public property needed for the operation of the risk assessment system.

Terminology

Term1. *Type 2 Basis Research*: This research is a research type where various known and new knowledge is combined and integrated in order to achieve the specific goal that has social value. It also includes research activities that develop common theories or principles in technology integration (see page i).

Term2. *Product Realization Research*: This is a research type where the results and knowledge from *Type 1 Basic Research* and *Type 2 Basic Research* are applied to embody use of a new technology in the society (see page i).

Term3. Endpoint: This is the target condition or situation in the assessment exposure and risk. In the case of human risk, it is a concrete event, such as the occurrence of lung cancer caused by oral inhalation or kidney damage due to oral intake of toxic substances.

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Discussions with reviewers

1 Significance in *Synthesiology* of this research as *Type 2 Basic Research* and *Product Realization Research*

Question & comment (Akira Ono)

I think this research is an excellent work intended to solve the problems of complex correlation between risk and environment by *Synthesiology* approach of *Type 2 Basic Research*. The completion of the risk assessment system, which enables its utilization in society, has great value in terms of *Product Realization Research*.

Question & comment (Shigeko Togashi)

This research presents a scenario for a research strategy to be regarded for an outcome obtained by a *Synthesiology* process. This paper is favorably evaluated, because it provides a good example of its application to industry in a study of *Synthsiology*, and presents future tasks and prospecting ideas.

2 The correlation among toxicity, exposure and risk

Question & comment (Akira Ono)

In the paper, there are the technical terms of exposure, risk and toxicity. What is the relation among the terms and their meanings?

What is the real situation of direct ingestion and inhalation as exposure pathways, where such intake or ingestion may occur in the situation of direct intake from contaminated soils, and how much exposure has been considered in the cases of ingestion and inhalation? Is the exposure rate negligible or not in terms of human risk?

Answer (Takeshi Komai)

The meanings of the terms are explained in figure 3. Exposure is defined as the rate of intake of chemical substances through environmental media. Risk is the result of exposure, as defined in the form of the probability of adverse effects to health and/or the environment. Risk can be calculated by the product of toxicity and the rate of exposure, or by other regulated methods in the case of cancer risk assessment.

Direct ingestion of soils is the situation that a human intakes soil grains during field work and/or when playing with soil and sand. The exposure due to direct ingestion is considered to be a large amount in the case of playing outdoors in childhood. According to the formal data in a paper of dioxin risk assessment reported by the Ministry of the Environment, the average intake of soil is assumed to be 100 mg/day and 200 mg/day for an adult and child, respectively. The exposure due to inhalation is the intake of soil particles in a common environment and during works in a garden. The estimation of exposure and risk for heavy metals (Pb, lead) shows that the rate of direct ingestion is more than 50 percent and that of inhalation is about 5 percent. The rates in these pathways are quite large relative to the total amount of exposure from contaminated soil.

3 Introduction of a common criterion or unified index

Question & comment (Akira Ono)

In chapter 3, the significance of a common criterion or unified index is discussed. In conducting the *Type 2 Basic Research* where several technological elements are selected and synthesized into a form of product, the incorporation of such a common criterion and unified index is one of the important points.

What are the concrete objects of the common criterion or unified index in this research? Please explain also the background and concept behind the introduction of these terms.

Answer (Takeshi Komai)

The existing criterion is a uniform standard or target value for maintaining human health in the environment. However, the situation of very little risk to humans should be possible when the land is well managed and monitored for contaminated soil and groundwater. Thus we introduce the risk-based assessment for quantifying a specified situation. The term "common criterion" defined in this research is "exposure obtained by risk assessment". The rate of exposure from contaminated soil differs very greatly depending on the land utilization, properties of soil and groundwater, and lifestyle. The term "unified index" is defined as "human risk of exposure to chemicals from the environment". The methodology to assess the exposure precisely is a general and scientific method used to make decisions on the effects on humans and the environment.

4 The reliability of the result of risk assessment

Question & comment (Akira Ono)

As mentioned in chapter 6.1, the reliability of results obtained from the developed risk assessment system is of great interest to users, particularly the methodologies and databases utilized in this system. Since the reliability of results depends on the uncertainty of risk assessment, what do you think about the major sources behind the uncertainty of the risk assessment result? Please explain the possible sources for both methodology and databases.

How much uncertainty, roughly what percentage, do you estimate for the final result of risk assessment for As and TCE, as shown in section 5.3?

Answer (Takeshi Komai)

In order to ensure the reliability of the risk assessment result, it is essential to improve the precision of applied exposure models and the quality/quantity of databases in risk assessment system. The developed risk assessment system has already been well evaluated by experts on the verification of the reliability of assessment results. In addition, the system has been validated using feedback data and the results of risk assessment at actual sites. The quality of risk assessment depends on two factors; the uncertainty due to the lack of information or data, and the variability relevant to the inherent diversity. In this assessment, the major sources behind the uncertainty are based on the properties of soil and groundwater. It should be possible to reduce the uncertainty if we can carry out a sufficient number of geological and geophysical surveys. Since the variability of factors is not considered in this assessment, the level of uncertainty can be estimated to be less than 5 percent in the final results of As and TCE risk assessment.

5 The extension of the developed risk assessment system to ecosystem issues

Question & comment (Akira Ono)

Expansion of the risk assessment system developed for soil and groundwater environment to other applications may be possible. What are the future tasks in solving the problems, if we intend to expand the system to the risk assessment for the ecological system?

Answer (Takeshi Komai)

The methodology for exposure and risk assessment has general-purpose features that enable its extent to other targets, such as the atmosphere, hydrosphere and global environment, such as an ecosystem. We already intend to expand the developed system to a broad range of utilizations, such as the assessment of the environmental impacts of chemicals on aquatic and plant life. For such a development, it is necessary to overcome the problems of clarifying the intake mechanisms for plants and microbes and the endpoints for assessing the diversity in ecosystem. Since the linkage with other exposure models for the atmosphere, rivers and the ocean is necessary, we will conduct collaborative research and development with research groups in AIST and others.

6 The features in *Synthesiology* research and relevant research areas

Question & comment (Shigeko Togashi)

Please clarify the relationship between the table and figure 2, which is a good explanation of the trial of *Synthesiology* research.

Answer (Takeshi Komai)

In order to explain the features and importance in *Synthesiology* research, the process of integration among research areas and their contributions are newly described in figure 2. The list of research areas, technology components is amended in the table to clarify the relationship between the purposes and academic fields.

7 The spiral structure in risk management and risk assessment

Question & comment (Shigeko Togashi)

Some erroneous uses of the technical terms risk management and risk assessment may exist in the text, where both terms have vague definitions and relations.

Answer (Takeshi Komai)

Some misuses of the technical terms risk management and risk assessment were corrected to their appropriate uses in the text of the paper. The description of complicated structures in figure 9 was amended to simplify the relationship between risk management and risk assessment.

The loop-like structure is described in figure 9 to illustrate the process of risk management. In order to understand the whole spiral structure of risk management, the figure was simplified and modified into multiple spiral structures.