

(4) Effects Assessment

In the beginning when the measures concerning the endocrine disruption were started, listing up and indicating the substances to be studied from the limited information available at that time, served as a great driving force in the implementation of measures. However, as a result of the development of activities, it became evident that it would be mandatory to constantly update the substances that should be tested due to the accumulation of new scientific knowledge, and it might be necessary to change the category itself of the substances. Meanwhile it was pointed out that listing up the substances that should be studied at a certain point may give a false impression that they are the very substances with defined endocrine disrupting effects. As such, it would be desirable to clarify the methodology of selecting the substances to be tested and also the assessment procedures of substances rather than listing up the substances at a specific point of time.

For this purpose, the selection and assessment procedures of substances to be tested related to the endocrine disrupting effects of substances have been summarized in Figure 6. It is important to scientifically and objectively proceed with the actual operation and the set up of detailed conditions after obtaining an informed and considerable consent in a deliberation by intellectuals in a public setting.

The selection and assessment procedures of test substances concerning the endocrine disrupting effects (Figure 6)

As for the substances that are to be considered for investigation with regards to endocrine disrupting effects, since it is difficult to grasp the whole picture of production and transaction volumes, substances that are subject to chemical-regulations, those that have been used within Japan, and those that have been suspected to have an effect on the endocrine system or to have an endocrine-mediated effect in the reports published by public agencies such as international organizations will be subject to testing. Furthermore, not only artificial chemicals but also natural substances (i.e., phytoestrogens) and human/animal derived hormones will also be considered.

Firstly, the status of detection, measurement and usage will be assessed in terms of whether there is a possibility for exposure in the general environment of Japan, and if so, in terms of its exposure level. If a possible exposure is identified, the assessment of the information on the impact and phenomena related to the endocrine disrupting effects will be carried out based on the documentary information extracted by the latest search at the time to select the test substances. If the substances to be tested have not been investigated in a similar test either inside or outside of Japan, the test should be implemented for evaluation.

After comparing the information on the level of toxic effect and/or the level confirmed with an impact by the endocrine disruption obtained through the test carried out or through a similar test in Japan and abroad with the possible exposure level in the general environment, the substances will be separated into the following categories: [Substances in which endocrine disrupting effects have been conjectured in humans in a level that is relatively close to the environment], [Substances in which endocrine disrupting effects have been conjectured in living species other than humans in a level that is relatively close to the environment], and [Substances that have been conjectured with no definite endocrine disrupting effects at this time or substances that have a very small possibility of exposure at this time that have been found with no realistic risks].

Implementation of tests

The OECD certifies various testing methods for assessing the hazards of substances as test guidelines. For a test guideline to be established, the testing method must be developed, its supporting knowledge organized and the findings accumulated by carrying out tests for actual validation. None of testing methods for endocrine disrupting effects has been established as OECD's guideline at this present stage.

Until now, MOE has actually been carrying out tests over 20 test substances by developing tests that use rats and Medaka as methods of evaluating the impact caused by the endocrine disrupters. Although the tests have not yet been led to establishment as guidelines, part of the findings and assessment of the tests have already been reported to the OECD as important information, which has enabled Japan to play the role of leading the international development of *in vivo* tests. Based on past achievements, it is important hereafter to gather knowledge through more improved methods while further accumulating supporting data.

MOE is to get involved mainly from the perspective of environmental conversation in inter-ministerial agreement on the roles of ministries. As such, MOE will be prioritizing the test that uses Medaka as a test species for assessing the effect on the ecosystem based on past achievements, focusing on investigations of the ecosystem for the foreseeable future. On the other hand, the test using rats for assessing the effect on the human health must be implemented as required, particularly if endocrine disrupting effects is suspected and exposure on humans is envisioned in view of the evaluations of the findings of tests using fish, documentary information, and the exposure level in Japan.

Until now, tests using Medaka have been carried out under the testing system with vitellogenin assay and partial life cycle test and, if necessary, full life cycle test, but in the future, an efficiency-oriented testing system will be examined anew in view of the information obtained from the tests and the required testing period for the test.

Moreover, the dosage region with a possibility of human exposure has been focused in setting up the test doses in tests using rats until now. In the future, although there is a limitation in the number of setup groups, the dosage setup could be changed allowing for information that can contribute to hazard assessment, by including not only the dosages with a possible human exposure but also those with possible adverse effects that have already been reported, by referring to various techniques of toxicity assessments.

It is advisable to secure a place for a full public discussion for analysis and evaluation of the test results.

(5) Risk Assessment

An environmental risk assessment of chemicals is for evaluating the degree of risk by carrying out two assessments; a [hazard assessment] for sorting out the dose (level) – reaction (effect) relationship by identifying the hazards on the ecosystem and human health and an [exposure assessment] for estimating the amount of exposure of the chemicals from the environment on the ecosystem and human health. (Figure 7)

In the risk assessment of chemicals, it is not appropriate to make the assessment by simply in terms of endocrine disrupting effects. This is because chemicals have various effects, and as the living organisms subjected to exposure will have various complex and associated reactions, there is a risk of producing oversight on the hazards on living organisms and misunderstandings concerning the cause and effect. The endocrine disruption must be assessed as an aspect of various effects of chemicals or as one that has been combined with other effects on living organisms.

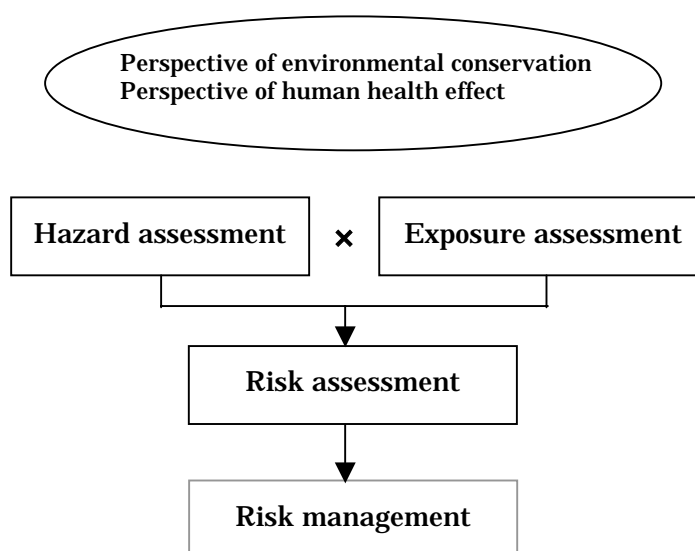


Figure 7 Conceptual diagram of Risk assessment and Risk management

(6) Risk Management

At this point, there seems to be no chemical that requires a regulatory risk management from the perspective of endocrine disrupting effects. However, depending on information accumulated in the future, it is advisable to lay out a framework that would allow for measures when required.

(7) Promotion of information sharing and risk communication

Regarding endocrine disrupting effect of substances, there are many questions still left to be answered by science, and scientific understanding requires high-level expertise. Around 1998, the issue of endocrine disruptors, regarded as a severe environmental problem, was a great public concern in Japan. There is a tendency for people not to change their attitude toward a “chemical

suspected of danger” and continue to consider it as “dangerous” even after overruling information is released to say that such once suspected chemicals have been discovered to be safe. In addition, according to some social psychologists, people’s feeling of anxiety is increased whenever they encounter something “unknown” or something “alleged to be fatal.”

In order to prevent any unverified hypothesis from increasing social anxiety, it is important for the government to promote distribution of reliable information, including messages to clarify which information is a proven fact and which is unverified theory, and also frequently update people with the latest information such as results of reliable scientific research.

Furthermore, it is necessary to promote “risk communication” between industries (suppliers) and consumers (users) so that they can make appropriate judgments on which potential environmental risks could be tolerable and which should not be accepted. Topics to be discussed for risk communication include the difficulty of completely eliminating all risks, convenience and necessity of chemicals, potential new risks and unavoidable increase of burdens on natural resources in return for introducing replacements, existence of phytoestrogens and other natural hormone-like substances, etc..

At the same time, it is hoped that environmental education for children will be promoted so that they will be able when they are grown up, to properly understand the potential risks of using chemicals, have a positive attitude toward participation in promotion of risk communication, and develop the ability to make appropriate judgments on the use of chemicals. To this end, it is important to aggressively promote distribution of reliable information and create opportunities for people to obtain the necessary information.

Information sharing

i) Sufficient provision of information

Although people’s interest in environmental risks caused by chemicals is generally high due to the direct potential impact on their living, such high interest does not necessarily lead to appropriate conduct for diminishing environmental risks in their daily life. This is due to the fact that information on chemicals requires scientific expertise and that people usually obtain only fragmentary knowledge which is insufficient for them to find a truly effective way to solve problems.

Especially, information on endocrine disruptors is quite unique and difficult to accurately understand in some aspects compared with general scientific information on chemicals. Therefore, one-way information, without any follow-ups or checkup of feedback, could most possibly make people merely confused.

Unique characteristics of information on endocrine disruptors

- It often includes a hypothesis alleged to be supported by certain results of scientific research with its credibility actually still unconfirmed among many experts. In many cases, people’s feeling of anxiety comes from unverified hypotheses. Also, “hazard” information easily

attracts people's attention and gets around quickly in many cases, while people often fail to properly understand "potential risks" even though they have been carefully determined based on comprehensive analysis of a hypothesis.

- No specific effects on mammals have been observed yet. In addition, it is impossible to draw any final conclusion to support or deny hypotheses. In some cases, people are only informed of a certain hypothesis and fail to hear any conflicting theories. Generally, once a hypothesis is widely known to the public, conflicting research results or theories to deny the hypothesis tend to be ignored.
- In many cases, people's feeling of anxiety has been simply triggered by the sudden emergence of discussions and debate on the issue of endocrine disruptors as a public concern, and such feeling tends to increase automatically.
- Many people do not know the fact that many physiological mechanisms in ecological systems of living organisms including human beings are still unknown and that the relationships between the mechanisms and respective suspected chemicals are also unknown in many aspects.

ii) Approach toward promotion of information sharing (Figure 8)

1) Updating people with the latest information utilizing internet websites

It is necessary to frequently update people with the latest information so that they may properly understand the current status and be aware that some arguments are hypothesis-based and that there exist conflicting research results. Internet websites are effective media to send necessary information directly and continuously to the public.

2) Utilizing symposium

A symposium is a good opportunity for efficient information distribution, where the content of discussions can be designed flexibly so that effects can be maximized. For example, MOE needs to pay attention to the role of "program for general public" in MOE's international symposium. This program has been considered to be a supplement to "program for experts" which is the main part of international symposium. But hereafter, it is required to effectively utilize the "program for general public" to raise the level of understanding of ordinary citizens, where it is indispensable to provide easy-to-understand information. It is also necessary to verify proper understanding of attendants through checkup of their feedback.

As for the "program for experts," participation of experts from various countries is important, since international cooperation is essential to promote studies on endocrine disruptors. MOE's international symposium will continue to provide valuable international opportunities for information exchanges among experts. Also, MOE will continue to maintain bilateral cooperation, including the existing Japan-UK and Japan-the Republic of Korea joint programs, to further promote information exchanges.

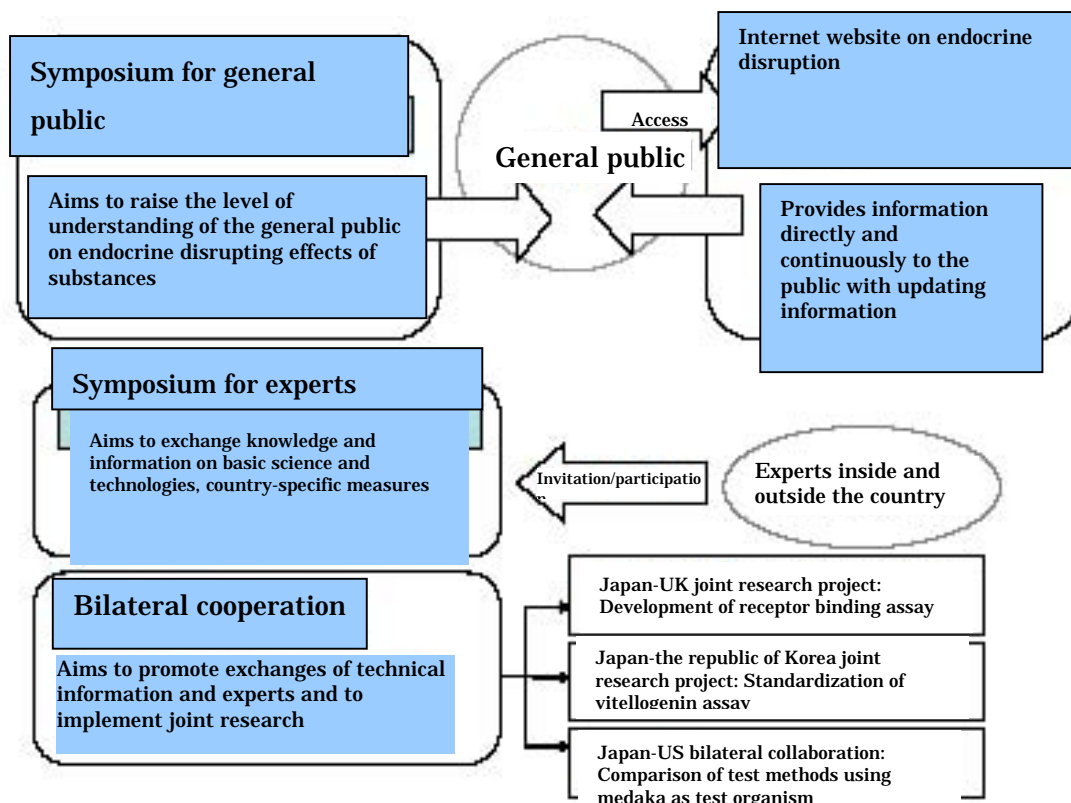


Figure 8 Conceptual diagram of Approach toward promotion of information sharing

3) Promotion of information sharing multilaterally by the ministries, industries, academia, local public organizations and the general public

It is important for relevant ministries and agencies of the government to promote information exchanges among them while clarifying their respective roles (Figure 9).

It is desired that not only the government but also experts, industries (chemical suppliers, etc.) and academic organizations will actively provide relevant information as necessary.

In addition, MOE intends to assist local public organizations in promoting community-level information sharing by providing them with all necessary information in a timely manner.

MOE also hopes to see active commitment by the general public for the promotion of information distribution, based on enriching scientific sound understanding on endocrine disruption.

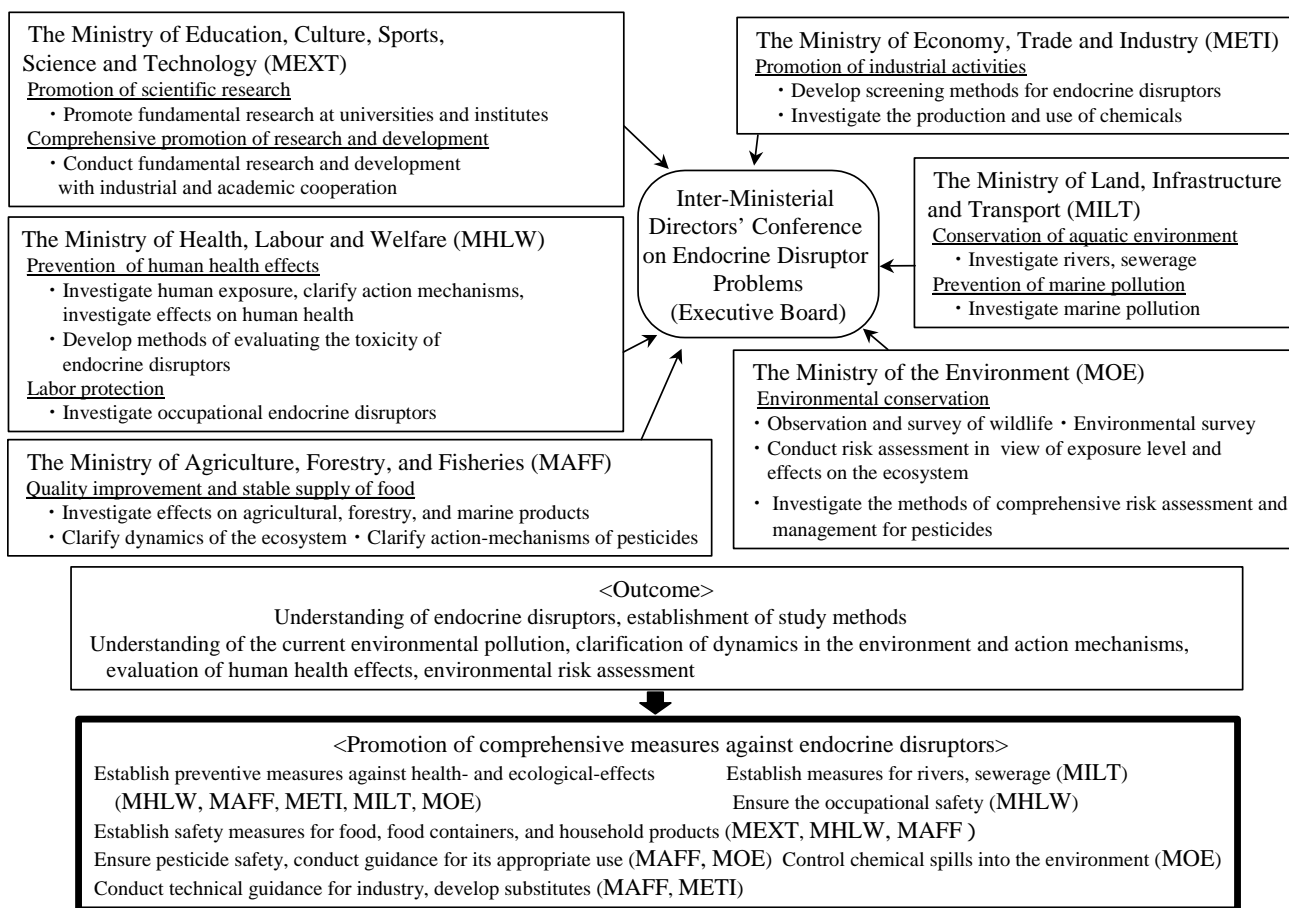


Figure 9: Inter-Ministerial Cooperation on Endocrine Disruptor Problems

Risk communication

According to the 2004 Environmental White Paper issued by MOE, risk communication in the field of chemicals can be defined as the efforts to promote mutual understanding and information sharing among all units of the society, including general public, industries and governments, on accurate knowledge regarding chemicals.

Generally, risk communication in the field of chemicals is based on bilateral information exchanges between a pollution-causing industry and general public of an affected community with the aim of finding effective measures to prevent pollutions and promote self-management of the industry. However, in the field of endocrine disruptors, where the level of social anxiety tends to be especially high due to the presence of various scientifically-unknown factors, multilateral information exchanges involving various people in different fields and positions are essential. First of all, it is necessary to find the most effective, practical way to develop risk communication on endocrine disruptors, where experts and specialists in this field are expected to play an important role.

At the same time, MOE considers it important to create information sharing opportunities involving the general public, experts, industries and governments (Figure 10), for the purpose of

promoting mutual understanding among them. One of the good examples of such opportunity is a round-table meeting among representatives of general public, industries and governments hosted by MOE for discussing the environmental risks of endocrine disruptors. (<http://www.env.go.jp/chemi/entaku/index.html>) It is hoped that such opportunities will be created by local public organizations also. Through interviews conducted by MOE over local public organizations to find their opinions and approaches (Appended Materials 6), it became evident that they were also aware of the importance of risk communication. Therefore it is hoped and expected that community-level risk communication will be further promoted and that such communication will effectively respond to local needs.

Sense of values varies according to individuals, and there are various kinds of opinions on how environmental risks of endocrine disruptors should be managed or how much risk can be considered as acceptable. In the light of such diversity of opinions, it is important to create opportunities to deepen mutual understanding.

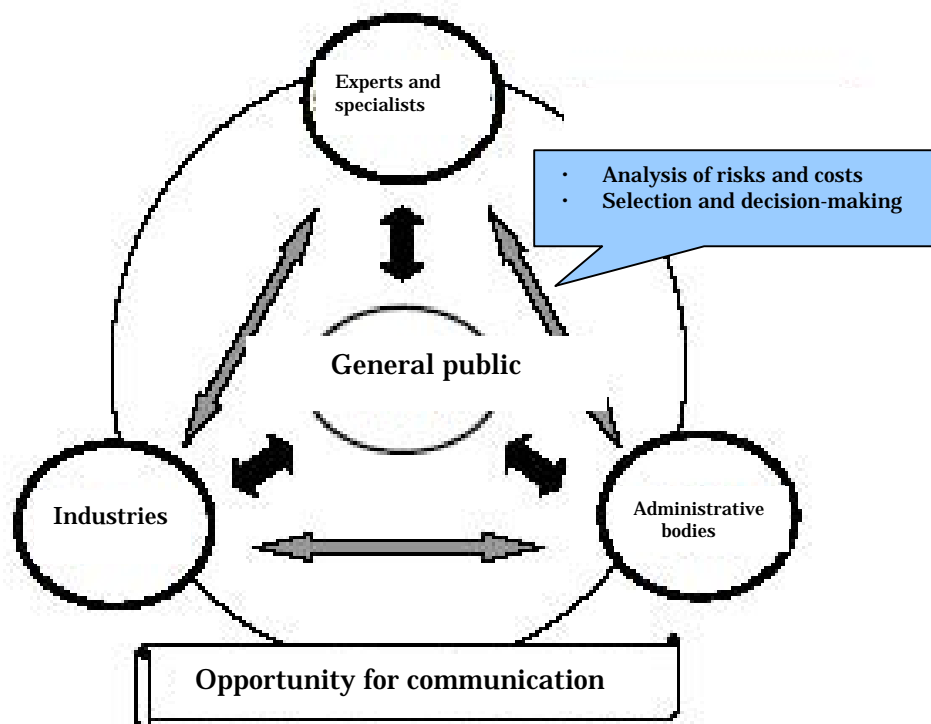


Figure 10: Concept of risk communication

Environmental education

There is an opinion that teaching scientific knowledge to children at the early age might be dangerous because of the possibility of creating biased opinions/attitudes due to the immature

ability of those children to accurately understand and critically assess science. Meanwhile, it is also true that children are already exposed to considerable amounts of scientific information. Information on endocrine disruptors is complicated and difficult to understand even for adults. Also, such information has been attracting a lot of public attention because of the alleged serious impacts on future generations. In addition, it is concerned that children could be influenced by opinions of adults close to them or affected by social anxiety without a clear understanding of the issue.

It is hoped that well-designed educational programs for children will be developed so that children can foster their ability to make appropriate, independent judgment, when they are grown up, on potential risks, benefits and costs of chemicals and make a decision at their own discretion on how to use chemicals. In an effort to help children foster such ability, MOE intends to promote distribution of easy-to-understand information designed for children. It is also hoped that the administrative bodies, industries and academic organizations should make efforts to release reliable information and at the same time offer effective educational tools to help children understand the information properly.

Conclusion

In order to implement effective measures in accordance with the policy and future plans mentioned herein, it is necessary to establish a comprehensive and open-to-the-public planning/evaluation scheme for all necessary surveys, researches and projects. See Figure 11 for the framework of overall approaches to address the issues of endocrine disruptors.

It is important that all information and research results obtained through implementation of administrative measures be shared with international communities. To this end, MOE needs to actively participate in international activities, such as standardization process of test methods. In addition, further efforts will be necessary to clarify roles of respective ministries and agencies and promote information exchanges among relevant organizations.

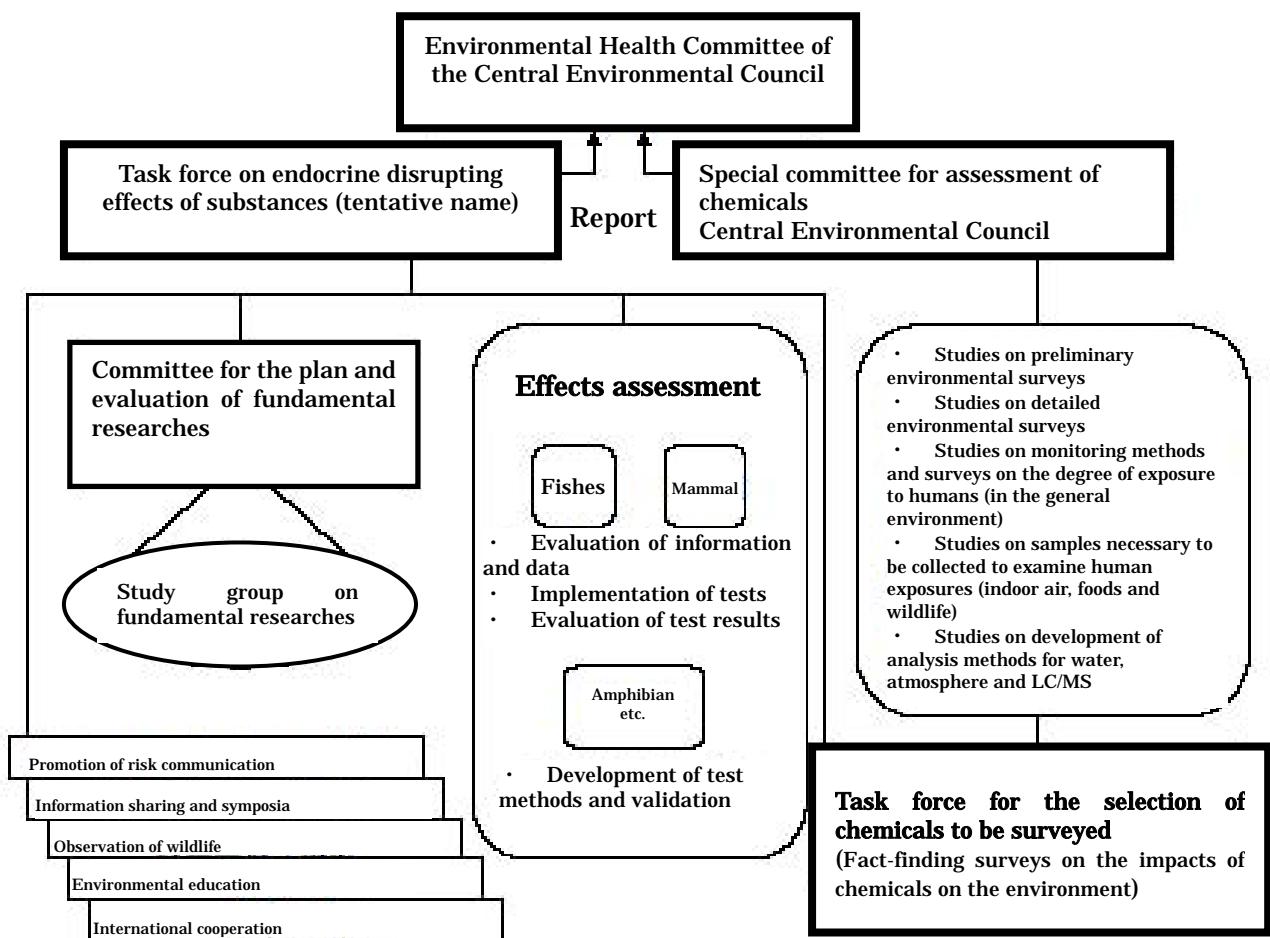


Figure 11: Comprehensive framework of measures to be implemented by MOE

MOE intends to promote effective measures aggressively in accordance with the policy and objectives mentioned in this document, with aiming to meet people's needs and contribute to international activities.

All objectives and planned measures mentioned above in this document are based on scientific knowledge and information MOE has obtained by the time of writing. It is expected that any

necessary revision to this report will be made whenever it is appropriate to do so, judging from any new scientific information, data or knowledge obtained through future researches and/or surveys.