

2. Basic policies

Problems of endocrine disruptors require immediate research and studies and, also necessary measures as occasion demands because there are indications that these substances may affect human health, and, in particular, may harm multiple generations. However, the problems that endocrine disruptors cause are not easy to solve because they are often beyond conventional understanding and knowledge in the scientific field, and these substances vary in type and characteristic. Accordingly, the problems are diverse and complicated. Also, these chemicals may have various effects in everyday life. Under such circumstances, a fundamental policy to solve endocrine-disruptor problems comprehensively and smoothly should be urgently set up, based on the information in previous sections of this report. This section describes a basic policy for coping with endocrine disruptors which will protect human health.

(1) Concept of chemical safety

In the past, chemical safety was focused on preventing acute toxicity, due mainly to unintentional consumption of pesticides. Half the lethal dose obtained from animal experiments was used as the index of toxicity. Hazardous chemicals eventually came to be labeled adequately, and the number of accidents resulting from these chemicals decreased.

In recent years, carcinogenicity has been used as an important index for chemical safety. This approach was taken because cancerous diseases have become high-ranking causes of human death, and efforts have been made to study relationships between chemicals and cancers in toxicology and pathology. In addition, teratogenicity and reproductive toxicity have been used as indexes, consequent to the occurrence of teratogenicity from a pharmaceutical, thalidomide.

In safety evaluations of food additives, various indexes are used, including one-year repeated dose toxicity, reproductive toxicity, teratogenicity, carcinogenicity, antigenicity, and mutagenicity. Guidelines for the safety evaluation of additives require data obtained from studies using these indexes.

Epidemiological indexes are however not appropriate in evaluating chemical

safety, except for acute toxicity, such as food poisoning. In evaluating chronic toxicity, as there are various causes which are mutually acting, it is difficult to evaluate the direct effects of chemicals through epidemiological investigations.

Endocrine disruptors are new types of problems which have occurred recently. There are many questions which remain to be solved, such as the presence or absence of endocrine disrupting activities, and the type and extent of activities. Also, evaluation methods have not been established yet. Therefore, Japan and other countries are working extensively on research to clarify these various points and to establish safety-evaluation approaches for endocrine disruptors.

If standardized evaluation-methods are established, the adoption of these methods should be considered for safety evaluation of any food additive and pesticide which will be developed.

(2) Development of an information management and distribution system, based on a database

It is expected that scientific research will be promoted globally. To solve problems effectively, a time- and cost-saving management system must be established, which enables the general management of various types of research, and helps to avoid duplication. Because there are divers target chemicals for research, and information on these chemicals also varies, various pieces of information should be integrated for effective risk assessment and risk management.

At the moment, the WHO is working to produce a database to manage information worldwide. Japan needs to establish an information management system based on that database in cooperation with international organizations and other countries. Compiled information should be widely available not only to the governmental agencies concerned and foreign countries, but also to Japanese consumers. Exchange of information should be encouraged among administrative agencies, academic institutions, and private organizations.

(3) Encouragement of international cooperation

Endocrine disruptors are now recognized as global problems common to many countries. The WHO and OECD are leading the build-up of a framework for

tackling these problems. The United States and European countries are discussing how to proceed with research and how to regulate endocrine disruptors on their own. Under such circumstances, Japan needs to join the international activities under this framework, and to encourage cooperation in taking measures against endocrine disruptors.

Japan heavily depends on importation for many kinds of domestically consumed products, such as food. There is a high possibility that the use of chemicals in exporting countries may cause health effects in the Japanese population. To protect the health of the Japanese population, we have to provide exporting countries, especially developing countries, with necessary information based on research findings. This also will help to prevent the occurrence of health hazards in developing countries and to promote environmental conservation.

(4) Promotion of comprehensive research

It is necessary to thoroughly investigate the adverse effects of chemicals which are suspected of having endocrine disrupting actions and which are drawing the public attention. Unnecessary public concern should be removed by clarifying questions, such as those concerning the presence or absence of health effects and the type and extent of these effects, based on these investigations. Also, appropriate measures should be taken immediately, as occasion demands.

The chemicals currently suspected to be endocrine disruptors have been focused upon as a result of the investigations of their effects on wildlife and effects on cells *in vitro*. The number of chemicals used in Japan is estimated at several tens of thousands. Therefore, it is necessary to identify the effects of these chemicals and to take action to prevent them because there is the possibility that they may have endocrine disrupting actions on humans and wildlife, now or in the future. To that end, it is necessary to promote research on the potential endocrine-disrupting actions for the chemicals for which observations have not yet been obtained.

There are not enough data to draw conclusions on combined effects of multiple chemicals and responses to low dosages. It is necessary to explore methods of evaluation and to carry out sufficient studies under the international framework for accumulating data.

In 1996, Japan began research on problems of endocrine disruptors in view of the prevention of health hazards, mainly under the framework of the Health Sciences Research Program. These activities were promoted in cooperation with the industrial and academic sectors. In addition, the promotion of comprehensive research is needed, adding to the voluntary conduct of research in the industrial sector and the provision of information, such as study data, by foreign countries and related governmental agencies.