

**Report of the Health and Environment Epidemiological  
Study Working Group**

The Future of Japan Environment and Children's Study (JECS)

**March 29, 2022**

**Health and Environment Epidemiological  
Study Working Group**

<b>Introduction</b>	<b>1</b>
<b>I Assessment of Activities Conducted to Date</b>	<b>2</b>
(1) Implementation Structure	
(2) Operational Structure	
(3) Roadmap	
(4) Hosting of Symposiums in Japan and Overseas	
(5) Budgetary Amounts by Fiscal Year	
(6) Participation Rates	
(7) Research Findings	
(8) Human Resources Development	
<b>II Necessity of Extending the Study from Childhood Onwards</b>	<b>6</b>
<b>III Issues and Future Actions for Extending the Study from Childhood Onwards</b>	<b>7</b>
1. Issues and Future Actions from an Analytical Perspective	7
(1) Chemical Analysis	
(2) Genetic Analysis	
2. Issues and Future Actions from a Structural and Infrastructure Upgrades Perspective	9
(1) Operational Structure	
(2) Initiatives to Retain Participants	
(3) Attention Paid to Research Ethics	
(4) Linkages with Health and Medical Data	
(5) Collection and Storage of Biological Samples	
3. Issues and Future Actions from a Utilization of Findings Perspective	14
(1) Usage and Application of Data	
(2) Policies for Effectively Returning the Benefits of Findings to Society	
(3) HBM for Effective Usage of JECS Findings	
(4) International Networks	
<b>Conclusion</b>	<b>18</b>
<b>Progress of the Health and Environment Epidemiological Study Working Group</b>	<b>19</b>
<b>Members of the Health and Environment Epidemiological Study Working Group</b>	<b>20</b>
<b>Observers to the Health and Environment Epidemiological Study Working Group</b>	<b>21</b>
<b>Participants in the Health and Environment Epidemiological Study Working Group Third Open Hearing Session</b>	<b>22</b>
<b>Participants in the Health and Environment Epidemiological Study Working Group Fourth Open Hearing Session</b>	<b>22</b>

## Introduction

- It was recognized that children worldwide were facing the threat from toxic substances in the environment at the G8 Environment Ministers' Meeting in Miami, Florida in 1997, where a declaration stated the importance of prioritizing initiatives addressing issues regarding children's environmental health. At the 2002 World Summit on Sustainable Development (WSSD) it was agreed to "aim to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment". In 2006 the Strategic Approach on International Chemical Management (SAICM) was adopted as an internationally-agreed policy framework to achieve at the WSSD, promoting risk reduction based on scientific risk evaluation, information collection and dissemination, as well as capability building and technical collaboration. In 2009, at the G8 Environment Ministers' Meeting on Children's Health and the Environment held in Syracuse, Italy, the then Japanese Minister of Environment delivered the keynote speech and the countries agreed to cooperate in conducting large-scale epidemiological studies.
- In Japan, the 2006 "Report of the Advisory Commission for Children's Environmental Health" proposed a direction for future policies aimed at addressing issues in terms of children's vulnerabilities and environmental health. In addition, the 2008 "Report on Epidemiological Study for Children's Environmental Health" provided the outlines of epidemiological studies, based on which pilot studies began in the same year and continue to the present day. After receiving a Superior rating at the Japan Cabinet Office Council for Science and Technology in 2009, and based on the "Japan Environment and Children's Study (JECS) Conceptual Plan" formulated in 2010, recruitment of pregnant women took place from January 2011 to the end of March 2014. As a result, approximately 100,000 pregnant women, 50,000 fathers, and 100,000 babies became participants in the JECS.
- Thus, the JECS, a large-scale epidemiological study aiming to identify the effects that environmental factors such as chemicals on children's health, began in 2011. To date, the study has been conducted according to specific plans covering the fetal period until school age. With its sound findings, the study has gathered attention both within Japan and abroad.

- There is growing interest in the effect of chemicals on neuropsychiatric development, the immune system and allergies, metabolism and the endocrine system including reproductive functions, as children grow into adults from childhood onwards. It is hoped that identifying such influences and implementing effective policies for the risk management of chemicals will lead to the creation of safe and secure societies as well as a healthy environment for raising the next generation.
- Currently, follow-up surveys are being conducted on approximately 100,000 mother-child pairs recruited between 2011 and 2014, with participant children now aged 7 to 10. However, the current Conceptual Plan only covers children up to 12 years old.
- As the next step, the Health and Environment Epidemiological Study Working Group was established on July 19, 2021. This expert panel has met six times, summarizing the findings of the JECS to date, as well as discussing issues related to health and the environment from childhood onwards, the future of JECS, and policies for effectively returning the benefits of findings to society. This report brings together the discussions of the Working Group and lays out the directionality for measures that should be promoted in the future.

## **I Assessment of Activities Conducted to Date**

### **(1) Implementation Structure**

- The Ministry of the Environment is responsible for the overall coordination of the JECS, while the National Institute for Environmental Studies plays the central role in its implementation, with the cooperation of the National Center for Child Health and Development, 15 Regional Centers around Japan, and other related institutes.
- The specific division of responsibilities is as follows.
  - The Ministry of the Environment considers environmental policies based on study findings, secures budgets for the study, liaises with related government agencies and international institutions, and conveys the benefits of study findings to society through broad public relations and communications efforts.
  - The JECS Programme Office in the National Institute for Environmental Studies is the primary institution for conducting the study, and manages data systems as well as sample storage, analysis, and quality control.
  - The Medical Support Center in the National Center for Child Health and Development provides medical expertise related to the study.
  - The 15 Regional Centers around Japan collect biological samples, administer questionnaires, communicate with participants, and build community networks.

## **(2) Operational Structure**

- To carry out their respective roles, the Ministry of the Environment, the Programme Office, and the Medical Support Center have established several committees and use management techniques such as PDCA (Plan, Do, Check and Act) cycles to ensure the appropriate execution of the JECS.

## **(3) Roadmap**

- The JECS carries out the following studies and analysis:
  - Approximately 100,000 children recruited between 2011 and 2014 are administered questionnaires in the Main Study every six months, as well as “School Age Testing” by urine sampling in the second year and urine and blood sampling in the sixth year of elementary school.
  - Approximately 5,000 children were randomly selected from among the 100,000 for the “Sub-Cohort Study,” which includes environmental measurement inside and outside the home, neuropsychiatric development testing, blood testing, and physical measurement.
  - Approximately 100,000 mothers are administered questionnaires and have blood sample taken in the early stages of pregnancy, the second-to-third trimester, and one month after delivery.
  - Approximately 50,000 fathers are administered questionnaires and have blood samples taken on recruitment.
- In addition, the chemical analysis of biological samples (blood, urine, cord blood, breast milk, and milk teeth) is prioritized based on the latest research status and the availability of analytical procedures, while being guided by the research plan.

## **(4) Hosting of Symposiums in Japan and Overseas**

- Symposiums have been held in Japan and overseas to promote understanding and increase awareness of the JECS and to convey the benefits of study findings to society. In addition, dialog programs and workshops have been held to engage stakeholders.

## (5) Budgetary Amounts by Fiscal Year

- The budget necessary for the JECS has been secured as shown in Table 1.

Table 1: JECS Budgetary Amounts by Fiscal Year

(Hundred million yen)												
Fiscal Year	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Initial Budget	31	46	45	40	47	45	45	45	51	59	55	56
Supplementary Budget, etc.	-	16	21	10	12	13	13	9	-	5	6	6

## (6) Participation Rates

- More than 10 years have now passed since the JECS began, but as Table 2 shows, a high participation rate is being maintained.

Table 2: The JECS participation rate (number of children currently participating/number of births)\*

(%)							
Fiscal Year	2015	2016	2017	2018	2019	2020	2021
Participation Rates	98.1	97.3	96.7	95.9	95.3	94.7	94.1

\* Number of births: Number of babies for whom the Programme Office or Regional Centers received completed questionnaires at least once after birth

Number of children currently participating: The number of births excluding children for whom information can no longer be obtained, such as where the children have declined cooperation and where the address is unknown.

## (7) Research Findings

- By the end of September 2021, 214 scientific articles had been published using the JECS data from approximately 100,000 mother-child pairs (and fathers if accessible) nationwide. Among them, 23 relate to the central hypothesis that exposure to environmental factors such as chemicals during the fetal period to early childhood may affect pregnancy and reproduction, congenital anomalies, neuropsychiatric development, the immune system and allergies, metabolism and the endocrine system, and other health conditions. In addition, 191 scientific articles relate to aspects other than the central hypothesis, 39 relate to Adjunct Studies, and 86 were other types of

articles.

- Study findings based on the JECS data have been utilized in the formulation of guidelines related to the health of pregnant women and children, such as the Ministry of Health, Labour and Welfare's revision of the obstetric medicine compensation system, the Cabinet Office Food Safety Commission's "Risk Assessment Report; Lead," "Risk Assessment Report; Food Allergens: Eggs," "Guidelines for Food Allergy" and atopic dermatitis diagnosis and care guidelines, "Pregnancy Weight Gain Curve by Pre-Pregnancy BMI," and "Infant Developmental Screening Questionnaires: Ages & Stages Questionnaires®, Third Edition, Japanese version."
- Looking ahead, data cleaning of questionnaire results and chemical analysis of biological samples, as well as ascertaining of health data, will continue. In addition, the Programme Office has started establishing structures to enable effective utilization of the JECS data by third parties. Based on this progress, it is projected that findings closely related to the central hypothesis will increase in the future.

#### **(8) Human Resources Development**

- By the end of March 2021, the JECS project had trained 211 specialists in fields such as environmental science and public health. In addition, 222 graduate students had been involved in the project, with 34 master/doctoral theses based on the JECS data.
- By the end of September 2021, 108 had been hired for post-doctoral positions in the JECS, and 199 were involved in the study as instructors or facilitators.
- The JECS has contributed to the development of specialists such as epidemiological researchers and medical doctors with a deep understanding of environmental health by providing opportunities for young researchers affiliated to different institutions to learn from each other through sharing advice and suggestions in the paper writing process.
- Conducting the JECS requires close engagement with participants, and a range of awareness campaigns, public relations activities, and dialogs in local communities, as well as liaison with governments have fostered communication and management capabilities among the JECS staff, making the JECS a platform for human resources development.
- The human resources developed through involvement in the JECS are expected to contribute to its further advancement by applying the skills they have learned, creating a virtuous circle of improvement.

## **II Necessity of Extending the Study from Childhood Onwards**

- The current research plan covers children up to age 13. However, from a life course approach perspective, extending the study beyond age 13 to the reproductive age range would enable the ascertainment of the relationship between exposure to chemicals during the fetal period and age-dependent diseases that occur in and after adolescence, such as infertility (in both men and women), psycho-neurologic diseases, and lifestyle-related diseases. Furthermore, it would also enable the ascertainment of the health effects on the next generation of children participating in the study - investigating long-term health effects over three generations can make clear the actions and impacts on a new generation.
- The JECS is a large-scale national government project. The data that such a long-term study imparts about the Japanese people creates an accumulation of important evidence, which not only improves medical knowledge but also provides insights into social impacts. The study can therefore be a platform for considering a wide range of policies and measures.
- In addition, the JECS data is invaluable from the perspective of enabling international contributions by comparing differences in disease occurrence rates by factors such as ethnicity between countries. This is another reason why extending the study beyond childhood is necessary.
- Considering that in 2016, women had their first child at an average age of 30.7, and that for men that age may have been even higher, follow-up surveys until around age 40 is preferable.
- The need to extend the JECS study to around age 40 is reinforced by the limited amount of epidemiological research conducted in Japan and globally covering people aged between 10 and 30, and by the fact that in Japan, Specified Health Checkups are conducted for people aged 40 to 74.
- If the study is to be extended to around age 40, it would be important to obtain buy-in from society as a whole by returning the benefits to society from study findings.



### **III Issues and Future Actions for Extending the Study from Childhood Onwards**

- The following issues and future actions have been identified from the analytical, structural and infrastructure upgrades, as well as utilization of findings perspectives with regard to extending the JECS study beyond childhood.

#### **1. Issues and Future Actions from an Analytical Perspective**

##### **(1) Chemical Analysis**

###### **Issues**

- ✧ At the current point in time, some of the biological samples have yet to undergo chemical analysis. Looking ahead, it will be necessary to comprehensively investigate the relationship between exposure of unanalyzed factors and health effects, as well as identify points that have yet to be clarified regarding the hypotheses in the current version of the study protocol.
- ✧ Responding to the concerns of the Japanese people about the health effects of chemicals, is a crucial function of the JECS. However, it is often difficult to publish the findings that epidemiologically indicate “no relationship with health effects could be determined.”
- ✧ Collecting biological samples and conducting chemical analysis at or after age 13 is necessary to study the effects that current exposure and exposure after adolescence have on pregnancy and reproduction, neuropsychiatric development, the immune system and allergies, metabolism and the endocrine system.

###### **Future Actions**

- ✧ In terms of chemical analysis, improved work efficiency in obtaining results is anticipated through securing personnel and increasing automation.
- ✧ It is important to consider academic support for writing and publishing articles about findings that indicate “no relationship with health effects could be determined,” and to actively promote the dissemination of such findings.
- ✧ In order to evaluate the relationship between health effects determined by childhood and those determined at or after age 13, comprehensive studies, such as evaluation based on thorough tracking data at the individual level as well as comparisons with existing knowledge about the mechanisms by which the concerned effects occur, are necessary.

## **(2) Genetic Analysis**

### **Issues**

- ✧ The relationships between environmental factors and health effects identified through the findings of the JECS, an observational study, constitute one form of evidence for inferring causality. However, an ongoing accumulation of evidence is essential in order to fully establish causal relationships.
- ✧ Analysis data on genetic anomalies provide particularly sensitive information, and delivering consequential results requires discussing not only data handling but also the utilization of analysis results with specialists.
- ✧ It will be necessary to establish arrangements for liaison with specialists in clinical fields as part of the process of confirming the results obtained from genetic analysis.

### **Future Actions**

- ✧ Mendelian randomization is one method of inferring causality in observational studies. It is possible to infer causality at a similar level of evidence as randomized controlled trials even in an observational study such as the JECS by conducting genetic analysis with participants randomized based on randomly-inherited genetic polymorphism.
- ✧ In terms of congenital anomalies, as chemicals in the environment have a particular effect during the short organogenetic portion of the fetal period, the effect of various confounding factors in the postnatal living environment is small, a phenotype where genetic factors carry a relatively great deal of weight. Therefore, it is anticipated that conducting genetic analysis can identify confounding factors in terms of genetic susceptibility.
- ✧ Whether or not a relationship between environmental factors and increased frequency of developmental disorders exists may be clarified, including the interaction between genetic factors and environmental factors.
- ✧ In genetic analysis, research must be conducted on a large scale to obtain highly-reproducible analysis results. In a format that gives sufficient consideration to personal information, initiatives such as sharing data and conducting integrated analysis with other cohorts both within Japan and internationally can be envisaged.
- ✧ Performing epigenome analysis or omics analysis is preferable, as it allows comprehensive examination of the broad range of environmental factors that affect health, in addition to gene expression and subsequent biological reactions.

## **2. Issues and Future Actions from a Structural and Infrastructure Upgrades Perspective**

### **(1) Operational Structure**

#### **Issues**

- ✧ A consideration of the operational structure is necessary if the JECS were to be extended beyond childhood.

#### **Future Actions**

- ✧ To ensure continuity of the study, it is preferable that the structure centered on the National Institute for Environmental Studies, which has established a track record, continues to carry out the JECS.
- ✧ In addition to the National Center for Child Health and Development, which has thus far provided medical expertise for the study, it is deemed essential to establish connections with institutions such as the Highly Specialized National Medical Research Centers, which specializes in the field of adult diseases.
- ✧ In regards to the various initiatives by the Regional Centers in encouraging participant cooperation over an extended period, it is necessary to establish a structure that can track participants as they may move, keeping in mind that they may relocate for further study or employment.
- ✧ Sharing the JECS data is expected to create connections with researchers who previously had no connection with the JECS, as well as accelerate the dissemination of study findings to society.

### **(2) Initiatives to Retain Participants**

#### **Issues**

- ✧ The Regional Centers, including the Participant Communication Committees and each of the Sub-Regional Centers, have placed a strong emphasis on communicating with participants through methods such as distributing newsletters, holding workshops and organizing seminars. These efforts have deepened participants' understanding and trust in the JECS, resulting high response rates for questionnaires and high participation rates in School Age Testing.
- ✧ To date, the target of communication has mostly been guardians, but moving forward, communication with the children themselves will become increasingly important. This shift means that not only provision of information and participation in workshops, but also initiatives to engage participants in the study's content and utilization of findings

will become vital.

### **Future Actions**

- ✧ The publicity of the study will play a crucial role in encouraging children – the participants in JECS – to continue their participation into adolescence and adulthood. Therefore, it will be necessary to devise effective methods of publicity to show the benefits participants receive through participation in the JECS, as well as instilling a sense of pride in being part of a globally significant study.
- ✧ With regard to the questionnaires administered to children themselves, which began at age 10, supplementary assent materials in the form of informational leaflets have been developed to boost participants' motivation to participate in the study. The use of such materials in the study past age 13 is under consideration.

(\*Assent: Agreement/approval from children which is not subject to legal restrictions)

- ✧ As the study moves beyond age 13, organic linkages with the school health field are critical. The health and physical education textbooks supplied to senior high schools in the country from the 2022 academic year introduce the JECS as “research and study that residents cooperate with” under the heading “residents’ understanding of health measures and social initiatives.” In addition to educational professionals and students using the textbooks, this description is likely to play an important role in shaping participants’ attitudes toward the JECS.
- ✧ Looking ahead, as participants may potentially move to locations around Japan for further study or employment, it will be necessary to consider methods for maintaining connections and fostering trust with them. One way to accomplish this is through surveys using a participant portal system and regular, proactive communication via the internet. To achieve this goal, it would be beneficial to establish arrangements in which researchers and participants work together in a collaborative manner, drawing inspiration from similar studies such as the ALSPAC (Avon Longitudinal Study of Parents and Children) in the U.K.
- ✧ With regard to strategies for retaining participants, transitioning to the use of ICT tools has the potential to provide benefits in terms of cost-effectiveness and reducing the burden on participants. However, there are concerns that this approach may result in lower participation rates as observed in examples from other countries. Therefore, it is crucial to carefully consider specific arrangements, such as the design of applications, to ensure high participation rates are maintained.
- ✧ Even if ICT tools are employed, it is still crucial to preserve the framework under which the Regional Centers have operated to date.

- ✧ If the study is extended beyond age 13, and particularly into adulthood, it will be essential to evaluate initiatives for maintaining participation and confirm the quality of the data being collected.

### **(3) Attention Paid to Research Ethics**

#### **Issues**

- ✧ At the current stage of the JECS, consent is obtained on behalf of participating children from their mothers during pregnancy. As the study is considered for extension beyond age 13, it is imperative to re-inform the children and obtain their individual consent.
- ✧ As the age of participants increases, it becomes crucial to pay attention to consent, withdrawal, and other related matters.

#### **Future Actions**

- ✧ In order to extend the study beyond age 13, specific methods of obtaining assent from participating children from age 13, informed consent from participants between the ages of 16 and 18, and consent from their spouses will need to be considered.
- ✧ The Review Committee on Epidemiological Studies organized by the Ministry of the Environment, serves as the forum for regular reporting on the progress of the JECS and other related matters from the National Institute for Environmental Studies, as well as the deliberation of ethical consideration for the future. These discussions will continue to be in accordance with the ethical guidelines for studies stipulated by the national government.
- ✧ The National Institute for Environmental Studies serves as the lead research institution and has adopted the central review process for research ethics review of the JECS. In addition, the institutional review boards of the National Institute for Environmental Studies, the National Center for Child Health and Development, and the respective Regional Center organizations will also deliberate and approve matters that require ethical consideration.
- ✧ The basic policy regarding genetic analysis is to not report the results to participants, but any incidental findings during the genetic analysis process will need to be addressed appropriately in conjunction with specialists.
- ✧ Obtaining consent from participants regarding the usage and application of data by companies, requires consideration from a research ethics standpoint.

#### **(4) Linkages with Health and Medical Data**

##### **Issues**

- ✧ Unlike in various countries where epidemiological studies of a similar scale to the JECS are being undertaken, there is currently no established disease registry in Japan. As such, it is necessary to rely on family doctors to provide the necessary data in order to receive information about diseases of JECS participants. Moving forward, it is crucial to explore ways to establish linkages with other sources of health and medical data in order to improve the efficient implementation of the JECS.
- ✧ The JECS is currently linking with data from demographic surveys. However, there are no established linkages with public medical check-up data such as prenatal check-ups, infant and toddler check-ups, and school check-ups. Additionally, there are no current linkages with public databases in the public health field, such as the National Cancer Registry database, the Designated Intractable Disease database, the Specific Pediatric Chronic Disease patient database, the DPC database, and MID-NET.
- ✧ In order to effectively analyze data from multiple sources on the individual level, it is important to think ahead about how to enable these linkages. However, this task is faced a wide range of issues, including restrictions based on the Act on the Protection of Personal Information, the need for anonymization, and the procedures for information management. Without proper legislative backing, linking these databases with the JECS data is extremely difficult in practice.
- ✧ The insurance identification number is the leading candidate for the key information needed for linking databases. However, this number changes each time an insured individual transfers and confirming the identity of the same individual across multiple insurance identification numbers is currently problematic in research operations.

##### **Future Actions**

- ✧ To ensure the capability of linking individual records in the JECS with other databases, it is important to obtain informed consent and their individualized insurance identification number, and to record them in the database from this point forward.
- ✧ Coordinating with relevant institutions is essential to allowing the JECS to verify the identity of the same individual using the history of a change history of individualized insurance identification numbers in the future.
- ✧ Building trust and positive relationships with participants is crucial in the provision of health and medical data, and it is therefore essential to implement strategies to alleviate any concerns they may have.

## **(5) Collection and Storage of Biological Samples**

### **Issues**

- ✧ The collection of over 4.5 million biological samples through the JECS is of immense value as a national project and proper management is needed to ensure effective utilization in the medium to long term.
- ✧ Advances in measurement technology may expand the range of uses for these samples beyond the original intent. However, currently, access to samples is manually managed, making it challenging to efficiently manage these valuable samples.
- ✧ Collecting biological samples and conducting chemical analysis at or after age 13 is essential for studying the impact of current and post-adolescence exposure on pregnancy and reproduction, neuropsychological development, the immune system and allergies, metabolism and the endocrine system, and other health conditions. As the number of stored samples is expected to continue growing, it is necessary to establish an appropriate management structure.
- ✧ It is beneficial from both technical and practical perspectives to store and manage biological samples of human biomonitoring (HBM)\* in the same facility as the JECS samples. These projects play as two policy pillars in chemicals risk assessment.  
(\*Regular monitoring of the amounts of chemicals accumulating in the bodies of people)
- ✧ As genetic analysis will soon begin, it is necessary to consider appropriate methods of storing biological samples that align with the analysis method.

### **Future Actions**

- ✧ Ensuring quality management of these valuable biological samples is fundamental for the JECS and HBM data. Efficient sample quality management, including dispensing new and existing samples into smaller amount, is a crucial task. Systematization encompassing automation of access management is essential.
- ✧ Utilizing the latest measurement technology to ensure data accuracy management and considering a long-term plan for facility upgrades are also important.
- ✧ For certain substances where toxicity is a concern, it is essential to not only store but also use and analyze biological samples to compare and present exposure levels.
- ✧ After obtaining informed consent, arrangements for providing biological samples to researchers should also be considered.

### **3. Issues and Future Actions from a Utilization of Findings Perspective**

#### **(1) Usage and Application of Data**

##### **Issues**

- ✧ As a vital database that comprises data related to environmental, genetic, social, and lifestyle factors through a national project, the JECS has received requests for data sharing from researchers across diverse fields, from social science to economics.
- ✧ The transition to open data will enable data sharing and bring greater benefits in a variety of fields, while also addressing issues in the bio, psycho, and social dimensions of children.
- ✧ Being a birth cohort study that comprises a large number of biological samples and data items during pregnancy and post-birth, the JECS also enables study of long-term health effects on women. Utilization of the data is also anticipated from a life-course approach perspective.

##### **Future Actions**

- ✧ It is imperative to devise a data sharing implementation plan and make preparations for the initiation of data sharing operations.
- ✧ The operations for data sharing are being designed so that users access the data sets managed at the Programme Office. Testing of these operations for researchers at public research institutions and universities within Japan will be undertaken as a first step.
- ✧ Once stable and reliable data sharing has been established, expanding the scope of data sharing to include overseas researchers and companies is desirable.

#### **(2) Policies for Effectively Returning the Benefits of Findings to Society**

##### **Issues**

- ✧ In fiscal year 2020 surveys, awareness of the JECS was around 11% among approximately 5,000 members of the general public and 45.4% in around 900 doctors, respectively. Despite showing an upward trend, further efforts in increasing public awareness are still necessary.
- ✧ The relationships between environmental factors and health effects identified through the findings of the JECS, an observational study, constitute one form of evidence to infer causality. Therefore, to fully establish causal relationships, it is crucial to continuously gather more evidence. It is essential to adopt a risk



communication perspective when communicating the findings of the JECS, by engaging specialists and referencing known findings to avoid misinterpretations.

- ✧ In fiscal year 2021, as children participating in the study have now all reached elementary school age, liaison with schools, where children spend a large portion of their days, is required.
- ✧ In cases where the toxicity of chemicals or other risks is suggested from the findings of the JECS, making progress on further studies and/or necessary risk reduction based on the state of exposure are key tasks.

### **Future Actions**

- ✧ The findings of the JECS, to date, have been reflected in a variety of guidelines. Going forward, it is expected that active efforts will be provided to provide societal benefits through the expansion and enhancement of measures related to chemicals based on the JECS findings. Placing the JECS central, it is important to work together with influencers which have a strong influence on the generation who will become parents in future, expectant and nursing mothers, and those currently bringing up children, policymakers such as related government agencies, and companies selling products which are strongly interested in the interest and purchasing intention of the target people. It is necessary to communicate information and provide benefits to society in order to promote behavioral change among the general public.
- ✧ Besides analyzing data from the whole participants around Japan, the findings of the JECS are also expected to include analyses of environmental- and health-related issues in each region.
- ✧ Initiatives that leverage the networks built around the respective Regional Centers are likely to be effective, which include providing JECS-related documents to government agencies and medical institutions as a source of reliable information.
- ✧ Collaboration with the educational sector is very important when disseminating information to children on a large scale, and thus, strengthening organic communications with the educational sector through the JECS will be needed.
- ✧ In response to possible toxicity of chemicals indicated by the JECS, anticipated benefits for society include voluntary initiatives by companies, the development of safe substitute products, appropriate product labeling, and other risk reduction measures.
- ✧ The JECS is particularly relevant to two of the 17 Sustainable Development Goals

(SDGs) laid out in the “SDGs Action Plan 2022”: Good Health and Wellbeing (#3) and Responsible Consumption and Production (#12). By returning the benefits of the research findings to society, participants will come to understand the significance of their involvement in the study, which will contribute to maintaining a high participation rate. Furthermore, actively participating in the JECS for the benefit of future children will also become a message conveying SDG initiatives about children to society more broadly.

### **(3) HBM for Effective Usage of JECS Findings**

#### **Issues**

- ✧ The results of biological sample analysis reveal individual's actual exposure to and absorption of chemicals, providing valuable information when investigating the total amount of exposure from multiple sources and past exposure levels.
- ✧ The JECS gathers a vast amount of data on various evaluation items from approximately 100,000 mother-child pairs (and fathers where available). However, even if this data suggests the toxicity of chemicals, accurate risk evaluations are not possible without conducting HBM to ascertain a background comparison point for the state of exposure, as the levels of chemicals ingested into the body and past exposure levels remain unknown.
- ✧ Exposure levels are highly likely to vary significantly according to countries, as well as certain aspects of genetic background. Without evaluating exposure levels in Japan through HBM, international comparisons are not possible.
- ✧ HBM is already being utilized internationally for effectiveness evaluation under the Stockholm Convention on Persistent Organic Pollutants, and is also being considered for effectiveness evaluation under Minamata Convention on Mercury, which Japan leads the world.

#### **Future Actions**

- ✧ As building a database using HBM takes around 10 years, it is necessary to consider the HBM format as one of the two pillars of environmental policy that needs to be implemented concurrently with the JECS.
- ✧ The requirements of HBM include a balance of regional, gender, and age representation, a certain scale (comprehensiveness, scale), tracking trends (continuity), collection of exposure data as well as health and disease information (association evaluation with diseases), nutritional information to enable analysis of

compound influences (compound impact evaluation), and data being available to researchers and administrative officials (public openness).

- ✧ The National Institute for Environmental Studies, which is in charge of operating the JECS, is expected to consider the implementation structure of HBM based on its experience in biological sample analysis and storage and to provide findings to the relevant government agencies about chemicals measures.

#### **(4) International Networks**

##### **Issues**

- ✧ In terms of health effects, information related to rare diseases such as pediatric cancers and congenital anomalies is extremely valuable in making international comparisons. However, due to the low incidence, there are limitations in conducting statistical analysis based solely on the JECS data.
- ✧ The know-how gained through the JECS may have potential for international usage and support as part of chemicals measures.

##### **Future Actions**

- ✧ The analysis of rare diseases needs to be promoted through specific initiatives, such as international collaborative research, with due consideration given to personal information.
- ✧ In the future, it is necessary to utilize the knowledge and technology developed through the JECS to provide technical support for developing countries.
- ✧ It is anticipated to monitor international trends related to management of chemicals, particularly those led by the European Union, and work to provide the JECS findings in Japan to international initiatives.
- ✧ Consideration will be given to strengthening connections with international institutions, including providing information to organizations such as the World Health Organization (WHO).

## **Conclusion**

- The JECS project is an important national initiative that serves as a foundation for measures related to children's well-being. By promoting the JECS, which examines all aspects of the environment affecting children, society as a whole can assist in fostering the healthy growth of children.
- As the oldest children participating of the study will reach the age of 13 in fiscal year 2024, it is necessary to formulate a conceptual plan and a study protocol for extending the JECS beyond age 13 during fiscal year 2022.
- When extending the study from age 13 to age 40, it will be essential to consider the sustainability of the study by reviewing it in its entirety through a PDCA cycle exercise around 10 years after the start of the study beyond age 13, during which period many participants are expected to begin their adult life.
- In addition, the study will not be concluded once participants reach age 40, conducting an evaluation that takes into account a study beyond age 40 is anticipated.
- As the environment changes in various ways in the future, it will be necessary to discuss the shape of a new cohort corresponding to the changes in society and the environment as well as sustaining the JECS, in addition to linkages between the existing JECS and the new cohort.

## Progress of the Health and Environment Epidemiological Study Working Group

### **First meeting Monday, July 19, 2021, 3PM to 5PM**

- (1) Summary of JECS to date
  - Overview of JECS
  - Findings obtained through JECS to date
- (2) Issues related to health and the environment from childhood onwards
- (3) Issues regarding extending the study from childhood onwards
- (4) Policies for effectively returning the benefits of findings to society
- (5) Other

### **Second meeting Friday, September 10, 2021, 1PM to 3PM**

- (1) Recap of discussion to date
- (2) JECS operational structure and Programme Office initiatives
- (3) Future schedule
- (4) Other

### **Third meeting Friday, October 22, 2021, 1PM to 3PM**

- (1) Recap of discussion to date
- (2) Open hearing sessions featuring JECS participants and related academic societies
- (3) Future schedule
- (4) Other

### **Fourth meeting Wednesday, December 15, 2021, 1PM to 3:30PM**

- (1) Recap of discussion to date
- (2) Open hearing sessions featuring related academic societies, etc.
- (3) Returning the benefits of findings to society
- (4) Future schedule
- (5) Other

### **Fifth meeting Thursday, January 20, 2022, 3PM to 5PM**

- (1) Draft report
- (2) Other

### **Sixth meeting Friday, February 18, 2022, 1PM to 3PM**

- (1) Report (draft)
- (2) Other

Members of the Health and Environment Epidemiological Study Working Group  
(Titles omitted, alphabetical order)

Name	Affiliated organization and position
Naoko ARATA	The Japan Endocrine Society
Toshihide ARIMURA	Professor, Faculty of Political Science and Economics, Waseda University
Mari ASAMI	Chief Senior Researcher, Department of Environmental Health, National Institute of Public Health
Satoko HIRATA	Tamago Club Editorial Department, Fusansha Co., Ltd. “Tamago Club” Deputy Chief Editor, “First Tamago Club” Chief Editor.
Hiroaki ITOH	Japan Society of Obstetrics and Gynecology
Kichiro MATSUMOTO	Executive Board Member, Japan Medical Association
NA-CHAN	YouTube Expert Mom
Yumiko NARA	Professor, Faculty of Liberal Arts, Open University of Japan
Junko OBATA	Professor, Graduate School of Law, Sophia University
Kazuhiko OHE	Professor, Graduate School of Medicine, University of Tokyo
Akira OKA	President, Japan Pediatric Society
Hiroshi SATOH	Professor Emeritus, Tohoku University
Atsushi TAJIMA	Professor, Faculty of Medicine, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University
Naoko TAKASAKI	Director of Chemicals Management Department, Japan Chemical Industry Association
Akiko TAMAKOSHI	Professor, Public Health Division, Social Medicine Field, Graduate School of Medicine, Hokkaido University
Akihiro YONEDA	Vice President, The Japanese Society of Pediatric Hematology/Oncology

Observers to the Health and Environment Epidemiological Study Working Group  
(Titles omitted)

Name	Affiliated organization and position
Takashi IGARASHI	President and Chief Executive Officer, National Center for Child Health and Development
Michihiro KAMIJIMA	Chair, JECS Operational Committee, Manager, Aichi Regional Center Professor, Graduate School of Medical Sciences Department of Occupational and Environmental Health, Nagoya City University
Shoji NAKAYAMA	Deputy Manager, JECS Programme Office, National Institute for Environmental Studies
Yukihiro OYA	Manager, Medical Support Center of JECS, Director, Allergy Center, National Center for Child Health and Development
Takashi TOMISAKA	Deputy Manager, Planning Division, National Institute for Environmental Studies
Iwao UCHIYAMA*	Chair, JECS Project Evaluation Committee Professor Emeritus, Kyoto University
Zentaro YAMAGATA	Manager, JECS Koshin Regional Center Chair, JECS Strategic Publicity Committee Professor, Basic Science for Clinical Medicine, Division of Medicine, Graduate School Department of Interdisciplinary Research, University of Yamanashi
Shin YAMAZAKI	Manager, JECS Programme Office, National Institute for Environmental Studies

\*Participated from the fourth meeting of the “Health and Environment Epidemiological Study Working Group”

Participants in the Health and Environment Epidemiological Study Working Group  
Third Open Hearing Session

(In order of presentations, titles omitted)

Name	Affiliated organization and position
Takashi ETOH	Board Chair, The Japanese Association of School Health
Hiroaki ITOH	Japan Society of Obstetrics and Gynecology (member of this Working Group)
Shigenobu KANBA	Former Board Chair, The Japanese Society of Psychiatry and Neurology
KOBAYASHI	Father of a JECS participant
Norio OZAKI	Board Member, The Japanese Society of Psychiatry and Neurology (Chair, Research Promotion Committee)
HIROSE	Mother of a JECS participant

Participants in the Health and Environment Epidemiological Study Working Group  
Fourth Open Hearing Session

(In order of presentations, titles omitted)

Name	Affiliated organization and position
Koshi HASHIMOTO	Department Chair, Diabetes, Endocrine and Hematology Department, Dokkyo Medical University Saitama Medical Center
Seiichiro HIMENO	Visiting Professor, School of Pharmacy, Showa University
Hiroyasu ISO	President, Japanese Society of Public Health
Kazuhiko OHE	Professor, Graduate School of Medicine, University of Tokyo (member of this Working Group)
Akira OKA	Hospital Director, Saitama Prefectural Children's Medical Center (member of this Working Group)