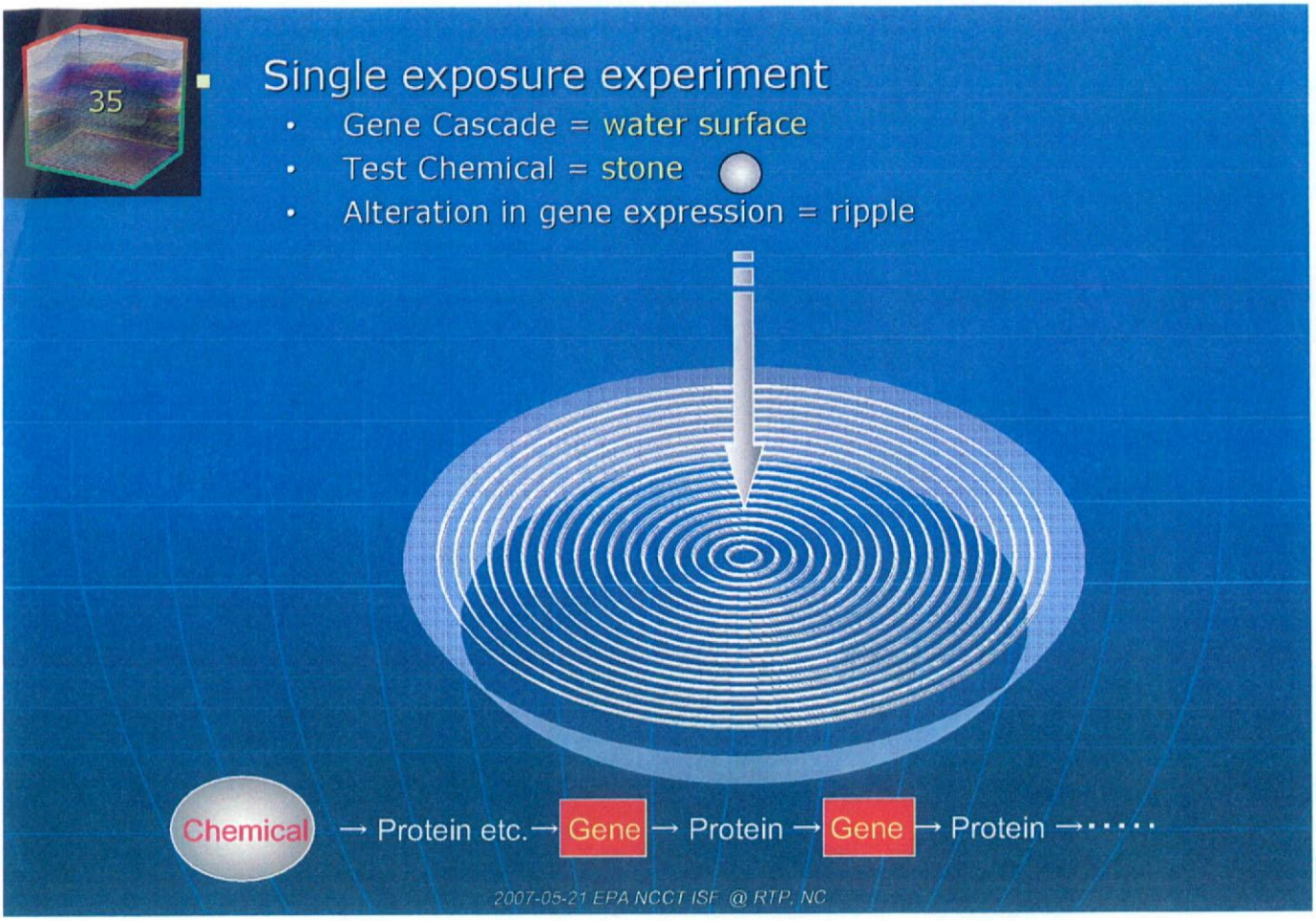
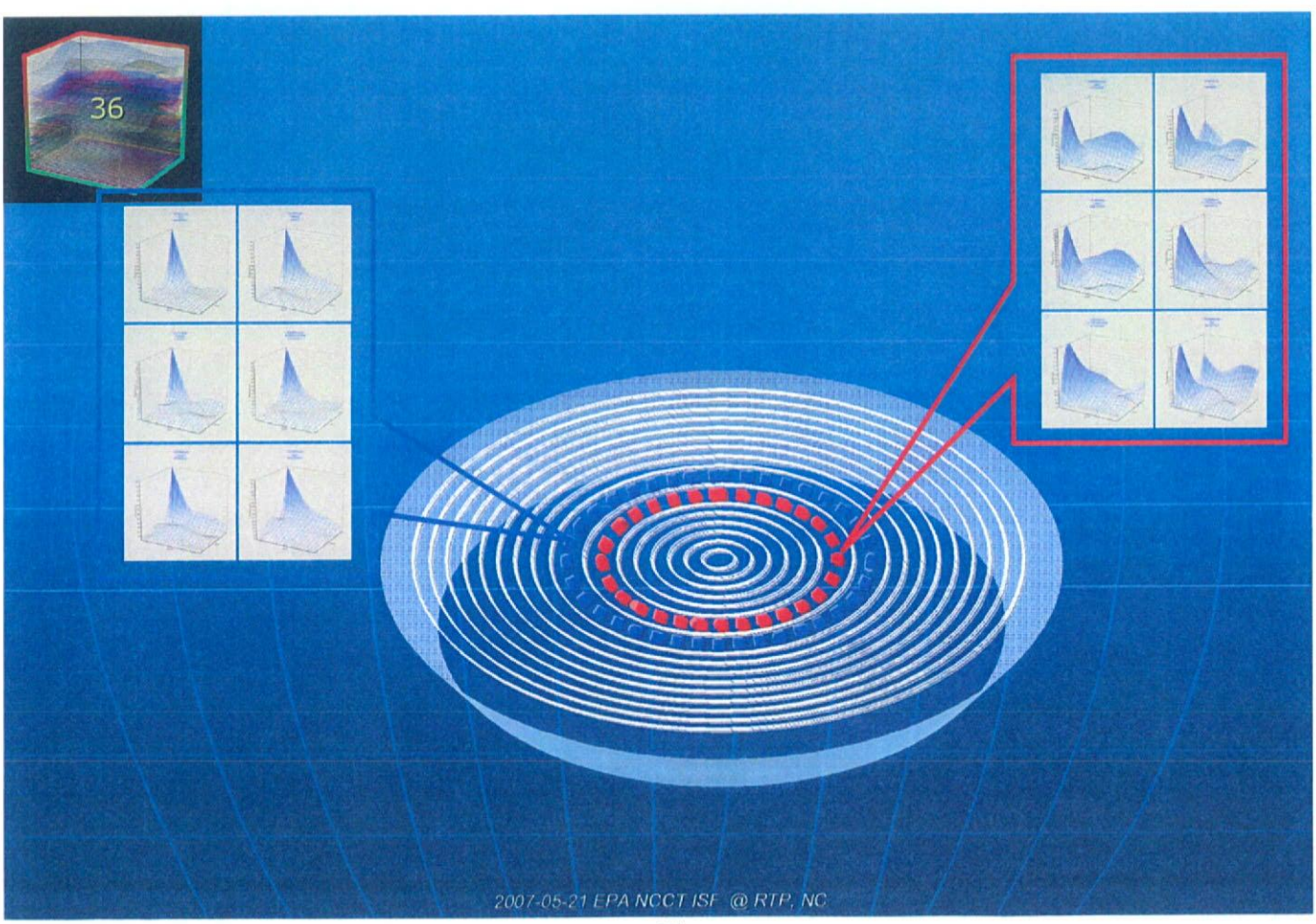

35
Single exposure experiment
Gene Cascade = water surface
Test Chemical = stone
Alteration in gene expression = ripple
Chemical
→ Protein etc.→ Gene → Protein → Gene → Protein →·····
2007-05-21 EPA NCCT ISF @ RTP, NC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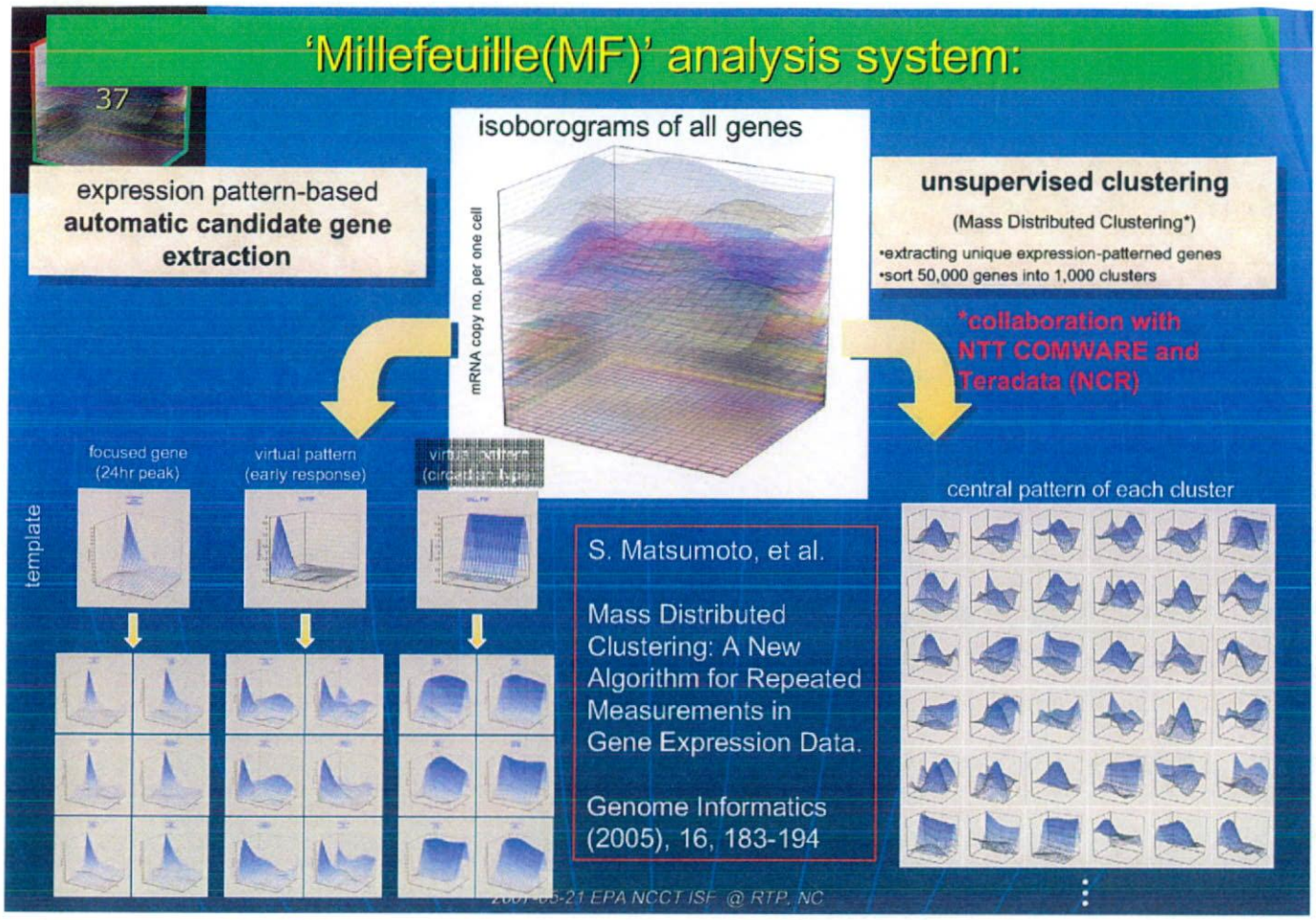
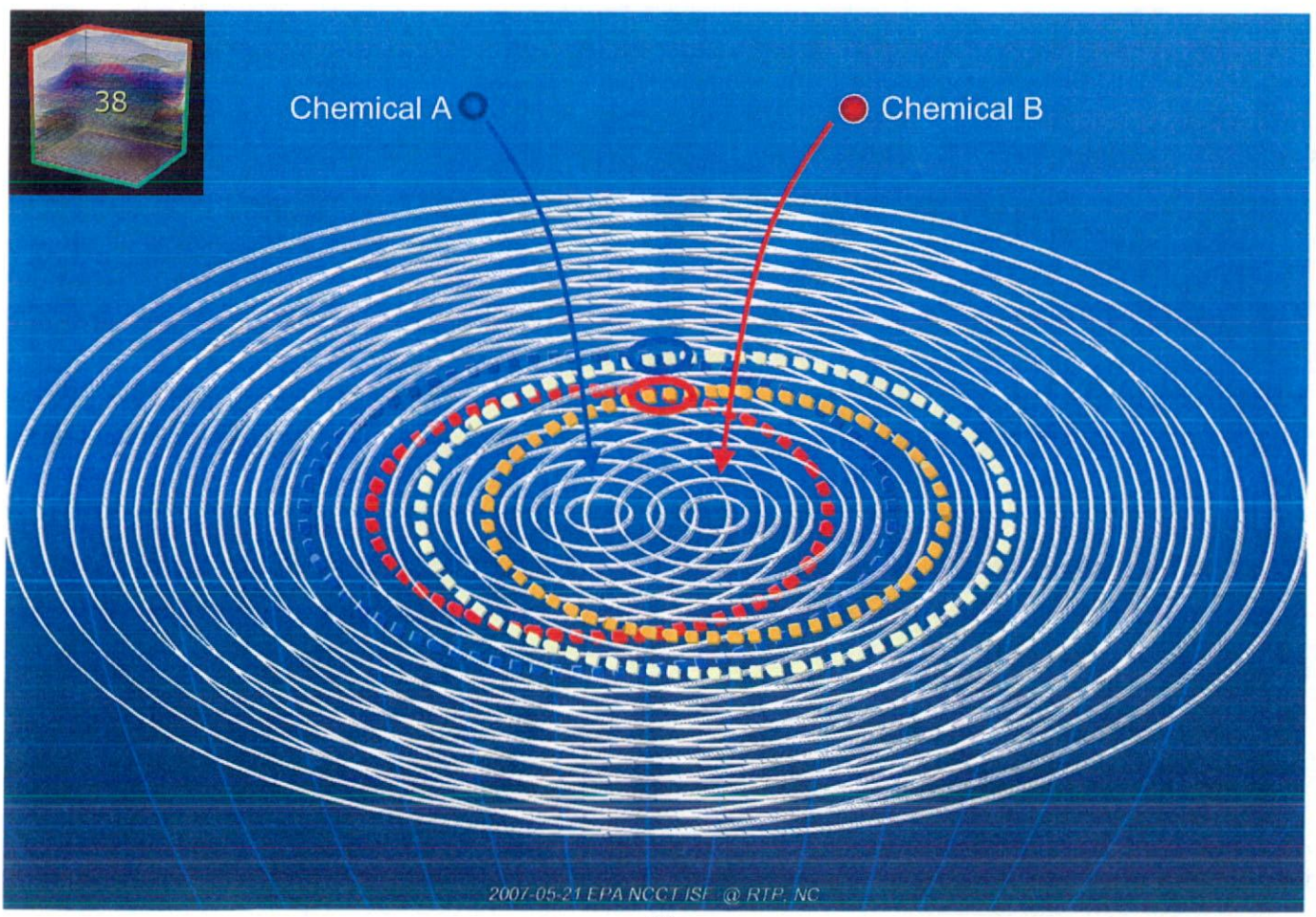
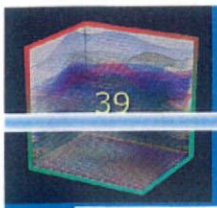
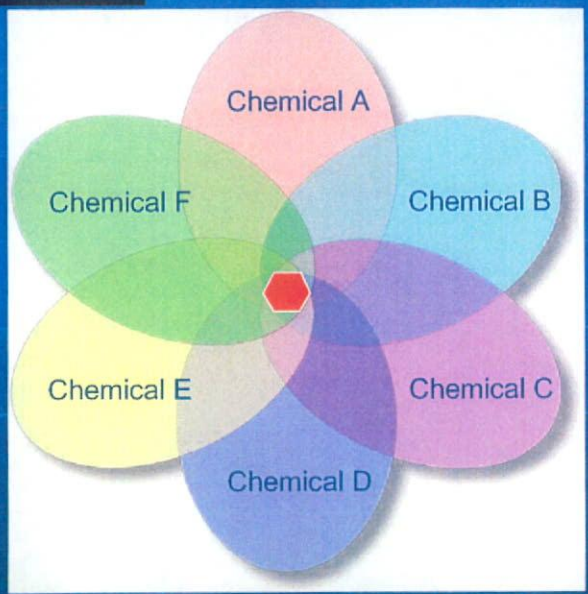

'Millefeuille(MF)' analysis system:
37
expression pattern-based automatic candidate gene extraction
isoborograms of all genes
mRNA copy no. per one cell
unsupervised clustering
(Mass Distributed Clustering*)
•extracting unique expression-patterned genes
•sort 50,000 genes into 1,000 clusters
*collaboration with NTT COMWARE and Teradata (NCR)
focused gene (24hr peak)
virtual pattern (early response)
template
central pattern of each cluster
S. Matsumoto, et al.
Mass Distributed Clustering: A New Algorithm for Repeated Measurements in Gene Expression Data.
Genome Informatics (2005), 16, 183-194
2007-05-21 EPA NCCT ISF @ RTP, NC

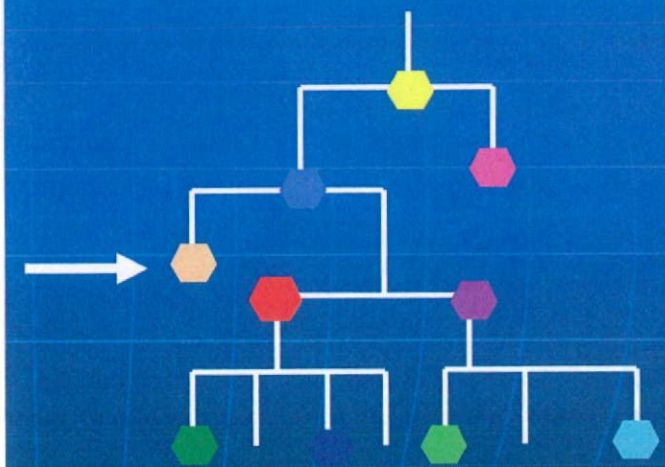

38
Chemical A
Chemical B
2007-05-21 EPA NCCT ISF @ RTP, NC



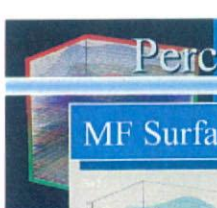
"synchronized" gene concept



Signal cascade

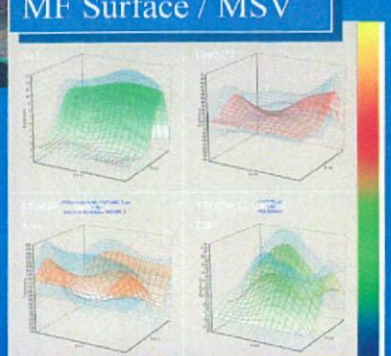


2007-05-21 EPA NCCT ISF @ RTP, NC

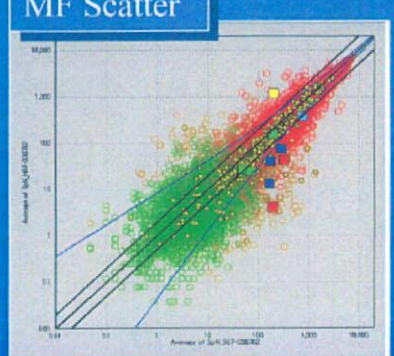


Percellome (Millefeuille data system) Visualization tools

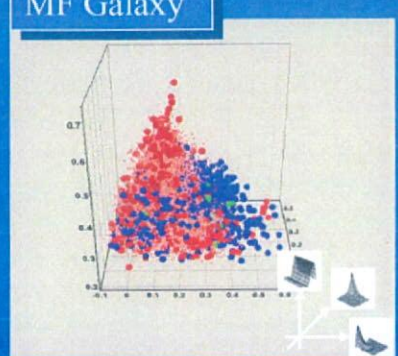
MF Surface / MSV



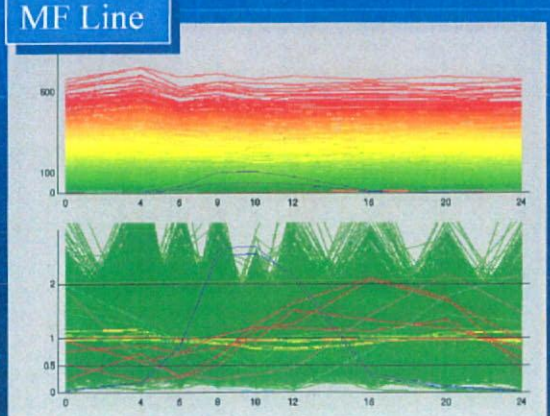
MF Scatter



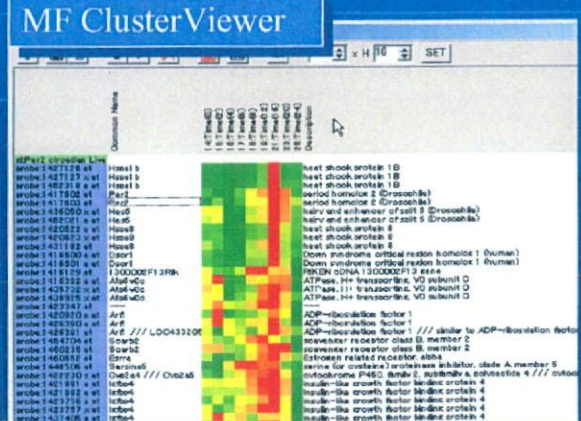
MF Galaxy



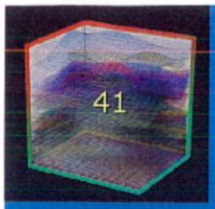
MF Line



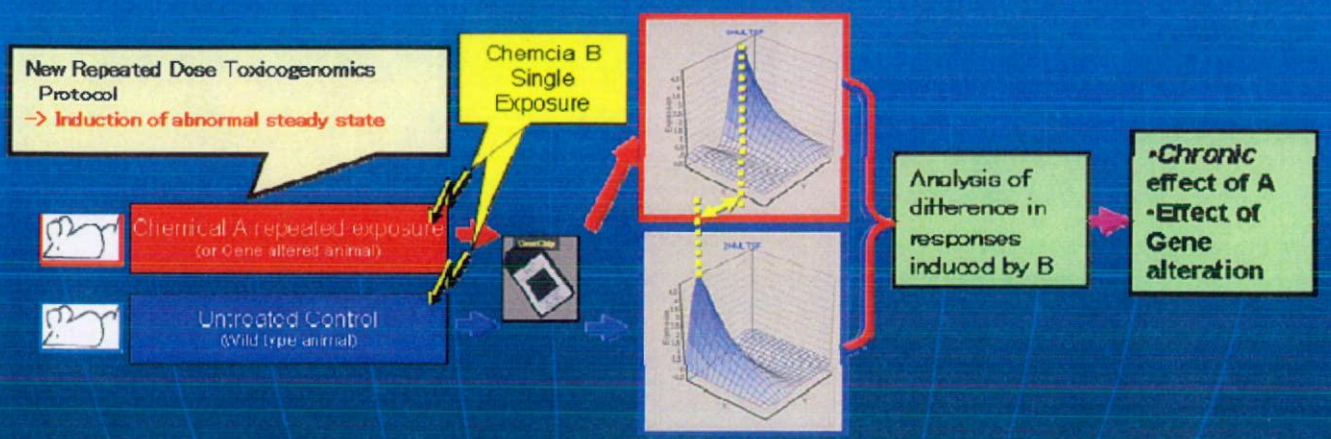
MF ClusterViewer

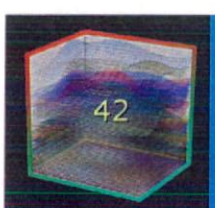


EPA NCCT ISF @ RTP, NC



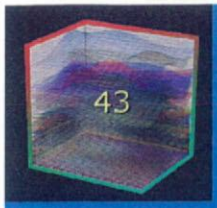
New concept of Repeated dose Toxicogenomics (which should enable direct comparison with Gene KO mouse data)



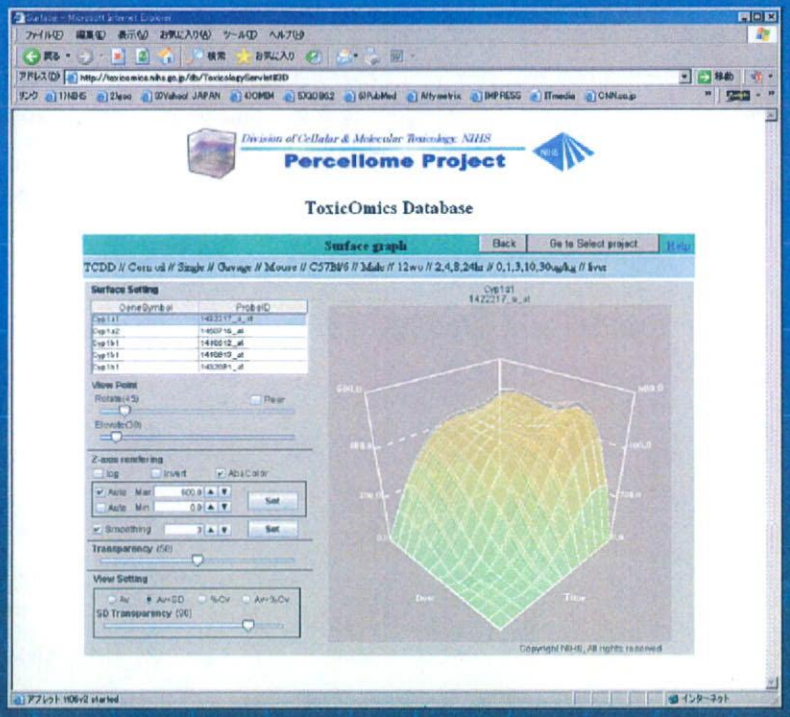


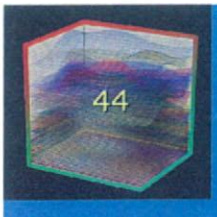
Summary

- Percellome method is developed for easy and direct comparison among samples/studies (and platforms).
- Percellome Toxicogenomics database (mouse liver, single gavage, early responses at 2, 4, 8, and 24 hrs) is developed (90~chemicals).
- Repeated dose data by new chronic study concept will be generated in next few years.
- Fetus Percellome approach seems to be very promissing for developmental toxicity studies.
- Inhalation toxicogenomics provides with higher sensitivity at low concentration near the "Sick building syndrome" levels.



http://toxicomics.nihs.go.jp/db/

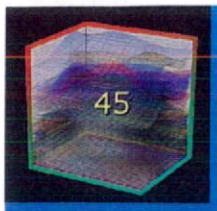




Percellome essentials

- dose-graded spike cocktail; GSC
  - synthesized from ATCC clones
- DNA quantification protocols (manual and for PerkinElmer JANUS robot)

GSC stock and protocol are available on a collaboration basis, please contact kanno@nihs.go.jp.



Development of Percellome (2001~)

Jun Kanno, MD, PhD
Katsuhide Igarashi, PhD
Ken-ichi Aisaki, MD, PhD
Atsushi Ono, PhD
Tomoko Ando, Ms
Noriko Moriyama, Ms
Yuko Kondo, Ms
Yuko Nakamura, Ms
Maki Abe, Ms

Millefeuille Softwares

Ken-ichi Aisaki, MD, PhD

IT collaboration

NTT COMWARE
with Teradata, NCR
(Shinya Matsumoto,
Bun-ichi Tajima)

Percellome Projects (2003~)

Ken-ichi Aisaki, MD, PhD
Katsuhide Igarashi, PhD
Noriyuki Nakatsu, PhD
Yukio Kodama, DVM
Tomoko Ando, Ms
Noriko Moriyama, Ms
Yuko Kondo, Ms
Yuko Nakamura, Ms
Maki Abe, Ms
Kenta Yoshiki, Mr
Nae Matsuda, DVM
Chiyuri Aoyagi, Ms
Kouichi Morita, Mr
Ayako Imai, Ms
Shinobu Watanabe, Ms
Yukio Ogawa, DVM (Inhalation)
Satoshi Kitajima DVM, PhD (Fetus)
Kentaro Tanemura PhD

NIHS TGP (with 17 Pharm) startup group (~summer 2002)

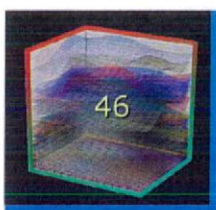
Akihiko Hirose	Risk Assess/ BSRC/ NIHS
Takayoshi Suzuki	Mutagen/ BSRC/ NIHS
Makoto Shibutani	Path/ BSRC/ NIHS
Katsuhide Igarashi	Tox/BSRC/NIHS
Atsushi Ono	Tox/BSRC/NIHS
Ken-ichi Aisaki	Tox/BSRC/NIHS
Jun Kanno	Tox/BSRC/NIHS

Percellome Collaborator Scientists

Dr. Shigeaki Kato
Dr. Yoshiaki Fujii-Kuriyama
Dr. Bruce Blumberg
Dr. Hironobu Sasano
Dr. Yumiko Saga
Dr. Seiichi Hashimoto
Dr. Yasufumi Shigeyoshi
and others

Grants

Ministry of Health, Labor, and Welfare (MHLW) Grant-in-Aid H18-Kagaku-Ippan-001, H15-kagaku-002, H14-Toxico-001, H13-seikatsu-012, & MOE



- END

MEETING OF THE EXTENDED OECD/IPCS ADVISORY GROUP ON TOXICOGENOMICS

To be held at Room C 111, U.S. EPA Facility, Building C –Auditorium, 109 T.W. Alexander Drive, Durham, North Carolina, USA, 24 May 2007

DRAFT AGENDA (Version 18 May 2007)

The meeting starts at 08h30 and closes at 17h30 on Thursday, 24 May 2007.
Overall Chair for Meeting: Robert Kavlock, U.S. EPA/ORD/NCCT

Thursday, 24 May 2007		
08h30	**1**	**Opening (10min)**
		• The meeting will be opened by the OECD/IPCS Secretariats. The host country, the U.S. EPA [Bob Kavlock, ORD/NCCT], will deliver welcoming remarks. • The Secretariat will explain housekeeping items. The Secretariat will also confirm that the participants have all meeting documents. • The participants will briefly introduce themselves to the meeting. • The meeting will be asked to approve the agenda, and discuss changes in meeting papers and scheduling of the agenda items if necessary.
08h40	**2**	**Background and specific interests of participants (30min)**
		• The lead country, the U.S.EPA [Bob Kavlock, ORD/NCCT], will present the background on the OECD Molecular Screening Project, proof of concept from pharma experience. The overall goal of the meeting is to begin to identify areas of cooperation centered around five types of activities: – Endpoints of concern – Chemicals of concern – Modes of action of concern – Screening data generation adding new assays for common chemicals, or new chemicals to common assays – Data analysis/sharing • The OECD Secretariat [Take Fukushima, OECD/ENV/EHS] will present the synopsis of responses and interests from survey forms and countries and stakeholder interests.
09h10	**3**	**Report from member countries and stakeholders: Part 1** **(70 min: time inclusive of questions)**
		• Presentations from member countries and stakeholders will be made to share information on activities/data using toxicogenomics and other methods (e.g., High-Throughput Screening (HTS), High-Content Screening (HCS)) for prioritizing further testing of environmental chemicals. This will provide a background to the following agenda item in which possible partnerships among member countries and stakeholders and the next steps for the OECD project will be discussed. • The lead country, the U.S. EPA will make a presentation on (1) U.S. EPA s ToxCast program for chemical prioritization [David Dix, ORD/NCCT] and (2) regulatory perspectives on ToxCast [Phil Sayre, OPPT/RAD]. • OECD member countries will be invited to present their own activities. 09h50: George Douglas (Health Canada) & Sean Kennedy (Environment Canada)
10h20		*Coffee break (15min)*
10h35	**3**	**Report from member countries and stakeholders: Part 2**

		(115 min: time inclusive of questions)
		• OECD member countries will be invited to present their own activities (cont.). 10h35: Jun Kanno (NIHS, Japan) 11h05: Tomoyuki Shirai (Nagoya City Univ., representing METI/NEDO, Japan) 11h35: Sue Nie Park (NITR/KFDA, Korea) 11h55: Jan van Benthem (RIVM) & Rob Stierum (TNO, the Netherlands) 12h25: Take Fukushima (OECD) on behalf of the Spanish Ministry of Environment
12h30		*Lunch break (50min)*
13h20	**3**	**Report from member countries and stakeholders: Part 3** **(105 min: time inclusive of questions)**
		• OECD member countries will be invited to present their own activities (cont.). 13h20: Ray Tice (U.S. NIEHS/NTP) 13h30: Chris Austin (U.S. NIH/NCGC) • Other stakeholders (industry and academia) will be invited to present their own activities and views. 13:40 Rick Becker & Mark Maier (BIAC) 14:05 Remi Bars (ECETOC) 14:20 Gladys Ouedraogo & Stephanie Ringeissen (L'Oreal Research) 14:35 Rich Peffer (Syngenta Crop Protection) 14:50 Ingemar Pongratz & Maria Bondesson (Karolinska Institute)
15h05	**4**	**Initial discussion about the Molecular Screening Project (55min)** [David Dix, U.S.EPA/ORD/NCCT = Lead; Sean Kennedy; Environment Canada = Co-lead]
		• This session will serve to find common areas of interest among member countries, given the Reports from Item 3 of the Agenda. The lead country, represented by the U.S.EPA, will discuss with member countries possible proposals for next steps in the work plan for an OECD-wide project. The proposal for this collaborative effort would include (i) a workshop with member countries and stakeholders in 2008; (ii) the development of an issues paper and/or publication for the workshop which summarizes approaches and case study data of member countries; (iii) the development of draft criteria for selection of chemicals and assays for the project, as well as informatics and other support for the project. • The participants will be invited to consider the proposal and provide comments as appropriate. Partnerships and participation in the project would be also sought. - Endpoints of concern - Chemicals of concern - Modes of action of concern - Screening data generation ***** adding assays, or chems to common assays - Data analysis/sharing - MOUs
16h00		*Coffee break (20min)*
16h20	**5**	**Development of Action Items (40 min)** [Sean Kennedy, Environment Canada = Lead; Phil Sayre, U.S.EPA/OPPT/RAD = Co-lead]
17h00	**6**	**Conclusions from Item 5 and Next Steps (30min)** [Bob Kavlock, U.S. EPA/ORD/NCCT ; Take Fukushima, OECD/ENV/EHS]

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

18-Oct-2007

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

TOXICOGENOMICS - REPORT FROM THE EXTENDED ADVISORY GROUP

41st Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology

13-15 June 2007, beginning at 10h00 on 13 June

OECD La Defense Site (Tour Europe)
33 Place des Corolles
92049 Paris La Defense 2 - France

Mr. Take Fukushima
Tel: +33 (0) 1 45 24 79 07, Fax: +33 (0) 1 45 24 16 75, Email: take.fukushima@oecd.org

JT03234257

ENV/JM/RD(2007)3/REV
For Official Use

English - Or. English

This document is the final report of the meeting of the extended OECD/IPCS Advisory Group on Toxicogenomics held on 24 May 2007, which provides the outcomes of the meeting and next steps. The provisional draft was submitted to the 41st Joint Meeting on 13-15 June 2007 and it was sent to the extended Advisory Group meeting seeking comments and approval by a written procedure in June 2007. The report was approved by the extended Advisory Group with some editorial changes.

BACKGROUND

1. As part of the OECD/IPCS collaborative effort on toxicogenomics, the OECD has started the project *"Molecular Screening for Characterizing Individual Chemicals and Chemical Categories Project"* (Molecular Screening Project), which will select a number of chemicals and evaluate them in a series of molecular screening assays with the aim of establishing a strategy for rationally and economically prioritizing chemicals for further evaluation based on molecular properties and categories linked to potential toxicity (see Annexes 1 and 2). The project is led by the United States and is under the supervision of the joint OECD/IPCS Advisory Group on Toxicogenomics.

2. As an initial step to the project, the 40th Joint Meeting in November 2006 agreed, upon a proposal from the lead country, to hold a meeting of the extended Advisory Group inviting participants from member countries and stakeholders outside the Advisory Group who are active in research management or regulatory decision making related to chemical prioritization [ENV/JM/M(2006)2, paragraphs 42 and 43].

3. The Advisory Group developed a plan for the meeting and a set of background questions to be addressed at the meeting, holding a series of teleconferences in December 2006 – January 2007. Background questions were sent to the Heads of Delegations to the Joint Meeting in January 2007, together with an announcement of the meeting [ENV/EHS/RV/2007.06]. The responses were received from Canada, Japan, Korea, the Netherlands, Spain, Sweden, and the United States,

MEETING

4. The meeting of the extended OECD/IPCS Advisory Group was held on 24 May 2007 at the U.S. EPA's Main Campus in Research Triangle Park, North Carolina, the United States, hosted by the U.S. EPA. The meeting was attended by experts nominated by Canada, Japan, Korea, the Netherlands, Sweden, the United States, BIAC and ICAPO, invited experts from industry (ECETOC; L'Oreal Advanced Research; Syngenta Crop Protection) and academia (Karolinska Institute) and the OECD Secretariat. A list of participants is attached to this document as Annex 3. The meeting was chaired by Bob Kavlock (U.S. EPA) and co-chaired by Sean Kennedy (Environment Canada).

5. The objectives of the meeting were to (i) assess the overall feasibility of the approach to molecular screening, (ii) to solicit partnerships for collaborative efforts, and (iii) to propose next steps.

Opening

6. The meeting was opened by the host country, the United States. Following the Secretariat's introduction on activities of the Advisory Group and objectives of the meeting, the United States presented the background and targets of the Molecular Screening Project as a lead country of the project.

Report from member countries and stakeholders

7. To provide a background to the discussion concerning partnerships among member countries and stakeholders and the next steps for the Molecular Screening Project, member countries and stakeholders made presentations to share information on activities/data using toxicogenomics and other methods (e.g., High-Throughput Screening (HTS)[1], High-Content Screening (HCS)[2]) for prioritizing further testing of environmental chemicals, as well as their views on possible regulatory application of such methodologies:

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[1] *High-Throughput Screening (HTS)* examines large numbers of chemicals against a generally narrowly defined biological target (for example, inhibition of an enzyme or activation of a receptor); because of their simplicity, such assays can be capable of being applied to thousands of chemicals in a short time period (days to weeks).

- United States (lead country): U.S. EPA's *ToxCast Program* for prioritizing the toxicity testing of environmental chemicals which should proceed in collaboration with the OECD's Molecular Screening Project; EPA's views on utility of genomics and HTS approaches for the assessment of industrial chemicals.

- Canada: Health Canada's research projects including validation studies and biomarker discovery; Environment Canada's research projects using or developing genomics methods; Status of chemical prioritization in Canada and toxicogenomics data's potential.

- Japan: MHLW/NIHS's *Percellome Toxicogenomics Project* for the mechanism-based toxicology; As an extension, the project database should be used in the near future as a reference database for faster, cheaper and smaller-scale *in vivo* screening. Using main Percellome database as reference, data from small-scale *in vivo* screening assays are effectively analysed to increase specificity and predictivity of the toxicologic profiles of the chemicals. METI/NEDO's project for the *Development of a Short-term Prediction Method for Carcinogenicity of Chemicals Based on Toxicogenomic in Rats.*

- Korea: NITR/KFDA's *National Toxicogenomics Program* consisting of various research projects including the development of a database for toxicological prediction profiles and the development of toxicity test methods.

- Netherlands: RIVM's toxicogenomics research; TNO' toxicogenomics and associated bioinformatics research; *Netherlands Toxicogenomics Centre* participated by RIVM, TNO etc. with the aim of the development of toxicogenomics-based in vitro approaches similar in part to ToxCast for the evaluation of chemical safety with the human health endpoints.

- Spain (absent and substituted by the Secretariat): Ministry of Environment's interest in chemical prioritization/categorization/hazard identification under the context of REACH.

- United States: NIEHS/NTP's *High Throughput Screening Initiative* and collaboration with EPA's ToxCast Program; NIH Chemical Genomics Center's *Quantitative high-throughput screening (qHTS)* and collaboration with NTP' HTS Initiative and EPA' ToxCast Program.

- BIAC (ACC and CropLife): industry perspective on benefits, current challenges and future directions of regulatory applications of toxicogenomics; variability and limitations of toxicogenomics and HTS data; interest in considering collaborations with the Molecular Screening Project/ToxCast.

(Invited experts)

- ECETOC: outcomes of *ECETOC/LRI Workshop on Toxicogenomics and Male Reproductive Development* in November 2006; ECETOC's current and future omics initiatives

- L'Oreal Advanced Research (France): interest in toxicogenomics and HTS/HCS as prioritization methods and interest for joining the Molecular Screening Project/ToxCast.

- Syngenta Crop Protection (United States; United Kingdom): perspectives and some suggestions on toxicogenomics: e.g., omics would be appropriate for prioritization, not for direct regulation; need to create appropriate data analysis methods; need data on large and unbiased training and test set.

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[2] *High-Content Screening (HCS)* examines the response of a generally broad range of biological targets (for example, microarray based toxicogenomics); because of the expense of the technology and the complexity of analyzing the large volume of data derived from each sample, these techniques are usually applied to relatively small numbers of chemicals (tens to hundreds).

- Karolinska Institute (Sweden): *CASCADE (Chemicals as contaminants in the food chain: a Network of Excellence for research, risk assessment and education)* which is networking experts in Europe, coordinated by the Karolinska Institute. The Karolinska Institute has ongoing work similar to ToxCast.

8. Some general observations on perspectives and approaches of countries and stakeholders were provided as follows:

- Participating member countries and stakeholders generally recognize that the toxicogenomics methods and HTS/HTC have a great potential for providing useful data for the evaluation of chemical safety.

- Participants generally presented approaches along two main dimensions: (i) HTS approaches for chemical prioritization and categorization; and (ii) HCS approaches (generally in vivo microarray based genomics) for determination of mode/mechanism of action of chemical toxicity. There appeared to be some overlap in the types of chemicals under study in both areas, but further analysis of the overlap appears necessary.

US proposal for the Molecular Screening Project

9. Following introductory presentations, the United States presented its proposal for the work plan of the Molecular Screening Project (see Annexes 1 and 2) inviting participation in collaborative efforts such as (i) data generation through additional assays and/or additional chemicals to the U.S. EPA's ToxCast Program, (ii) data sharing and/or (iii) analysis of gathered data. It was also suggested to make all data publicly available.

10. Given the U.S. EPA's workplan that raw data of ToxCast Phase 1 (proof-of concept phase) will be available in September 2007 and will be partially analyzed by December 2007 (see Annex 2), participants were invited to (i) indicate their initial interests in collaborative efforts through CRADA (cooperative research and development agreement), bilateral agreements or other mechanisms and (ii) participate in the project as soon as possible. This participation could be in the form of augmenting ToxCast Phase 1 assays/chemicals/molecular targets/informatics, and/or through participation in ToxCast Phase 2 which will begin in the spring of 2008.

11. Participants were also invited to consider the following issues for implementing OECD-wide collaboration in the Molecular Screening Project:

- Endpoints of concern (e.g., cancer, reprotox, devtox, neurotox and immunotox)
- Chemicals of concern (e.g., pesticides, HPVs, PBTs, water contaminants, etc.)
- Modes of action of concern (e.g., genotoxic and non-genotoxicic carcinogenicity; nuclear receptor mediated xenobiotic response)
- Screening data generation (e.g., new assays for common chemicals; new chemicals for common assays)
- Data management, analysis and sharing

Initial discussion of the Molecular Screening Project

12. Participants generally recognized that the Molecular Screening Project would be a very useful initial opportunity to explore regulatory application of toxicogenomic methods and HTS/HTC methods in chemical assessment.

13. General comments on the U.S. EPA's proposal were as follows:

- The project should keep regulatory focuses and pay attention to quality assurance and quality control (QA/QC) issues.

- The U.S. EPA's ongoing ToxCast Program and its proposal for the Molecular Screening Project are focusing on HTS approaches for chemical prioritization and categorization, and this approach gained supports from member countries and stakeholder representatives; however, interests in *in vivo* genomics approaches for mode/mechanism of action research were also expressed. A concept of future extension of this approach to a faster, cheaper and smaller-scale *in vivo* screening was introduced. Current interest focused at least in part on collaborative research, data sharing, data interpretation, and linking this category of research to HTS outcomes.

- While participants from governments were generally supportive to make data publicly available, a concern for CBI data was indicated by an industry expert. It was also suggested that industry could participate in the project with non proprietary data.

- Participation in the Molecular Screening Project would be assisted by identification of the chemicals which are included in ToxCast Phase 1. The list of chemicals will be made available as soon as possible after the meeting.

- There was interest expressed by member countries and BIAC in a Winter 2007 White Paper and the next meeting in 2008 as proposed in the Program of Work (see Annexes 1 and 2). The next meeting would be based at least in part on data analysis and utility of results from ToxCast Phase 1 and other similar efforts.

14. Member countries and stakeholders indicated various level of interest in the Molecular Screening Project, including participation; however, there was general recognition that member countries and stakeholders need further time to consider the level and timing of their participation in the Molecular Screening Project.

NEXT STEPS

15. The participants in the extended Advisory Group will continue to communicate via teleconferences and email exchanges in order to (i) develop an agreement on the Molecular Screening Project, such as target chemicals, assays, endpoints of concern and the way of data sharing, (ii) confirm member countries' and stakeholders' participation in the Molecular Screening Project and (iii) develop a plan for the next meeting in 2008 including a host country and organisation of the meeting.

16. Member countries and stakeholders participating in the Molecular Screening Project will be invited to start collaborative efforts as soon as possible, in tandem with the ToxCast Phase 1 data analysis in September-December 2007. The U.S. EPA's ToxCast White Paper foreseen in February 2008 will provide further information for efforts of partnering countries/stakeholders and for consideration of possible future partners. Details and the status of participation will be reported to the 42nd Joint Meeting in February 2008.

OTHER ISSUES

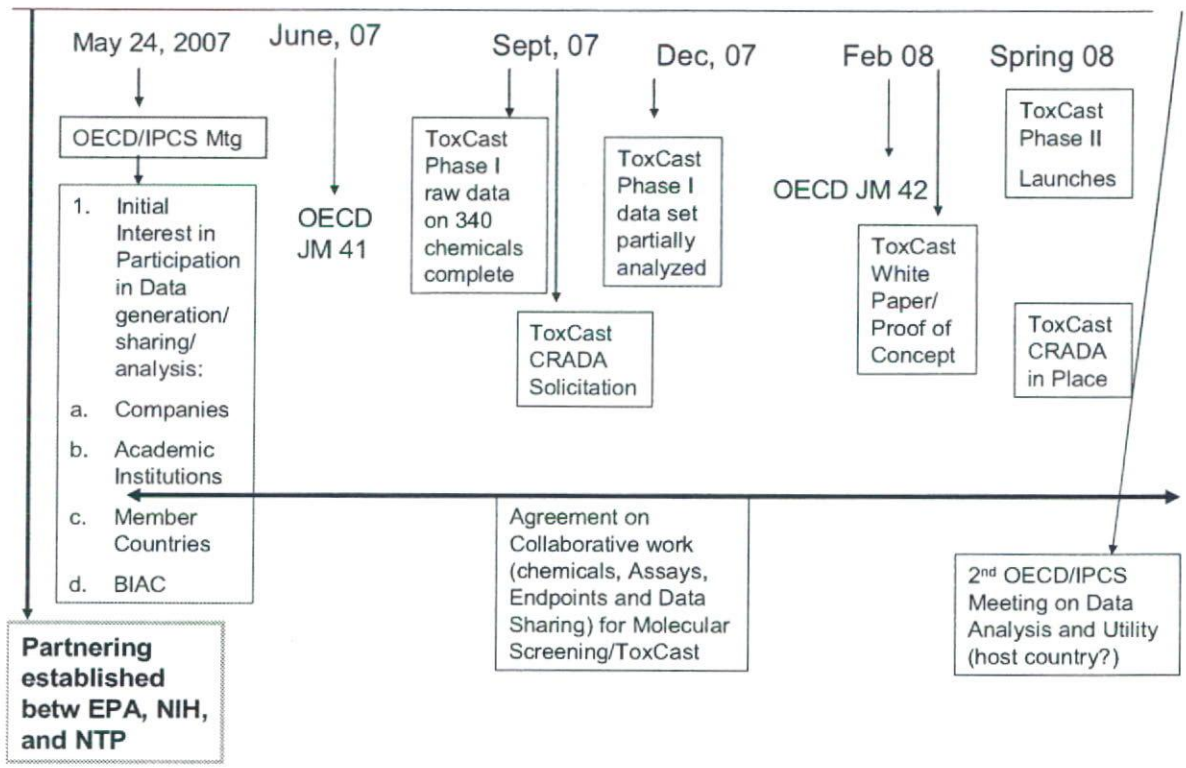
17. Japan submitted the first draft report of the *Survey on Available Omics Tools* to the meeting of the extended Advisory Group as information material. This draft will be submitted to the Advisory Group and then to the Joint Meeting, seeking endorsement for declassification by a written procedure.

ANNEX 1: Outline of the Molecular Screening Project

Work Item 1: **Molecular Screening for Characterizing Individual Chemicals and Chemical Categories**	
Lead	U.S.EPA
Secretariat	OECD
Objective	To establish a strategy for rationally and economically prioritizing chemicals for further evaluation, based on molecular properties and categories linked to potential toxicity.
Outcome	1. New prioritization tools for individual chemicals and categories. 2. Findings for categories could provide independent support for existing categories, expand existing categories, or lead to formation of new categories.
Proposed Work	With the aim of a demonstration of the tools and techniques useful to the objective; 1. Select a fairly large number of chemicals which have been well examined using traditional mammalian toxicity testing methodologies, and hence have known properties representative of a number of differing structural classes and phenotypic outcomes (e.g., carcinogens, developmental toxicants, reproductive toxicants, and neurotoxicants). 2. Evaluate these chemicals in a series of molecular screening assays.
Work Plan	1. Gather and consider case studies from ToxCast proof-of-concept phase for a meeting of the extended OECD/IPCS Advisory Group. Additional initiatives of member countries with similar molecular screening data, and industrial and academic work, should be included. Communicate ToxCast approach to the international community and determine stakeholder interest in pursuing follow-on projects involving environmental chemicals prioritization (May 2007). 2. Prepare an issue paper and/or publications summarizing the ToxCast proof-of-concept data, and other OECD member countries' case study data. Include draft criteria for chemical selection, assays proven effective, and resultant data (Spring, 2008). 3. Hold a meeting with stakeholders to discuss the issue and ToxCast data papers, evaluate working relationships and seek further partnerships and participation for the OECD Molecular Screening Project (2008). 4. Define partnering arrangements and infrastructure for implementation of the OECD Molecular Screening Project, select a list of chemicals and methodologies for these projects and initiate the OECD effort leading to development of biologically based chemical prioritization and categorization systems (late 2007-2009).

Extracted from ENV/JM(2006)42 with updates

ANNEX 2: Timeline of the Phase 1 of the U.S. EPA's ToxCast Program and the OECD Molecular Screening Project



ANNEX 3: Participants list for the Extended OECD/IPCS Advisory Group on Toxicogenomics

Research Triangle Park, North Caroline, United States, 24 May 2007

Canada

Dr. George R. DOUGLAS
Head, Mutagenesis, Environmental Health Science Bureau
Health Canada

Dr. Sean KENNEDY
National Wildlife Research Centre
Environment Canada

Mr. Tim SINGER
Senior Toxicologist, New Substances Assessment and Control Bureau
Health Canada

Japan

Dr. Jun KANNO
Division Head, Division of Cellular and Molecular Toxicology, Biological Safety Research Center, National Institute of Health Sciences (NIHS)

Mr. Hiroshi MATSUMOTO
Chief Researcher, Chemicals Assessment Center
Chemicals Evaluation and Research Institute (CERI)

Dr. Masaru SEKIJIMA
Director, Research Division for Advanced Technology, Kashima Laboratory
Mitsubishi Chemical Safety Institute Ltd.

Prof. Tomoyuki SHIRAI
Department of Experimental Pathology and Tumor Biology
Nagoya City University Graduate School of Medical Sciences

Dr. Hideko SONE
Senior Reseacher, Research Center for Environmental Risk
National Institute for Environmental Studies (NIES)

Dr. Kayo SUMIDA
Research Scientist, Environmental Health Science Laboratory
Sumitomo Chemical Co.,Ltd.

Dr. Hajime WATANABE
Associate Professor, Ohazaki Institute for Integrative Bioscience
National Institutes of Natural Science

Korea

Prof. Kyoung Tai NO
Departmnet of Biotechnology, Yonsei University
Director, Bioinformatics and Molecular Design Research Center

Dr. Sue Nie PARK
National Institute of Toxicological Research (NITR)
Korea Food and Drug Administration (KFDA)

Netherlands	Dr. Zhi-Chao DANG Senior Risk Assessor, Expertise Centre for Substances National Institute for Public Health and the Environment (RIVM)
	Dr. Rob STIERUM Head Toxicogenomics, Business unit Biosciences Organisation for Applied Scientific Research (TNO)
	Dr. Jan VAN BENTHEM National Institute for Public Health and the Environment (RIVM)
	Prof. Henk VAN LOVEREN Immunotoxicology and Infection National Institute for Public Health and the Environment (RIVM)
	Dr. Harry VAN STEEG National Institute for Public Health and the Environment (RIVM)
Sweden	Dr. Lena HELLMÉR Principal Scientific Officer, Risk Assessment Division Swedish Chemicals Agency (KEMI)
United States	Dr. Christopher AUSTIN Director, NIH Chemical Genomics Center National Institute of Health (NIH)
	Dr. David DIX Research Biologist, National Center for Computational Toxicology (NCCT) US Environmental Protection Agency (EPA)
	Dr. Keith HOUCK Toxicologist, National Center for Computational Toxicology (NCCT) US Environmental Protection Agency (EPA)
	Dr. Richard JUDSON Research Chemist, National Center for Computational Toxicology (NCCT) US Environmental Protection Agency (EPA)
	Dr. Robert KAVLOCK Director, National Center for Computatuional Toxicology (NCCT) US Environmental Protection Agency (EPA)
	Dr. Jesse MEILLER Office of Science Coordination and Policy/OPPTS US Environmental Protection Agency (EPA)
	Dr. Phil SAYRE Risk Assessment Division, Office of Pollution Prevention and Toxics US Environmental Protection Agency (EPA)

United States *(cont.)*	Dr. Shirlee TAN Office of Science Coordination and Policy/OPPTS US Environmental Protection Agency (EPA)
	Dr. Raymond TICE Deputy Director, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) US National Institute of Environmental Health Sciences (NIEHS)
Business and Industry Advisory Committee (BIAC)	Dr. Richard BECKER Senior Director, Public Health Team American Chemistry Council (ACC)
	Dr. Mark MAIER Health Science Policy Leader CropLife America
International Council on Animal Protection in OECD Programmes (ICAPO)	Dr. Martin STEPHENS Vice President for Animal Research Issues Animal Research Issues HSUS (Humane Society of the United States)
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)	Dr. Remi BARS Toxicology Laboratory Bayer Crop Science
L'Oréal Advanced Research	Dr. Gladys OUEDRAOGO Research Scientist, Head of Genotoxicity and Cancer Laboratory, Safety Research Department - Genotoxicity L'Oréal Advanced Research
	Dr. Stéphanie RINGEISSEN Safety Research Department - Predictive Toxicology L'Oréal Advanced Research
Syngenta Crop Protection, Inc.	Dr. Richard PEFFER Senior Toxicologist Syngenta Crop Protection, Inc.
Karolinska Institute	Dr. Maria BONDESSON Department for Biosciences and Nutrition Karolinska Institute
	Dr. Ingemar PONGRATZ Department for Biosciences and Nutrition Karolinska Institute
OECD	Mr. Takehiko FUKUSHIMA OECD/ENV/EHS

Target Audience

The book is targeted as an important reference for academic, industrial, and regulatory researchers, working primarily in the area of toxicology and risk assessment. Since toxicogenomics is a rapidly evolving discipline and is currently in a state of transition, this book represents a timely contribution to the toxicology community that will provide an important resource for understanding the practical applications of toxicogenomics to risk assessment. The intended audience will hold scientific degrees, mostly M.S. and Ph.D. level.

Expectations for Chapter Authors

Authors for each chapter have been selected based on their expertise in the particular chapter focus area. In keeping with the intended scope of the book, the authors are expected to focus on practical applications of toxicogenomics given the current state of the science; however, more theoretical, forward thinking views may be included as a closing aspect of the chapter. Authors are strongly encouraged to use examples, case-studies and/or figures to highlight or explain concepts. Prior to initiating the writing of the chapter, authors will be asked to prepare a brief outline/abstract on what information will be covered to ensure consistency in approach and overarching messages among the different chapters while avoiding potential redundancy.

Chapter Length

The chapters should be between 10-20 final print pages, which corresponds to 20-40 double-spaced typed pages or 5,000 to 10,000 words. The final book should be 250- 350 pages total with 20-40 figures. A tentative table of contents is attached to this proposal.

Time line

We would like to receive the completed chapter at your earliest convenience, but no later than the end of October, 2008.