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ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

Cancels & replaces the same document of 6 February 2024

First meeting of the Advisory Group on Emerging Science in Chemicals Assessment

Summary record

Held on 29-30 June 2023 at OECD Headquarters, 2 rue André-Pascal, 75016 Paris, France.

The Advisory Group on Emerging Science in Chemicals Assessment (ESCA) was recently established as an OECD level 3 body, a subsidiary body beneath the Working Party of the National Coordinators of the Test Guidelines Programme (WNT) and the Working Party on Hazard Assessment (WPHA).

The ESCA suggested that the summary record of the first meeting is submitted to the Chemicals and Biotechnology Committee (CBC) for declassification. Although the intention is not to publish this summary record, its declassification would facilitate the use and distribution of the document by ESCA members to their networks.

The WNT and the WPHA approved the request for declassification by the CBC on 26 January 2024.

The Chemicals and Biotechnology Committee declassify this report on 18 March 2024.

Nathalie Delrue, Administrator, Test Guidelines Programme
Nathalie.delrue@oecd.org

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SUMMARY RECORD

First Meeting of the Advisory Group on Emerging Science in Chemicals Assessment

Item 1. Welcome, tour de table and introduction

1. This meeting was the first meeting of the new Advisory Group on Emerging Science in Chemicals Assessment (ESCA). It was opened by Maurice Whelan (EC) and Rusty Thomas (US), co-chairs of ESCA.

2. The delegates of the Working Party of the National Coordinators of the Test Guidelines Programme (WNT) and of the Working Party on Hazard Assessment (WPHA) were invited to listen to the meeting on Day 1, since the first day of the meeting dealt with the vision of ESCA and how the WNT and WPHA may interact with the Advisory Group.

3. Experts around the table and online introduced themselves and summarized their expertise and field of activity. The tour de table confirmed that expertise in ESCA covers a broad range of relevant fields such as computational approaches, in vitro technologies, omics, radiation, and Adverse Outcome Pathways. The advisory group also brings together expertise in toxicology and ecotoxicology in the same group and covers various regulatory sectors. The co-chairs emphasised the important role that ESCA members have in acting as ambassadors for disseminating and promoting the work of ESCA and in identifying experts/expertise within their member countries that could be channelled into ESCA/WP projects. The approach from Germany, who has set up a national network of experts to support OECD projects, aroused interest since it could be a useful model for other member countries to follow.

4. The list of participants is included in the Annex.

5. All the presentations of the meeting are available to ESCA members in the meeting documents of the ESCA community site: Emerging Science in Chemicals Assessment - Home (oecd.org)

Item 2. Adoption of the draft agenda

6. The draft agenda [ENV/CBC/TG/A(2023)3] was adopted with no change.

Item 3. Presentation of the ESCA mandate

7. At their annual meetings, respectively in April and June 2023, the WNT and WPHA supported the establishment of ESCA, as an OECD level III body, under the WPHA and the WNT of the Chemical and Biotechnology Committee (CBC). The two parent Working Parties (WPs) also reviewed the draft mandate [documents ENV/CBC/TG(2023)4 and ENV/CBC/HA(2023)2 respectively] and formal approval of the mandate will be requested by written procedure in Q3 2023.

8. The role of ESCA includes the following:

- Advise on emerging scientific approaches to support next generation chemical assessment.
- Develop guidance or recommendations on emerging science and technologies for the benefit of regulatory applications.
- Oversee the essential elements of the AOP Programme of relevance to OECD interests.

9. ESCA works jointly with one or more WPs on projects on emerging science in response to a solicitation from a parent WP, or on the initiative of ESCA (see Figure 1). It is up to a lead country to decide to bring a project to a WP or ESCA. Projects need to be relevant, feasible and suitably resourced. For potential joint ESCA/WP projects, proposals may be submitted to ESCA, who will advise WPs on the relevance of a project, or they may be submitted to the WP who then solicits ESCA participation. The project proposal should be submitted using the appropriate template. It is expected that getting support from ESCA would facilitate inclusion on a WP workplan.

10. Having projects on a WP workplan gives visibility to the action of ESCA at the level of the OECD Programme of Work and Budget. In addition, the process of project proposals gives a structure to the organisation of the work. It was noted though that it should still allow some flexibility. In particular at the WNT meeting, the WNT mentioned the importance of unsolicited advice from ESCA as appropriate e.g. provide advice on new priorities, as they emerge, and potentially outside the scope of a project proposal. ESCA is expected not only to advise on questions submitted to them but also to share ideas and insights that would be brought to regulators e.g. assessing what science/tools have the most impact, assessing their readiness etc. Emerging science is not always mature enough to be brought to a WP as a project proposal but may deserve upstream consideration by ESCA. In such a context, ESCA could develop an briefing paper for example, informing a WP that something is coming through and deserves attention.

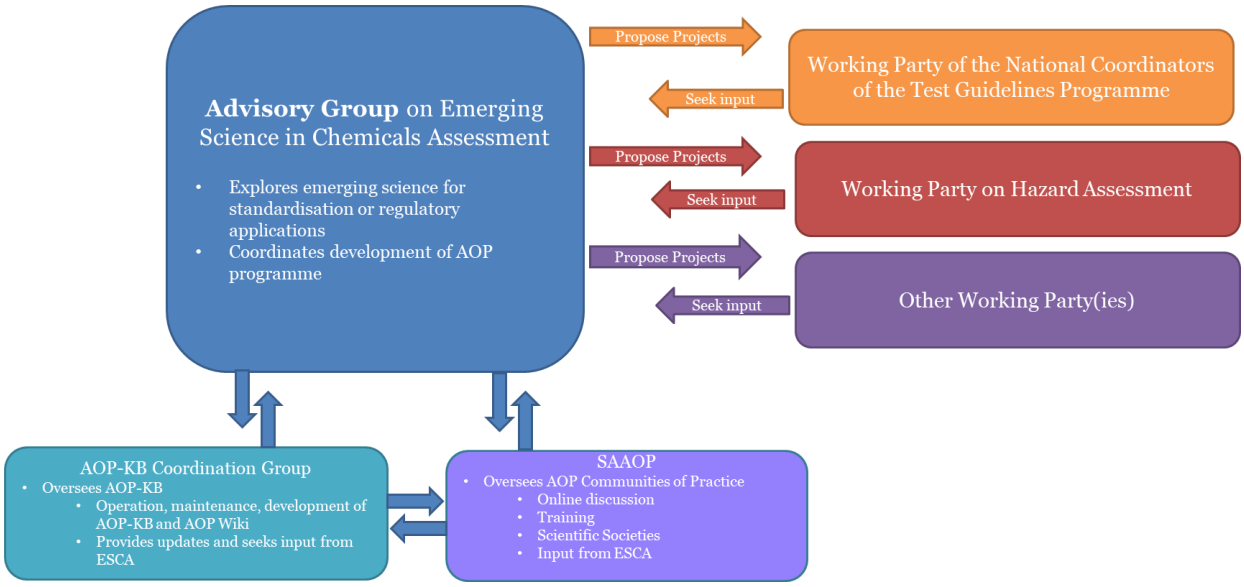
11. Prior to bringing an idea or project proposal to ESCA, it is essential that ESCA delegates discuss first with their WPHA and WNT colleagues. As per their mandate, ESCA delegates should liaise with their Working Party delegates to ensure a fluid two-way communication and they should also be able to identify subject matter experts within their stakeholder networks.

12. Projects should be time-limited and lead to concrete deliverables such as the organisation of an event (e.g. conference, webinar, workshop), a review of the state of the science in a particular area, a case study application, an advisory document/white paper, a briefing paper, guidance document, etc. .

13. In order to facilitate initial informal discussion at the ESCA level, a dedicated forum page will be created in the ESCA community site. This can facilitate maturation of ideas to the point that they are mature enough for developing a project proposal. At any point in time, a lead will be able to share a thought-starter or pre-proposal within the group and hear feedback from ESCA members.

14. Since ESCA is an Advisory Group, consensus, although desirable, is not necessary before delivering advice or opinions, provided the differences in opinion are transparently reflected.

Figure 1: Diagram of ESCA interactions with other bodies



Item 4. Presentation of WNT, WPHA and WPEA programmes and functioning

15. The Secretariat presented the functioning, standing projects and priorities of the WNT, the WPHA and the Working Party on Exposure Assessment (WPEA). Key issues from the WPs can be sources of inspiration for the work of ESCA. For example, short-term to longer-term perspective at the WNT level include the following:

Short to medium-term:

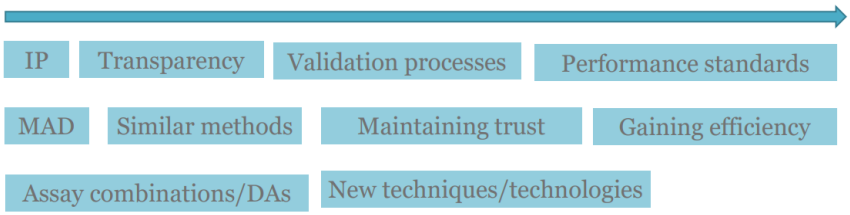
- Updating of the GD 34 on Validation
- Facilitating the emergence of Defined Approaches for complex endpoints (DNT, thyroid disruption,…)

Medium to long-term:

- Emerging technologies offering opportunities to transform Test Guidelines
- Developing/maintaining the framework to ensure trust, including elements such as Transparency – Data integrity - Access to the technology (IP) – Transferability

Item 5. Potential ESCA contribution to WNT projects

16. The Secretariat presented ongoing programme-related discussions within the WNT that may be of potential interest to ESCA, as listed below:



17. Some of these topical discussions were illustrated by a few examples:

- Korea presented current work on, 'Hepatotoxicity evaluation platform using human pluripotent stem cell-derived liver organoids'. The Secretariat suggested that more insight into the use of Pluripotent stem cells could be helpful to the WNT, e.g. discussing the state-of-the-science, readiness, advantages and limitations, utility, availability, quality, standardisation or intellectual property issues.
- Taking the example of the Developmental Neurotoxicity (DNT) in vitro testing battery, the JRC brought to the group's attention transferability and standardization-related issues for in vitro methods based on (bio)technologies that are new to regulatory testing, in particular challenges related to cellular models and imaging endpoints, including artificial intelligence (AI)-assisted image analysis.

18. ESCA took note of the various challenges and issues where ESCA may play an advisory role to the WNT in the future, in particular the use of iPSC in Test Guidelines; machine learning, AI-based data analysis and how to integrate AI-supported approaches in TGs; standardisation, performance characterisation and reference materials; transferability of complex assay batteries; on-going WNT project on GD 34 update, etc.

Item 6. Potential ESCA contribution to WPHA and WPEA projects

19. The following projects were presented and identified as joint WPHA-ESCA projects:

- Projects already on the WPHA workplan
  - Using AOP to address combined exposures to chemicals with relevant effect-biomarkers
  - Revision of OECD Guidance Document 194 on Grouping (e.g., biological similarity and use of AOPs etc.)
  - Omics application reporting module (ARM) for Chemical Grouping
- Three new projects recently accepted on the WPHA workplan were also identified as joint projects with ESCA:
  - Completion of the Enrichment Analysis Module of the OECD Omics Reporting Framework (OORF) (Canada/US)
  - Development of proteomics modules for the OECD Omics Reporting Framework (OORF) (Switzerland/Austria)
  - Guidance on the best practices and standardisation of sample collection and preparation suitable for omics analysis (EC/ECHA)

20. It needs to be clarified how the contribution of ESCA would best be organised, e.g. ESCA members joining existing or future expert groups, ESCA consultation for ad hoc advise on projects already on a workplan. For some new projects, WPHA and ESCA delegates will be called for nomination of experts to support the lead(s).

21. ESCA also discussed a project proposal from the UK for a 'Guidance Document for a standard analysis method for the analysis of transcriptomics data'. The project was not recommended for submission to a WP workplan as proposed but served as a basis for a broader discussion on omics. Omics data need to be (i) clearly presented – and this is addressed with the reporting template, (ii) trustable – quality assurance and reliability of the data would need more discussion and (iii) interpretable in a decision-making context - currently this lacks standardisation.

22. Using the UK proposal as a basis, ESCA agreed to follow up and discuss a possibly revised project and to come up with recommendations for ESCA on point (ii) above i.e. how to evaluate data quality from an omics perspective. A discussion group on quality assurance of omics data for regulatory

use will be created[1], led by the ESCA chairs. Delegates from Canada, EC-JRC, US-EPA, UK, and BIAC expressed interest to join. In addition, in the future, more work will be needed to develop guidance for the regulatory community on interpretation of omics data, particularly as regards feasibility, transparency and consistency.

23. The US presented the development of a New Transcriptomics-Based Assessment Product for Data Poor Chemicals. It was proposed that this might help with introducing omics into regulatory tests, and eventually contribute to bridging between in vivo (rodent) and in vitro studies.

24. Several other areas of potential interest for ESCA were presented. They include:

- Develop an OECD reporting framework/template for the results from non-targeted (chemical) analysis (NTA) of environmental samples e.g. by adapting existing OORF and reporting templates
- Support the development of AOPs that will guide the development of New Approach Methodologies (NAMs)
- Cross species extrapolation
- Framework for NAM-based hazard classification systems
- In Vivo-to-In Vitro Extrapolation (IVIVE), High Throughput Toxicokinetics (HTTK), in vitro Point of Departure, in vitro disposition
- Human Biomonitoring

25. These could be sources of inspiration for the work of ESCA provided they can be connected to an OECD regulatory context.

Item 7. AOP Programme

26. The ESCA, SAAOP and AOP-Wiki Coordination Group, whose activities are described below, are independent but share the will to working cooperatively to assure the sustainability and growth of the AOP program and the application of AOPs to support chemical assessment.

Item 7.a. Overview of the AOP Programme

27. The Secretariat described the role of ESCA with respect to the AOP Development Programme. ESCA will:

- Review AOP project proposals;
- Coordinate AOP scientific reviews with journals or through suitable third parties, and AOP endorsement at the level of Working Parties;
- Orient the AOP development programme, i.e. identify gaps and needs, encourage/prioritise the development of AOPs in these areas – making links with other programmes that use AOPs;
- Ensure effective interfacing with the AOP-KB coordination group and the Society for the Advancement of AOPs (SAAOP).

28. The Secretariat described the process of AOP development, review, OECD endorsement and publication (declassification). The Secretariat also stressed (i) the importance of the AOP scientific review, (ii) the terms of the cooperation that have been established between the OECD and some scientific

[1] Subsequent discussions identified the WPHA Omics group as a potentially suitable forum for these discussions rather than forming a new group

journals, and (iii) the continued need for support from various stakeholders in the context of the scientific review, i.e. from national institutes, scientific journals and other trusted parties.

29. The group acknowledged the significant contribution of Japan in putting in place the AOP coaching programme, now under the umbrella of SAAOP (see below), which provides support to AOP developers. ESCA supported the continuation of the coaching programme.

30. The endorsement phase is made of three steps under (i) ESCA, (ii) the WPs and (iii) the CBC. The ESCA community site includes a section where AOPs for ESCA review are made available. Each time new AOPs for review are posted, ESCA will be notified by the Secretariat. The review by ESCA follows completion of the scientific review and its objective is to make sure that a given AOP is ready for Working Party (WNT/WPHA) review e.g. comments from scientific review have been addressed by the authors, and the AOP is pertinent for submission to WNT/WPHA endorsement.

Item 7.b. Update from the Society for the Advancement of AOPs (SAAOP)

31. The SAAOP effectively functions like any other scientific society. Its mission is to promote and foster the development and application of AOPs in different contexts, and to perform outreach, mentoring and to provide several practical and strategic support services to the AOP-Wiki. It serves as the primary interface between ESCA and the broader AOP community that is not engaged directly with the OECD. The SAAOP also hosts webinars, technical sessions, and symposia related to development and application of AOP. In addition, the SAAOP ensures implementation of certain functions (e.g. coaching, wiki-gardening, wiki-user registration) that support the AOP programme, in coordination with ESCA and the AOP-KB coordination group where appropriate.

32. The SAAOP may also assist ESCA in identifying experts willing to contribute to AOP-related projects included in a WP workplan, and is expected to be a conduit for innovative ideas concerning the AOP framework, including the AOP-KB. The SAAOP will also work closely with AOP-KB Coordination Group (see section 7.c) via the establishment of a SAAOP KB interest group.

33. It was noted that people wishing to join the SAAOP can fill in a membership form on the SAAOP website, or can approach Dan Villeneuve and Kristie Sullivan directly, respectively president and vice president of SAAOP and both also members of ESCA.

Item 7.c. Update from the AOP-KB coordination group

34. The AOP-KB Coordination Group (AOP-KB CG) is in place to ensure the maintenance and further development of the AOP-Wiki as well as facilitate interoperability with OECD and third party tools that draw upon information from the AOP-KB. Members of the coordination group are those who fund the AOP-Wiki tool, the tool developers, plus a representative of the OECD Secretariat (observer/liaison).

35. The AOP-Wiki is continuously evolving to adapt to the needs of user communities. The current version of the AOP-Wiki (Version 2.6), released in April 2023, includes new features such as improved findability or new licensing conditions that are more protective and transparent regarding reuse policies and rights of authors/developers. In addition, several AOP pages have been updated for adding prototypical stressors to AOPs, displaying the electronic version of the AOP User's Handbook and providing an entry to acknowledge the coaches' names of a given AOP.

36. In the shorter-term (Version 2.7 scheduled for release in October 2023), the AOP-Wiki will include:

- New properties currently available in the eAOP Portal. The new properties will be added to the AOP search result tables, including: iLibrary links, links to Review Reports, timestamps for the creation and modification dates.

- New functionalities for the OECD Secretariat: (i) Ability to post Review Reports that will be accessible to all users, under a new section of each AOP; (ii) Ability to add links from iLibrary & Journal published versions of AOPs.
- Addition of visual displays of AOP-Wiki usage metrics.
- XML updates to align with data model properties introduced in the Version 2.5 and 2.6 Wiki releases.

37. The longer-term objective is a more fundamental remodeling of the AOP-Wiki towards Version 3.0. The vision of AOP-Wiki 3.0 includes:

- Enhanced End-User/Developer Experience.
- Enhanced provenance tracking throughout the system.
- Enhanced format consistency between contributions and across KEs, KERs and AOPs.
- Increased adherence to FAIR (Findable, Accessible, Interoperable and Re-usable) Principles (see recent publication in ALTEX).

38. Five initial ideas (the "Big Five") are being developed to implement this vision and include (i) stressor tagging, (ii) contributor tagging, (iii) domain of evidence (to avoid confusion with the terminology 'domain of applicability' i.e. empirical vs plausible), (iv) reference tagging, and (v) test methods. Regarding the latter, the Methods2AOP project has the objective to describe methods more explicitly, enable methods to be re-used across AOPs, facilitate insertion of additional information by method developers and finally ensure a way for stressor information to be linked to AOPs (via the methods). The Methods2AOP projects was acknowledged by the group as very promising with the caveat that it would not substitute to the development of IATAs and some issues would need to be considered, e.g. how to deal with potential issues related to Intellectual Property.

39. The development of AOP-Wiki 3.0 is subject to identification of solid financial backing. A proposal for funding is being prepared for submission in the coming months to the US National Institute of Health (NIH).

Item 8. Project proposals and ideas from ESCA members

40. ESCA reviewed the following project proposals:

- AOP projects
  - AOP network leading to genotoxicity (proposal submitted by Belgium and France, the work is planned to be performed within the framework of the EU funded PARC project).

    Ultimately, the objective of the project is to bring the NAMs recently developed to address current issues in genotoxicity (e.g. misleading positives generated by the current in vitro battery) into an IATA.

    The proposal received support from ESCA who recommends its submission to the WNT for inclusion in the WNT workplan. It was noted that there is a need to ensure connection with other groups working in the field. Connection between PARC and HESI GTTC will be ensured and it was noted that coordination between PARC and the biomarkers projects would be useful too.

  - AOP on energy deposition leading to microcephaly (proposal submitted by France).

ESCA supported the project, recognising its scientific relevance and the cross disciplinarity and cross-sector nature of AOPs. It was also noted that there is a common MIE between this project and the project mentioned above. ESCA recommends this project is submitted to the NEA Committee on Radiological Protection and Public Health (CRPPH) for inclusion on their workplan.

41. AOP projects would automatically be joint projects with ESCA when approved on a WP workplan.

- Non-AOP projects
    - Identification of an emerging hazard class for cardiotoxicity of chemical substances (proposal submitted by Greece).

      The project was proposed to address a gap in the regulation which doesn't allow regulators to specifically assess this hazard class. Although there was consensus that cardiotoxicity is a significant public health concern and the scientific merit of the project was recognised, the proposal, as written, was not supported as an activity to be undertaken by ESCA. It was considered that the heart is a target organ that could be captured by repeated dose toxicity hazard class for regulatory purposes. The submitters of the proposal noted though that in the last 12 years no such relevant harmonised classification (i.e. Specific Target Organ Toxicity Repeated Exposure (STOT RE) target organ heart or the cardiovascular system) has been discussed in the Committee for Risk Assessment (RAC) of ECHA. It was noted that if the project is brought to the WPHA, and if WPHA gives ESCA a specific mandate (e.g. to explore criteria for classifying chemicals with regards to cardiotoxicity based on AOP-informed NAMs, or to explore how to make better use of academic data using case studies), then based on such a reframing of the project, ESCA could provide input. Translating new science into criteria for the purpose of classification is of great interest to ESCA. It was considered reasonable to bring the proposal to WPHA and that Greece has some discussion with their UN GHS delegate. ESCA expressed its appreciation to Greece for bringing this proposal for discussion.

Item 9. Next steps

42. A mid-year TC will be organised in December 2023 to take stock of how the ideas and projects discussed during the meeting are being implemented.

Annex –List of registered participants to the Advisory Group on Emerging Science in Chemicals Assessment (ESCA AG) (includes face to face and on line participants)

Australia

Sneha SATYA
Director Capability, Scientific Integrity & International Section
Australian Government Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme (AICIS)

Rhian COPE
Principal Toxicologist
Risk Assessment and Capability
Australian Pesticides Veterinary Medicines Authority

Austria

Martin PAPARELLA
Toxicologist
Institute of Medical Biochemistry
Medical University of Innsbruck

Alexandra SCHAFFERT
Medical University of Innsbruck

Belgium

Dries KNAPEN
Associate Professor
Veterinary Sciences
Universiteit Antwerpen Campus Drie Eiken

Sivakumar MURUGADOSS
Scientist
Risk and Health Impact service Sciensano

Canada

Tara S. BARTON-MACLAREN
Research Manager, Emerging Approaches Unit
Existing Substances Risk Assessment Bureau
Health Canada

Mark BONNELL
Senior Science Advisor, Ecological Assessment Division
Science and Risk Assessment Directorate
Environment and Climate Change Canada

Vinita CHAUHAN
Research Scientist, Ionizing Radiation Health Sciences Division
Consumer and Clinical Radiation Protection Bureau,
Healthy Environments and Consumer Safety Branch
Health Canada

Sabina HALAPPANAVAR
Research Scientist, Mechanistic Studies Division,

Environmental Health Science and Research Bureau
Healthy Environments and Consumer Safety Branch
Health Canada

Matthew MEIER
Senior Bioinformatician, Mechanistic Studies Division
Healthy Environments and Consumer Safety Branch
Health Canada

Jason O'BRIEN
Research Scientist, Molecular Ecotoxicology, Science and Technology Branch
Ecotoxicology and Wildlife Health Division
Environment and Climate Change Canada

Carole YAUK
Research Scientist, Genomics
Department of Biology
University of Ottawa

Colombia

Sergio Alejandro ROPERO SANTIAGO
Senior Advisor
Department of National Planning

Denmark

Terje SVINGEN
Head of Research Group, Senior Researcher
National Food institute
Technical University of Denmark

France

Nathalie ALEPEE
L'Oréal

Pierre-André BILLAT
Unité Toxicologie expérimentale (TEAM)
National Institute for Industrial Environment and Risks (INERIS)

Germany

Tanja BURGDORF
Department Experimental Toxicology and ZEBET
German Federal Institute for Risk Assessment (BfR)

Sebastian EILEBRECHT
Fraunhofer Attract Eco'n'OMICs
Fraunhofer Institute for Molecular Biology and Applied Ecology

Judy CHOI
Pesticides Safety
Federal Institute for Risk Assessment (BfR)

Greece

George LIADAKIS
Senior Officer
General Chemical State Laboratory

Christina TSITSIMPIKOU
Senior Toxicologist
General Chemical State Laboratory

Italy

Cecilia BOSSA
Environment and Health Department
National Institute of Health (ISS)

Olga TCHEREMENSKAIA
Researcher
Environment and Health Department
Istituto Superiore di Sanita (ISS)

Barbara VIVIANI
Università degli Studi di Milano, Department of Pharmacological and Biomolecular Sciences

Japan

Kunihiko YAMAZAKI
Deputy Director, Policy Planning Division, Environmental Health Department
Environmental Health Department
Ministry of the Environment (MOE)

Shiro KAWAHARA
Deputy Director, Environmental Health and Safety Division, Environmental Health Department
Ministry of the Environment (MOE)

Koji OHARA
Technical Official, Environmental Health and Safety Division, Environmental Health Department
Ministry of the Environment (MOE)

Taisen IGUCHI
Professor
Graduate School of Nanobioscience
Yokohama City University

Yoko HIRABAYASHI
Director, Center for Biological Safety Research (CBSR)
Center for Biological Safety Research
National Institute of Health Sciences (NIHS)

Dai NAKAE
Professor
Animal Medical Course
Teikyo Heisei University

Takuya NISHIMURA
Section Chief, Division of Cellular and Molecular Toxicology
National Institute of Health Sciences (NIHS)

Hiroshi YAMAMOTO
Deputy Director
Health and Environmental Risk Division
National Institute for Environmental Studies

Koichi OHNO
Section Head
Health and Environmental Risk Division
National Institute for Environmental Studies

Masaaki TSUKANO
Senior Analyst for International Affairs on Chemical Safety
Office of Chemical Safety, Pharmaceutical Evaluation
Division, Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare (MHLW)

Korea

Sang Hee LEE
Research Manager
Risk Assessment Division, Chemicals Registration & Evaluation Team
Ministry of Environment - National Institute of Environmental Research

Il Ung OH
Director
Toxicological Research Division
National Institute of Food and Drug Safety (NIFDS)

Tae Sung KIM
Scientific Officer
Toxicological Research Division
National Institute of Food and Drug

Jin Hee LEE
Scientific Officer
Toxicological Research Division
National Institute of Food and Drug Safety Evaluation

KANG, NAMHEE
Senior Scientific Officer
Korean Center for the Validation of Alternative Methods (KoCVAM)
Food Safety Evaluation Department, National Institute of Food and Drug Safety Evaluation, Korea Food and Drug Administration

Myung Jin SON
Principal Scientist
Korea Research Institute of Bioscience & Biotechnology (KRIBB)

Yongkwon SONG
First Secretary
Environment
Permanent Delegation of Korea to the OECD

So-Hye HONG
Research Scientist
Toxicity and risk assessment

Luxembourg

Tommaso SERCHI
Environmental Research and Innovation

Netherlands

Betty HAKKERT
Deputy Head Bureau Reach
Department for Industrial Chemicals, RIVM Centre for Safety of Substances and Products
National Institute for Public Health and the Environment (RIVM)

Yvonne STAAL
Dutch National Inistitute for Public Health and Environment (RIVM)

Petra VAN KESTEREN
Toxicologist
National Institute for Public Health and the Environment (RIVM)

Norway

Knut Erik TOLLEFSEN
Professor/Senior researcher Ecotoxicology
Norwegian Institute for Water Research (NIVA)

Spain

Vicente RODILLA ALAMA
Professor of Toxicology
University Cardenal Herrera

Switzerland

Lothar AICHER
Regulatory Toxicology Unit
University of Basel

Ksenia GROH
Head of Bioanalytics Group
Department Environmental Toxicology
Eawag (The Swiss Federal Institute for Aquatic Science and Technology)

Robert PASANEN-KASE
Scientific Officer

Labour Directorate, Section Chemicals and Work (ABCH)
State Secretariat for Economic Affairs - SECO

United Kingdom

Timothy GANT
Head of the Toxicology Department
Toxicology
UKHSA

Miriam JACOBS
UK National Coordinator (Human Health)
Toxicology
UK Health Security Agency

Morné VAN DER MESCHT
Specialist (Chemical assessment scientist)
Chemicals Assessment Unit
Environment Agency

United States

Michelle ANGRISH
Toxicologist
Chemical Pollutant Assessment Division
U.S. Environmental Protection Agency (EPA)

Iris CAMACHO
Office of Pollution Prevention and Toxics
US Environmental Protection Agency (EPA)

Rebecca CLEWELL
U.S. Air Force Research Laboratories
Force Health Protection

Suzanne FITZPATRICK
Senior Advisor for Toxicology
Center for Food Safety & Applied Nutrition / US Food and Drug Administration
DHHS/FDA/OC/OSHC

Natalia GARCIA REYERO VINAS
Deputy Director
Office of the Secretary of Defense
U.S. Department of Defense

David REIF
Chief, Predictive Toxicology Branch.
National Institute of Environmental Health Sciences / Division of Translational Toxicology
National Institute of Health (NIH)

Nakissa SADRIEH
Director, Division of Cosmetics
Center for Food Safety and Applied Nutrition (CFSAN)
FDA

Jon SOBUS
Center for Computational Toxicology and Exposure
Environmental Protection Agency

Russell THOMAS
Director
Center for Computational Toxicology and Exposure
US Environmental Protection Agency (EPA)

Daniel VILLENEUVE *Research Toxicologist*
Great Lakes Toxicology and Ecology Division
U.S. Environmental Protection Agency (EPA)

EU

Chantra ESKES
Risk Assessment Production Department
EFSA European Food Safety Authority

Mounir BOUHIFD
Computational Assessment Unit
European Chemicals Agency (ECHA)

Laure-Alix CLERBAUX
JRC Ispra

Julia MALINOWSKA
Directorate F – Health, Consumers and Reference Materials
Joint Research Centre

Orla MORIARTY
Translational Sciences Office
Scientific Evidence Generation Department
European Medicines Agency

Sharon MUNN
Scientific Officer
EURL ECVAM
European Commission/DG Joint Research Centre

Katrin SCHUTTE
Policy Officer
DG Environment

Idoia-Lucia SELFA-ASPIROZ
Scientific Expert
European Commission - JRC Centre

Maurice WHELAN
Head of Unit - Chemical Safety and Alternative Methods
Directorate for Health, Consumers and Reference Materials
European Commission Joint Research Centre (JRC)

Clemens WITTWEHR
Senior Expert
Health & Food Directorate, Systems Toxicology Unit
European Commission (Joint Research Centre)

Brazil

Dr. Luciene BALOTTIN
Brazilian National Coordinator (Inmetro)
Directorate of Scientific and Industrial Metrology and Technology (Dimci)
National Institute of Metrology, Quality and Technology

Business at OECD (BIAC)

Nadira DEABREW
Senior Scientist/Toxicologist

Gladys OUEDRAOGO
Scientific Officer
Alternative methods and reconstructed skin department
L'Oréal Research & Innovation

Nico WATZEK
Regulatory Toxicologist - Group Leader of one Toxicology
Regulatory Group within the Product Safety Department
Product Safety
BASF

International Council on Animal Protection in OECD Programmes

Vera ENGELBRECHT
Adviser
PETA Science Consortium International e.V.

Donna MACMILLAN
Senior Strategist, Regulatory Science
Research and Toxicology Department
Humane Society International (HSI)

Jessica PONDER
Regulatory Testing Analyst
Physicians Committee for Responsible Medicine
International Council on Animal Protection in OECD Programmes (ICAPO)

Kristie SULLIVAN
Vice President, Education and Outreach
Institute for In Vitro Sciences, Inc.

Endocrine Society

Scott BELCHER
Biological Science

Joe LAAKSO
Government and Public Affairs

Shirlee TAN

Other

Stephen EDWARDS
Biostatistics and Epidemiology Division
RTI International