
ICCA LRI & JRC 2017国際ワークショップ

**Fit-For-Purpose Exposure Assessment
For Risk-Based Decision Making**

参 加 報 告

日化協 LRI 研究報告会

2017年8月25日

有限会社 イカルス・ジャパン
武居 綾子



ICaRuS Japan Limited

International Consultants in Regulatory Sciences

-
- ◆ 21世紀の化学物質リスク評価の課題
 - ◆ ICCA LRI 国際ワークショップ
 - ◆ 毒性評価のパラダイムシフト
 - ◆ 21世紀のリスク評価に適応する暴露評価
 - ◆ 予測モデルの標準化、バリデーションへの国際的アプローチ
 - ◆ 今後の課題



21世紀の化学物質リスク評価の課題

- ◆ 膨大な未評価既存化学物質と限られた予算、人材、時間
- ◆ 国際的な動物実験削減の推進
- ◆ 科学的知見の急速な進歩
 - e.g. ゲノミクス、エピジェネティクス
- ◆ 広範な技術革新
 - e.g. ハイスループット・テクノロジー、コンピュータ毒性予測、システム・バイオロジー、バイオインフォマティクス、ハイコンテンツ・アナリシス
 - 「大容量データ」の時代
- ◆ 複合暴露によるリスク評価の必要性
- ◆ 新たな懸念
 - e.g. バイオ燃料、ナノテクノロジー、気候変動、バイオテクノロジー



ICCA LRI 国際ワークショップ

- ◆ 日化協/ACC (American Chemistry Council)/CEFIC (European Chemical Industry Council)
- ◆ 産業界/パブリック共催
 - ICCA LRI 2015 in New Orleans: ACC/U.S.EPA
 - ICCA LRI 2016 in Awaji: 日化協/国立衛研
 - ICCA LRI 2017 in Como: CEFIC/JRC (Joint Research Center – European Commission)
- ◆ LRI研究成果の公表
- ◆ 産官学の研究者および化学物質管理に関わる行政官に国際的なディスカッションの場を提供



2017 Workshop Organizing Committee

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Inc.



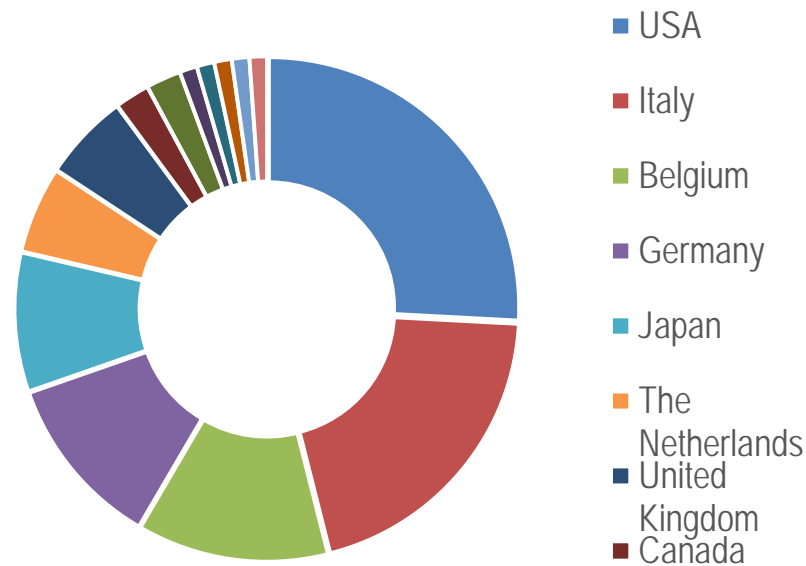
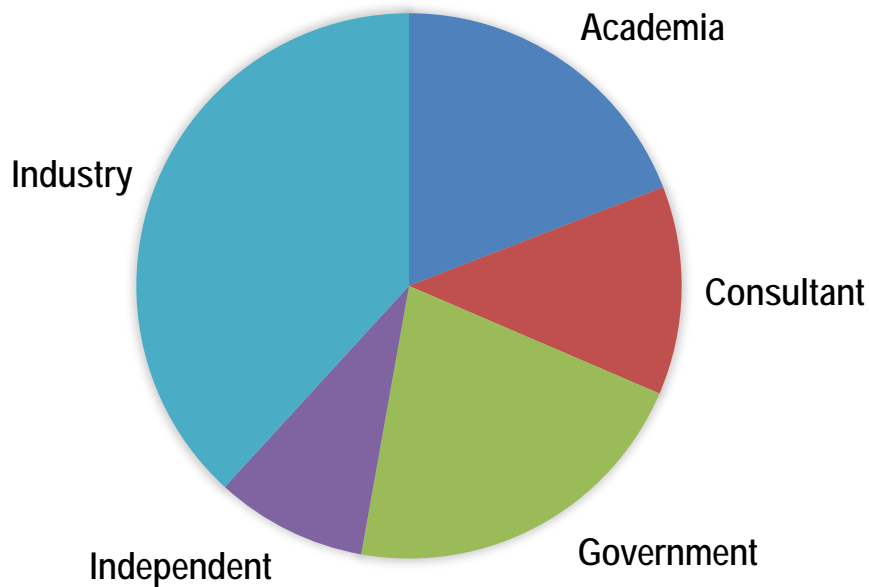
ICCA-LRI & JRC Workshop

- ◆ **Como, Italy, 21 -22 June 2017**
- ◆ **Fit-For-Purpose Exposure Assessment for Risk-Based Decision Making**
- ◆ **産官学研究者による発表19件:**
 - 産総研: 内藤 航 氏
 - NITE: 桑 詩野 氏
 - 国環研: 磯部友彦 氏
- ◆ **行政のアプローチ紹介4件:**
 - Health Canada
 - U.S.EPA
 - European Food Safety Authority
 - ECHA
- ◆ **ポスター発表10件:**
 - 愛媛大学: 仲山 慶 氏

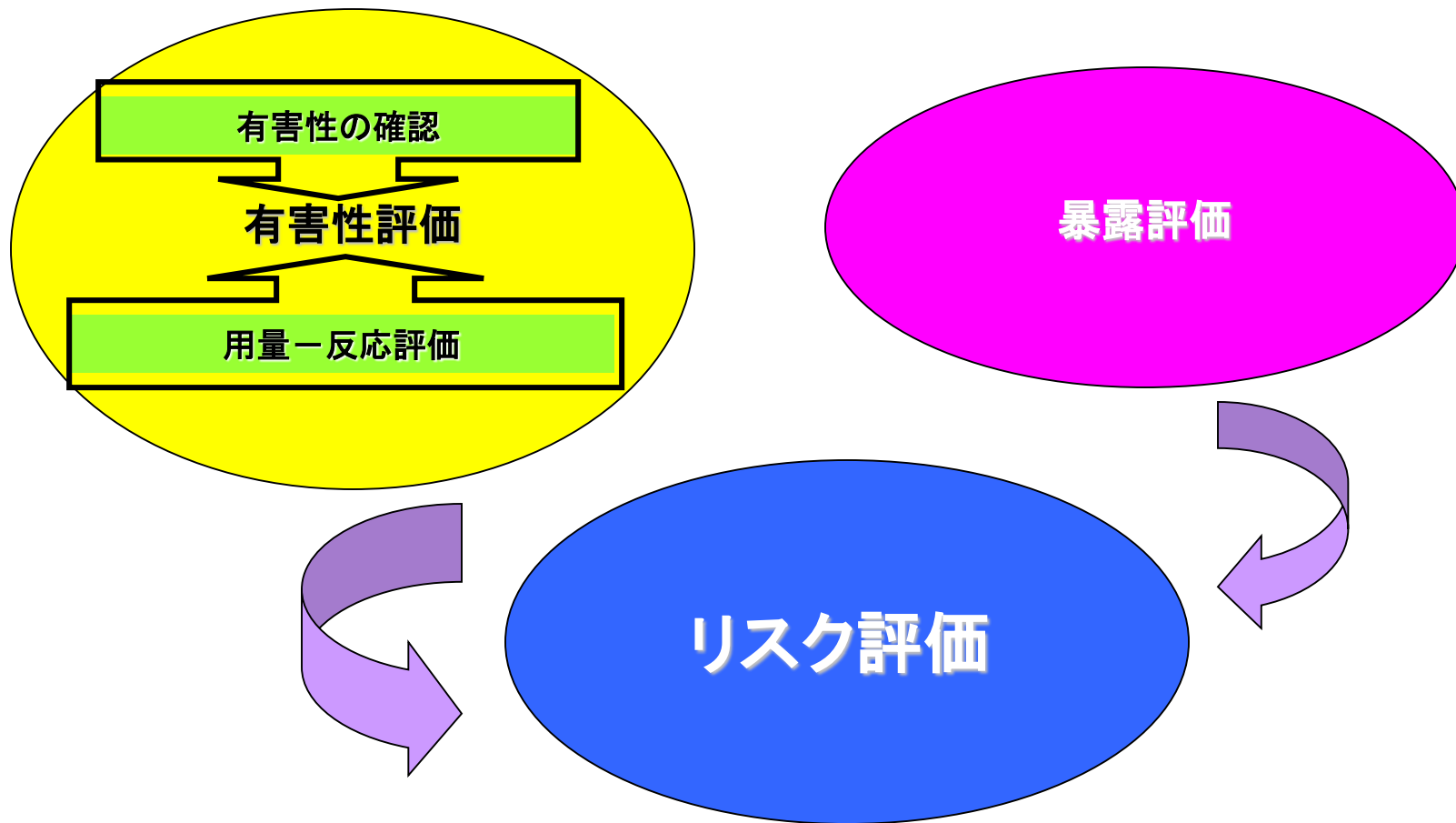


Workshop Participation

Final Attendee Count: **89**



Exposure Assessment for Risk-Based Decision Making

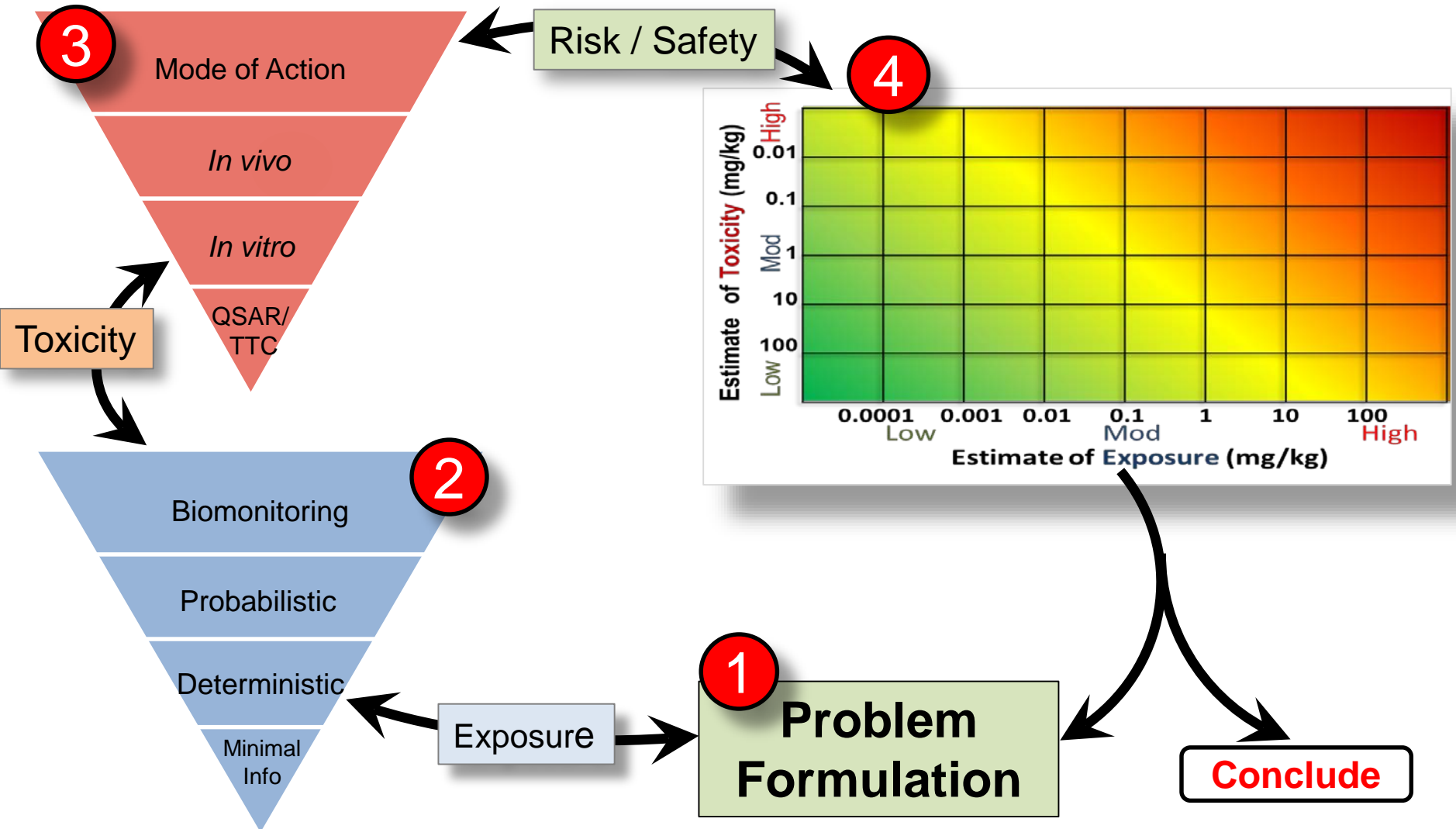


Fit-For-Purpose

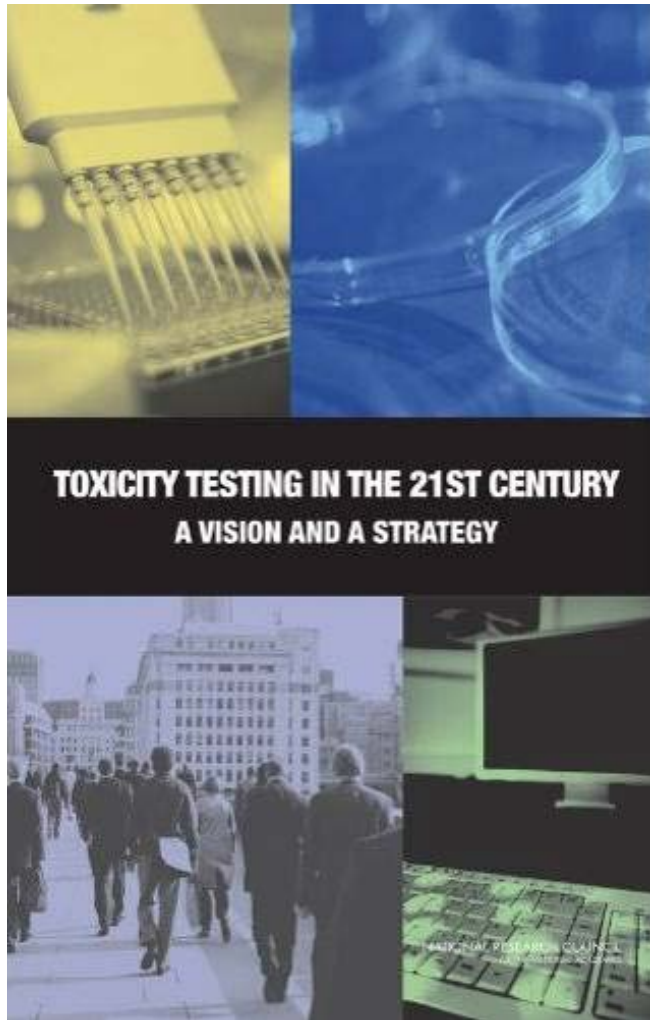
- ◆ 目的に即した評価
- ◆ 目的に適した手法
- ◆ 目的に応じた簡素化と精緻化
- ◆ デフォルトとチェックリストからの脱却
 - e.g.動物実験データと不確実係数に基づくADI/TDI
 - e.g.一律の規制要件



RISK21マトリックス・ロードマップ (Poster ID 7)



毒性評価のパラダイムシフト

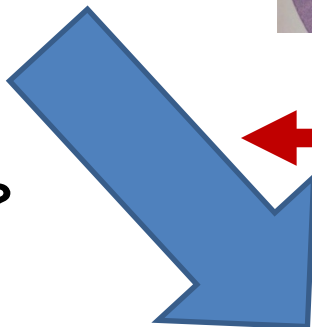
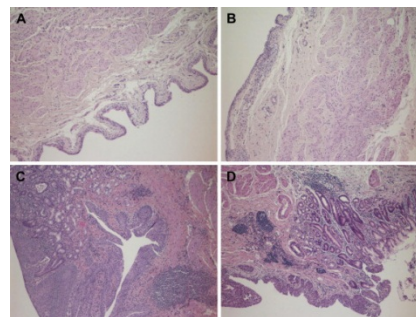
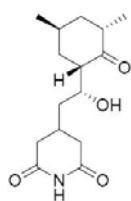


- 分子レベルのデータとコンピュータ解析を適用
- 毒性試験法の効率と精確性を向上
- 動物実験への依存度を軽減
- 毒性予測の新しい技術への転換

National Research Council (NRC) of the
National Academy of Sciences (NAS), 2007

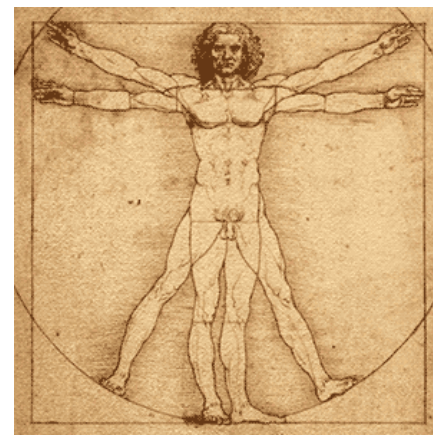
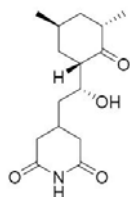


毒性評価：パラダイムシフトの必要性



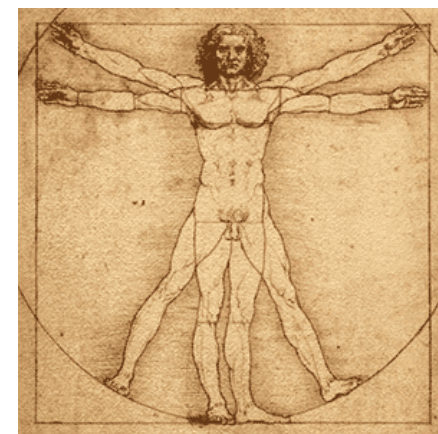
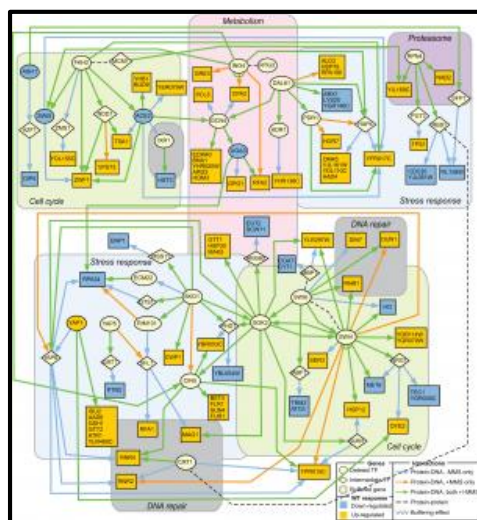
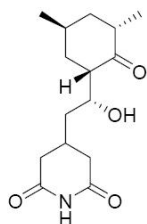
動物実験削減の圧力

- 種差？
- 高用量から低用量への外挿？
- 毒性メカニズム？
- ヒトへの外挿の妥当性？

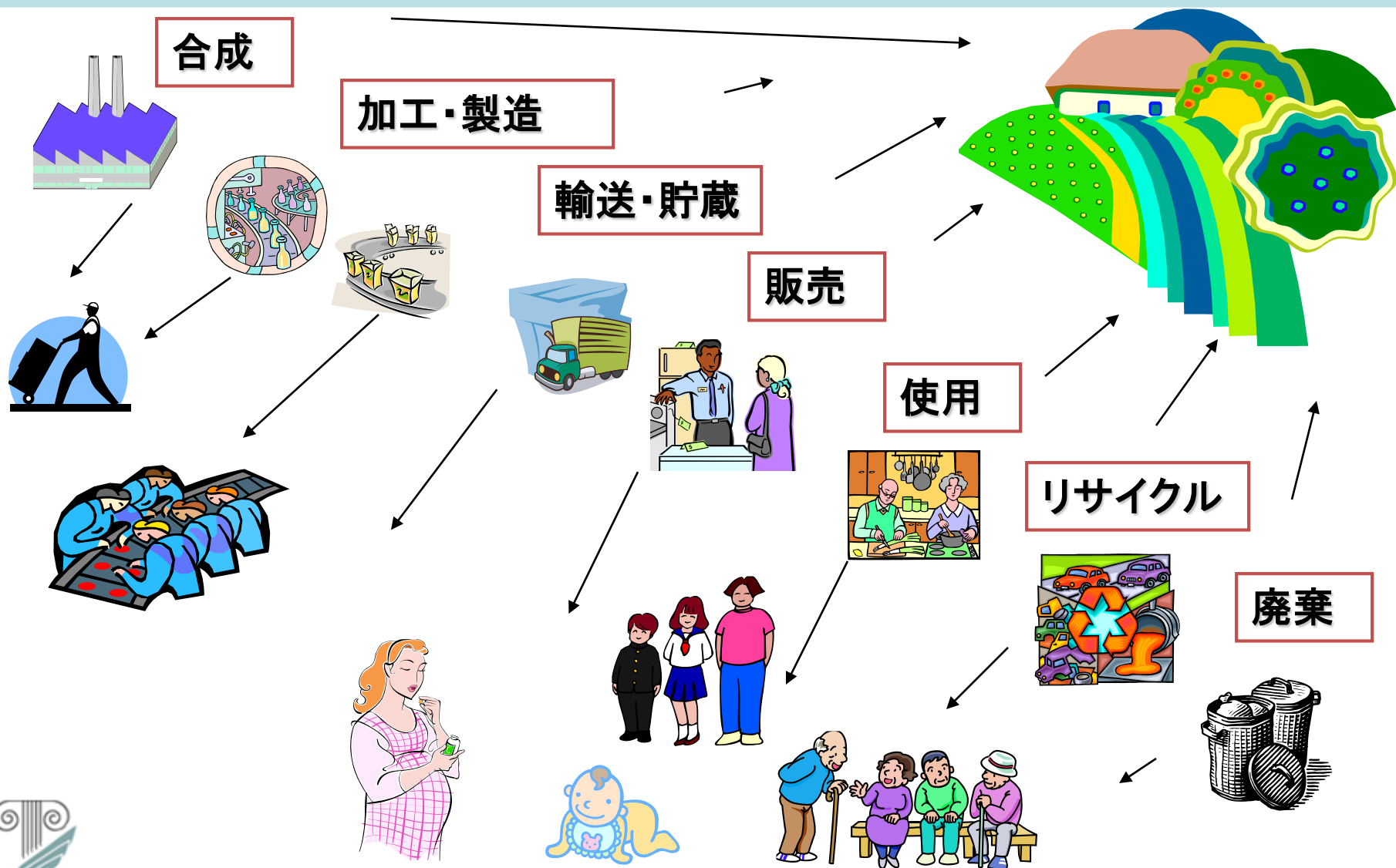


毒性評価：パラダイムシフトの必然性

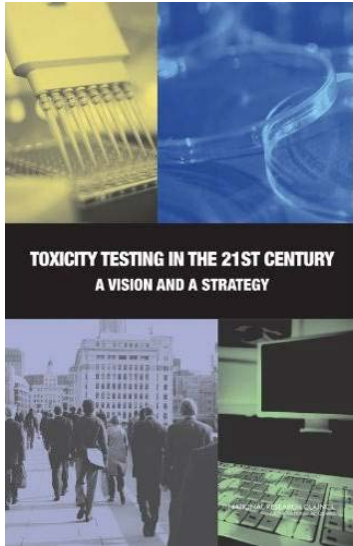
- 分子レベル、遺伝子レベルの解析技術の進歩とデータの蓄積
- 毒性発現メカニズムに関する理解とデータの蓄積
- 多様なHTS試験系の開発と適用
- コンピュータを用いた大容量データ管理と解析・モデリング技術の進展
- システム・バイオロジーの進展



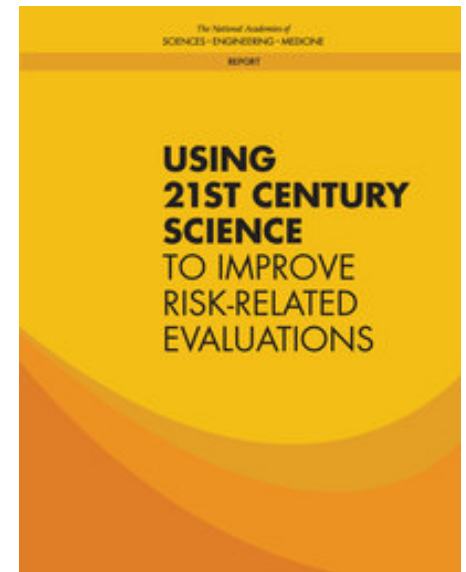
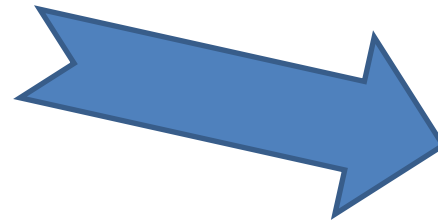
化学物質のライフサイクル



21世紀のリスク評価に適用する暴露評価



U.S.EPA, U.S.FDA, National Institute of Environmental Health Sciences (NIEHS), National Center for Advancing Translational Sciences (NCATS)の要請を受け、National Academies of Sciences, Engineering, and Medicineが検討委員会を招集



Committee on Incorporating 21st Century Science into Risk-Based Evaluations; Board on Environmental Studies and Toxicology; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine

Session 1: Setting the Stage

Fit-For-Purpose Exposure Assessment into Risk-Based Decision-Making: Framing the Technical Challenges and Opportunities

Jon Arnot

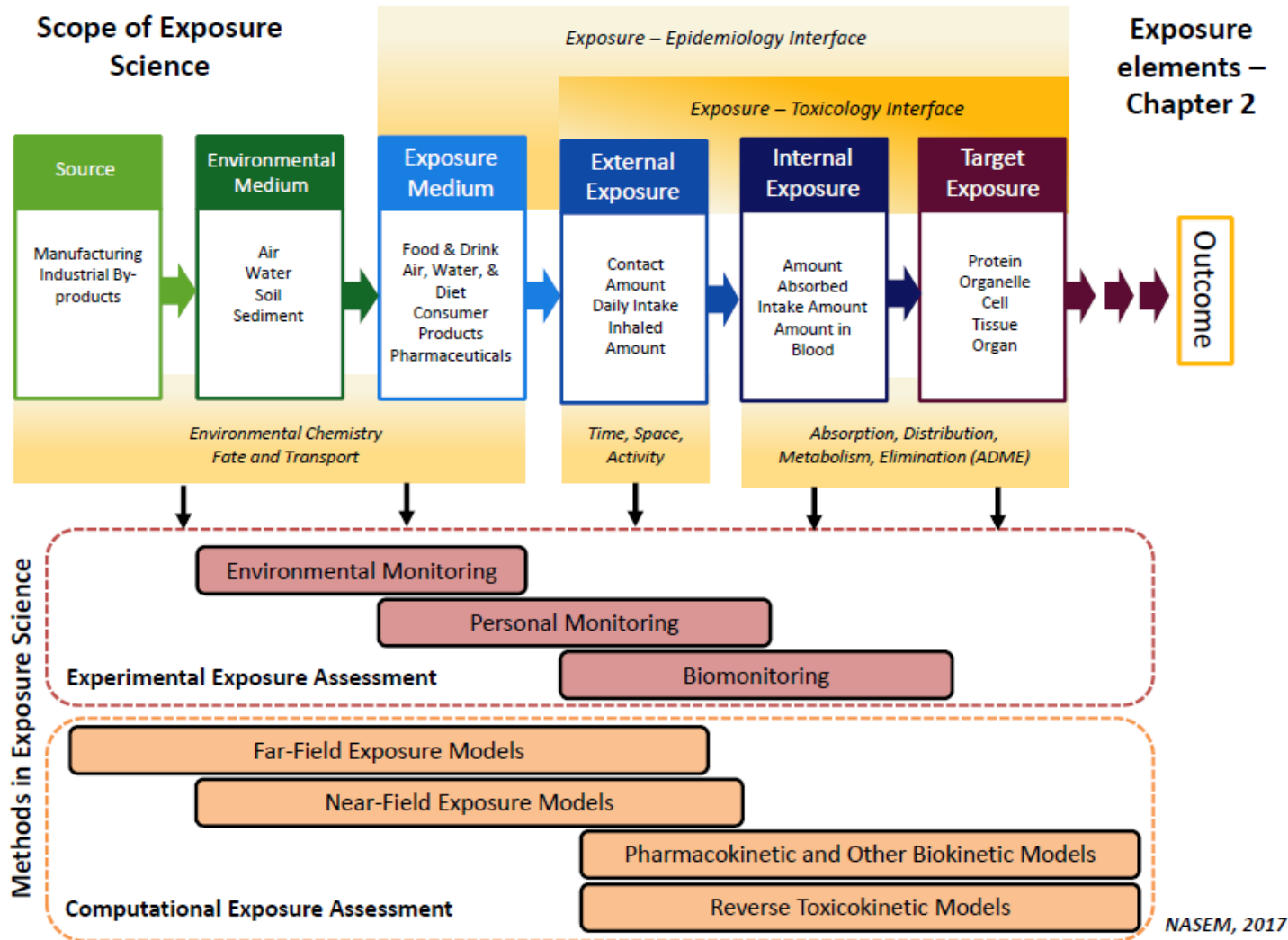
ICCA-LRI Workshop

Como, Italy

June 21-22, 2017



Session 1: Arnot

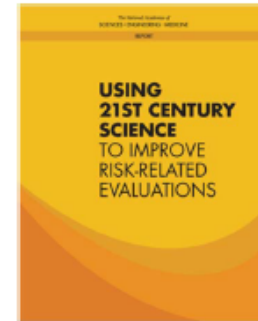


Session 1: Arnot

Summary recommendations (and challenges):

- 1 Expand and coordinate exposure science infrastructure to support decision-making
- 2 Identify chemicals or other stressors and quantify sources and exposures
- 3 *Align environmental and test-system exposures*
- 4 *Integrate exposure information*
- 5 *Improve knowledge of processes that determine chemical fate in systems*
- 6 Determine exposure assessment priorities

Exposure (Ch. 2)



Session 2: Isaacs



Advancing Consumer Product Composition and Chemical Use Information to Facilitate Risk-Based Decision Making

Kristin Isaacs

National Exposure Research Laboratory, U.S. EPA

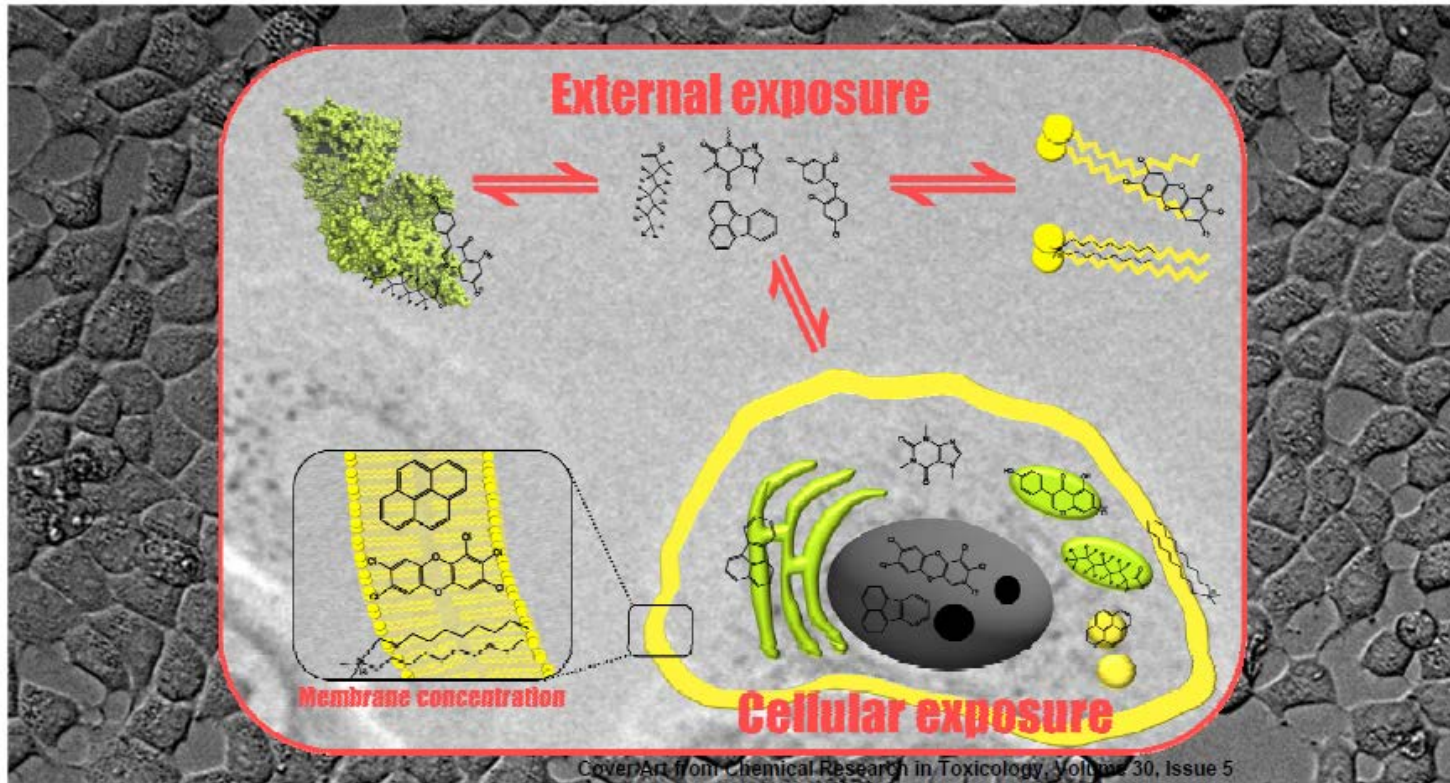


The views expressed in this presentation are those of the authors and do not necessarily reflect the views or policies of the U.S. EPA

*Fit-For-Purpose Exposure Assessments For Risk-Based Decision Making
ICCA-LRI and JRC Workshop
Como, Italy
June 21, 2017*



Session 3: Fischer



Mass balance modelling to describe exposure in *in vitro* high-throughput systems

June 22, 2017

Speaker: Fabian Fischer

Luise Henneberger, Rita Schlichting, Beate I. Escher




HELMHOLTZ
ZENTRUM FÜR
UMWELTFORSCHUNG
UFZ




Session 4: Kephelopoulos



European Commission



Joint Research Centre
the European Commission's
in-house science service



Joint Research Centre

ICCA-LRI and JRC Workshop Fit-For-Purpose Exposure Assessments for Risk-Based Decision Making

21-22 June 2017, Como

“SOLVING THE CHEMICAL PUZZLE” – Understanding chemical exposure and effects to humans and environment : The role of the European Commission’s IPCHEM Platform and its next generation development plans

Stylianos Kephelopoulos (JRC/F.2)
Silvia Dalla Costa (JRC/B.6)
European Commission’s Joint Research Centre



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COUNCIL OF
CHEMICAL
ASSOCIATIONS



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Session 4: Tan



Integrating Aggregate Exposure Pathway (AEP) and Adverse Outcome Pathway (AOP) frameworks to estimate exposure-relevant responses

Cecilia Tan

U.S. Environmental Protection Agency

U.S. Environmental Protection Agency

The views expressed in this presentation are those of the presenter, and do not necessarily reflect the views and policies of the Agency.



Session 4: O'Mahony



Models, Data and Software for Cumulative and Aggregate Exposure

Cian O' Mahony, Chief Science Officer



Session 3: Paini



The European Commission's science and knowledge service

Joint Research Centre

PHYSIOLOGICALLY-BASED KINETIC MODELLING IN RISK ASSESSMENT – REACHING A WHOLE NEW LEVEL IN REGULATORY DECISION-MAKING

Alicia Paini, Phd, ERT

Chemical Safety and Alternative Methods Unit, EURL ECVAM
- Directorate Health, Consumers and Reference Materials,
Joint Research Centre, European Commission, Ispra, Italy.

Como, 21th – 22th June 2017

** Contents of this presentation do not necessarily
represent the organizational views of the co-authors*



Joint
Research
Centre

PBKモデルの行政判断への適用を目指す国際的取組み

- ◆ **新世代のPBK (Physiologically-Based Kinetic)モデルの行政判断への適用**
 - EURL ECVAM Strategy Document on Toxicokinetics (2015)
 - Workshop on physiologically based kinetic modelling (2016)
 - Survey of PBK model use in science and regulation (2017)
 - OECD Proposal for guidance on PBK modelling (2017)

- ◆ **HESI PBPK (Physiologically-Based Pharmacokinetic) Working Group**
 - 産官学の研究者が参加
 - 化学物質リスク評価へのPBPKモデルの適用を推進する(デフォルトの不確実係数より適していると判断できる場合)
 - U.S.EPAの農薬安全性評価へのPBPKモデル適用をサポート



Path Forward: Research and Collaborations

- Need for **strategies to connect fragmented exposure science communities**: researchers, regulatory, product stewardship & public & env. health practitioners
- Use **risk-based decision contexts to organize FFP exposure approaches** and tools
 - to **add value not complexity**
 - **models** should be **simple, succinct, explicit, & robust** for intended purpose
 - strive for a **collaborative collection of high quality data**
- We have the opportunity to **share data and work globally**, especially in the area of model development, **including aggregate & cumulative**. This will prevent redundancies.
- We should work to **promote initiatives to share data** and approaches for using big data (analysis/fusion/developing prediction models)
- Explore opportunities for (through a **formal initiative**) for **sharing case examples**

日本における化学物質リスク評価の課題

- ◆ 毒性評価のパラダイムシフトの推進
- ◆ 数理モデルによる予測手法を活用する柔軟なアプローチの開発と導入の促進
- ◆ データの共有化と大容量データの活用
- ◆ 産業界とパブリックの国際的共同研究への参画
- ◆ 国際的な標準化、バリデーションの枠組みの活用
- ◆ リスク評価改革の国際的ディスカッションへの積極的な参加
- ◆ 人材育成



ICCA LRI 2018

- ◆ 2018年6月中旬
- ◆ 北米で開催
- ◆ ACCと北米行政機関との共催
- ◆ 新しい評価手法を活用するより具体的なケーススタディ



ICCA LRI 2017 Workshop

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Password: welcome



ご清聴ありがとうございました

ご質問

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