

Risk Assessment to Risk Management- Terminology of Risk Assessment:

An Introduction
or
The Terminology of Harmoni[s][z]ation

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At first look- it's simple!

Chemicals are Global so...

- *if assessed /used in one country, why not used everywhere?*
- *If banned in one country, why not banned globally?*

...in reality it's complex!

Regulatory policies/approaches can differ with little transparency. eg

- Hazard or risk based system?
- Basis for decision making: eg Precautionary/ Mode of Action (Key Events) /Mechanism of Action (All Events)?
- Information based? Voluntary? Co-regulatory? and/or Control based?
- Pre-manufacture? and/or pre-marketing approval? and/or post marketing?
- Differences in HSE policy/management vs risk assessment?
- What is level of acceptable risk? /risk tolerance of a society?

WHO Harmonisation

Harmonisation: A framework for a global approach to chemical risk assessment and related methodology:

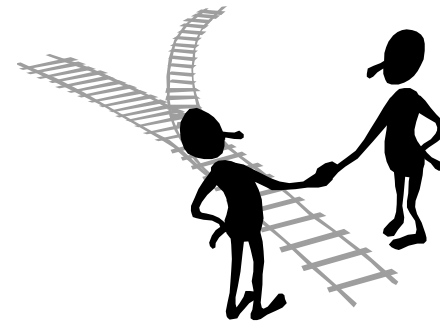
Enhance Transparency

Reduce duplication

Share information

Increase scientific integrity in RA

Enhance confidence in concept of “safety”.



Understanding & harmonising RA methods and practices used worldwide provides:

Confidence in RA from other governments/organisations

Use of RA (elements) into national programs (even if generated using different methodologies and/or approaches)

Robust and transparent RA and decision making

Why Harmonisation?



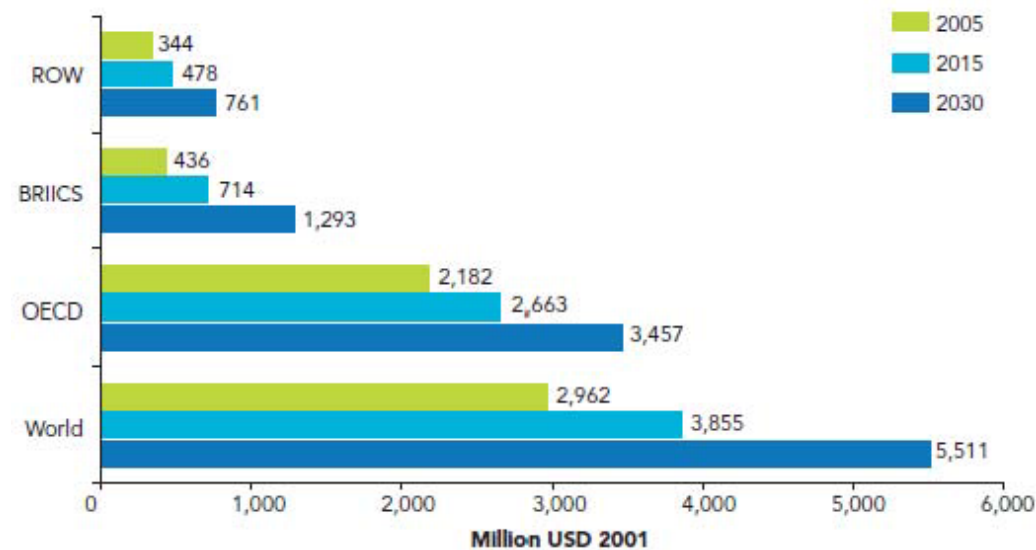
International Impetus

- UNCED (Rio World Summit): 1992
 - *Insufficient HSE data/Risk Assessments available, as RA resource intensive called for cooperation, common frameworks for RA*
- World Summit on Sustainable Development 2002:
 - *“by 2020, that all chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using **transparent science-based risk assessment procedures and science-based risk management procedures**”.*
- SIACM 2006:
 - Called for development and use of new and harmonised methods for Risk Assessment

...and the Ongoing Challenge

World chemical production due to ~double from 2005 to 2030

Projected Chemicals Production by Region (2005-2030)



Source: OECD, 2008b³

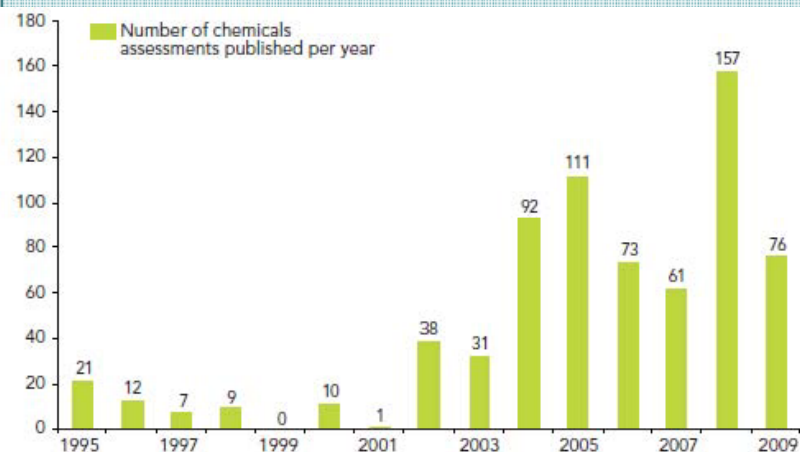
Why Harmonise Terminology?

Harmonised Terminology

- the basis for common principles, understanding and approaches to RA
- enhanced transparency in risk assessment.
- promote best practice science
- enhances the utility of the RA for regulatory purposes globally
- enhances the availability of chemical safety information globally through consistent use of terms
- aids understanding and enhances public communication of risk and safety

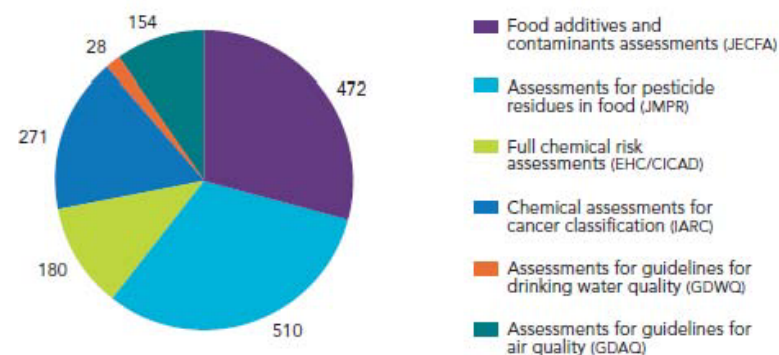
Expanding International Risk Assessments through cooperation & harmonisation

700 HPV Chemical Assessments (1995-2009)



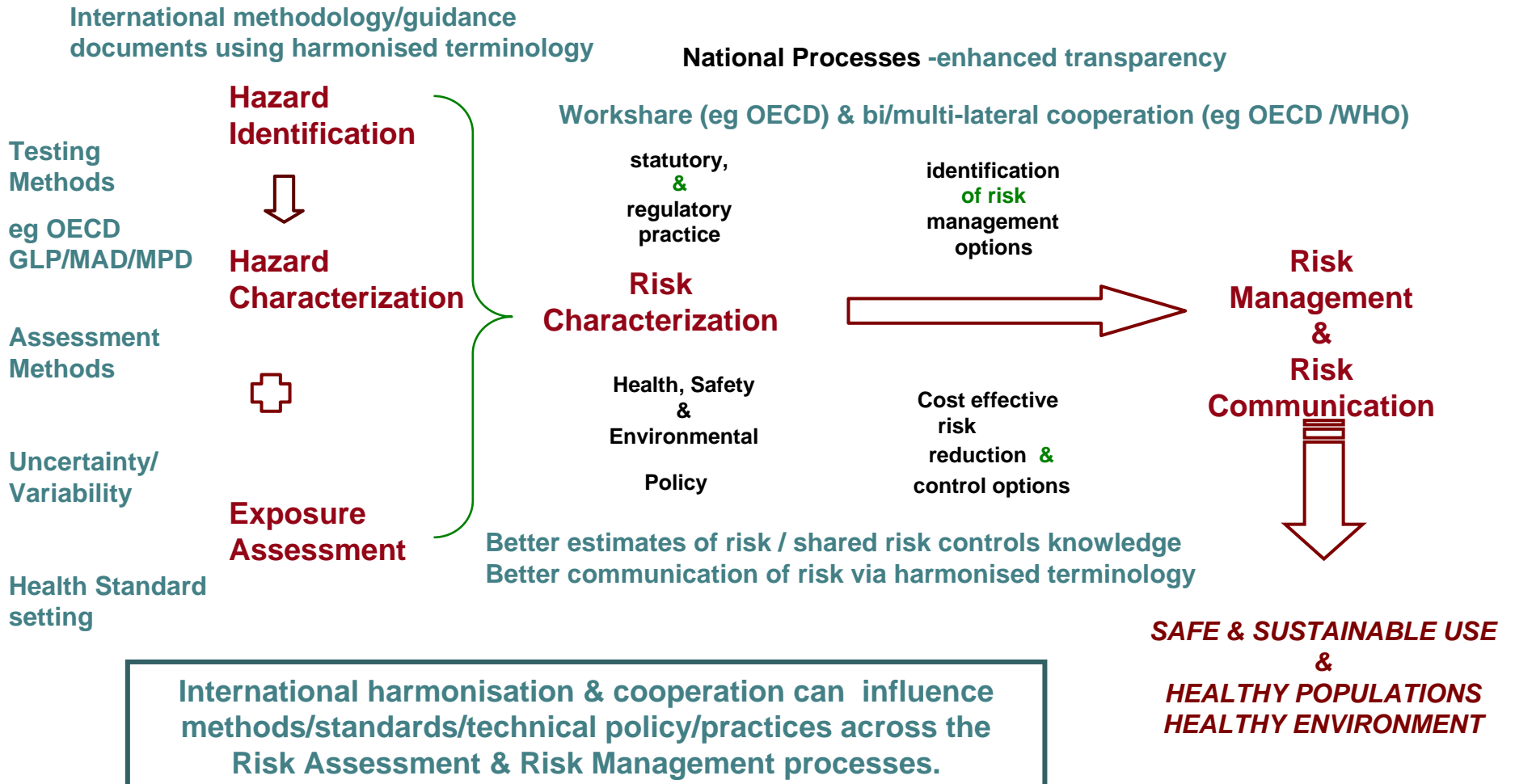
Source: OECD, 2009a

1600 International Chemical Assessments (1992-2009)



Source: WHO, 2009a

Impact of Harmonisation and Co-operation in Risk Assessment



e.g. WHO Harmonization Products

- Generic hazard/risk assessment terminology, **followed** by:
 - Mode of Action Framework (cancer & non cancer)
 - Chemical-specific adjustment factors guidance
 - Guidance on PBPK modelling
 - Uncertainty in Hazard Assessment (in development)
- Exposure assessment terminology, **followed** by:
 - Characterizing and applying human exposure models
 - Characterizing and communicating uncertainty in exposure assessment
 - Hallmarks of Data quality in exposure assessment

Case 1. Terminology enhances transparency: *International Mode of Action (MOA) /Human Relevance (HR) Frameworks*

- **Objective is transparency**
 - organizes information
 - clarifies extent of weight of evidence as a basis for decision making
 - Requires multidisciplinary teams, peer engagement
 - clear definition of critical data gaps in a risk assessment context
- Leading to consistency of documentation
- Leading to convergence?
- Basis for developing appropriate data

Case 2: *Finding New Terminology: Combined Exposures*

- 2007 WHO Workshop identified different terminology as a barrier to addressing this issue
 - Different definitions of cumulative and aggregate, "mixtures"?, how to describe all the scenarios?
- WHO Combined Exposures Framework 2010 precisely describes scenarios, rather than using differently understood terms, eg
 - Single chemicals, all routes
 - Multiple chemicals by a single route
 - Multiple chemicals by multiple routes, etc.

Case 3: Characterising and Communicating Uncertainty in Risk: The Challenges

- input sources in developing expressions of risk:
 - Exposure- quantitative / qualitative (high/low/likely/unlikely);
 - Hazard- quantitative (eg GHS cut offs)/ qualitative (high/low/+++);
 - Risk/Benefit or cost/cost data- quantitative / qualitative (outweighs etc).
 - Risk Mitigation- single/multiple options
- expression of risk as part of risk management/ risk communication needs some common terminology approaches

Some insights...

- Success needs to be underpinned by:
 - collaboration that is open, transparent, receptive to new ideas, flexible, efficient and pragmatically focussed on results
 - involving national influencers/decision makers (ie an activity grounded in practical/real application)
 - Outreach
 - A global approach
 - Wide involvement of stakeholders and decision-makers
 - Access to Practical Guidance & Training

International Impetus



- UNCED (Rio World Summit): 1992
- WSSD 2002:
 - *“by 2020, that all chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using **transparent science-based risk assessment procedures and science-based risk management procedures**”.*
- SIACM 2006:
- **Rio World Summit + 20 in 2012**
 - How much impact have we had?
 - What are the “new priorities”?

Thank you

WHO Risk Assessment Network
<http://www.who.int/ipcs>

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