DATA DRIVEN RISK ASSESSMENT AT EFSA: TOOLS AND METHODOLOGIES

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OUTLINE

Introduction: Risk assessment paradigm

Part 1: Hazard characterisation with EFSA's OpenFoodTox tool

Part 2: Overview of exposure assessment tools

THE RISK ASSESSMENT PARADIGM

HAZARD IDENTIFICATION

EXPOSURE ASSESSMENT

Occurrence data submitted to EFSA
×
Food/Feed consumption

HAZARD CHARACTERISATION

Toxicokinetic/ADME, animal toxicity, epidemiological data, mode of action, dose-response

RISK CHARACTERISATION

Relate exposure to a chemical in a given population with toxicological effects (Human Based Guidance Value (HBGV) / margin of exposure (MOE)) and concludes on the likelihood of adverse effects.

Part 1: Hazard characterisation with EFSA's OpenFoodTox tool

EFSA'S CHEMICAL HAZARDS DATABASE "OpenFoodTox"

Open-source database of toxicological information since EFSA's creation (2002)

✓**"One-click" tool** for risk assessors, risk managers and stakeholders

✓**Curated endpoints** deriving from **EFSA Risk Assessment** (EFSA Scientific Opinions)

Data model based on international standard data formats

- OECD Harmonised Templates (OHTs)

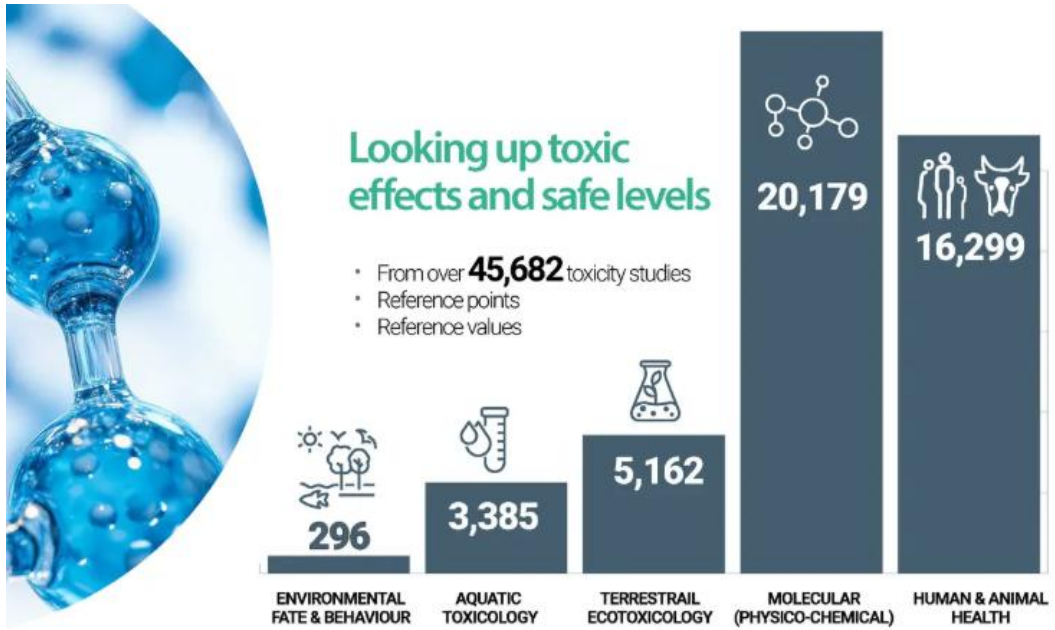
OECD
BETTER POLICIES FOR BETTER LIVES

Developing methods and tools as alternatives to animal testing

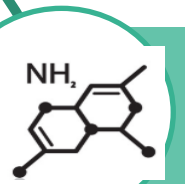
- In silico tools, Quantitative Structure-Activity Relationship (QSAR), Read-across

https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox

OpenFoodTox 3.0 CONTENT (APRIL 2026)



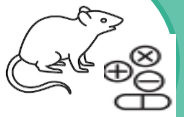
OpenFoodTox 3.0 AS BASIS FOR NEW APPROACH METHODOLOGIES (NAMs)



Chemical Information

→ Chemical structure

→ Physico-chemical properties



(Eco)toxicological Information

→ Genotoxicity

→ Toxicokinetics in vitro/in vivo

→ Toxicodynamics in vitro/in vivo

***NAMs - in silico* tools**

- *(Q)SAR**
- *Read-across*
- *Grouping*
- *PBPK models^*

EFSA TK Plate

*(Quantitative) Structure Activity-Relationship
^ Physiologically Based Pharmacokinetic

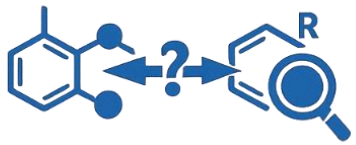
OpenFoodTox 3.0 & NEW APPROACH METHODOLOGIES (NAMs)

NAMs - *in silico* tools

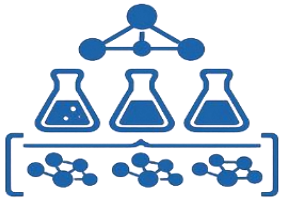
- (Q)SAR
- Read-across
- Grouping
- PBPK models

EFSA
TK Plate

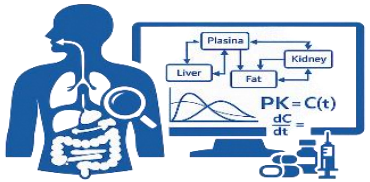
Models that **predict** intrinsic chemical properties (endpoints) based on the **chemical structure**



Tools/methods using data from one or more data rich chemicals "source chemical(s)" to **predict** properties/effects of a similar and data poor chemical "**target chemical”**



Tools/methods identifying and organizing chemicals into a **group** (or category) based on structural, physicochemical, toxicokinetic, and toxicological similarity



Models simulates the absorption, distribution, metabolism, and excretion (ADME) of chemicals in the body

DATA DRIVEN RISK ASSESSMENT AT EFSA: THE WEIGHT OF EVIDENCE FRAMEWORK

Guidance on the use of weight of evidence approach in scientific assessments

Combine data & evidence:

Overall scientific assessment

Problem formulation
- Define the question(s) for assessment
- Identify which questions require weight of evidence assessment

Weight of evidence assessment
1. Assemble the evidence
2. Weigh the evidence
3. Integrate the evidence

may occur at one or more points in the assessment, where evidence integration is needed

Uncertainty analysis
- Assess and combine uncertainties from all parts of the overall assessment
- Identify data gaps

Conclusion of overall assessment

Part 2: Overview of exposure assessment tools

OVERVIEW OF EFSA'S TOOLS BY APPLICATION DOMAIN

Dietary Exposure

- PRIMo
- DietEx
- FAIM
- FEIM
- FACE
- RACE

Non-dietary Exposure

- OPEX

Statistical Modelling

- Bayesian BMD
- TKPlate

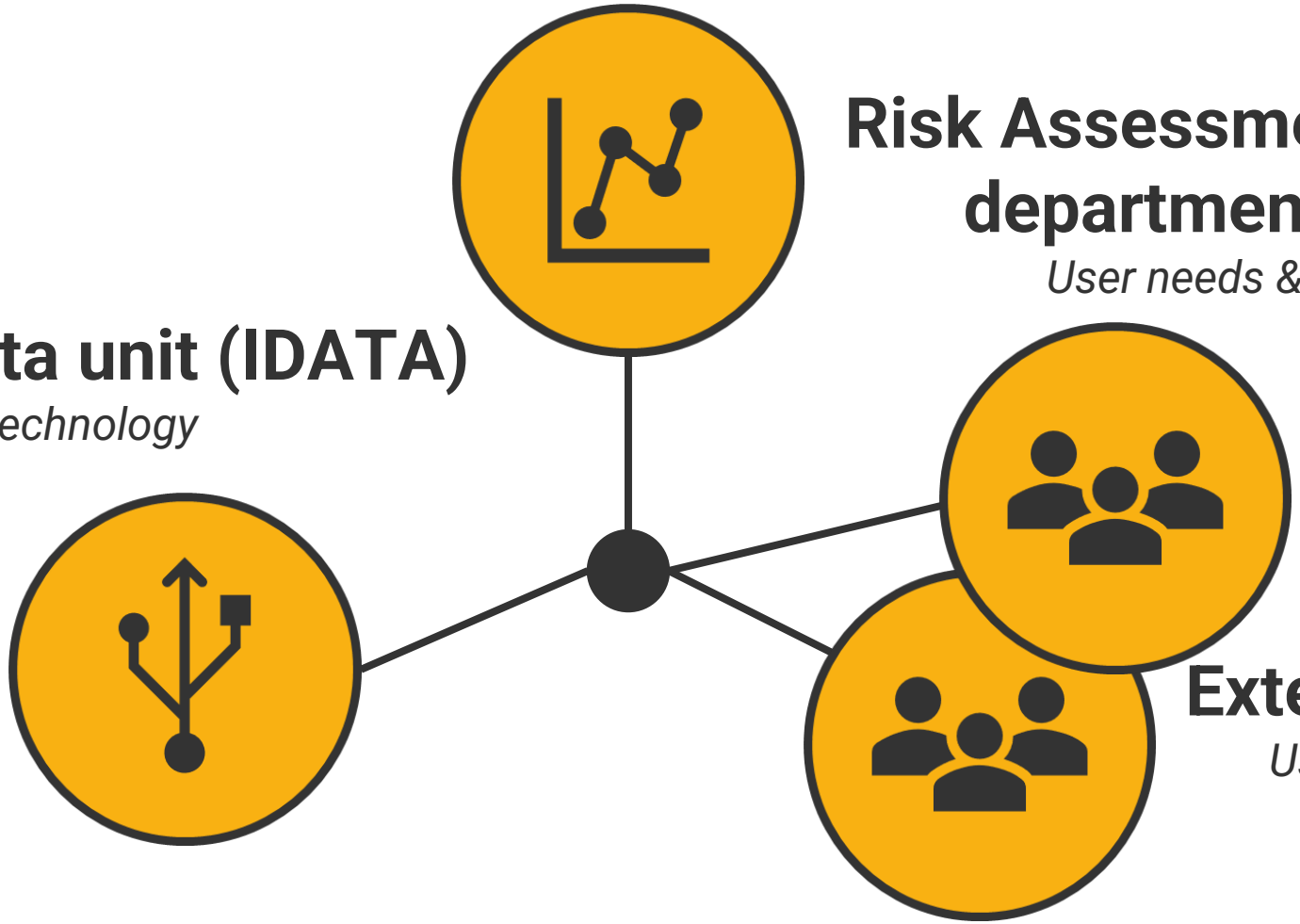
Environmental Risk Assessment

- B-Risk
- Birds and mammals

KEY ACTORS ON DIETARY EXPOSURE TOOLS

Methodology and Scientific Support unit (MESE)

Development & maintenance



Risk Assessment Production department (ASSESS)

User needs & requirements

Integrated Data unit (IDATA)

Data & technology

External Stakeholders

User needs & requirements

GENERAL PRINCIPLES DIETARY EXPOSURE

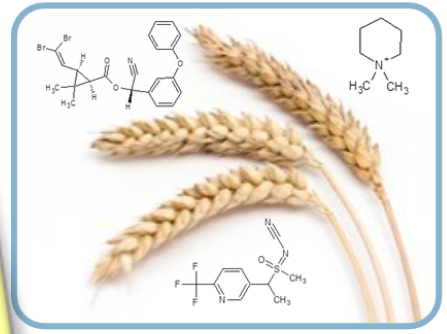
Acute or chronic ?

Prospective or retrospective ?

Conservative or refined ?

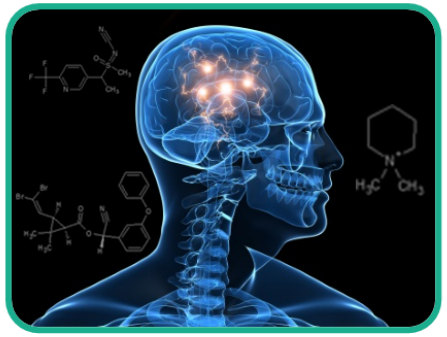
- ✓ Pesticide residues
- ✓ Contaminants
- ✓ Natural toxins
- ✓ Additives
- ✓ Food contact materials
- ✓ Nutrients
- ✓ Enzymes
- ✓ Flavourings
- ✓ Feed additives
- ✓ …

Occurrence

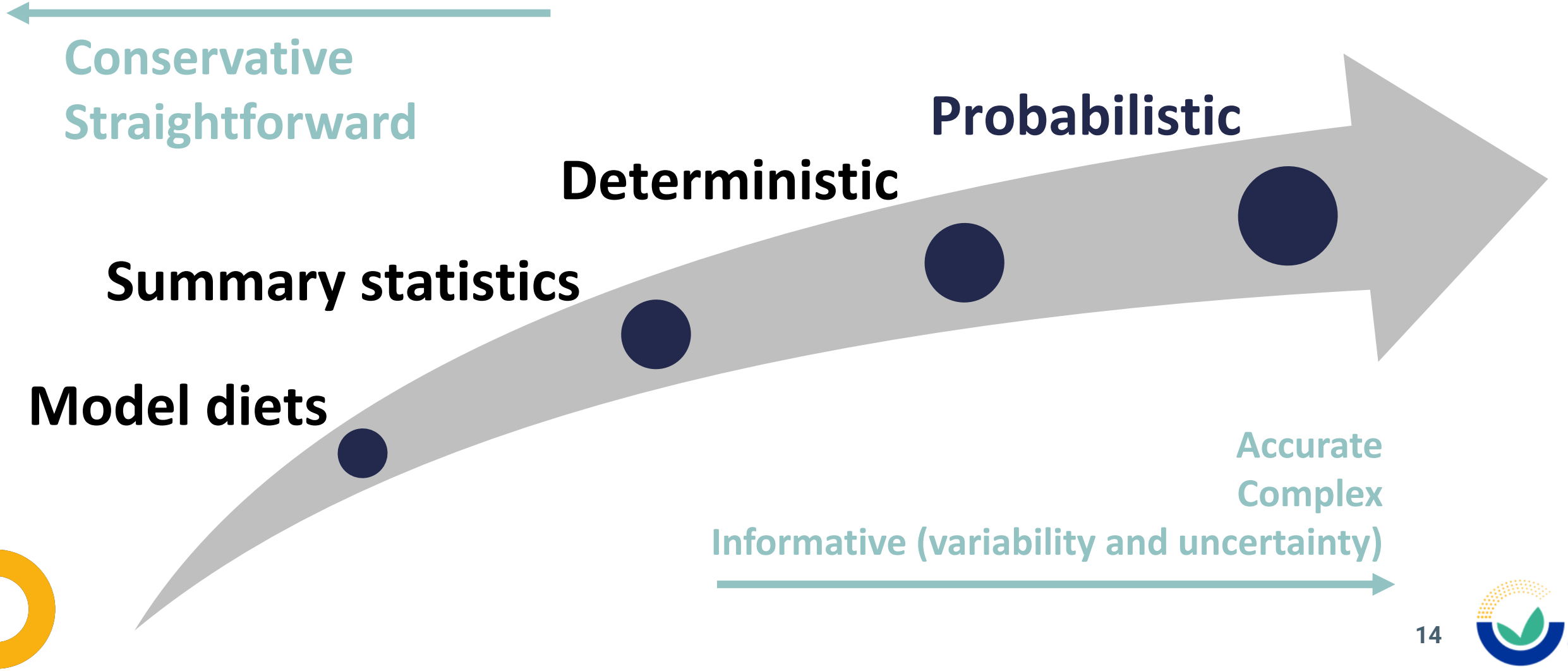


Consumption

Exposure



DIETARY EXPOSURE MODELLING



DIETARY EXPOSURE ASSESSMENT TOOLS

Deterministic

Probabilistic

EFSA Tools

- Dietary Exposure (DietEx)
- Rapid Assessment of Contaminant Exposure (RACE)
- Pesticide Residue Intake Model (PRIMo)
- Feed Additive Consumer Exposure (FACE)
- Food Enzyme Intake Model (FEIM)
- Food Additives Intake Model (FAIM)

External Tool

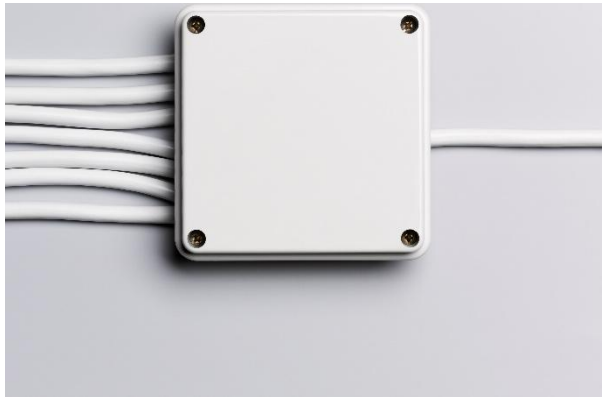
DETERMINISTIC EXPOSURE TOOLS

	FACE	PRIMo 4	RACE	DietEx	FEIM	FAIM
Domain	Feed additives	Pesticide residues	Chemical occurrence		Food enzymes	Food additives
Consumption	RPC Model		Food consumption			
Exposure	Acute & chronic			Chronic		
Specific features	For fast assessments, only at high level food category	IESTI formulas, manual entry of processing & conversion factors, ADI & ARfD	Comparisons with ADI/ARfD	Persistent Analyses API Access	Factors for processes Default built-in values	Uses the food additive legislative categories
Available at	Micro Strategy	R4EU	R4EU	Azure Analytics	R4EU	R4EU

*All tools use **FoodEx2** as **food classification** system*

FUTURE OF EXPOSURE ASSESSMENT TOOLS

Reduced complexity



Simplified access

Harmonized eco-system

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