



NEW METHODS, OMICS and NOVEL CONCEPTS IN RISK ASSESSMENT OF COSMETIC INGREDIENTS

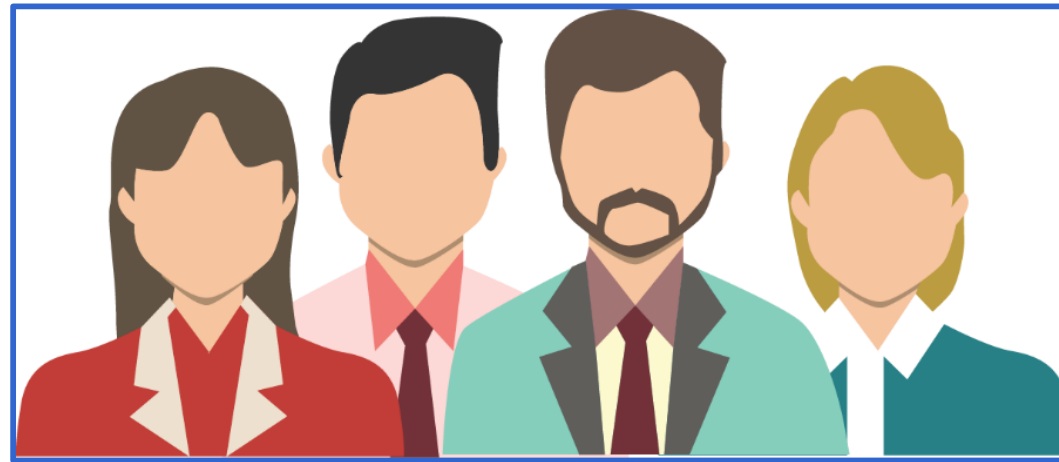
SCCS POSITION



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Co-chair SCCS,
chair WG Methodology*

WHAT IS THE SCIENTIFIC COMMITTEE ON CONSUMER SAFETY?

SCCS: group of **independent scientists** → **scientific advice** to the Commission



SCIENTIFIC
EXCELLENCE



INDEPENDENCE



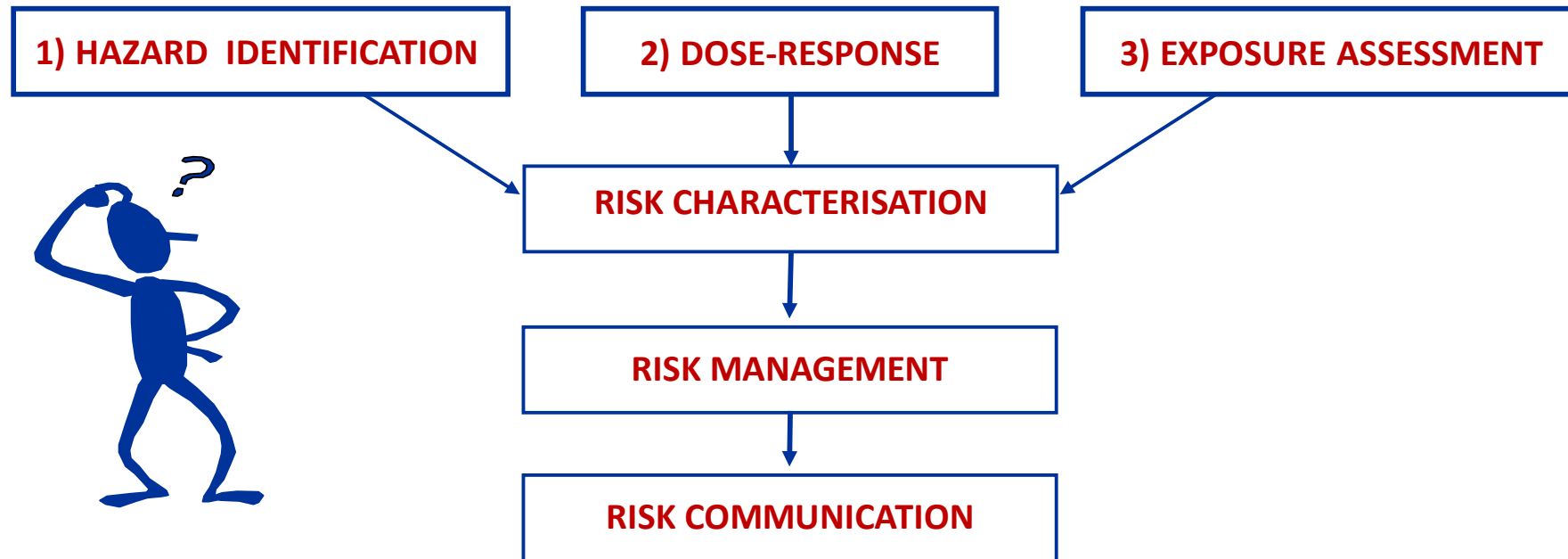
TRANSPARENCY

SCCS responds to given mandates (DG GROW)

RISK ASSESSMENT BASED ON TRANSPARENT SCIENTIFIC CRITERIA

Classification of substances according to hazard is not a task for SCCS

HUMAN HEALTH RISK ASSESSMENT



general scheme for industrial chemicals, plant protection products,
food additives, medical devices, pharmaceuticals,.....

→ also for **cosmetic ingredients** with some specific elements

HUMAN HEALTH RISK ASSESSMENT FOR COSMETICS

COSMETICS REGULATION (EC) N° 1223/2009
→ HIGH LEVEL OF PROTECTION FOR HUMAN HEALTH



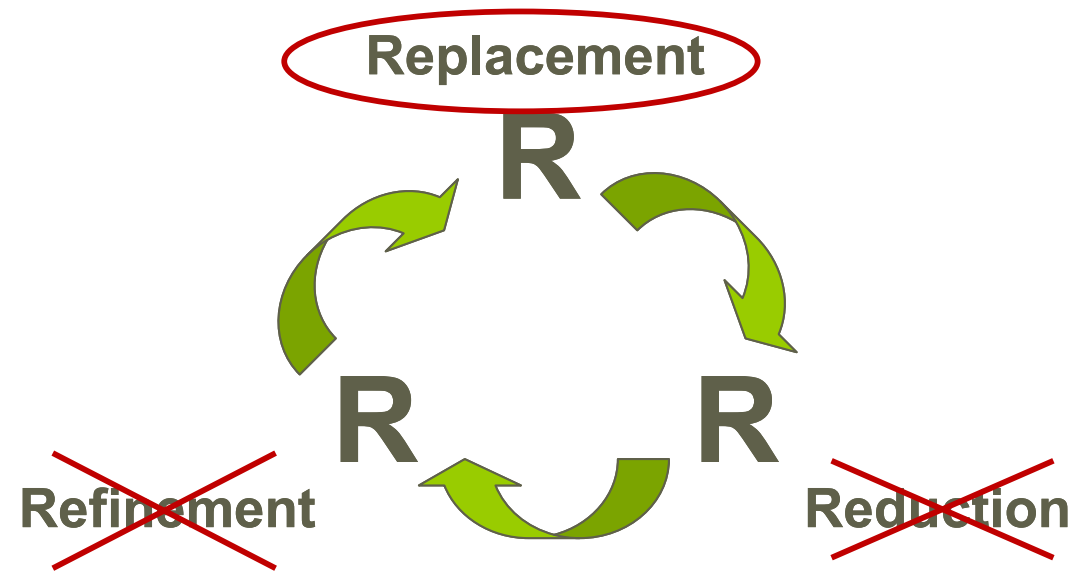
- **COSMETIC PRODUCTS MUST BE SAFE**
 - **SAFETY IS BASED UPON SAFE INGREDIENTS**
(toxicological profile, chemical structure, exposure)
 - **DEMONSTRATION OF SAFETY**
 - **CHALLENGE: TESTING AND MARKETING BANS FULLY APPLY SINCE 2013**
- RISK ASSESSMENT**



ONLY USE OF NEW APPROACH METHODOLOGIES (NAMs)
ANIMAL-FREE ALTERNATIVE METHODS

CHALLENGE FOR RISK ASSESSMENT OF COSMETICS

COSMETICS: UNIQUE SITUATION !! ONLY VALIDATED REPLACEMENT TESTS
ANIMAL-FREE TESTS → NEW APPROACH METHODS (NAMs)



WHAT NAMs DO WE HAVE ?

IN CHEMICO methods: physico-chemical properties

IN SILICO methods: read across, QSAR

IN VITRO methods: 2D- & 3D- cultures, organ-on-chip, spheroids, stem cells,...

only historical IN VIVO data may be used: animal, human

CHALLENGE FOR RISK ASSESSMENT OF COSMETICS



AVAILABLE VALIDATED *IN VITRO* NAMs?

HAZARD TESTS	VALIDATED <i>IN VITRO</i> REPLACEMENT TESTS	
Skin corrosion/ irritation	Green	
Eye irritation	Yellow	
Skin sensitisation	Green	
Phototoxicity	Green	
Toxicokinetics	A*	DME**
Repeated dose toxicity / Chronic toxicity	Red	
Reproductive toxicity	Red	
Mutagenicity/genotoxicity/ Carcinogenicity	CTA	Red

**USE OF NOVEL METHODOLOGY
NGRA**



NO CALCULATION of MoS = POD syst/ SED



**PROBLEM!!
NO NAMs FOR SYSTEMIC TOXICITY**

*A = Absorption (dermal); **DME = Distribution, Metabolism and Excretion; MoS = Margin of Safety; POD = Point of Departure; SED = Systemic Exposure Dose

PROPOSED NGRA FRAMEWORK FOR COSMETICS

NEXT GENERATION RISK ASSESSMENT (NGRA) FOR COSMETIC

exposure-led, hypothesis-driven risk assessment approach
to deliver human-relevant safety decisions without using anim

BASIC PRINCIPLE: UNDERSTANDING OF CONCENTRATIONS CAUSING CHANGE
CELLULAR PATHWAYS LEADING TO ADVERSE EFFECT

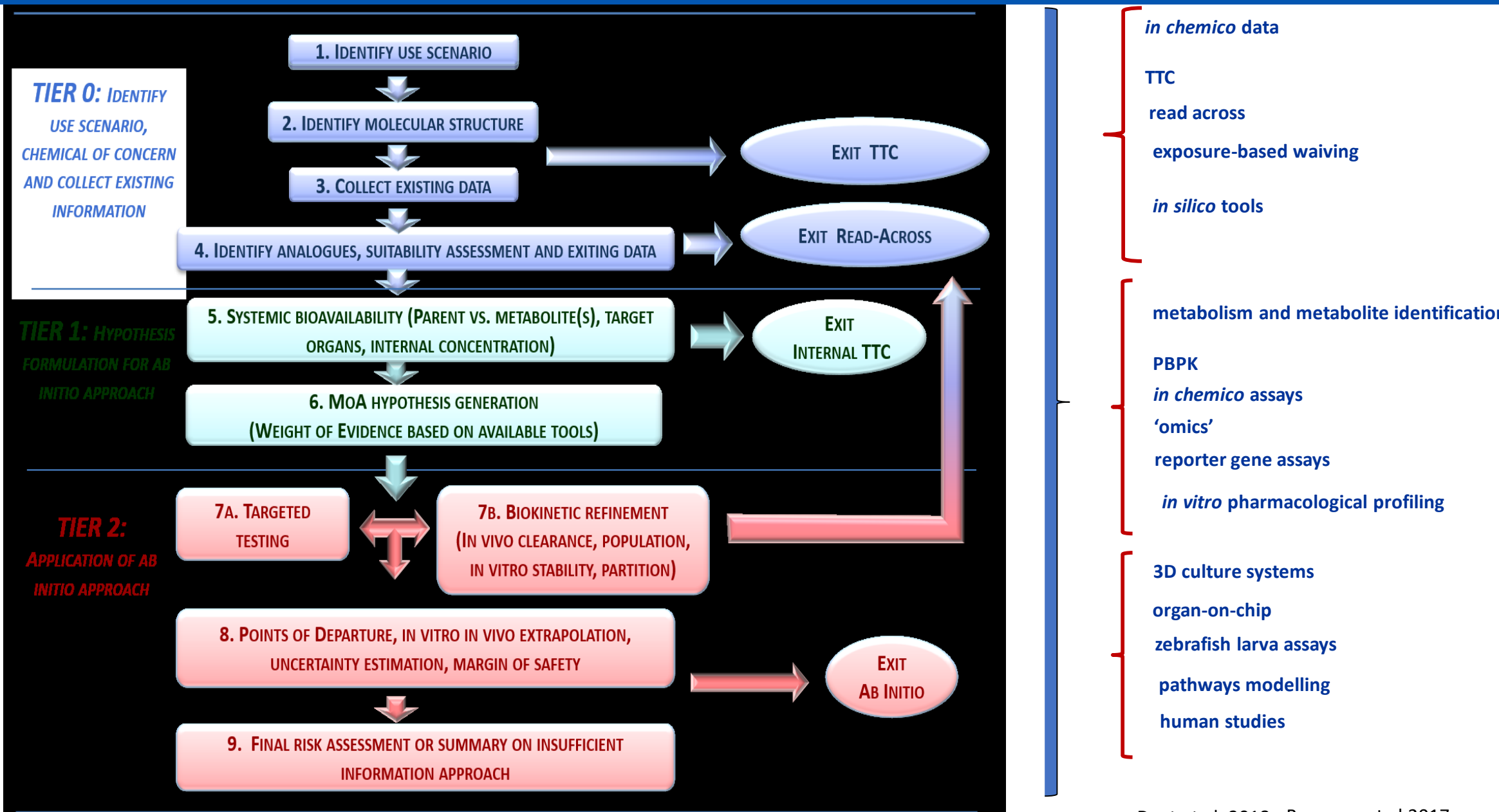
METHODOLOGY: INTEGRATING *IN CHEMICO*, *IN SILICO*, *IN VITRO* METHODS = NAMs
MOLECULAR TECHNIQUES, SYSTEMS BIOLOGY, BIOINFORMATICS,
HIGH THROUGHPUT, 'OMICS', COMPUTATIONAL MODELLING, TTC,



**WORKING IN TIERED STRATEGY → DECISIONS MADE
WHEN ENOUGH CONFIDENCE EXISTS IN UNDERSTANDING PATHWAY CHANGES**



PROPOSED NGRA FRAMEWORK FOR COSMETICS



PROPOSED NGRA FRAMEWORK FOR COSMETICS

NGRA PROPOSED FOR **SYSTEMIC TOXICITY** → *paraben, fenoxylethanol, coumarin, ...*

- ADAPTED FOR **SENSITISATION** → *resorcinol, geraniol, dibromoglutaronitrile,*



- ❑ **NAMs and NGRA FRAMEWORKS: PRESENT IN SCCS NOTES OF GUIDANCE 11TH REVISION (SCCS/1628/21)**
- ❑ **OPTIMISATION FOR SYSTEMIC TOXICITY: OFF TARGET ADVERSITY: SECONDARY/SAFETY PHARMACOLOGY < PHARMA**



SCCS FOLLOWS UP ON NEW ANIMAL - FREE METHODOLOGY

SCCS WANTS TO KEEP ITS INDEPENDENCE:

→ ONLY WAY TO MAKE PROGRESS IN ALTERNATIVE METHODS BASED ON SCIENCE

SCCS WANTS TO WORK IN A TIERED STRATEGY:

NOT ONLY FIRST TIER OF HAZARD ASSESSMENT, BUT FOLLOWED BY SECOND TIER OF RISK ASSESSMENT

IN GREEN DEAL: ONLY “ONE SUBSTANCE, ONE HAZARD ASSESSMENT” IS REALISTIC

RISK ASSESSMENT IS ESSENTIAL FOR SAFE COSMETICS