



Accelerating the Transition to Animal-Free, Sustainable Innovation

EPAA-ANNUAL CONFERENCE 2022

15 /11/2022



Vera Rogiers, Co-chair SCCS

for the mirror group

FIRST OF ALL!!

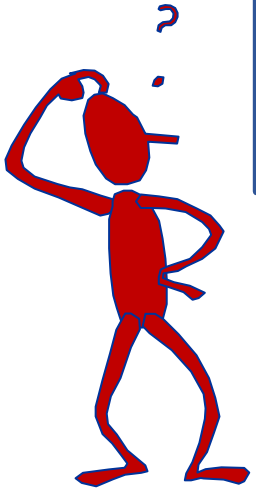


BIG 'THANK YOU' TO EPAA FROM MIRROR GROUP!!

During 2022, the Mirror Group was given the space :

- to propose ideas and discussion points and**
- become a strong discussion partner**

on the way forward to safe animal-free consumer products in Europe



The 2022 Annual Conference of EPAA

AIMS

- ❖ to give participants insight on the EPAA achievements in 2022,
- ❖ to announce the EPAA 3Rs Science Prize winner,
- ❖ **to discuss challenges to address**

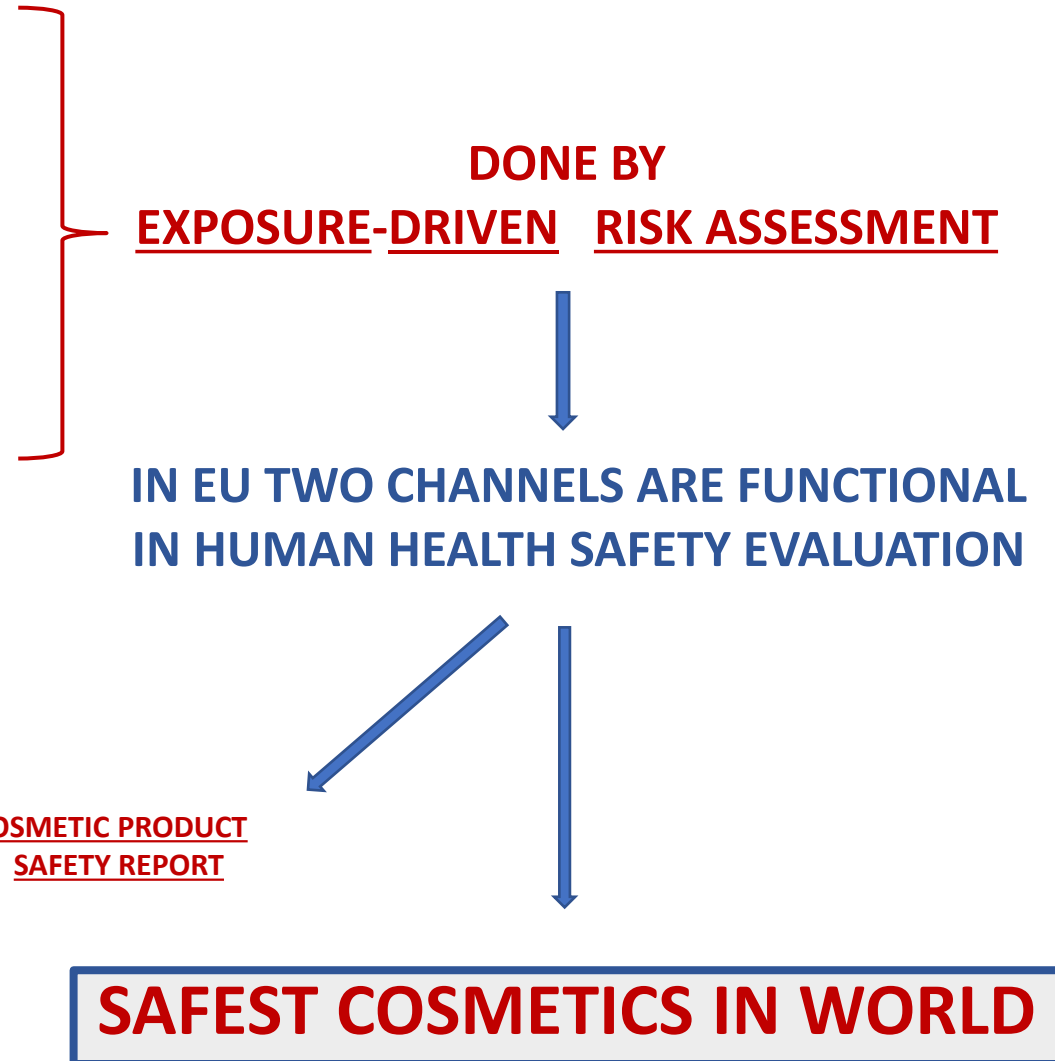
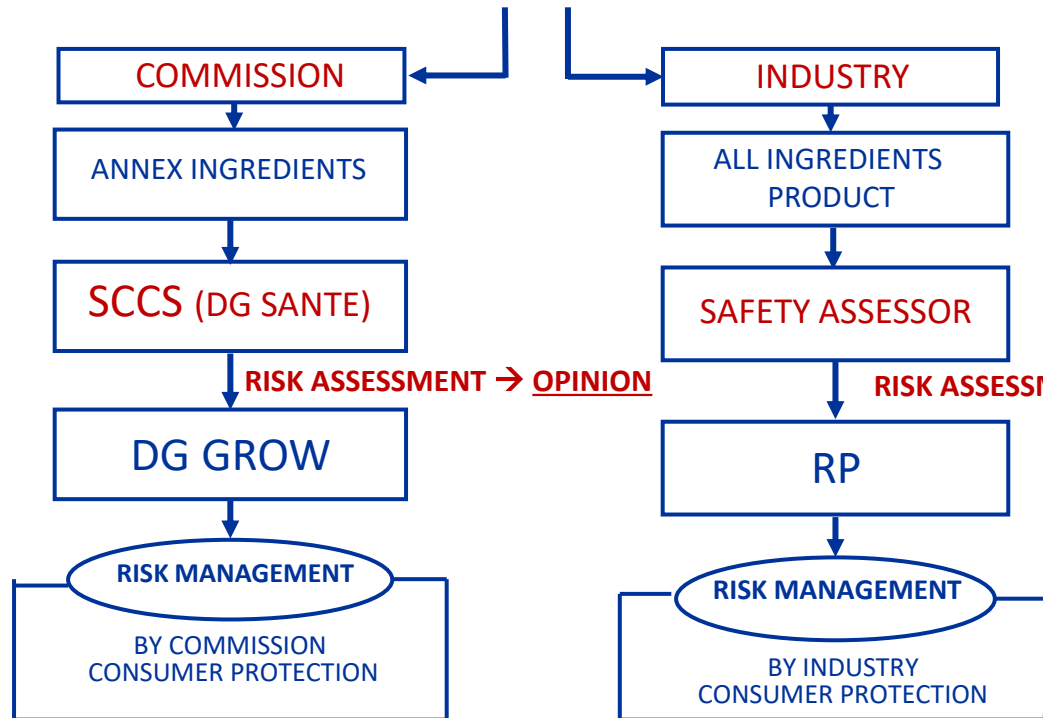
to make animal-free sustainable innovation a reality within the EU



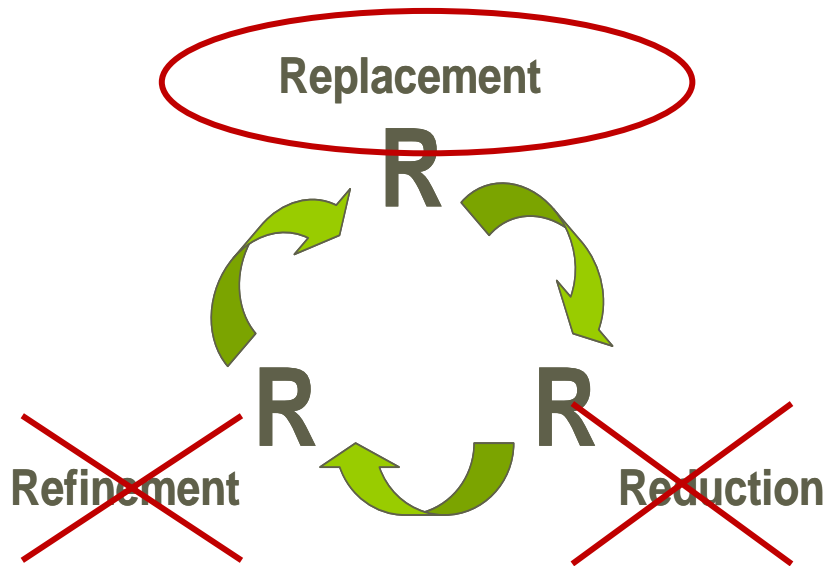
**CHALLENGE OF SAFE COSMETICS IN EUROPE
AND IMPACT ON ANIMAL USE & SUSTAINABLE INNOVATION**

RISK ASSESSMENT AS PRESENT IN COSMETICS REGULATION (EC) N° 1223/2009

- COSMETIC PRODUCTS ON EU MARKET MUST **BE SAFE**
- SAFETY IS BASED UPON **SAFE INGREDIENTS**
chemical structure, exposure, toxicological profile
- **DEMONSTRATION OF SAFETY OF ALL INGREDIENTS**



CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS



CHALLENGE 1

TESTING AND MARKETING BANS FULLY APPLY SINCE 2013

- ONLY ANIMAL-FREE METHODS: NAMs
New Approach Methodology
- STRONG SUPPORT BY PARLIAMENT**
- SAME DEGREE OF SAFETY PROTECTION IS NEEDED
- RISK ASSESSMENT IS KEY FOR SAFETY

RISK ASSESSMENT: ACCORDING TO SCCS NOTES OF GUIDANCE (NOG; SCCS/1628/21)

- *ABSOLUTE PRIORITY GIVEN TO NAMs: → shows the way forward
→ extension to other fields
→ worldwide attention

- *NGRA (Next Generation Risk Assessment) in NOG → exposure-driven strategy (sensitisation)
→ quality exposure data are available

**20/1/2022 Animal Welfare vote European Parliament

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS



CHALLENGE 2 GREEN DEAL STRATEGY

FOR CHEMICALS → ONE SUBSTANCE, ONE ASSESSMENT
HAZARD STRATEGY → APPLICABLE TO INDUSTRIAL CHEMICALS

NOT FOR COSMETIC INGREDIENTS: SAFETY IS OBTAINED BY RISK ASSESSMENT
HAZARD IS ONLY ONE OF THE 3 PILLARS



WHAT IS SUSTAINABLE FOR DIFFERENT LEGISLATIVE FRAMEWORKS?

ONE SUBSTANCE, ONE HAZARD ASSESSMENT

EU LEGISLATIONS OF CONSUMER PRODUCTS ARE VERTICAL & SPECIFIC PER PRODUCT TYPE:
INDUSTRIAL CHEMICALS: 3Rs (Refinement + Reduction + Replacement) with clear priority for NAMs
COSMETIC INGREDIENTS: 1R (Replacement), only NAMs

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

CHALLENGE 3

CLP REGULATION

Classification, Labelling and Packaging

→ REVISION OF CLP = Regulation EC N°1272/2008 IS ONGOING
COVERS ENDOCRINE DISRUPTING ACTIVITY (EDA)

- SCIENTIFIC APPROACH IS NECESSARY TROUGH RISK ASSESSMENT, NO GLOBAL BANNING
- PROPOSAL FOR COSMETIC INGREDIENTS WITH EDA → RULES AS FOR CMRs* WITH EXEMPTIONS
- EXEMPTIONS FOR 'ESSENTIALITY' → VARIABLE DEFINITION

'Are cosmetics and their ingredients essential?'

SAFETY OF COSMETIC INGREDIENTS IS IMPORTANT, NOT ESSENTIALITY

*Carcinogens, Mutagens, Reproductive toxic compounds

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

CHALLENGE 4

INTRODUCTION OF MAF Mixture Assessment Factor

- REACH DISCUSSION: GENERAL APPLICATION OF MAF (Mixture Assessment Factor)
- SEVERAL MAF DEFINITIONS → OUTCOME VERY DIFFERENT
- UNINTENDED MIXTURES TO REMAIN SAFE
- FOR 'UNKNOWN' MIXTURES OF TOXIC CHEMICALS, HIGH AMOUNT USES



NOT SUITABLE FOR COSMETICS

COMPOSITIONS ARE KNOWN, COSMETIC INGREDIENTS ARE SAFE BY DUAL EU STRATEGY

EVEN WITH THE LOWEST MAF

LOSS OF SEVERAL PRESERVATIVES (ALREADY SHORT LIST!)

HIGH COSTS FOR REDOING ALL OPINIONS OF ANNEX SUBSTANCES

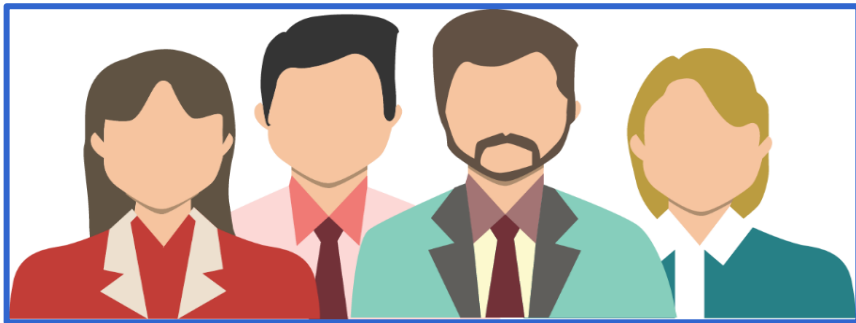
WHERE IS THE SUSTAINABILITY????

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

CHALLENGE 5

MOVING SCCS

SCCS is group of independent scientists → scientific advice on non-food consumer products to the Commission → mostly **risk assessment of cosmetic ingredients** based on industrial files



ACTUAL PROPOSALS

INDEPENDENT UNDER DG SANTE
INDEPENDENT UNDER ECHA
INCORPORATION INTO RAC (ECHA)



KEY DRIVERS:
SCIENTIFIC
EXCELLENCE



INDEPENDENCE



TRANSPARENCY

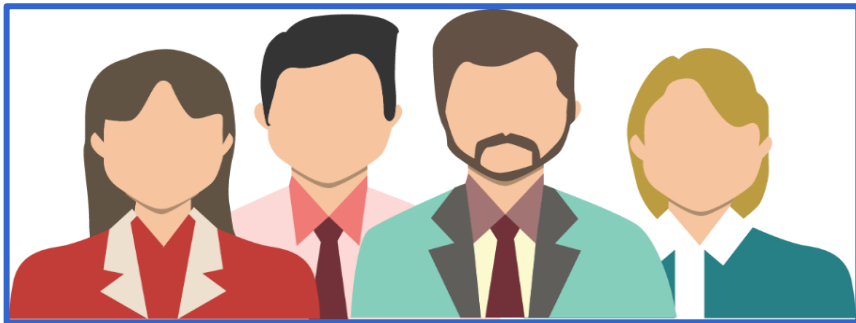
mandate until 2026

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

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SCIENTIFIC
EXCELLENCE



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TRANSPARENCY

KEY DRIVERS:

mandate until 2026

ACTUAL PROPOSALS

INDEPENDENT UNDER DG SANTE

WISHED, NOT POSSIBLE

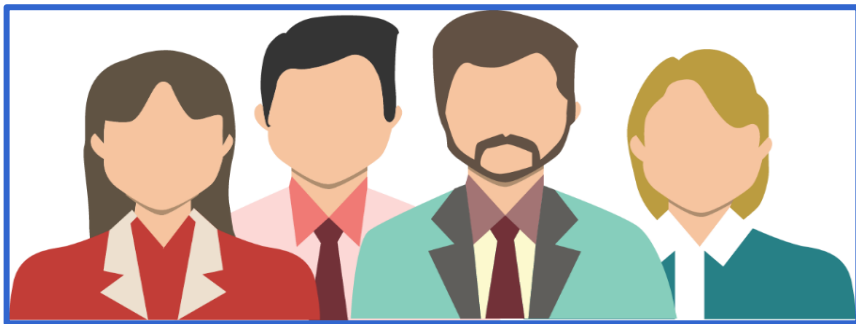
→ financial reasons & too busy with actual EU & world challenges

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

CHALLENGE 5

MOVING SCCS

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SCIENTIFIC
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TRANSPARENCY

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mandate until 2026

ACTUAL PROPOSALS

~~INDEPENDENT UNDER DG SANTE~~

INDEPENDENT UNDER ECHA

(5th Committee)

BEST SECOND OPTION

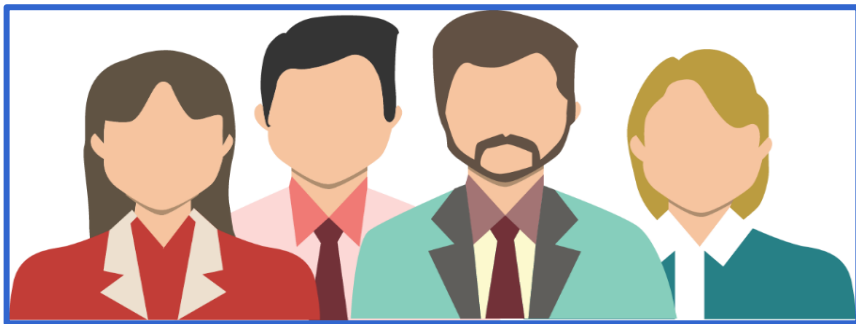
→ SHARING OF NAMs EXPERTISE

→ KEEPING SCCS INDEPENDENCE

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

CHALLENGE 5 **MOVING SCCS TO EXISTING AGENCY**

SCCS is group of independent scientists → scientific advice on non-food consumer products to the Commission → mostly **risk assessment of cosmetic ingredients** based on industrial files



SCIENTIFIC
EXCELLENCE



INDEPENDENCE



TRANSPARENCY

KEY DRIVERS:

mandate until 2026

ACTUAL PROPOSALS

~~INDEPENDENT UNDER DG SANTE~~

~~INDEPENDENT UNDER ECHA~~

INCORPORATION INTO RAC

WORST CASE

-LOSS OF INDEPENDENCE & CREDIBILITY

-LOSS OF ANIMAL-FREE POSITION

-PUSH TOWARDS ONLY HAZARD ASSESSMENT

-LOSS OF SCCS NOG STATUS IN WORLD

CHALLENGES FOR RISK ASSESSMENT OF COSMETIC INGREDIENTS

Validated & valid NAMs are effectively used by SCCS → SAFE COSMETICS



Key question of Mirror Group

Why is NAMs use NOT standard practice for chemicals within REACH?

An independent SCCS: help & credibility

→ ECHA to fulfill its legislative obligation to effectively use validated NAMs
SCCS incorporation in RAC → loss of identity & credibility & dynamics



Future positioning of SCCS: significant impact on sustainability

→ impact on NAMs incorporation into the REACH revision

→ effective use of NAMs by ECHA

TAKE-HOME MESSAGE

COSMETICS IN EU SHOW THE WAY FORWARD



- → SAFETY: ANIMAL-FREE RISK ASSESSMENT USING NAMs ONLY
- → INDEPENDENT, EXPOSURE-DRIVEN & SCIENTIFIC CRITERIA
- → 2 TIERS STRATEGY: 1) HAZARD ASSESSMENT AND 2) RISK ASSESSMENT
- → POSSIBLE THROUGH LONG EXPERTISE ON USING NAMs & NGRA WITHIN SCCS
- → EUROPEAN COSMETICS ARE TODAY THE SAFEST IN THE WORLD → TO BE KEPT LIKE THIS!
- → HIGH CREDIBILITY, NO POLITICAL INFLUENCE, NO LOBBYING, NO SCANDALS, STRONG SUPPORT BY PARLIAMENT

MODERNISATION OF REGULATORY TOXICOLOGY OF CHEMICALS IN GENERAL IS HIGHLY NEEDED

WITHOUT LOSS OF HUMAN SAFETY AND BY USING ANIMAL-FREE NAMs

NOT BY SIMPLIFICATION TOWARDS ONLY HAZARD

BUILDING UP OF ECHA's TRUST IN NEW ANIMAL-FREE METHODOLOGY

WORKING CLOSELY WITH RESPECT OF EACH OTHERS IDENTITY

COLLABORATION WITHIN EU 'PARC' PROJECT

THANK YOU!!



QUESTIONS?

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