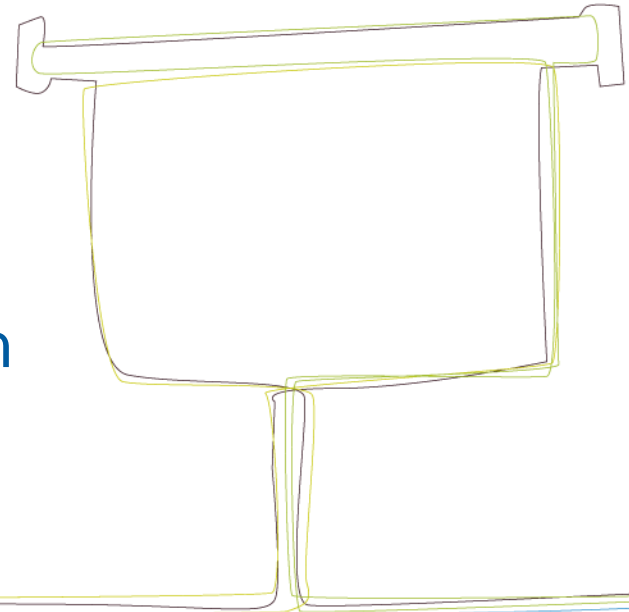




International **D**ialog for the **E**valuation of **A**llergens

**A Multi-stakeholder Dialogue with
Experts on Fragrance Allergy in
partnership with the EU Commission**



Background



- Fragrance induced allergy identified as an important issue in late '90s with increased number of allergic patients in clinics up to the year 2000.
- Fragrance industry recognized that its tools and procedures did not adequately address this human health issue.
- Approaches like the QRA aiming to 'eliminate' allergy were not sufficiently developed with and adopted by all relevant stakeholders.

Background



- The fragrance industry was not the master of its own destiny by relying too much on other organizations for dealing with the issue of fragrance allergens.
- SCCS Pre-consultation opinion on fragrance allergens in cosmetics (December 2011) served as a ‘wake-up’ call.
- In early 2012 IFRA decided to ‘step out of the shadows’, adopt a more prominent role and become fully engaged.
- Developing the tools to ensure a high level of consumer safety required a multi-stakeholder approach (incl. Academia, relevant services of the EU Commission, Dermatologists and Downstream User Industries)

Work Plan



- Work plan was designed from the outset to be conducted in partnership with the EU Commission.
- Officially announced at public hearing on the SCCS opinion on March 5th, 2012.
- Draft program presented to the EU Commission in April 2012.
- Iterative process to refine the Work Plan throughout 2012.
- Official endorsement by Commissioner Tonio Borg March 14th, 2013.

The Work Plan – basis for IDEA



Key items of the Work Plan related to Risk Assessment are:

- Definition of fragrance allergens
- Definition of fragrance allergens of specific concern
- Pre-haptens
- Pro-haptens
- QRA

IDEA is the project executing the Work Plan

IDEA – Strategic Objectives



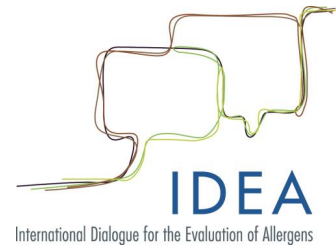
- **Allow for an open and transparent dialogue** leading to a comprehensive understanding of fragrance allergens and the assessment of the risk for the population.
- Using this as a basis to **develop effective, risk based strategies to protect the consumer, which are agreed by the partners in the dialogue.**
- **Ensuring that these strategies are understood and adopted** by the the fragrance and downstream user industries.



Multi-stakeholder
approach to allow
on open exchange
on different points
of view on the
same topic

MC Escher
1898 - 1972

IDEA – Steps in the process



- Develop a **transparent framework based on current scientific understanding** for assessing fragrance ingredients, in cooperation with all key stakeholders in a timely, prospective and sustainable way.
- Identify particular areas of concern and how they should be addressed.
- **Build a predictive model** dealing with the management of allergens.
- Ensure the relevance of the findings from the methodology to the real life situation through regular review.

The Annual Review



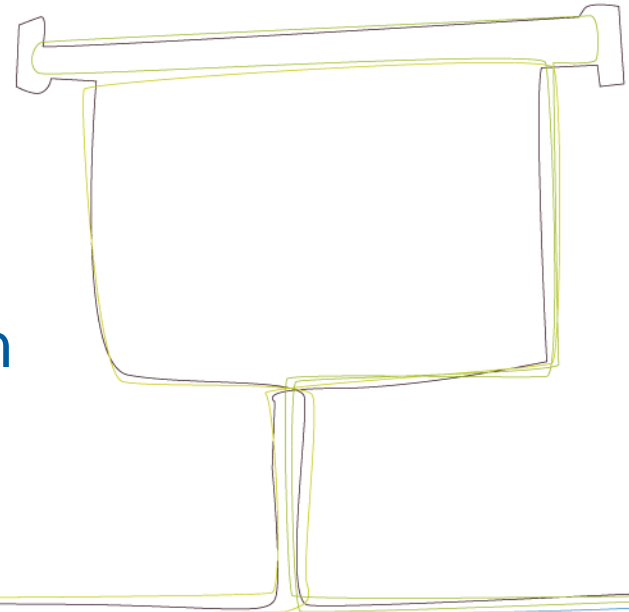
Under the auspices of the EU Commission the aim is to:

- **Critically review** the progress made.
- Provide a platform to allow an **open minded exchange** and pose questions regarding the general program and its further development.
- **Update the program and priorities** when needed based on this exchange.
- **Further broaden the stakeholder involvement** in the IDEA project to other industry sectors and globally.



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The IDEA Project Program and Timetable



WS I (QRA)



WS II (Pre- & Pro-haptens)

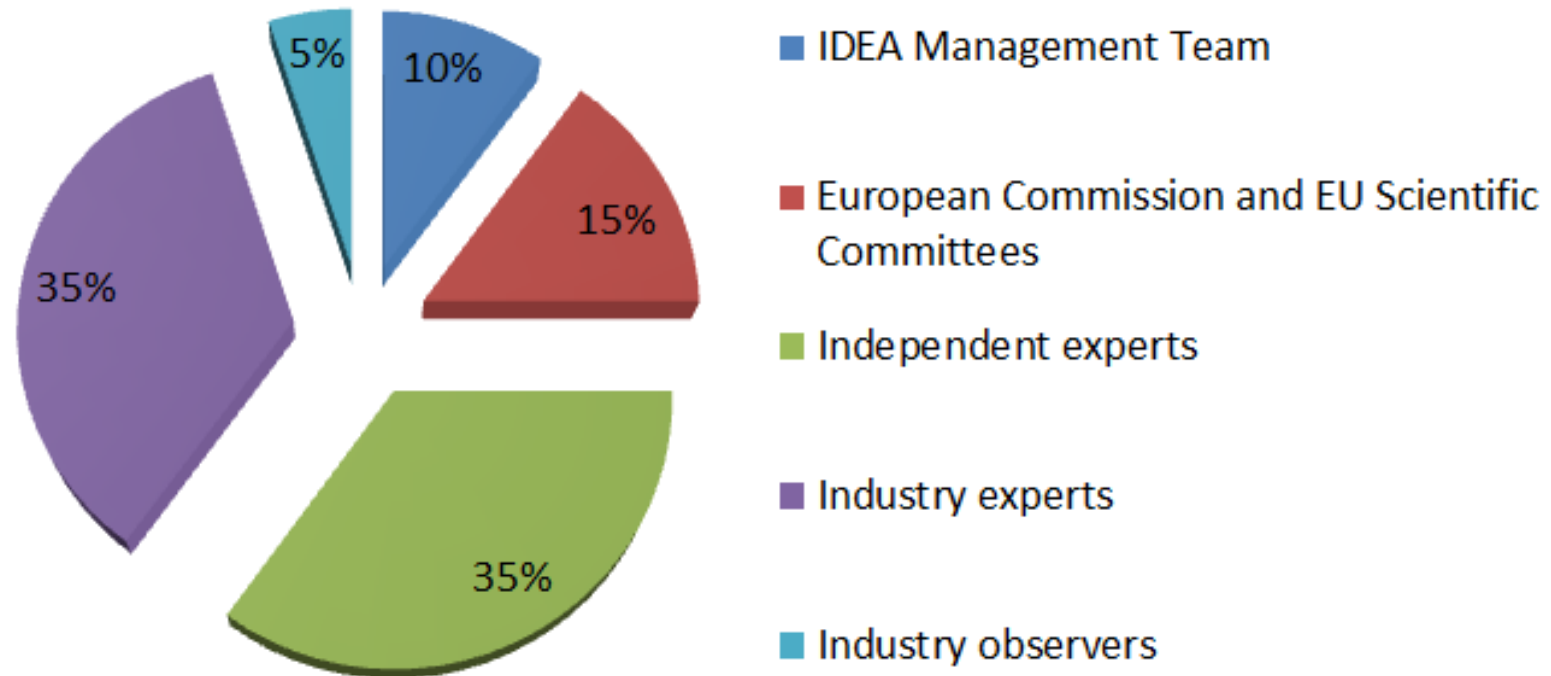


WS III (Characterization of Allergens)



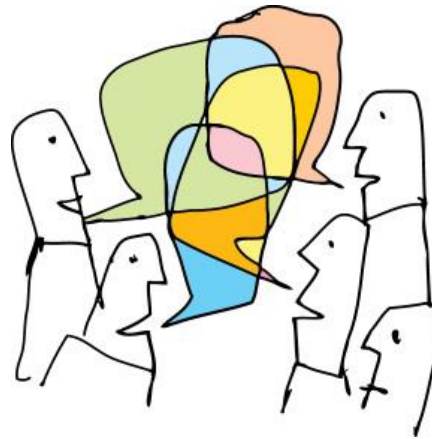
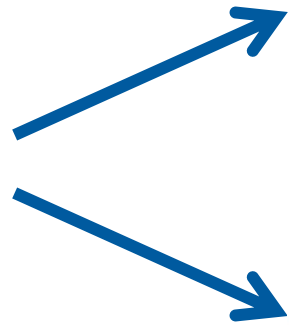
Annual Review

Participants in the workshops



- Participants are invited based on expertise and knowledge regarding the topic of the WS.
- The list of participants is overseen by the Supervisory Group and DG Sanco.

Outcome of the workshops



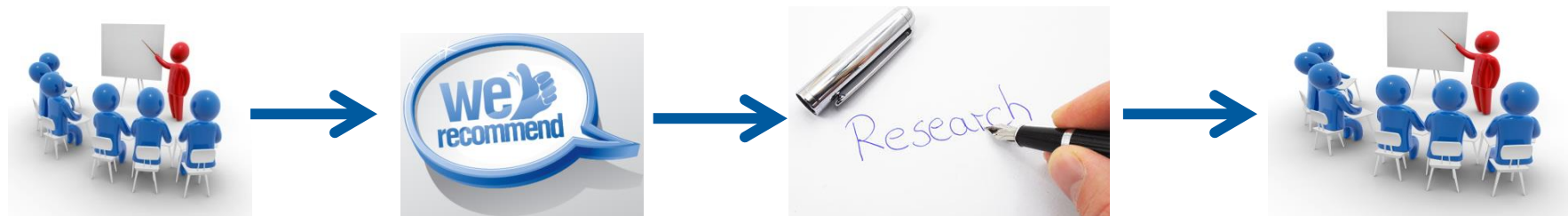
**Conclusions at
the meeting
(Moderator and
participants)**



**Progress report
(Rapporteur of
the WS)**

Stakeholder consultation leads to refinement and final version of both the conclusions and the progress report

Recommendations made at the workshops



- The WSs result in jointly agreed recommendations how to improve the RA methodologies discussed.
- Based on the recommendations IFRA (together with RIFM) develops an action plan, which is presented to the WS participants.
- Industry takes on the action items with involvement of other stakeholders as required.
- Results are presented and critically evaluated at the next WS.

Principles that underpin IDEA



Modus Operandi



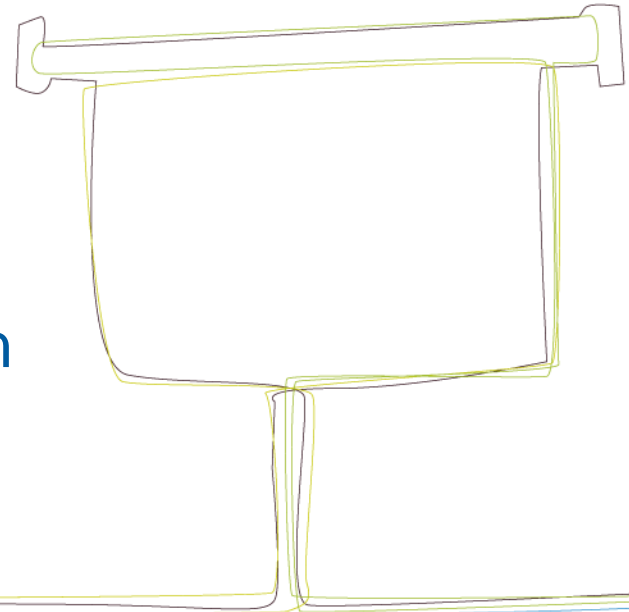
IDEA Supervisory Group

- Tripartite, continuing collaboration and transparency is vital for the success.
- A general Modus Operandi is essential and is shared with all participants.
- The Supervisory Group is accountable for the governance of IDEA and to ensure the scientific integrity of the WS debates.
- <http://www.ideaproject.info>



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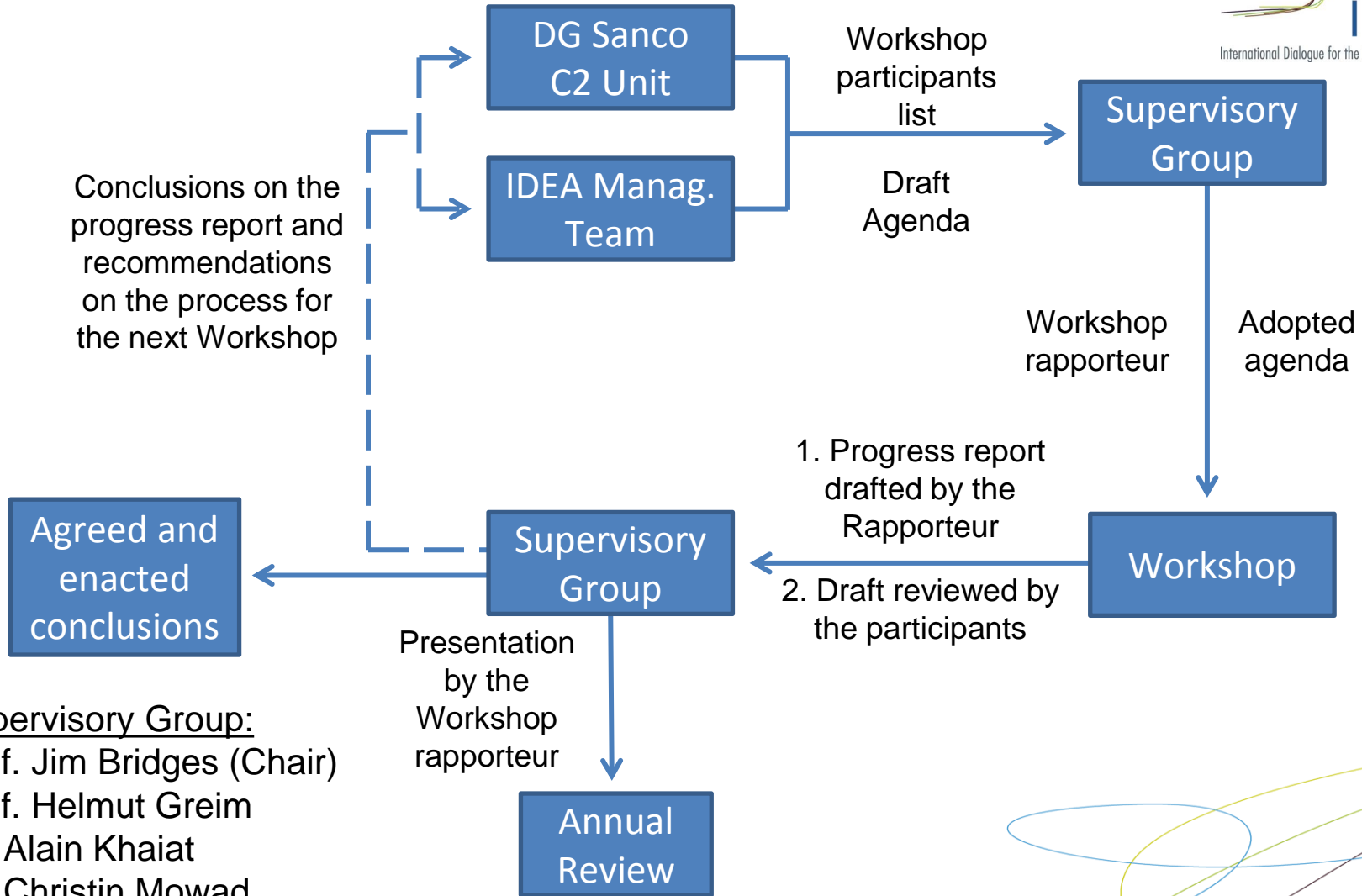


The IDEA Supervisory Group



- Currently consisting of four members with no vested interests in industry activities.
- Role: to supervise the process and to ensure the scientific integrity and full transparency of the overall project.
- Tasks include:
 - Validate the **participants list** of all IDEA WSs.
 - Agree the **program** of all IDEA WSs.
 - Nominate a Supervisory Group Member before each WS to serve as the **Rapporteur**, who has to ensure the scientific integrity of the discussions.
 - Adopt the **report** of the Rapporteur and the proposed action program.
 - Be available to discuss any concerns of the stakeholders on the scientific aspects

The Supervisory Process



Supervisory Group:
 Prof. Jim Bridges (Chair)
 Prof. Helmut Greim
 Dr. Alain Khaiat
 Dr. Christin Mowad



International Dialogue for the Evaluation of Allergens

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Thank you for your attention

