Joint Meeting of IDEA Supervisory Group (SG) and IDEA Management Team (London, Jan 9th, 2019)

Key Take-aways

Participants: **SG**: J.Bridges (Chair), H.Greim, T.Rustemeyer (by phone), I.White ; **MT**: H.Bender, M. Bianchini, C.Gonzalez, P.Griem, C.Laroche (by phone), M.Vey; **Guests**: M.Carlos, A.Irizar (by phone)

Debrief of IFRA Board Meeting (Nov 7th, 2018, Paris) with J.Bridges on the topic of IDEA

Participants reported on the Board's general appreciation of IDEA's achievements to date, but also on a controversial exchange on the future of IDEA. Board members seem split on whether IDEA should be a finite initiative with a concrete sunset date or an ongoing forum for exchange between industry, academia and regulators. The IDEA SG/MT was unanimous in the need for the latter and committed to transparency and ongoing dialogue with the IFRA Board on the topic.

QRA-2 – SCCS Opinion follow-up

Among several follow-up items that are being addressed, the "black box approach" of the Crème model remains a key stumbling block on the way to broad acceptance of QRA-2. These reservations are fully shared by SG members, who have reservations about methodology that is not published and hence not peer-reviewed. To address the apparent conflict between a protected business model and the need for open review, it was suggested to start the review of Crème with a small group of scientists, who would work under confidentiality agreements.

QRA-2 – Publication

IDEA SG/MT are all anxious to progress with publication. This should consist of an executive summary with appropriate supplements. Regarding Pre- and Prohaptens, the publication should focus on approach and strategy while details are still being worked by the respective taskforce. Regarding details of the risk assessment, the SG suggested full transparency and explanation of the SAF's and uncertainty around them.

Clinical surveillance

IDEA SG/MT reaffirmed its support for the project and expressed some concern about slow progress, possibly the result of a particularly laborious process to determine patch test concentrations. 5-6 clinics are now underway defining patch test concentrations and piloting simultaneously key logistics including data management. For future materials, a simplified procedure to determine concentrations will be explored. Beyond that, automated systems for gene profiling are under development with C.Tziotzios at Kings College and could help identify risk populations . The IDEA SG/MT will invite C.Tziotzios to their next meeting.

Pre- and Prohaptens

Analytical results of market samples with linalool and limonene are judged reassuring, yet don't fully address sensitization concerns, because clinical reactions remain, and one result with higher values is still being reported. To address the latter, Stockholm University is encouraged to participate in independent validation. Further, an analytical program, which looks at culprit samples of clinics with sensitized patients is proposed.

Characterization & Categorization in the context of Animal Alternatives

IDEA's engagement in several workshops on this topic was applauded, because the future of QRA is directly linked to the viability of animal alternatives. Likely IDEA will only add value if it can define its role narrowly with specific focus on potency of fragrances, building on existing data. To aid this, IDEA SG/MT recommends starting with a data base on relevant data from all sources ("weight of evidence"), which then can serve as reference for all future data on potency.

Key Future Meetings

IDEA Review with Regulators: Feb 25th, 2019 Brussels

IDEA SG/MT Meeting: Nov 6th, 2019 London