QRA II: where are we?

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Main changes to be introduced 1

- Estimates of aggregate exposure of consumers to individual fragrance materials rather than simply through the use of individual products

Outstanding issues

i) Provide worked examples of the impact of the change

ii) How to deal with the likelihood that all sources of exposure to a particular fragrance may not be identified

Main changes introduced 2

- Reconsideration of the data that supports the SAFs. Some values proposed to be changed.

Outstanding issues

i) To specify the recent published scientific data to support each SAF

ii) Provide worked examples of the use of the proposed SAF's

Main changes to be introduced 3

Include a protocol for the use of currently available clinical data bases on the 26 chemicals to characterise the validity of QRA I/II in achieving a high level of consumer protection.

Outstanding issue.

To ensure sufficient support to apply the protocol, apply quality control measures etc

No change proposed: exposure

- Professional users not included. Unclear whether further work is proposed for this group.

Outstanding issue

This group represents a potentially very important group in the early detection of a sensitiser. How can we ensure access to this data?

No change proposed: hazard

- Proposed that all aspects of hazard characterisation and the setting of the NESIL remain as for QRA I ie LLNA use and the extrapolation of data, HRIPT testing and use of the data

Outstanding issue

To justify why no change is needed

Not yet discussed

- The form in which QRA should be presented to the JRC
- How phys chem considerations including SAR, should inform the QRA process eg allow potential pre-haptens to be identified.

Three breakout groups

Group 1: Validation of QRA I/II

Develop a protocol and action plan to identify:

a) how and to what extent the QRA I/II it can be confirmed that its proper use enables a very high level of consumer protection. (NB The protocol to be part of QRA II submission).

b) The pros and cons of pro-active and retrospective approaches

c) An action plan

d) potential barriers to progress and how these may be addressed.

Breakout groups

Group 2. Development of the QRA II submission

based on the QRA II Draft by A-M Api. It should consider:

i) In what form should the submission be presented

ii) Is an explanation needed for the focus on SAFs and aggregate exposure

iii) Are all the key topics covered appropriately.

iv) Are the two worked examples discussed yesterday sufficient to illustrate the use of QRA II

v) Can a suitable mechanism be put in place to get feedback from participants on the revised QRA II protocol

breakout groups

Group 3: What should be the Priorities beyond QRA II.

i) The loss of animal tests is obviously driver for the development of a future QRA III. A strategy needs to be identified. Is LLNA the gold standard for comparisons?

ii) What work is needed on pre- and pro-haptens?

iii) What other areas should be given particular attention?