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Information Letter 801

IFRA: Applying the QRA to materials with an existing IFRA Standard

Introduction

In 2005 IFRA introduced a new Quantitative Risk Assessment (QRA) approach to restrict fragrance materials that have a potential to induce dermal sensitization. This new approach is a much more refined approach for evaluating sensitizing fragrance materials, and so provides more precise guidance on use levels of materials depending on the situation and the product in which they are used; ultimately it should better protect the consumer from becoming sensitized to a specific fragrance ingredient.

Maximum Use Levels

In some cases, due to the more exact science of the QRA approach, and especially because it is an exposure based risk assessment and specific to various product applications, the QRA methodology would suggest that a higher use level could be established for certain materials which have an existing IFRA Standard. This is particularly true for rinse-off product types. This would result in raising the maximum use level of materials known to have some capacity for inducing contact allergy for a number of specific product applications.

Raising the limit for fragrance ingredients on the basis of the QRA methodology is not expected to result in new inductions. However, increased exposure due to elevated use levels presents the theoretical possibility that certain pre-sensitized individuals might experience an allergic contact dermatitis where previously they had not. Should this occur, it would be impossible for the dermatologists to distinguish whether such an effect is the result of elicitation of an existing allergy or the result of a new induction. The scientific tools are not available today to allow for this distinction to be made.

Therefore, for materials that already have an IFRA Standard, IFRA and its members have decided, as a precautionary measure and at this moment in time, not to increase the existing maximum use levels for those already restricted materials other than for non-skin or incidental skin contact products (IFRA QRA Category 11). This would require a reduction of the acceptable exposure levels in the respective categories for the 14 Standards already introduced with the 42nd Amendment.

This proposed measure will have an added benefit of creating a degree of harmonization, for those materials, with former non-QRA use restrictions implemented by regulatory authorities like those currently under preparation in Europe.

To facilitate any potential necessary reformulation activities IFRA has decided to make this adaptation of Standards part of the upcoming 43rd amendment and to allow the same implementation time for existing fragrance compounds as is foreseen for any other QRA Standard that is part of the 43rd Amendment, which would be 2 years.

The QRA methodology is being used prospectively (creation of new Standards for formerly non-restricted materials) as well as retrospectively (creation of revised Standards for materials that already had a restriction based on sensitization). Its prospective use will continue to result in the establishment of IFRA Standards where none currently exist. Based on our discussions with key dermatologists, this community supports this prospective use of the QRA methodology. For all prospective uses (new IFRA Standards), restrictions will be established by the QRA methodology (for example, Citral, where the QRA Standard was introduced with the 40th Amendment in 2006). There will be no changes to the acceptable exposure levels established by the QRA methodology for all prospective uses of the QRA method.

Very best regards

Matthias Vey
IFRA Scientific Director