EFFA Position paper on EFSA Guidance on data requirements for the risk assessment of flavourings – business implications

The safety of flavourings is a key requirement for EFFA and its membership. EFFA supports a robust safety assessment of flavourings by the Risk Assessment body (EFSA) and acknowledges the need to update Guidance Documents (GD) based on continuous scientific and technological progress. However, EFFA would like to challenge the proportionality of the new and increasing data requirements in the most recently updated EFSA Scientific Guidance [1]. EFFA strongly questions whether these new requirements are adding value to the risk assessment process and significantly increase the current level of safety of European consumers.

EFFA is concerned that such highly demanding data requirements (which cause lengthy timeframe to get the approval and significantly increase the number of animal testing) may hamper innovation and competitiveness of the European Flavour industry compared to other regions worldwide.

EFFA believes that application of New Approach Methodologies (NAMs) can improve the relevance of data available for food safety assessment whilst avoiding unnecessary animal testing. EFFA would like the EFSA guidance documents on the safety risk assessment of food ingredients to reflect the new science and provide more flexibility for the use of NAMs.

EFFA remains open for a constructive dialogue that would allow innovation flexibility whilst ensuring the highest possible safety for the consumers.

Introduction – role & importance of flavourings

Flavourings are important food ingredients for food and beverage products. Though they are used in small amounts (i.e., at very low dosages), they bring a variety of tastes to consumers in a safe, affordable and innovative way. Besides the hedonic consideration, they compensate for flavour losses during the food and beverage production, like heating or spray drying. Moreover, flavourings are a key tool that supports the key objectives fixed by Authorities, such as the Commission's Farm to Fork Strategy. The Commission's ambition is to provide the consumer with sustainable food, to enable a choice for healthy foods containing less sugar, fat and salt as well as foods based on plant proteins. The use of flavourings will increase the acceptability of those foods whilst still contributing to an enjoyable eating experience.

Today about 2500 chemically defined flavouring substances are included in the EU Union List of Flavourings [2] and are approved for use in or on food products. Over the last few decades innovation has resulted in the development of about 170 new flavouring substances by the flavouring industry, which are now also part of the Union List. Innovation continues to be one of the main drivers of the EU Flavour Industry. According to a recent internal EFFA survey, R&D and Innovation represent more than 8-9 % of the annual turn-over of flavour companies.

New EFSA Guidance since 2022

In December 2022, based on a new mandate from the EU-Commission, EFSA published its updated Scientific Guidance (GD) on the data required for the risk assessment of flavourings to be used in or on foods [1]. This guidance applies to applications for a new authorisation as well as for a modification of an existing authorisation of a food flavouring, submitted under the Flavouring Regulation [3].

In the mandate from the EU-Commission, EFSA was asked to update the GD's from 2010 and 2012 [4,5], taking into account the latest cross-sectional documents relevant for flavouring evaluations that have been developed by EFSA since 2010. Compared to the 2010 GD [4], there are some fundamental changes:

- Data requirement: significant increase in study requirements, mainly on the toxicological endpoints;
- Concept of Read Across and Grouping Approach: Whereas in the former 2010 GD, the availability of experimental data and/or relevant literature data would be acceptable to demonstrate sufficient similarity of new flavouring substances to existing flavouring substances, according to the 2022 guidance ADME[1] studies are needed to support or preclude Read-Across approach.
- Exposure assessment of the consumer: Based on the EFSA GD from 2010 an exposure calculation was relatively easy to perform but would already lead to a certain overestimation of the exposure assessment. The current 2022 GD goes one bridge further: it introduces a new exposure tool, FAIM[2] (developed initially for food additives). FAIM not only adds another level of complexity but generates a hugely overestimated exposure figure for flavourings. Since the exposure estimation drives/defines, through a tiered approach, the type of the toxicity studies needed (incl. an ADME study), such overestimated exposure calculation will easily lead to additional unnecessary toxicity studies and hence to increased animal testing.
- Apart from standard toxicity studies[3], more extensive studies (including EOGRTS[4]) become part of the new GD standard requirements.

Given that the data requirements from the EFSA 2010 GD provide a high level of safety and ensure a robust safety assessment of new flavourings, EFFA wonders if the additional (toxicity) data requirements introduced in the 2022 GD bring any additional layer of safety to the consumer. The "proportionality" of the additional data requirements is questionable. To note, on its own the newly introduced toxicity study, the EOGRTS will result in the need for more than 1000 test animals (per individual tested substance).

EFFA, like other food and sectorial associations, believe that the use of NAMs (New Approach Methodologies) in the context of a scientific risk based safety assessment provides more relevant and informative way of the safety of food ingredients. Therefore, animal testing should become unnecessary, taking into account a growing political and societal demand to not sacrifice animals anymore. See also the joint Industry Position Paper on NAMs [6].

Business Implications

The new EFSA GD will inevitably hamper innovation and development of new flavourings in the European market because of the lengthy timeframe, additional resources requirements and increased mandatory animal testing. The impact on flavourings of the new GD, versus former requirements will be:

- An increase to 5 to 7 years for testing and dossier preparation *versus* 2 to 3 years in the past[5].
- An increase in animal requirement to >1500 animals per substance (due to the systematic requirement of the EOGRTS) vs ~100 animals under the 2010 GD requirements for a typical sub-chronic study.

Such challenging prospect will certainly and significantly discourage the flavour industry to submit new applications to EFSA for introduction of new flavouring substances in the EU-market in the coming years. The European flavour industry is put in an economic disadvantage compared to other regions worldwide. This will hamper innovation which is essential in the framework of the ambitious Green Deal and Farm to Fork policies; flavourings can be part of the solution for a sustainable food system.

[1] Absorption, Distribution, Metabolism, Excretion [OECD TG 417]
[2] Food Additives Intake Methodology
[3] e.g. the subchronic 90-day oral toxicity study which was also part of the data requirements for individual evaluations under the 2010 GD
[4] Extended One Generation Repeated Toxicity Study, which is an extended reproductive and developmental study
[5] The figure is based on experience from EFFA member companies who have notified new substances in the last years

Conclusion

- EFFA supports the need for a robust safety assessment of flavourings and other food ingredients and acknowledges the need to update guidance documents on a regular basis, taking into account continuous scientific and technological progress and developments.
- However, EFFA questions the proportionality of the ever increasing and more demanding nature of the data requirements. EFFA is concerned that such data requirements will hamper innovation and competitiveness of the European Flavour industry compared to other regions worldwide.
- EFFA strongly questions whether these new requirements are adding value to the risk assessment process and significantly increase the current level of safety of European consumers.
- In addition, EFFA strongly recommends that future mandates should include alternative methods (e.g. New Approach Methodologies) into the scientific and regulatory assessments as a key requirement.

EFFA remains open for a **constructive dialogue with the Commission's Services or any other stakeholder** to find workable ways to ensure health protection of the consumer and equally providing the flavour industry with the necessary flexibility to innovate in the future.

About EFFA

EFFA, the European Flavour Association, is a non-profit trade association representing European national associations and companies in the flavour industry based in Brussels. Our membership consists of 12 national associations and 11 company members. In total, EFFA is representing over 300 companies in Europe, ranging from smaller SMEs to stock market listed companies.

EFFA's main objectives are to promote and support a consistent European-wide strategy for flavour issues and to elaborate scientific dossiers, for evaluation by the EU Institutions – Scientific Committees, to stimulate, coordinate and monitor best practice in regulatory, safety, technical and scientific issues, between members of the flavour sector and related industries through standards, guidelines, and codes of practice. EFFA is registered in the Transparency Register under the following number: 7102243339711.

References

[1] EFSA Journal 2022;20(12):7673

[2] Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC.

[3] Regulation (EC) No 1334/2008 of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods

[4] EFSA Journal 2010; 8(6):1623

[5] EFSA Journal 2012;10(11):218

[6] Joint Industry Position Paper on NAMs: Integration of New Approach Methodologies (NAMs) in food safety risk assessment