Integration of New Approach Methodologies (NAMs) in food safety risk assessment

4 July 2023

IN BRIEF

FoodDrinkEurope, EU Specialty Food Ingredients, AMFEP, EFFA, and IOFI believe that the use of NAMs in the context of a scientific risk-based safety assessment provides a more relevant and informative way of assessing the safety of food ingredients, instead of unnecessary animal testing.

Therefore, we call for integrating NAMs routinely into scientific and regulatory risk assessments, specifically in the European context.

KEY MESSAGES

- **Application of NAMs can improve the relevance of data available for food safety assessment whilst avoiding unnecessary animal testing**
- **The adoption of NAMs aligns with growing political and societal demands to phase out animal testing**
- **The use of NAMs has a legal basis under current EU regulations**
- **There needs to be more consistency in the use of NAMs in food safety risk assessment**

FoodDrinkEurope, EU Specialty Food Ingredients, the Association of Manufacturers and Formulators of Enzyme Products (AMFEP), the European Flavours Association (EFFA), and the International Organization of the Flavor Industry (IOFI) call for the routine application of New Approach Methodologies (NAMs) in scientific and regulatory food safety assessment in Europe

WHY

i. Application of NAMs can improve the relevance of data available for food safety assessment and avoid unnecessary animal use

Next-generation, non-animal or reduced-animal safety assessments provide significant scientific advantages over traditional animal-based approaches, some of which are over 60 years old and can no longer be considered as the gold standard for all endpoints relevant for safety assessment. Specifically, animal studies are not readily suited to mechanistic underpinning of toxicological events at a molecular level. NAMs, using the combination of human exposure scenarios, relevant *in vitro* hazard assessment, computational approaches and physiologically based toxicokinetic/toxicodynamic data, are better suited to address the risk assessment questions, which can then be tailored to the human situation.

ii. Political and societal calls to phase out animal testing

In addition to the scientific benefits of NAMs compared with traditional animal use, there are political and societal calls to phase out animal testing, which are increasingly directed to the development of food ingredients. In particular, there is a strong interest from European consumers to stop unnecessary animal testing, as illustrated in the case of the recent European Citizens Initiative (ECI) on animal testing.

There is also the challenge of how new vegan ingredients are to be safety assessed, as the vegan certification bodies (e.g. European Vegetarian Union, Vegan Action, Vegan Society) all have a requirement for no animal testing.

HOW

i. Current EU regulatory framework allows for the use of NAMs

There is a legal obligation in the EU to replace, refine, and reduce the use of animals for scientific purposes (Directive 2010/63/EU). In September 2021, the European Parliament adopted a plan (2021/2784(RSP)) 'to accelerate the transition to innovation without the use of animals' and called on the Commission to draw up an EU-wide action plan. The latest CLP revision acknowledges the use of NAMs.

EFSA's 2027 strategy supports the importance of developing and integrating new scientific advancements that focus on NAM-based methods while minimising animal testing. In addition, EFSA defined a roadmap for action on NAMs in risk assessment, in which activities have been proposed to facilitate the implementation of new approaches and concepts in risk assessment. EFSA has several pilots currently in place for the use of NAMs to fill gaps in risk assessment

(neurotoxicity of pesticides, hazard assessment of nanofibers, immunotoxicity of per- and polyfluoroalkyl substances (PFAS), proteins toxicity and allergens) (EFSA, 2023[1]). Regulatory authorities across other industries (e.g. cosmetics, chemicals) are recognising the need to improve the relevance of evidence available for safety assessment and are also actively exploring the use of NAMs. In addition, during a meeting in October 2022, the EU Intergroup on animal welfare emphasised to MEPs that it is now time we move away from using animals in laboratory testing.

ii. Need for more consistency in use of NAMs for food safety risk assessment

We are pleased to see that the use of NAMs has been considered in the risk assessment of certain contaminants. However, despite this progress, NAMs are not consistently mentioned in the risk assessment frameworks for ingredients, with little flexibility for alternative approaches to be applied. This is illustrated by the recent EFSA Scientific Guidance on the data required for the risk assessment of flavourings to be used in or on foods (e.g. flavourings, smoke flavourings), where there continues to be a demand for more animal test data. In our view, appropriate weight should have been given to NAMs as part of an Integrated Approach to Testing and Assessment, instead of requiring more animal studies. This requirement for additional animal tests, without acknowledging the potential for the use of NAMs, is creating a high barrier to innovation, without adding value to the risk assessment process.

The preference of innovative companies is to use the most scientifically up to date NAMs. The length of time associated with traditional animal studies impacts the competitiveness of European businesses and speed to market. Important innovations that provide benefit to consumers and the food sector while improving sustainability are commonly brought to market outside of the EU, and in some cases, these may never reach the EU market.

Our industries 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, and call for the European Commission and EFSA to actively facilitate the increased application of NAMs.

Our position

1. Need to close the gap between modern safety science and regulatory requirements.

There needs to be greater flexibility for the application of latest science based and validated NAMs within the regulatory framework, for food safety risk assessments, to address the specific human-centric safety questions and avoid a prescribed check list approach of animal tests. To facilitate this and bridge the gaps in the EU context, our industries call for strengthening the use of NAMs within the scientific risk-based safety assessment approaches to provide more relevant informative data and avoid unnecessary use of animals, rather than mandatory reliance on sector specific animal testing.

[1] Cattaneo, I. et al (2023). Implementing New Approach Methodologies (NAMs) in food safety assessment: strategic objectives and actions taken by the European Food Safety Authority. Trends in Food Science & Technology 133 277-290.

2. Innovation requires the right regulatory setting and a NAMs approach is important for innovation in the food industry.

To facilitate innovation, the food sector needs contemporary and effective scientific approaches to assess the safety of new ingredients and materials. A NAMs-based approach provides more informative data (e.g. mechanistic understanding, tailored to the human situation/ response) and can be quicker to perform, without the unnecessary use of animals. Therefore, if the regulatory acceptance of NAMs in food safety risk assessments hinders use of modern scientific methods to evaluate the safety of new food ingredients, there is a serious risk that innovation in the food sector will slow dramatically or stop in the EU market.

3. The food industry welcomes partnership with the broad base of stakeholders.

The food industry welcomes partnerships with the broad base of stakeholders including other industries, academics, and regulatory authorities, to progress the adoption of NAMs in food safety risk assessment. We also welcome the opportunity to provide feedback on the new guidance documents under development by EFSA on the inclusion of NAM-based results in its safety assessments. Furthermore, when possible, we would like to have the opportunity to provide food safety expert feedback and case study support on the several pilots under development and new initiatives proposed for integrating NAMs in risk assessment.