Adoption of NAMs in EU Food Safety Risk Assessment – implications on emerging risk identification

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Presentation to EFSA Stakeholder discussion group on Emerging Risks (StaDG-ER)

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The Emerging Risk

- The legal obligation in EU to replace, refine, reduce use of animals for scientific purposes (Directive 2010/63/EU) is not being met in practice (e.g. recent draft Guidance on Flavourings makes no mention of NAMs)

- Although NAMs have been developed there is a risk that innovation in the food industry might slow if we do not use these tools to identify potential new hazards or reassess existing hazards, impacting the development of new foods/ ingredients (such as novel protein sources) and production technologies.

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European Citizens Initiative

European Union

EN

EUROPEAN CITIZENS' INITIATIVE - Central online collection system

SAVE CRUELTY FREE COSMETICS - COMMIT TO A EUROPE WITHOUT ANIMAL TESTING

Signatures collected online

1,413,383 / 1,000,000

End of the collection period: 31/08/2022

Objectives

- **Protect and strengthen the cosmetics animal testing ban.**

Initiate legislative change to achieve consumer, worker, and environmental protection for all cosmetics ingredients without testing on animals for any purpose at any time

- **Transform EU Chemicals regulation**

Ensure human health and the environment are protected by managing chemicals without the addition of new animal testing requirements.

- **Modernise science in the EU.**

Commit to a legislative proposal plotting a roadmap to phase-out all animal testing in the EU before the end of the current legislative term.

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The Science – ‘animal tests are now outdated’

- Rapid developments in non-animal science and New Approach Methodologies (NAMs)
- NGRA (Next Generation Risk Assessment) to assess safety risks using NAMs. Protection of health, not prediction of animal data.
- The best and most relevant science must be used for safety decision making
- Poor reproducibility of repeat dose animal studies (‘burning platform’)
- Animal-free science can be applied now to chemical safety decision making

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The Regulatory Environment

- Legal obligation in EU to replace, refine, reduce use of animals for scientific purposes (Directive 2010/63/EU)
- Regulatory authorities recognising the need to shift to non-animal approaches e.g. EPA, FDA, EFSA
- More integrated and holistic assessment of chemicals with EU agencies and scientific bodies moving towards 'one substance – one assessment' and a framework to define SSbD[1] (CSS[2] within EGD[3])
- EFSA 2027 strategy
  - Develop and integrate new scientific developments focussing on NAM based methods and the minimalization of animal testing
- EFSA roadmap for action on new approach methodologies in risk assessment

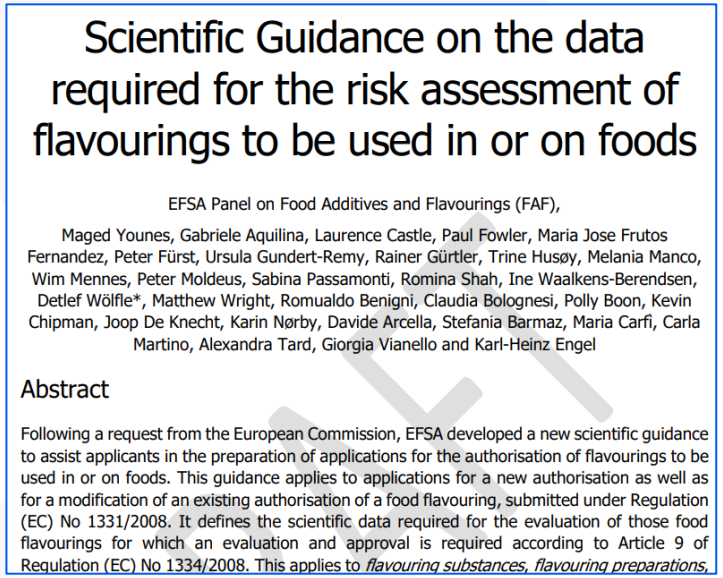
[1] SSbD – Safe & Sustainable by Design; [2] CSS – Chemicals Strategy for Sustainability; [3] EGD = European Green Deal

Need to “close the gap” between modern safety science and regulatory requirements

- Legal obligation in EU to replace, refine, reduce use of animals for scientific purposes

- Draft flavourings guidance (April, 2022)
  - Increase in animal testing requirements
  - No mention of NAMs/ NGRA
  - Constrained by requirement to be conducted to OECD TG and GLP
  - Missed opportunity?

- EU Intergroup on Animal Welfare
  - Revision of EU Chemicals Legislation as a step towards non-animal testing (20 Oct 2022)



Scientific Guidance on the data required for the risk assessment of flavourings to be used in or on foods

EFSA Panel on Food Additives and Flavourings (FAF),

Maged Younes, Gabriele Aquilina, Laurence Castle, Paul Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Ursula Gundert-Remy, Rainer Gürtler, Trine Husøy, Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle*, Matthew Wright, Romualdo Benigni, Claudia Bolognesi, Polly Boon, Kevin Chipman, Joop De Knecht, Karin Nørby, Davide Arcella, Stefania Barmaz, Maria Carfì, Carla Martino, Alexandra Tard, Giorgia Vianello and Karl-Heinz Engel

Abstract

Following a request from the European Commission, EFSA developed a new scientific guidance to assist applicants in the preparation of applications for the authorisation of flavourings to be used in or on foods. 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 Regulation (EC) No 1331/2008. It defines the scientific data required for the evaluation of those food flavourings for which an evaluation and approval is required according to Article 9 of Regulation (EC) No 1334/2008. This applies to *flavouring substances, flavouring preparations,*

The Emerging Risk

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END

EFSA Strategy 2027

Science
Safe food
Sustainability

Adopted at the Management Board meeting
held in virtual modality on 24 June 2021
For EFSA's Management Board
[SIGNED]
Raymond O'Rourke
Chair of the Management Board

efsa
European Food Safety Authority

STRATEGIC OBJECTIVE 2

Ensure preparedness for future risk analysis needs

Strategic Objective 2 is about sustaining and developing EFSA's core capabilities to ensure its long-term relevance and reputation. Strengthened partnerships within the food safety knowledge ecosystem are crucial, and will result in the identification of priority areas for knowledge sharing, knowledge development and capacity building. This, in turn, will allow EFSA to be prepared with the methodologies, data and expertise needed for its future risk assessment and communication activities.

The expected outcome under **Strategic Objective 2** is:

- Increased risk analysis capabilities (knowledge, expertise, methodologies and data) to maintain relevance for the future

EXPECTED OUTCOME 2.1

Increased risk analysis capabilities (knowledge, expertise, methodologies and data) to maintain relevance for the future

EFSA will ensure preparedness for future risk analysis needs by co-producing and making available knowledge, expertise, methodologies and data, and by contributing to the Horizon Europe programme cycle.

This will be done in *partnership* with Member States and other EU agencies, in *cooperation* with international fora and channels, shared platforms and infrastructures, capacity building initiatives, long-term partnerships, flexible and innovative workforce planning and sourcing; as well as strengthened approaches, leveraged by social science, for engaging with all actors who can provide input into EFSA's activities.

2.1.2 **The quality and scale of crisis preparedness and the identification of emerging risks is improved.** Strengthened foresight and horizon scanning will lead to this result, and so will the linking of early warning systems and data systems across the EU bodies, EU Agencies with different remits, Member States and international organisations such as WHO, FAO and OIE. This can be achieved by further evolving the existing networks on emerging risks. Better coordination in media and social media monitoring and early warning communications will support these efforts.

2.1.3 **The quality of scientific guidance and methodologies,** with the necessary risk assessment capabilities **is improved to address future challenges.** Within its risk assessment approaches, EFSA will develop and integrate new scientific developments focusing on NAM-based methods and the minimisation of animal testing, innovations in food systems, data, and technology, and strive to meet One health policy needs.

2.1.4 **Preparedness for future regulatory and policy needs addressing the EU Farm to Fork, Biodiversity and Chemical strategies is ensured,** with a view of contributing to the achievement

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