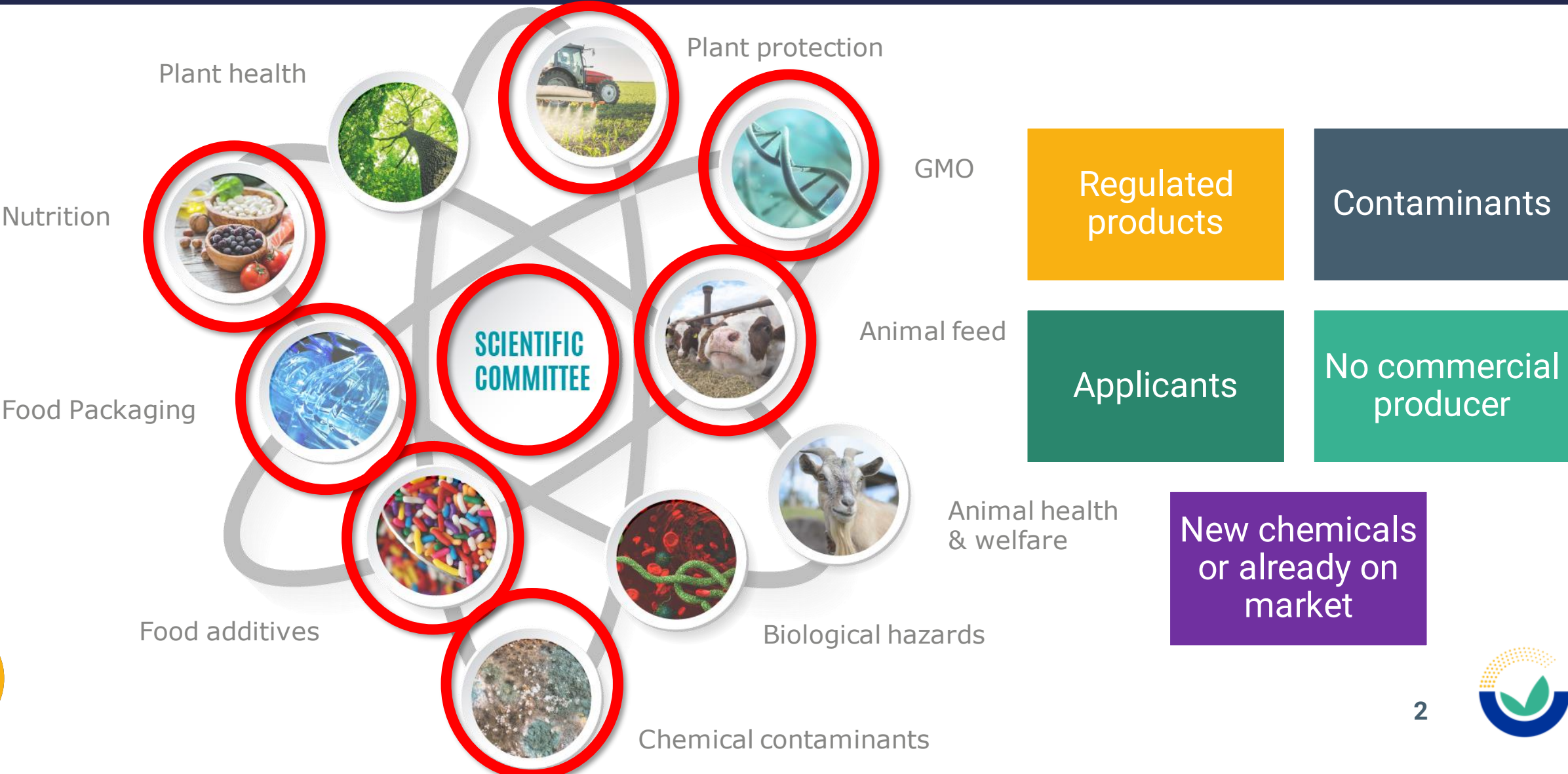


CHALLENGES AND OPPORTUNITIES FOR IMPLEMENTING NAMs:

Food & Feed Regulatory Context

George Kass
Lead Expert

SETTING THE EFSA SCENE (I)



SETTING THE EFSA SCENE (II)

L 354/16

EN

of the European Union

31.12.2008

REGULATION (F

REGULATION (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (Text with EEA relevance)

REGULATIONS

COMMISSION REGULATION (EU) No 283/2013

AND OF THE COUNCIL

3

, in accordance with Regulation (EC) No Council concerning the placing of plant he market

ance)

foods

AND OF THE COUNCIL

REGULATION (EC) No 1927

on the addition of vitamins and

REGULATION (EC)

on additive (Text with EEA

REGULATIONS

COMMISSION REGULATION (EU) No 10/2011

of 14 January 2011

on plastic materials and articles intended to come into contact with food

(Text with EEA relevance)



SETTING THE EFSA SCENE (III)



EFSA Journal 2012;10(7):2760

GUIDANCE

doi:10.2903/j.efsa.2021.6555

Guidance on the preparation and application for authorisation of a novel food of Regulation (EU) 2015/2283

EFSA Panel on Dietetic Products, Nutrition and Physical Activity
Dominique Turck, Jean-Louis Bresson, B. Susan Fairweather-Tait, Marina Heinonen, Kare Harry J McArdle, Androniki Naska, Monika Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Morten Poulsen, Seppo Salminen, Josef Schlatter, Agnès de Sesmaisons-Lecarré, Hans Verhagen, Maged Younes, Gabriele A. EFSA Peter Fürst, Ursula Gunder Peter Moldeus, Sabina Pas Matthew Wright, Romu Joop De Knecht, Ullrika Saf Alexandra

GUIDANCE

ADOPTED: 26 January 2021
doi: 10.2903/j.efsa.2021.6433

Scientific Guidance for the submission of dossiers on Food Enzymes

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel), Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Boet Glandorf, Lieve Herman, Jaime Aguilera, Magdalena Andryszkiewicz, Ana Gomes, Natalia Kovalkovicova, Yi Liu, Sandra Rainieri and Andrew Chesson
Morten Poulsen, Detlef Wölfle, * Matthew Wright, Romu and Karl-Heinz Engel, Maria Carfi, Kevin Chipman, Maria Carfi, Carla Martino, Giorgia Vianello and Karl-Heinz Engel



GUIDANCE

ADOPTED: 15 September 2021
doi: 10.2903/j.efsa.2021.6851

Scientific Guidance for the submission of dossiers on Food Enzymes

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel), Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Boet Glandorf, Lieve Herman, Jaime Aguilera, Magdalena Andryszkiewicz, Ana Gomes, Natalia Kovalkovicova, Yi Liu, Sandra Rainieri and Andrew Chesson



NAMs AND EFSA

SCIENCE-POLICY INTERFACE

The Commission will:

- foster multidisciplinary research and digital innovations for **advanced tools, methods and models, and data analysis capacities**¹⁰² to also move away from animal testing;

EFSA strategy 2027

STRATEGIC OBJECTIVE 2

Ensure preparedness for future risk analysis needs

KEY ACTIONS

- ▶ Develop and integrate new approach methodologies (NAMs) and omics for regulatory risk assessment



EC policy

Safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.



NAMs landscape



WHERE ARE WE WITH NAMs?

Investment in NAMs

- ✓ 32 EFSA-launched projects
- ✓ Areas addressed: Toxicokinetics, toxicodynamics, systems toxicology, modelling, read-across, data management: Emphasis on case studies
- ✓ Many collaborations: ECHA, JRC, MS
- ✓ Many project collaborations: PARC, ASPIS, APCRA, etc

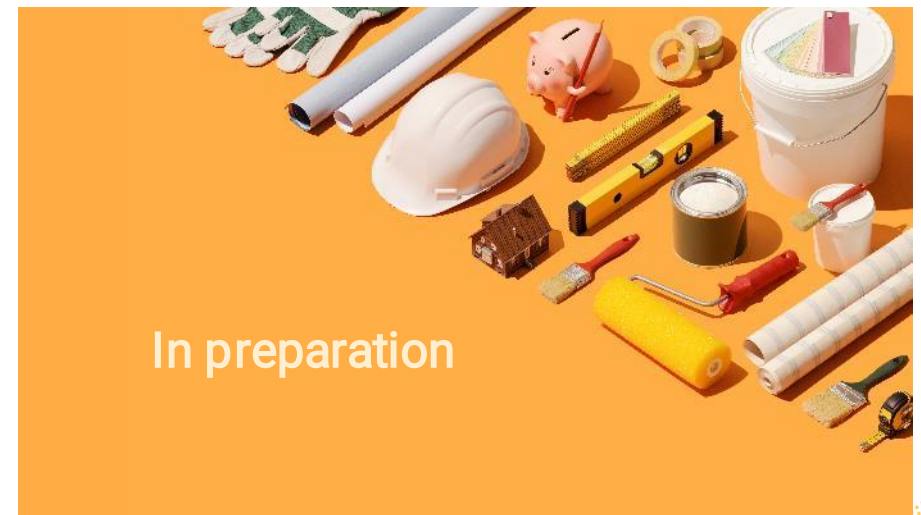
EFSA Guidance documents

- ✓ Grouping of chemicals
- ✓ Mixture assessment
- ✓ Pesticide residues
- ✓ Read-across (under development)



3 Guidance on the Use of the Read-
4 across Approach in Food Safety
5 Assessment

6 EFSA Scientific Committee



OUTSOURCED PROJECTS - EXAMPLES

SCIENTIFIC OPINION

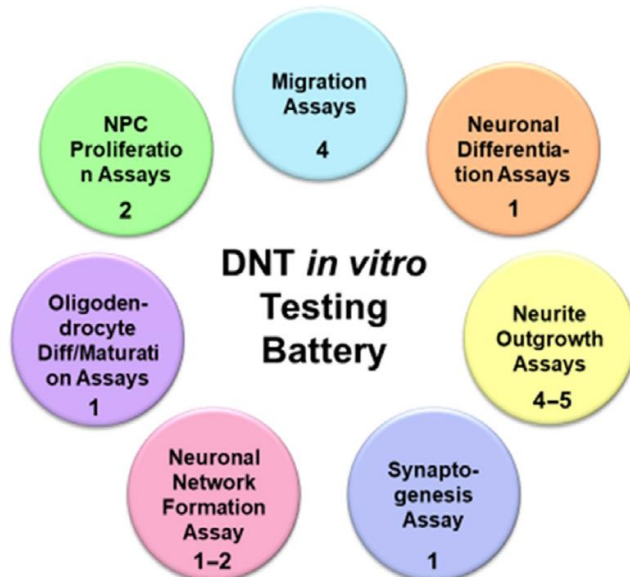


ADOPTED: 21 April 2021

doi: 10.2903/j.efsa.2021.6599

Development of Integrated Approaches to Testing and Assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment

EFSA Panel on Plant Protection Products and their Residues (EFSA PPR Panel),



n = number of assays



Guidance on Evaluation of Data from the Developmental Neurotoxicity (DNT) In-Vitro Testing Battery

Project 4.124: New Guidance Document on Developmental neurotoxicity (DNT) in vitro assays	
Lead:	EC (EFSA, JRC)/US/DK
Inclusion in work plan:	2017
Project status and	

WORK PLAN FOR THE TEST GUIDELINES PROGRAMME (TGP)



THE CHALLENGES

Lack of NAM data submitted to EFSA

- ✓ Guidance documents are 'young'
- ✓ NAM-based data remain optional

Need for confidence building

- ✓ Validated NAMs: performance standards, right chemicals, reproducibility, etc...
- ✓ Change in concept: NAMs are not a 1-to-1 replacement of a 90-d study
- ✓ Benchmarking and coverage of potential adversity
- ✓ Fit-for-purpose and ready-to-use
- ✓ Identification of low toxicity compounds



HOW CAN WE PROGRESS ANIMAL-FREE RISK ASSESSMENT?

Global
blueprint

Working
together

Efficient
validation
process

Adhere to
MAD
principle

1S1A

Capacity
building



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