CHALLENGES AND OPPORTUNITIES FOR IMPLEMENTING NAMs:

Food & Feed Regulatory Context

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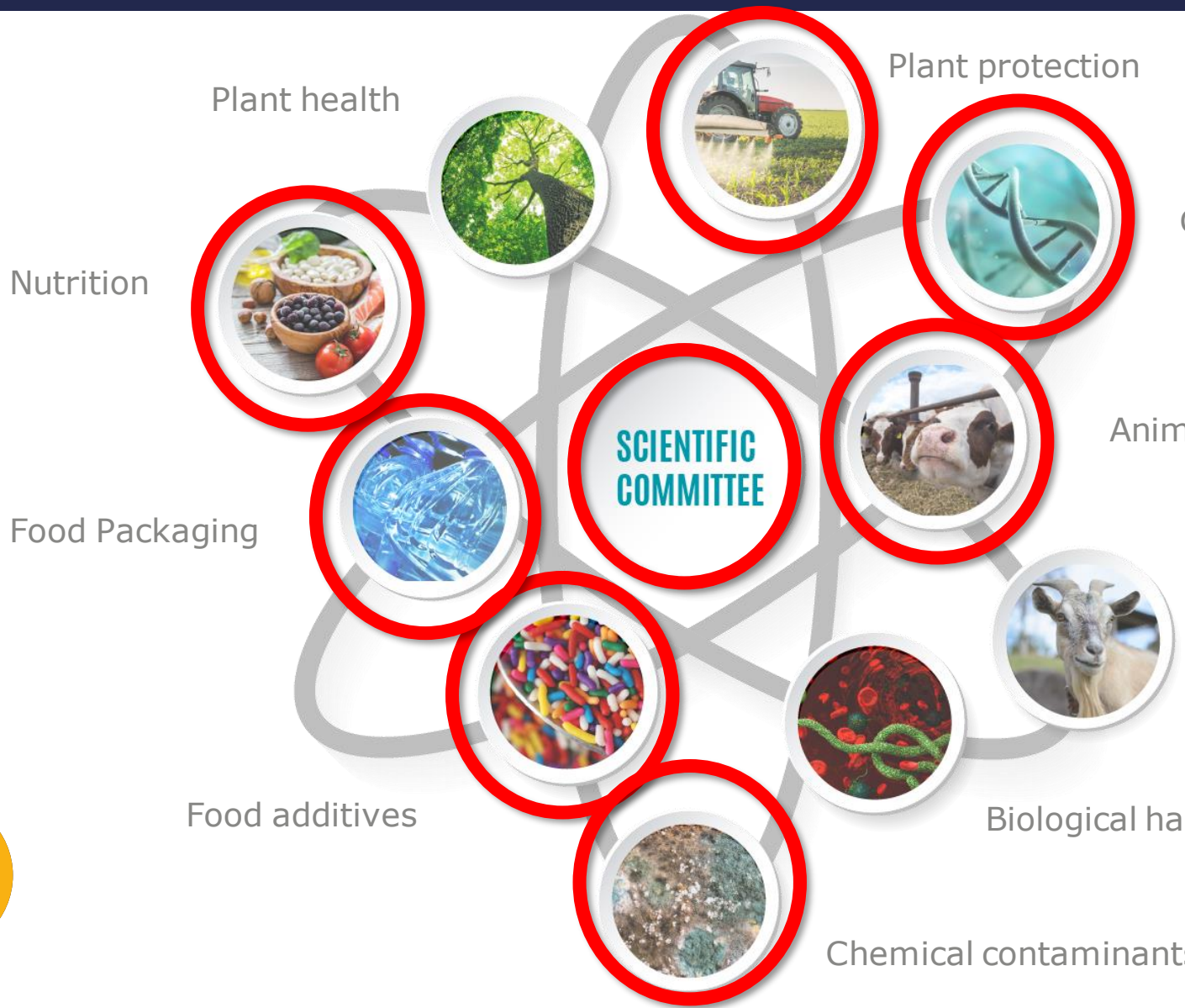
SETTING THE EFSA SCENE (I)



Regulated products

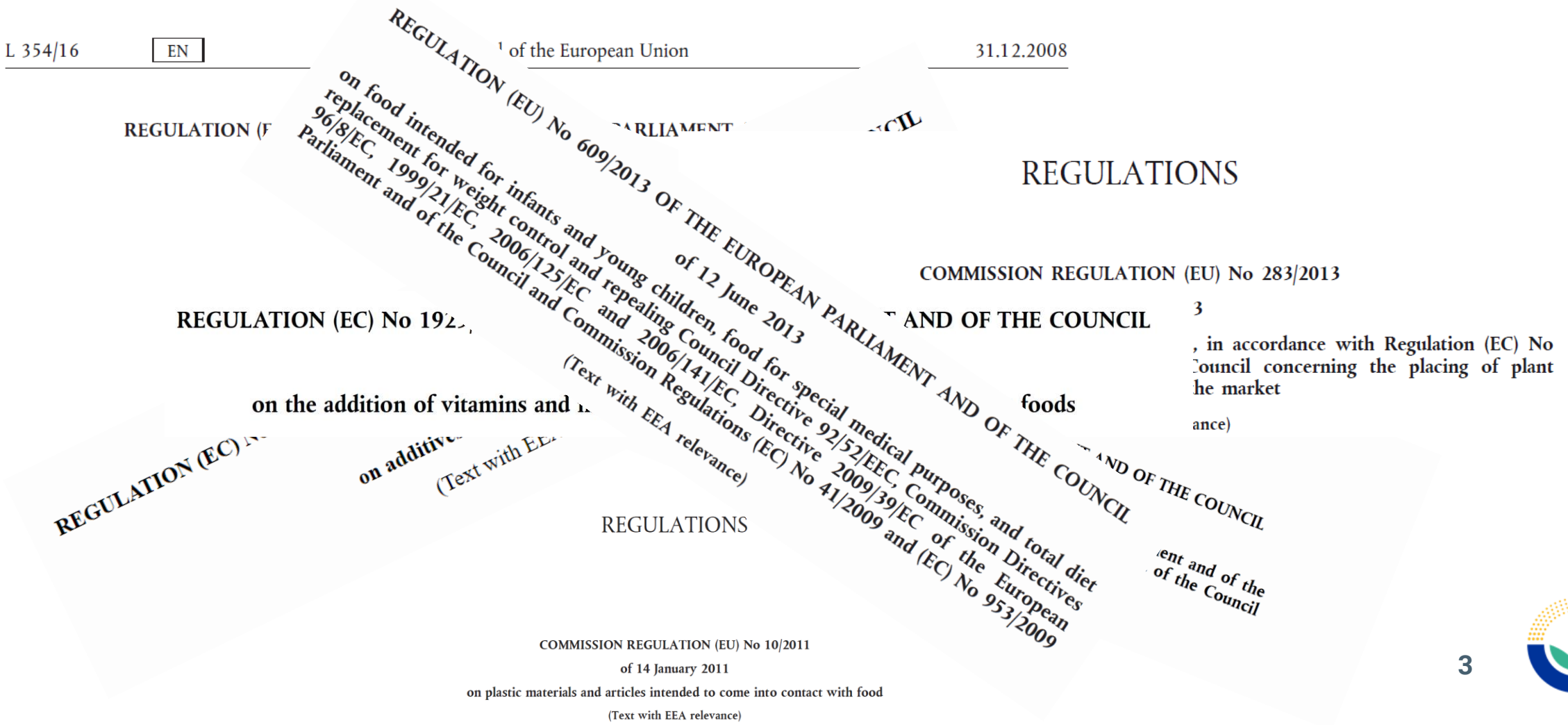
Contaminants

Applicants

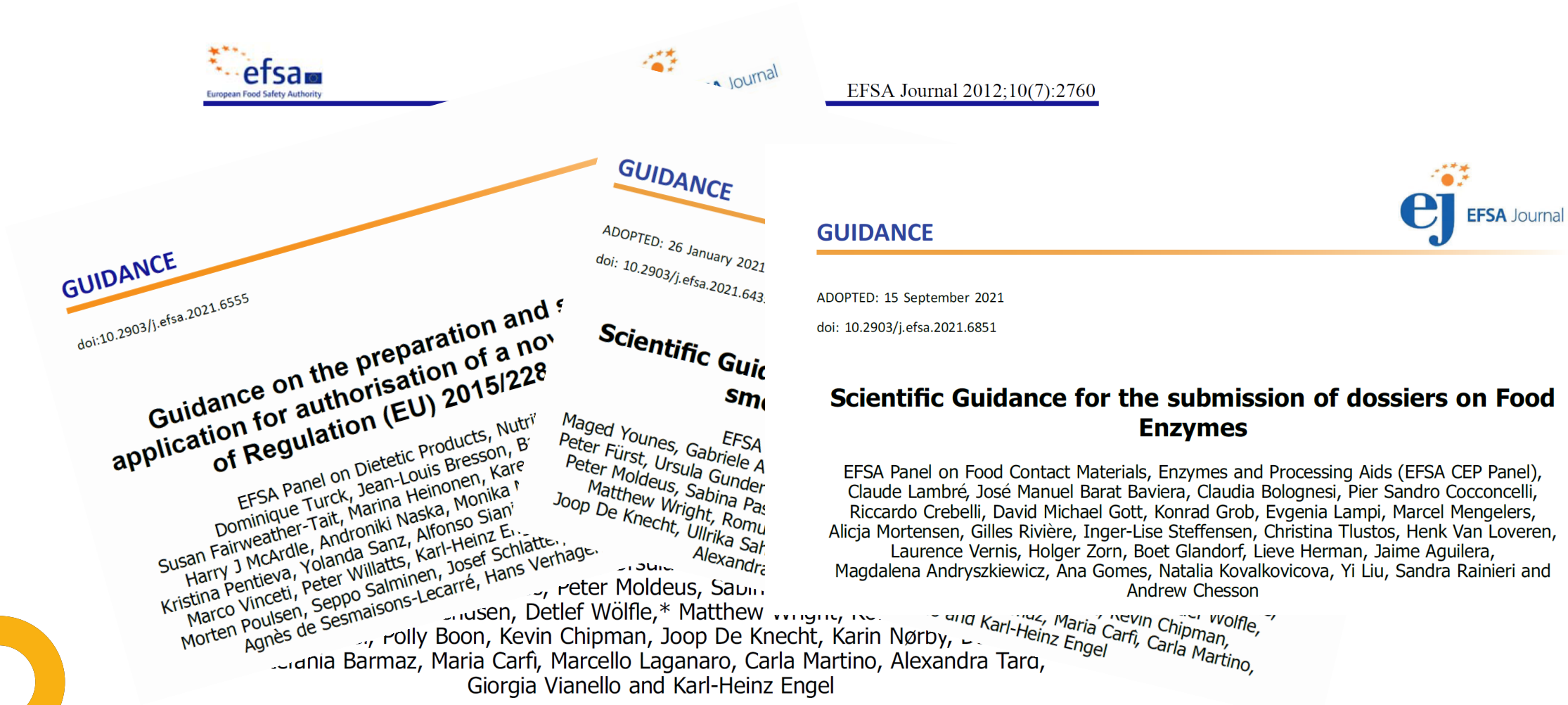
No commercial producer

New chemicals or already on market

SETTING THE EFSA SCENE (II)



SETTING THE EFSA SCENE (III)



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;

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.

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

NAMs landscape

European Partnership for the Assessment of Risks from Chemicals
Horizon Europe

EURL ECVAM
European Union Reference Laboratory for Alternatives to Animal Testing

APCRA

OECD

ASPIS Consortium (RISK-HUNT3R, ONTOX and PrecisionTOX)

efsa
European Food Safety Authority

ECHA

Global Coalition for Regulatory Science Research

ILMERAC

EUTOXRISK

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

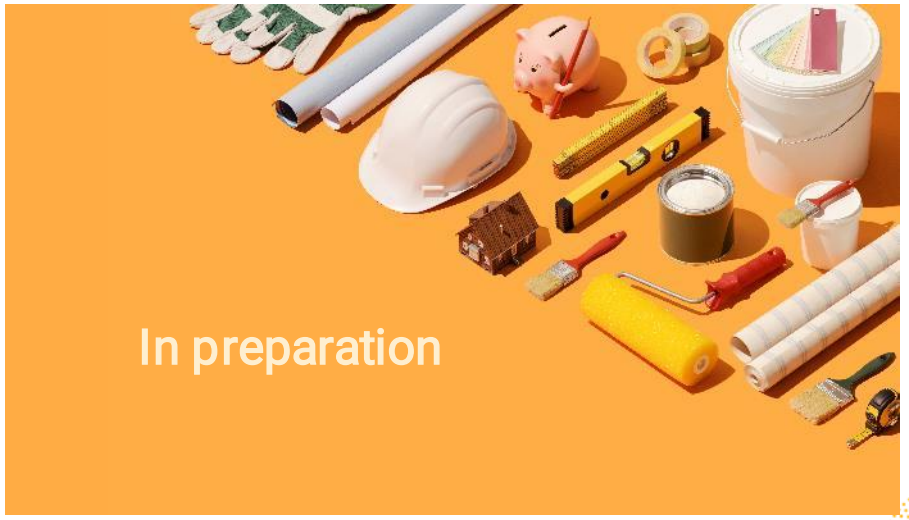
EFSA Guidance documents

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

EFSA GUIDANCE DOCUMENTS

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

EFSA Journal

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),

OECD

Organisation for Economic Co-operation and Development

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: Inclusion in work plan: Project status and	EC (EFSA, JRC)/US/DK 2017

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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