

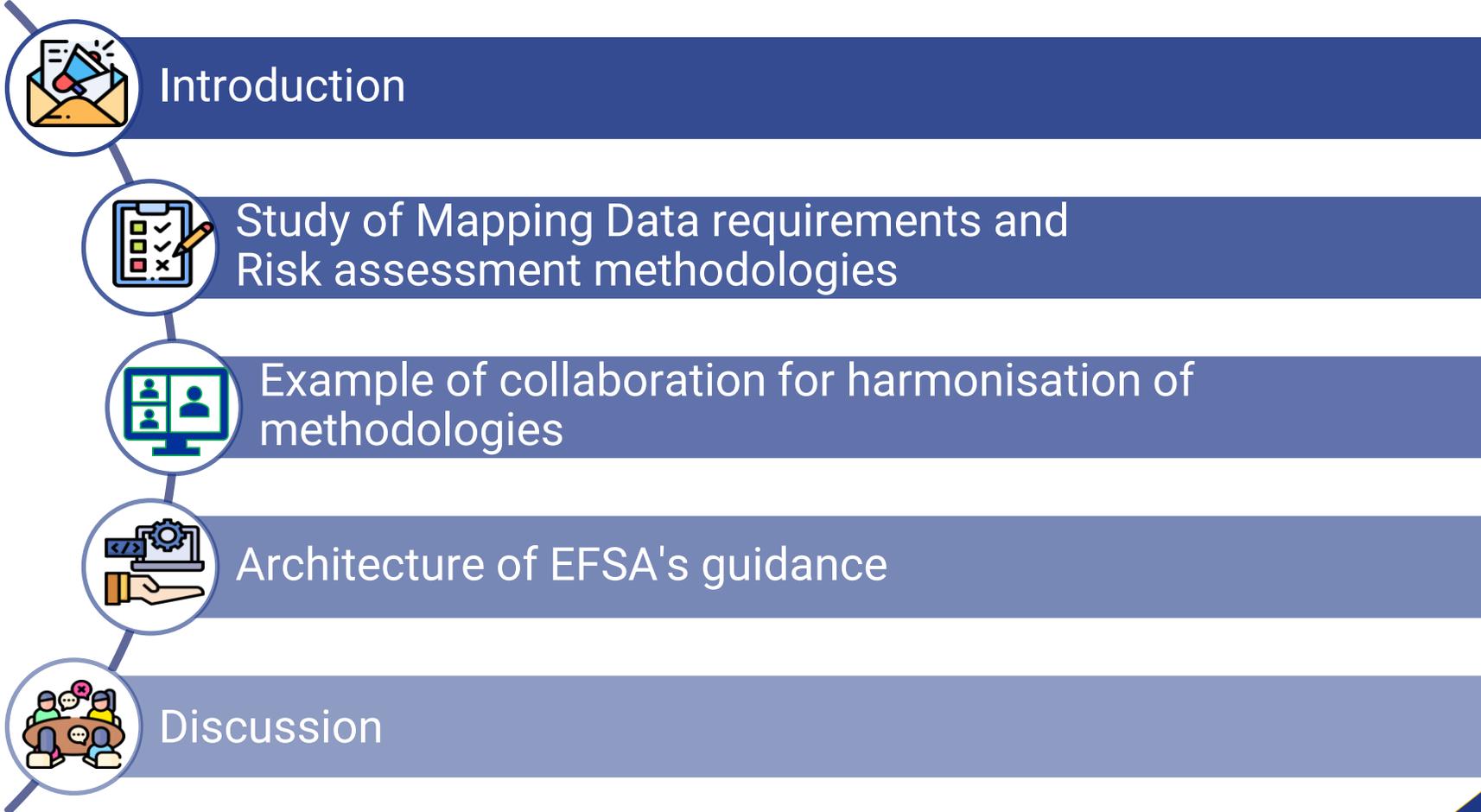
91ST ADVISORY FORUM
BRUSSELS, 06MAR-07MAR 2024



RISK ASSESSMENT SCIENTIFIC GUIDANCE: TOWARDS A COMMON APPROACH



NIK KRIZ





2. 1S1A: STUDY OF MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES

Gloria López-Gálvez

1S1A:

STUDY OF MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES: *BACKGROUND*

**Piloting 1S1A: Drinking Water Directive
Food Contact Materials**



Data requirements for genotoxicity do not fully match

Identify other misaligned areas

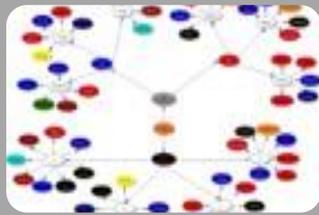
Contract: RPA Europe & FoBiG



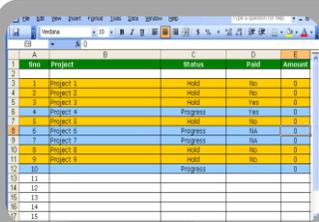
Study Report: <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2023.EN-8540>



Report on data requirements and risk assessment methodologies applied within the regulatory frameworks of EFSA, ECHA, EMA and the two EC Scientific Committees (SCCS and SCHEER)



1. To map the regulatory areas and the associated regulatory frameworks



Row	Project	Status	Exp.	Amount
1	Project 1	not	no	0
2	Project 2	not	no	0
3	Project 3	not	yes	0
4	Project 4	Progress	no	0
5	Project 5	not	no	0
6	Project 6	Progress	no	0
7	Project 7	Progress	no	0
8	Project 8	not	no	0
9	Project 9	not	no	0
10		Progress		
11				
12				
13				
14				
15				

2. To extract the information on *data requirements* and *risk assessment methodologies*



3. To identify, describe and analyse the commonalities and differences across the operating frameworks



MATERIALS

Digital data inventory developed
230 records: legal acts, guidance and
other documents

METHODS

Comparative analysis methodology
Information extracted on
data requirements
risk assessment methodologies

RESULTS

Differences between regulatory frameworks
Inconsistencies within areas
Harmonisation needs

DATA: some high-level findings

- Migration rate for food contact materials defines data requirements for toxicity
- Data for environmental fate/ecotoxicity conditioned to phase 1 trigger values (different in feed, vet. and human medicines)
- No data requirements for environmental fate and ecotoxicity for food chemicals
- Data requirements exist for substance identity, physico-chemical properties and toxicity in all areas
- Quality standards to perform the studies (GLP, other)



METHODS: some high-level findings

Principal Risk Assessment Methods

- ✓ Category 1: Risk factor = exposure / reference value
- ✓ Category 2: Risk factor = reference value / exposure

**Names of reference values –
human health**

- REACH (**DNEL**)
- Biocides (**AEL, ADI**) Pesticides (**AOEL, ADI**)
- Food (**ADI**) Feed (**ADI**) Vet. medicines (**ADI**)



HARMONISATION NEEDS



- Terminology
- Approaches to define data requirements
- Specific data requirements for each endpoint
- Testing provisions to meet a data requirement
- Risk Assessment definitions
- Provisions in the hazard assessment
- Exposure assessment – Models and tools

Relevant Stakeholders



- EFSA, ECHA, EMA, EC
- To analyse/validate the findings
- Draw up a list of areas where alignment would be needed



Organisation of a workshop



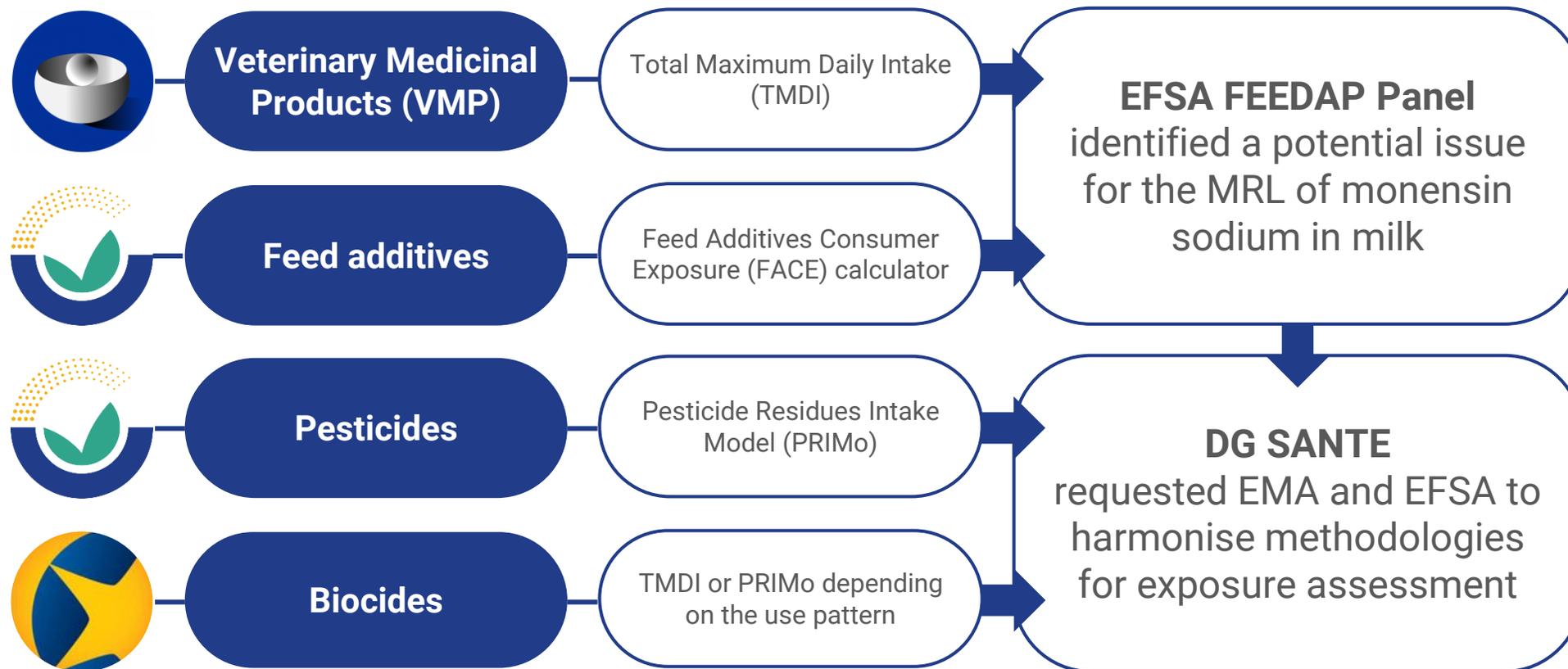
- Agreement on areas where alignment would be justified – legal texts and/or guidance documents
- Establish a roadmap with areas to be align

3. EXAMPLE OF COLLABORATION FOR HARMONISATION OF METHODOLOGIES

Bruno Dujardin

3. EXAMPLE OF COLLABORATION FOR HARMONISATION OF METHODOLOGIES *BACKGROUND & MANDATE*

Dietary exposure to residues in food of animal origin



3. EXAMPLE OF COLLABORATION FOR HARMONISATION OF METHODOLOGIES *WORKING GROUP*

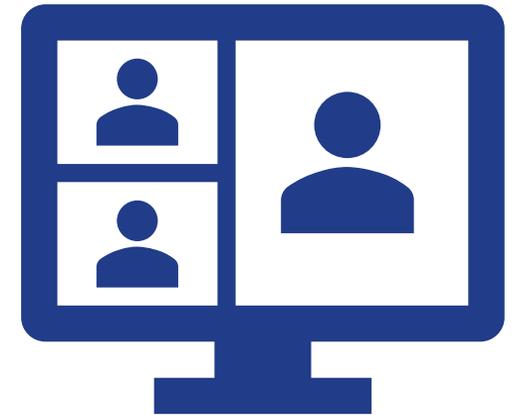
Expert working group (WG) on models of consumer exposure



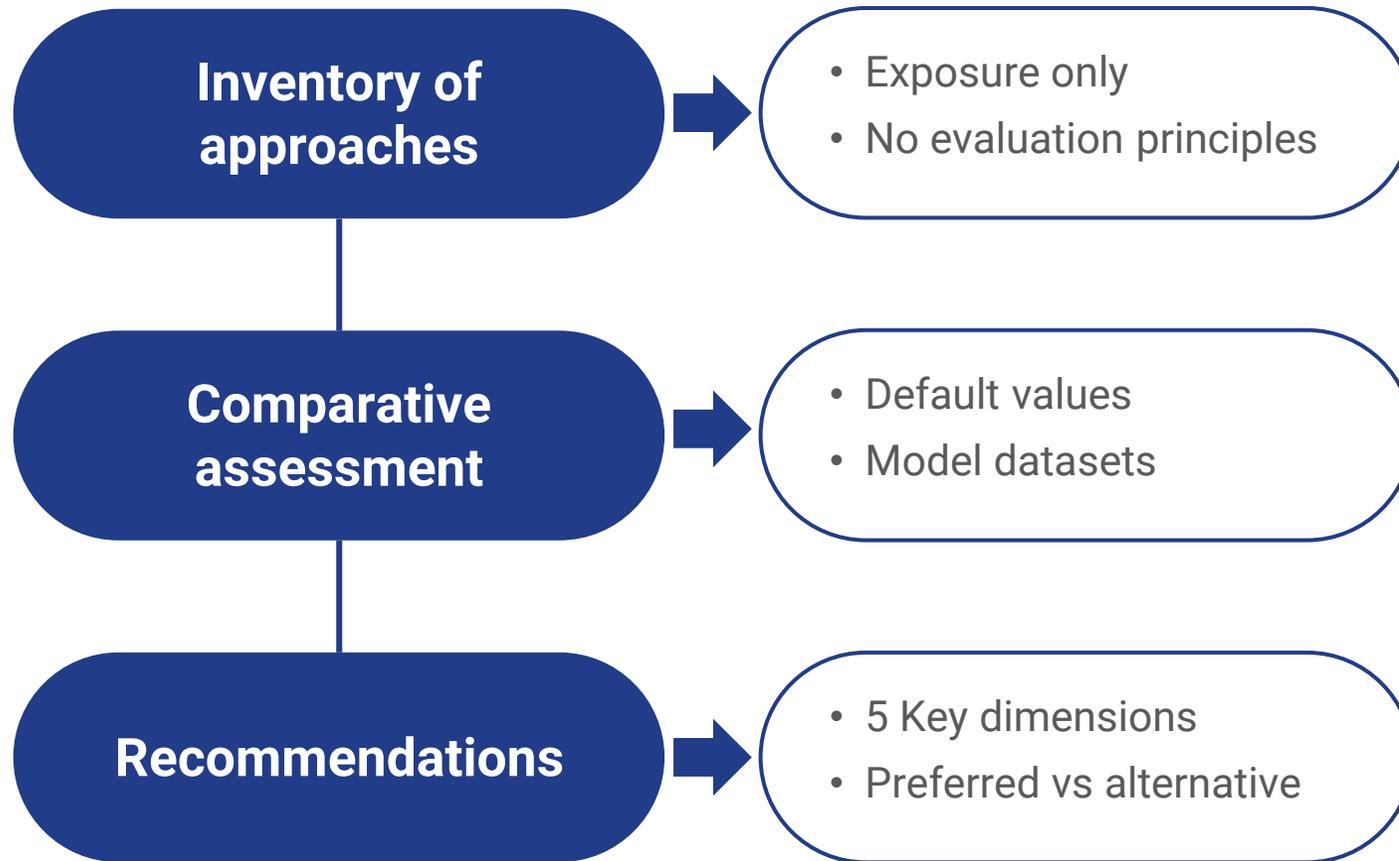
Overall coordination
Committee for Veterinary Medicinal Products (CVMP)
Member State experts (appointed by CVMP)
Approval by CVMP



Co-chair
Technical and scientific support
Endorsement by EFSA Scientific Committee



3. EXAMPLE OF COLLABORATION FOR HARMONISATION OF METHODOLOGIES *REPORT*



3. EXAMPLE OF COLLABORATION FOR HARMONISATION OF METHODOLOGIES *LESSONS LEARNT AND FOLLOW-UP*

Lessons learnt

- Risk assessment vs risk management
- One agency to take the lead
- Procedural guidance for adoption needed
- Interoperability of IT systems



Harmonised tool for exposure assessment

- DG SANTE and Member States to define requirements
- EFSA and EMA to develop a common tool
- Mandate currently under negotiation





4. ARCHITECTURE OF EFSA'S GUIDANCE

Claudia Roncancio-Peña

GUIDANCE DOCUMENTS IN EFSA

Total of 162 guidance in force

**Sectoral
Guidance**

Scientific
Panels



**Cross-Cutting
Guidance**

Scientific
Committee



**Administrative
Guidance**

EFSA



AS-IS

Different requestors

- EC
- EFSA – self mandates –

Different outputs

Guidances,
Guidelines,
(explanatory) statements
Note to the guidance

Preparation of Multiannual Work programmes:

- SC for CC guidance
- **Sectoral (not in place in all areas)**



Target audiences

- Applicants
- Risk assessors (RAs)
- Data providers
- Both Applicants and RAs

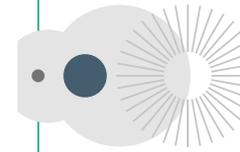
Knowledge

- Advanced knowledge
- Basic knowledge
- Extensive practical knowledge and "know how"

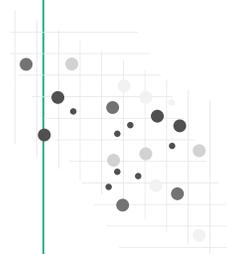


Why we need this project?

Definitions and overall mapping and organisation of EFSA's guidance



Are guidance documents relevant in this interconnected, fast, EU/International and complex environment?



Are they implementing the 1S1A approach?



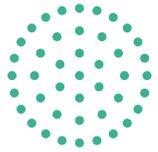
Are they able to address new challenges? Include new scientific developments at a pace that allows an appropriate response in the regulatory environment?

Communication and trainings

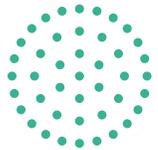


OBJECTIVES OF THE PROJECT

To develop a roadmap to build a future EU Food-Feed Safety/Risk Assessment guidance library



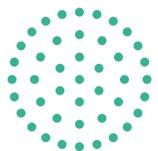
To develop at EFSA level an overview of the architecture of our guidance portfolio



To develop a **Target Operating Model** in consultation with partners



To develop a **work programme** for sectoral guidance and cross cutting guidance in consultation with partners



To prepare an action plan for the **co-creation of new guidance** (pilot on the Biomarkers of effect)



TARGET OPERATING MODEL GUIDANCE DOCUMENTS (SECTORAL AND CC)

Processes and delivery model:

Learning from experience from different users: **applicants and RA**

Increase capacity building

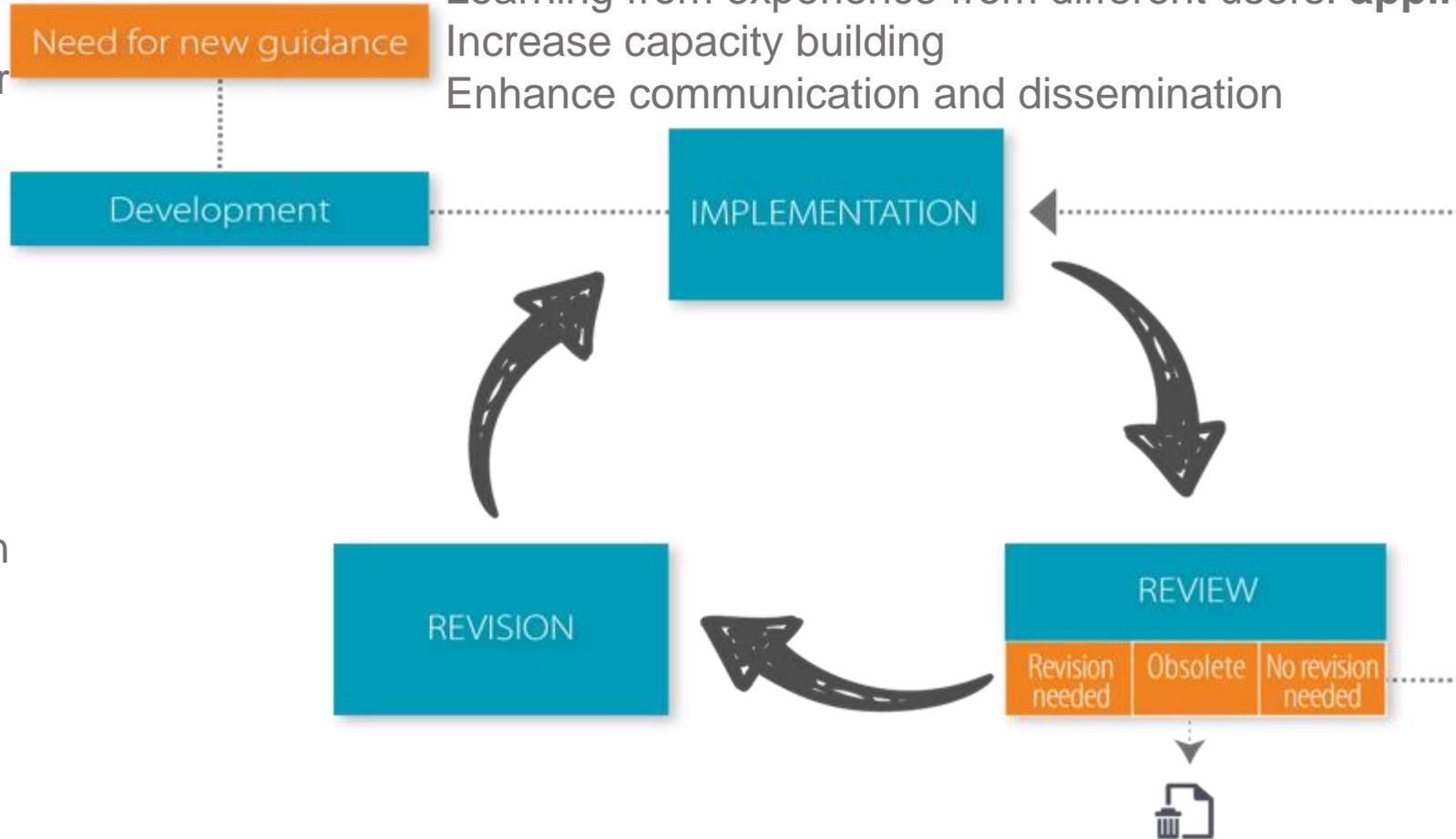
Enhance communication and dissemination

Governance:

- Multiannual WPs for sectoral and CC
- Collaboration: legal basis
- Prioritisation
- EU guidance

Technology:

applications/integration that enable and automate process.



Performance insights and data: Identify appropriate indicators



BUILDING THE SCIENTIFIC COMMITTEE WORKPROGRAMME

Feedback from
users on
Guidance

Fit for purpose
and clarity

Scientific
developments





5. DISCUSSION

All

5. QUESTIONS - DISCUSSION



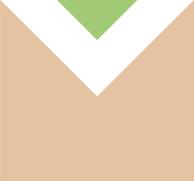
Are EFSA Guidance used by MS in national risk assessments?



Which Guidance documents do you have to support Food/Feed (or other areas) Risk assessments?



How often have you identified a discrepancy between MS Guidance and EFSA Guidance?



Would you see a benefit in having a unique EU set of Guidance documents to be used by all actors in food/feed and cross-cutting risk assessments? If yes, which areas would be of priority?



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