



# EFSA EMERGING RISKS IDENTIFICATION SYSTEM

Bernard Bottex

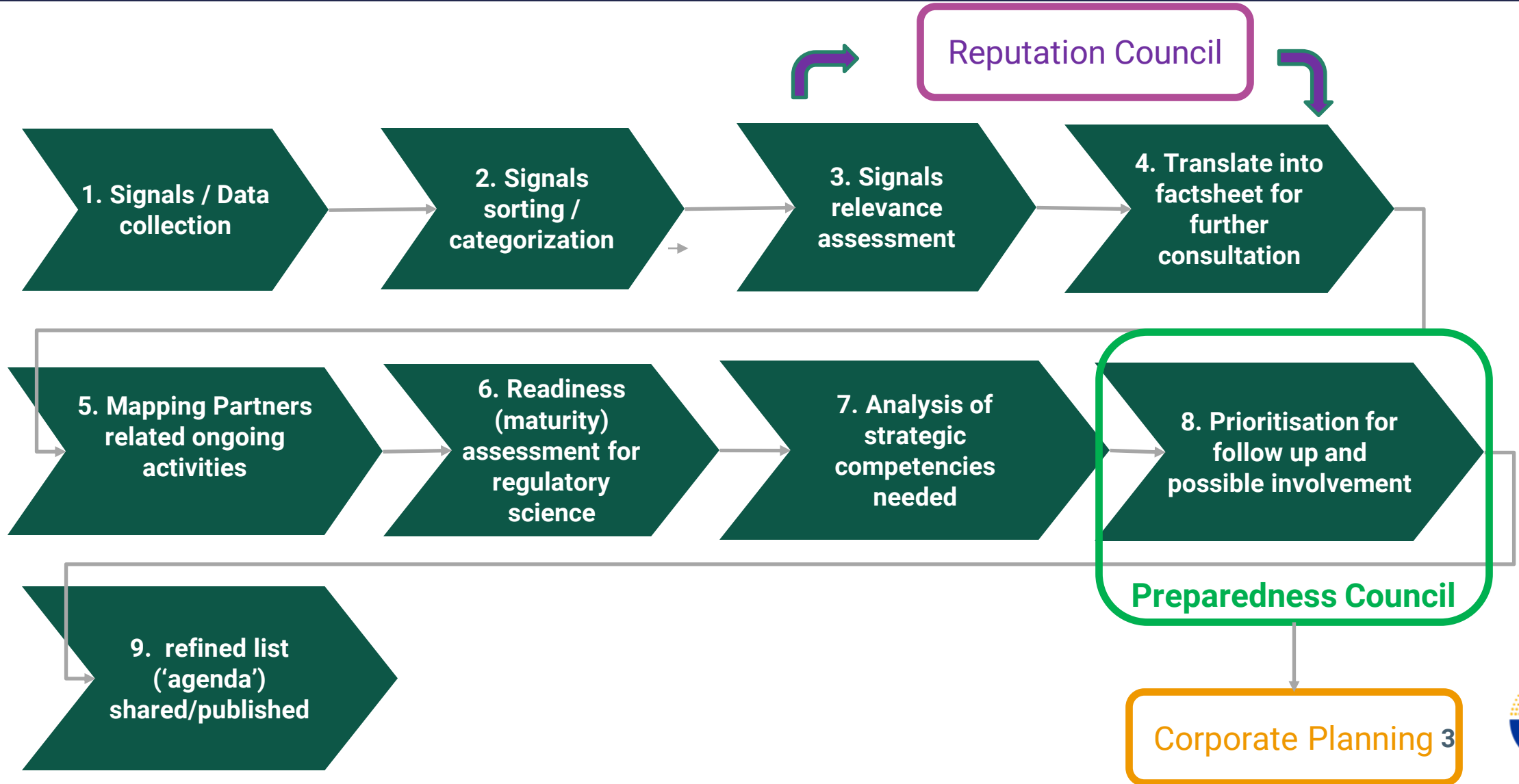
Knowledge, Innovation and Partnership  
Management (KNOW) Unit

# ENVIRONMENT SCAN & STRATEGIC OPTIONS DEFINITIONS

- Contribution to the **definition of EFSA's working agenda and long-term strategy**
- **Identification / anticipation of any gaps / opportunities** (scientific and non-scientific) that would prevent EFSA to fulfil its mission / allow EFSA to fulfil its mission more efficiently



# ENVIRONMENT SCAN & STRATEGIC OPTIONS DEFINITIONS



# REGULATORY OUTLINE

## REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

### *Article 23*

#### **Tasks of the Authority**

The tasks of the Authority shall be the following:

- (f) to undertake action to identify and characterise emerging risks, in the fields within its mission;

### *Article 34*

#### **Identification of emerging risks**

*‘...establish monitoring procedures...’*

*‘.. request additional information...’*

*‘... use all the information it receives...’*

## EFSA Strategy 2027

### STRATEGIC OBJECTIVE 2

Ensure preparedness  
for future risk analysis needs

2.1.2 The quality and scale of crisis preparedness and the **identification of emerging risks** is improved.



Anticipation of future Risk assessment needs



Anticipate & prevent future safety challenges

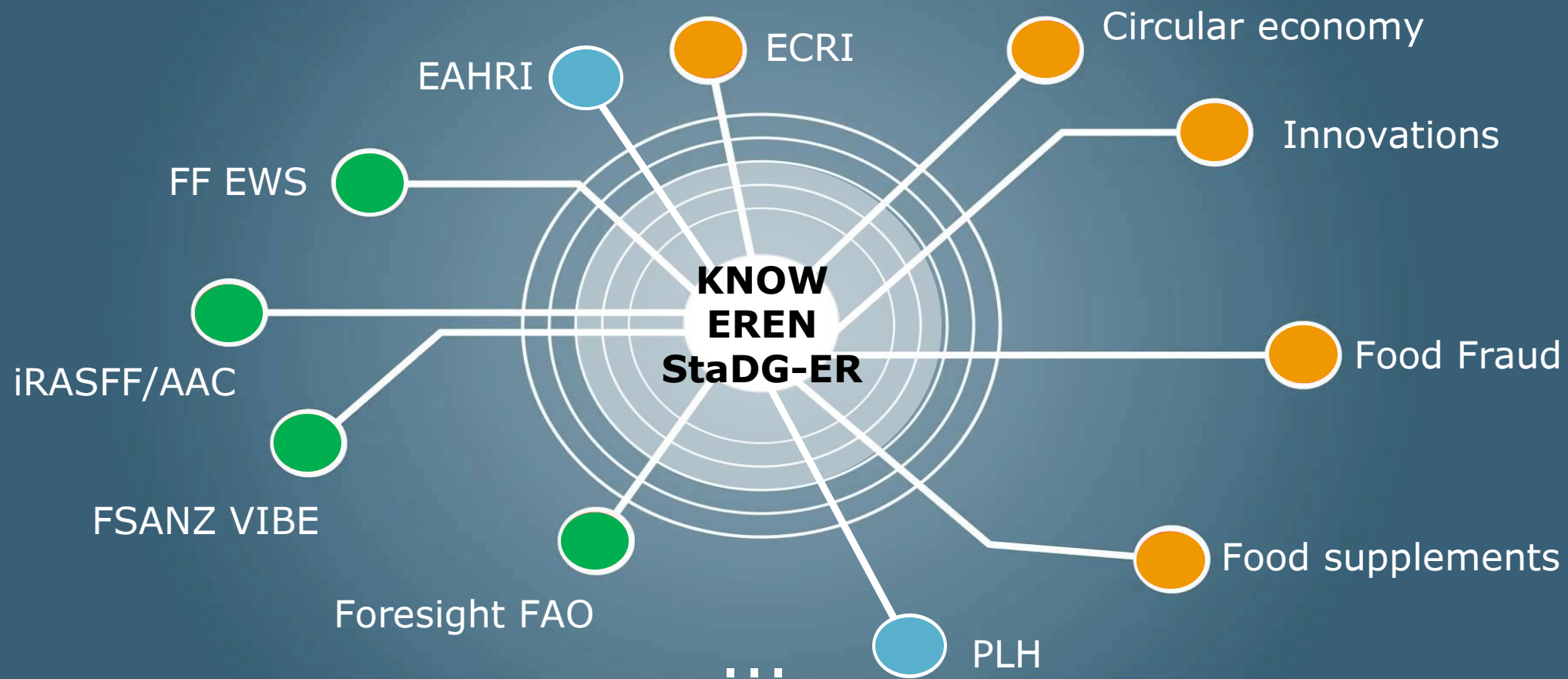


# EMERGING RISK DEFINITIONS

- An **emerging risk** is: “a risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard.”
- The **drivers** of emerging risks may include population growth, globalisation, resource and energy scarcity, slowing agricultural productivity, increasing concentration of the supply chain, price volatility, changing diet trends and the emergence of anti-microbial resistant strands to name a few.

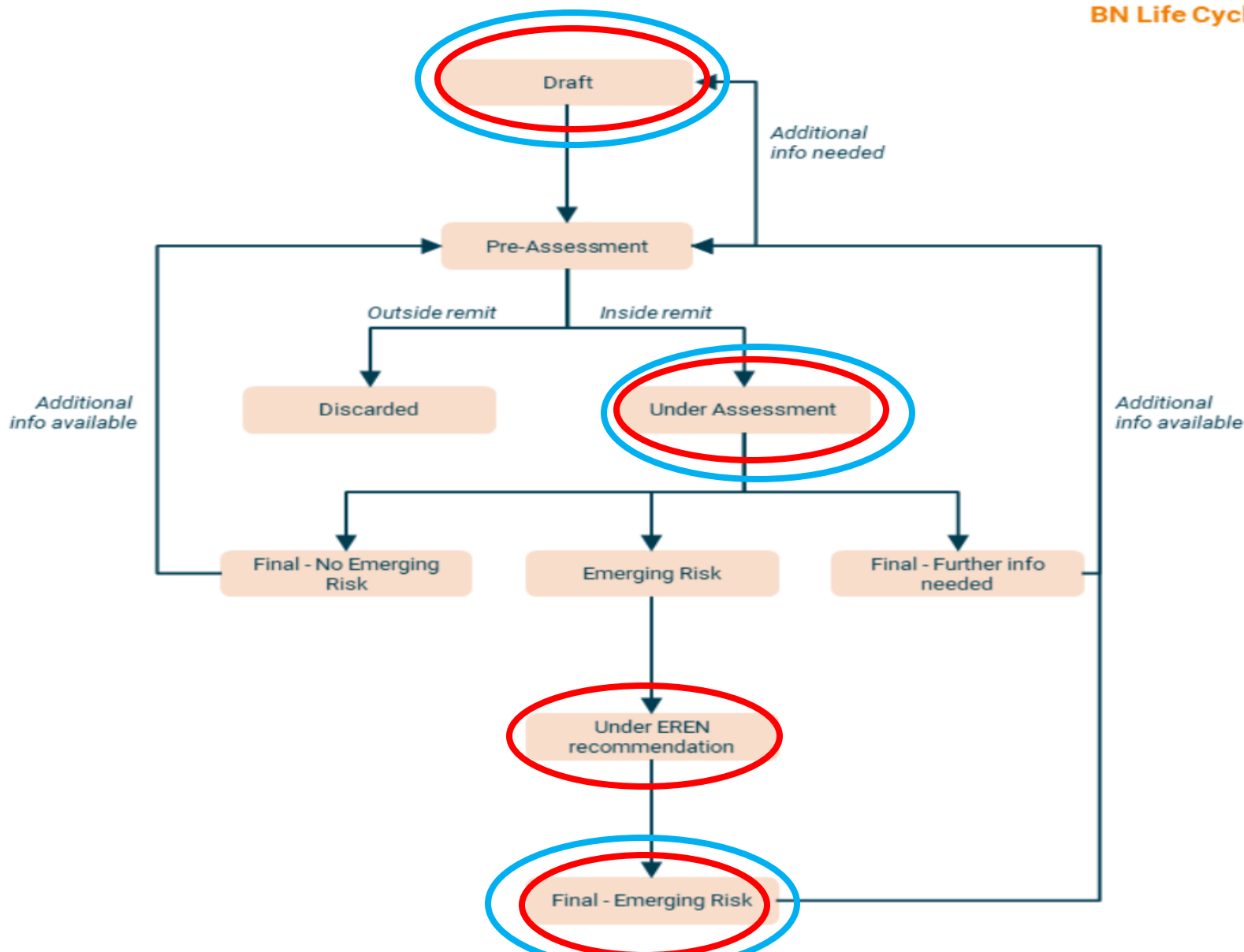


# EFSA ERI SYSTEM



# EFSA ERI SYSTEM

BN Life Cycle



**Emerging Risks Exchange Network**



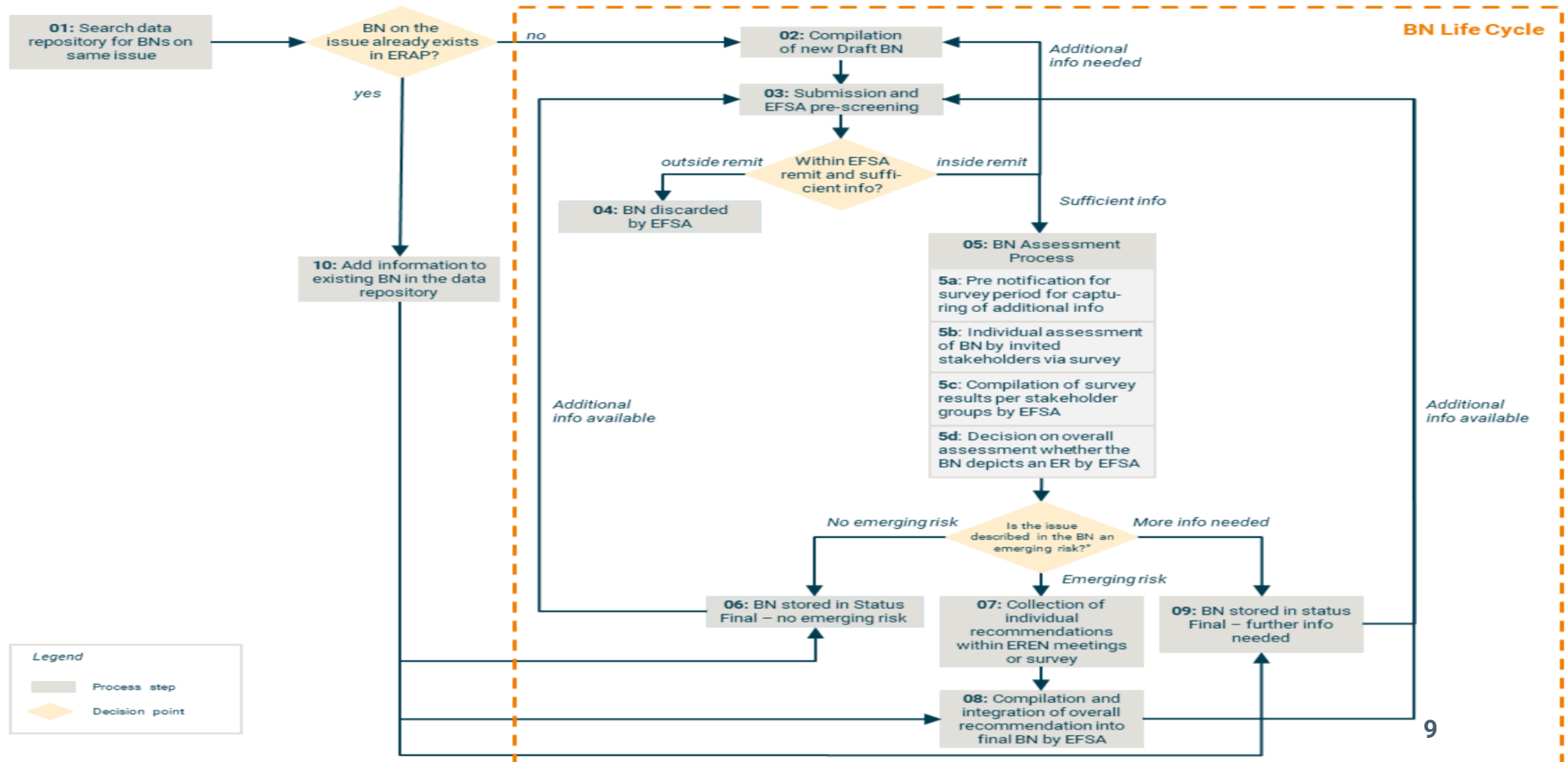
# DRAFT BN TEMPLATE

Urgency of the issue
Title
Author(s)
Affiliation/type of contribution
Metadata: <ul style="list-style-type: none"><li>• Entity subject of the issue (e.g. organism, chemical etc.)</li><li>• EFSA impacted area(s) → fixed pick list</li><li>• Driver(s) → possibility to propose new driver</li><li>• Route of transmission → fixed pick list</li><li>• Food matrix → possibility to propose food matrix</li></ul>
Abstract (500 characters max) <ul style="list-style-type: none"><li>• What is the issue about?</li><li>• Why is it relevant for EFSA?</li><li>• What could be the potential impact of the issue on e.g. humans, animals, environment?</li></ul>
<i>Detailed description of the issue</i>
<i>Restricted information / distribution limitations</i>
References





# EMRISK WORKFLOW





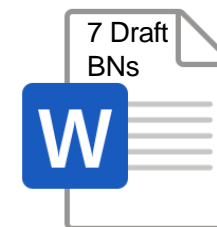
# OUTCOME OF THE 6<sup>TH</sup> SURVEY ON DRAFT BRIEFING NOTES

Roberta Giarnecchia

Trainee in Knowledge, Innovation and  
Partnership Management Unit (KNOW)

# SUMMARY OF THE OUTCOME

7 Draft BNs



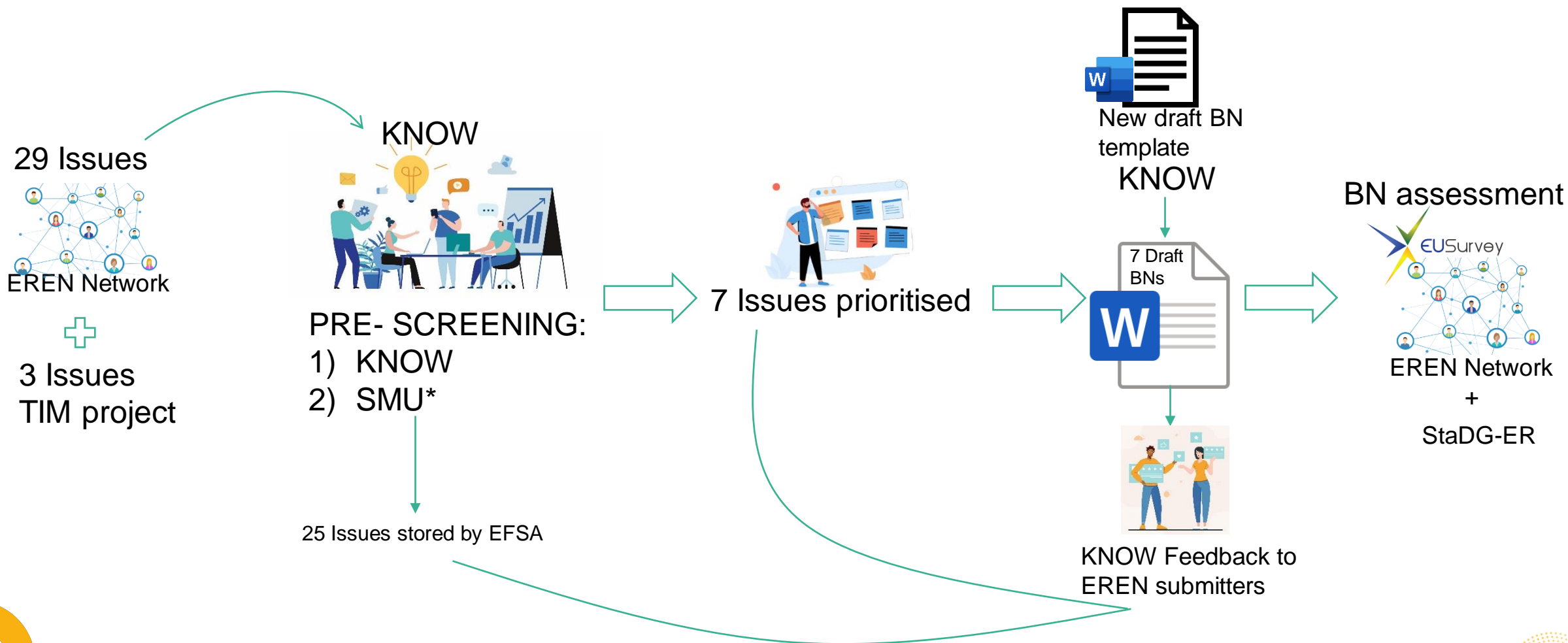
20 answers from EREN



10 answers from StaDG-  
ER



# 7 ISSUES FOR SURVEY: PRIORITISATION PROCESS

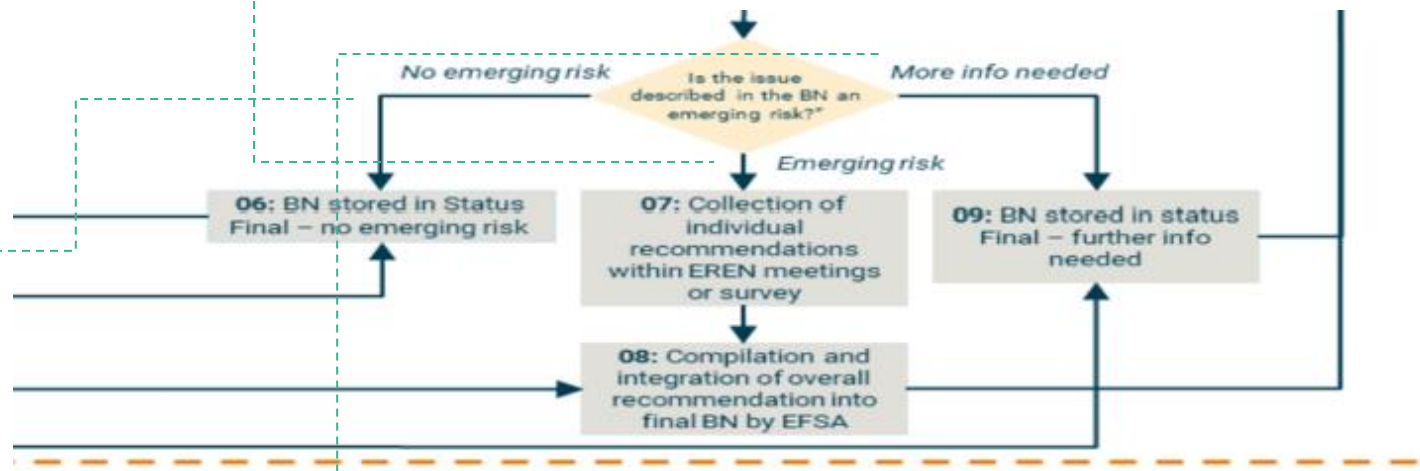


# CONCLUSIONS OF DRAFT BRIEFING NOTES

Emerging Risk

Final-No Emerging Risk

Final- further info needed



# CONCLUSION OF ISSUES: EREN AND STADG-ER

ISSUE		CONCLUSIONS IN SURVEY			DECISION
ID	ITEM	EMERGING RISK	FURTHER INFO NEEDED	NO EMERGING RISK	CONCLUSION
M0194	Hg And AMR	5/15	6/15	4/15	FINAL- NO EMERGING RISK
M0195	Toxic alga- fish die-off	4/10	6/10	0	FINAL-FURTHER INFO NEEDED
M0196	Ethanol for plants drought	2/12	6/12	4/12	FINAL- NO EMERGING RISK
M0197	Salicylaldehyde as weed control	1/8	4/8	3/8	FINAL- NO EMERGING RISK
M0198	Tara flour	3/15	8/15	4/15	FINAL- FURTHER INFO NEEDED
M0199	Burkholderia pseudomallei	5/14	7/14	2/14	FINAL- FURTHER INFO NEEDED
M0200	Explosives in Baltic sea	6/10	4/10	0	FINAL- FURTHER INFO NEEDED



# ISSUES CHARACTERIZED AS FINAL- NO EMERGING RISK

## Final-No Emerging Risk

M0194\_Influence of legacy mercury on antibiotic resistomes

We don't have at the moment evidence suggesting the issue to be potential emerging risk, thus it is stored as final- no emerging risk

M0196\_Pretreating soil with ethanol protects plants from drought

More information is needed on the application of this technology, the risk by now is still hypothetical. No emerging risk – stored for future enrichment if needed

M0197\_Salicylaldehyde for fungal and pre- and post-emergent weed control

More knowledge is needed on the effects of residues of SA. Need for vigilance system and information to national authorities of the potential use and the possible consequences. We don't have now elements to define if there will be a risk in the future related to salicylaldehyde.



# ISSUES CHARACTERIZED AS FINAL-FURTHER INFO NEEDED

## Final- further info needed

M0195\_Oder River fish dieoff\_Salt discharges caused mass proliferation of toxic alga

M0198\_Tara flour as potential cause of illnesses

M0199\_Spread of *Burkholderia pseudomallei*

M0200\_TIM Analysis of samples of explosives excavated from the Baltic Sea floor and explosives degradation products in dab (*Limanda limanda* L.) from a munition dumpsite in the Baltic Sea

- Nothing similar has happened before and it will probably repeat because of rising temperatures, more events like this will happen. The issue needs further surveillance, attention and measures.
- It is currently not clear whether this is a one-off contamination event or tara flour itself poses an emerging food safety risk via some as-yet unidentified toxin/contaminant. It was first categorised as no emerging risk, **after the EREN meeting it was concluded that it should fall under FINAL-further info needed**
- Additional information and, in the best case, a surveillance program is needed to keep track of the potential spread of *Burkholderia pseudomallei* in North America and Europe.
- It could be considered emerging risk but more info are needed as also a monitoring program to gather more information to decide which measures need to be taken.







# M0198\_TARA FLOUR- POTENTIAL CAUSE OF ILLNESSES

Roberta Giarneccia

Trainee in Knowledge, Innovation and  
Partnership Management Unit

# TARA FLOUR FACT AND CASES

Outbreak – April 2022

U.S.

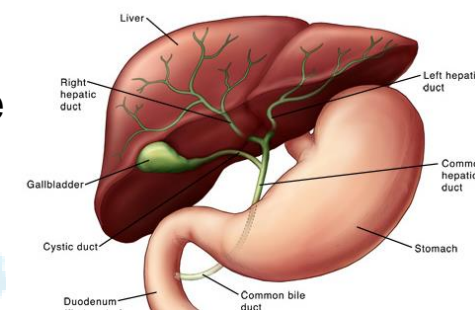
FDA reported:  
**393 cases** from **39 states** connected with product containing **tara flour**

Food Safety News

Daily Harvest recalls French Lentil + Leek Crumbles after complaints of illnesses and hospitalizations

FSN

**SYMPTOMS:**  
Patients reported gastrointestinal issues and liver problems, fatigue, body aches, fever and liver damage



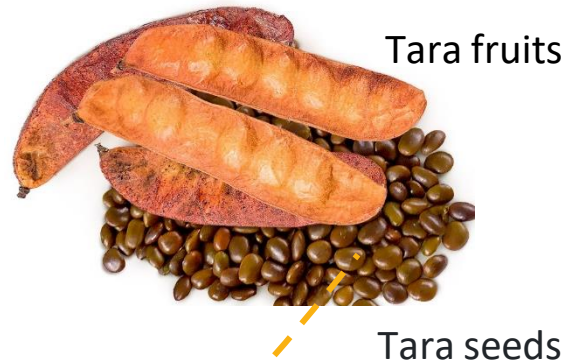
# BUT WHAT IS TARA?

*Caesalpinia Spinosa*  
commonly known as  
'Tara'



EFSA Opinion: Revaluation on **Tara gum** (E 417) as food additive  
<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4863>

*The Panel concluded that there is no need for a numerical ADI for tara gum (E 417) and that there is no safety concern for the general population at the refined exposure assessment of tara gum (E 417) as a food additive at the reported uses and use levels.*



Is tara flour coming from the seeds of Tara plant or from the tara fruits grinded?

# PRODUCT TESTING

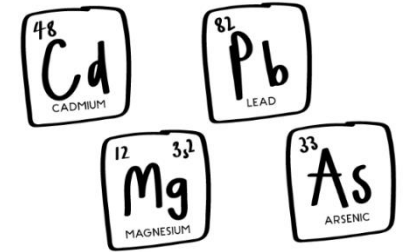
FDA tested individual ingredients including **Tara flour**

- **Heavy metals above the limit (200ng/g):** vanadium, chromium, cobalt, nickel, arsenic, selenium, cadmium, mercury, thallium and lead.
- 2 finished product samples tested negative for: mycotoxins and microbes incl. salmonella spp., Listeria spp., Hepatitis A and Norovirus



During FDA inspection a company conducted its own investigation:

*"The finished product sample reports indicated the product was tested for several bacteria, yeasts and molds, allergens, and aflatoxin. All tests were negative" the FDA report states.*





# OTHER EVIDENCE FROM SURVEY (EREN MEMBER FEEDBACK)



Information\_received  
\_via\_INFOSAN\_about.

1. **Has it been confirmed that Tara [protein] flour was the culprit? What was the exact cause, the ingredient itself or any contamination of this ingredient?**

Tara protein flour was an ingredient unique to the product of interest and sacha inchi powder was only used in a maximum of two other products. This information, combined with the relatively limited amount of information about these specific ingredients, led to these components being identified as ingredients of interest. The information and records provided to FDA's Coordinated Outbreak Response & Evaluation (CORE) Network indicated two ingredients of interest could be a potential source of adverse illnesses events associated with the Daily Harvest French Lentil and Leek Crumbles.

2. **Is it correct, that Tara [protein]flour was involved not to confuse with Tara gum?**

The tara ingredient of interest was tara protein flour, not tara gum

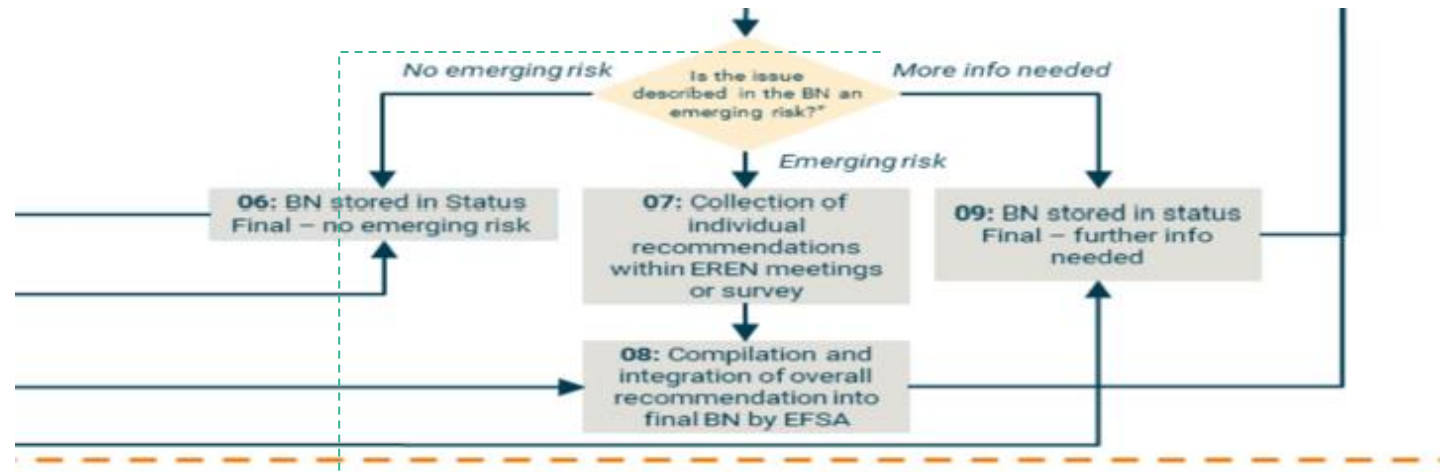
3. **Is Tara [protein] flour a recognized ingredient in the US? If so, what actions were taken to avoid any negative impact in future?**

microbial and other contaminants in the food they produce. The U.S. FDA does not have a food additive regulation or other regulatory notification for the use of tara protein flour in food. Under U.S. law, food manufacturers are responsible for ensuring data and information are available that demonstrate the safety of ingredients added to food prior to marketing. The U.S. FDA administers premarket regulatory programs to aid manufacturers in meeting their obligations and ensuring the safe use of ingredients added to food. The U.S.



# CONCLUSION- TARA FLOUR

- **New hazard:** not yet be named
- **Increased exposure:** with plant-based products (food and drink) exposure is expected to grow/no info on exposure in EU market, no supporting data
- **New target group:** no new susceptible group identified
- **New driver:** consequence of consumer demand and consumer behavior



Final- further info needed

Do you have additional information on Tara flour to share with us?





# EMERGING RISKS ANALYSIS PLATFORM (ERAP)

Milen Georgiev

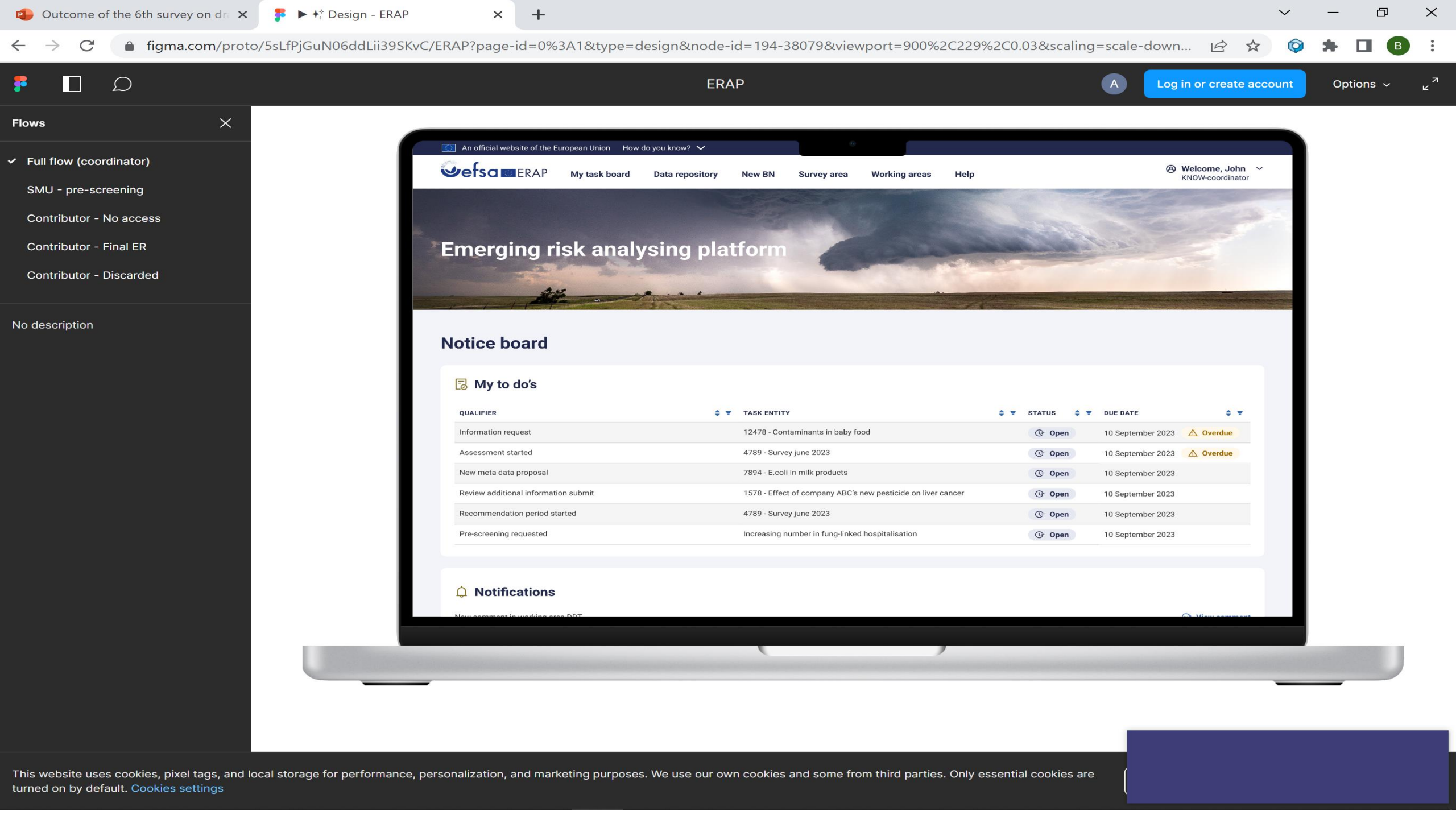
Knowledge, Innovation and Partnership  
Management (KNOW) Unit

# STATE OF PLAY

- Phasing down of DMS -> archiving
- Teams not adapted for our emerging risks characterisation activities.
- Need for a unique central place for the identification/characterisation of emerging risks in EFSA's remit
- Priority = content management system
  - repository of Briefing Notes and Short Issues, meeting minutes, annual activity reports
  - Surveys (review & prioritisation of short issues, follow up decisions (SI and BN))
  - Upload of additional data/information
- Platform accessible by
  - EREN
  - StaDG-ER
  - Networks of the ERI projects (food fraud, circular economy, new food/feed sources and production techniques, emerging chemicals)
  - Other interested parties (EU Institutions, international Partners)







- Flows
- Full flow (coordinator)
  - SMU - pre-screening
  - Contributor - No access
  - Contributor - Final ER
  - Contributor - Discarded
- No description

An official website of the European Union How do you know?

efsa ERAP My task board Data repository New BN Survey area Working areas Help

Welcome, John KNOW-coordinator

# Emerging risk analysing platform

## Notice board

### My to do's

QUALIFIER	TASK ENTITY	STATUS	DUE DATE
Information request	12478 - Contaminants in baby food	Open	10 September 2023 Overdue
Assessment started	4789 - Survey june 2023	Open	10 September 2023 Overdue
New meta data proposal	7894 - E.coli in milk products	Open	10 September 2023
Review additional information submit	1578 - Effect of company ABC's new pesticide on liver cancer	Open	10 September 2023
Recommendation period started	4789 - Survey june 2023	Open	10 September 2023
Pre-screening requested	Increasing number in fung-linked hospitalisation	Open	10 September 2023

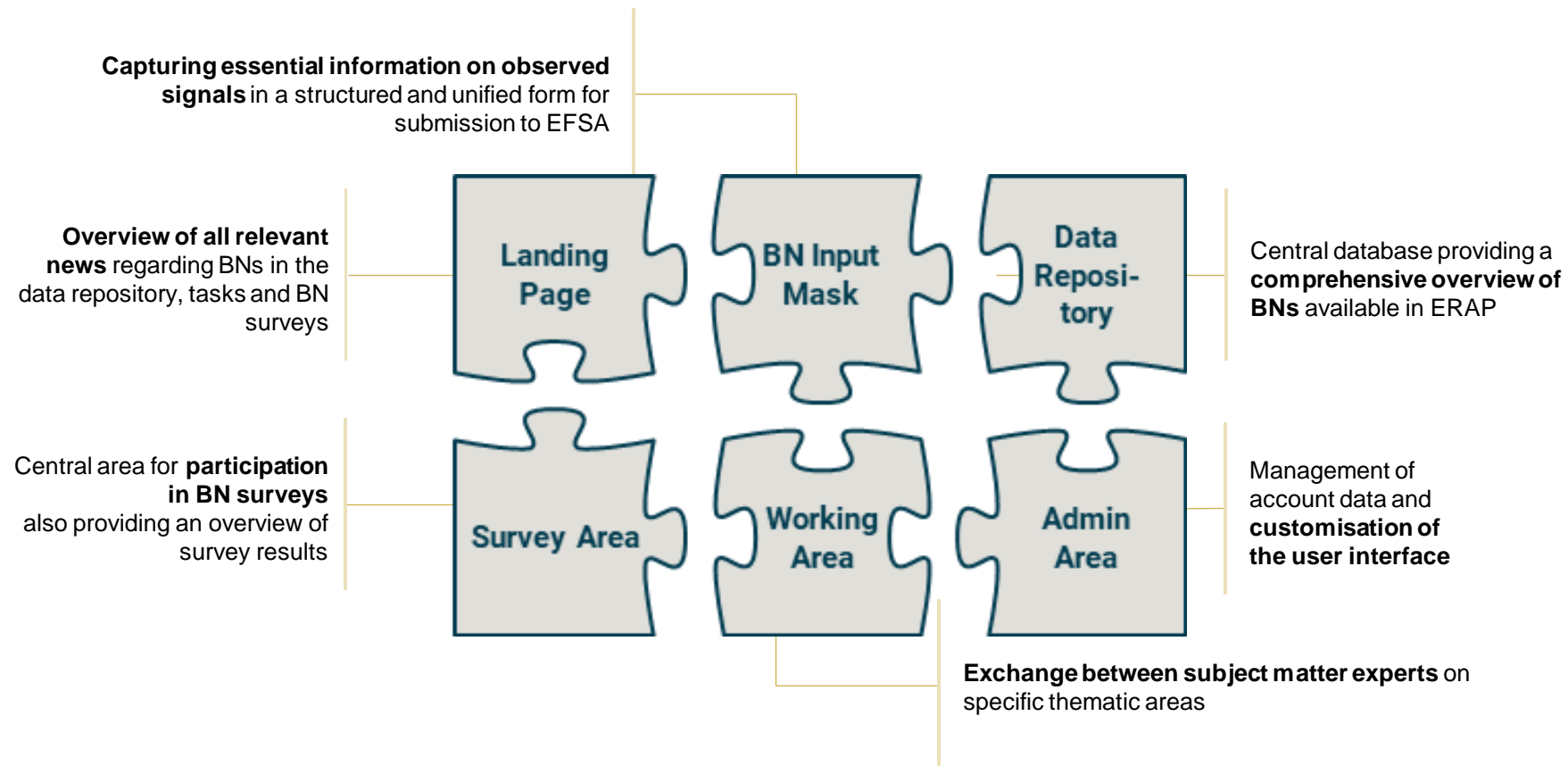
### Notifications

New comment in working area DDT

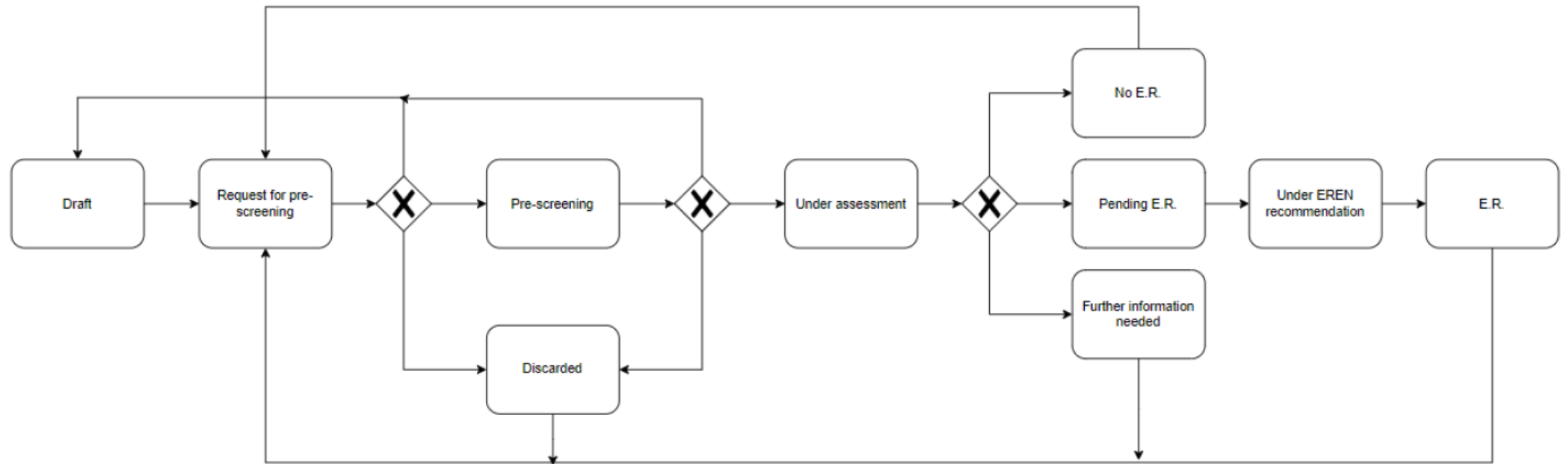
View comment

# EMERGING RISKS ANALYSIS PLATFORM

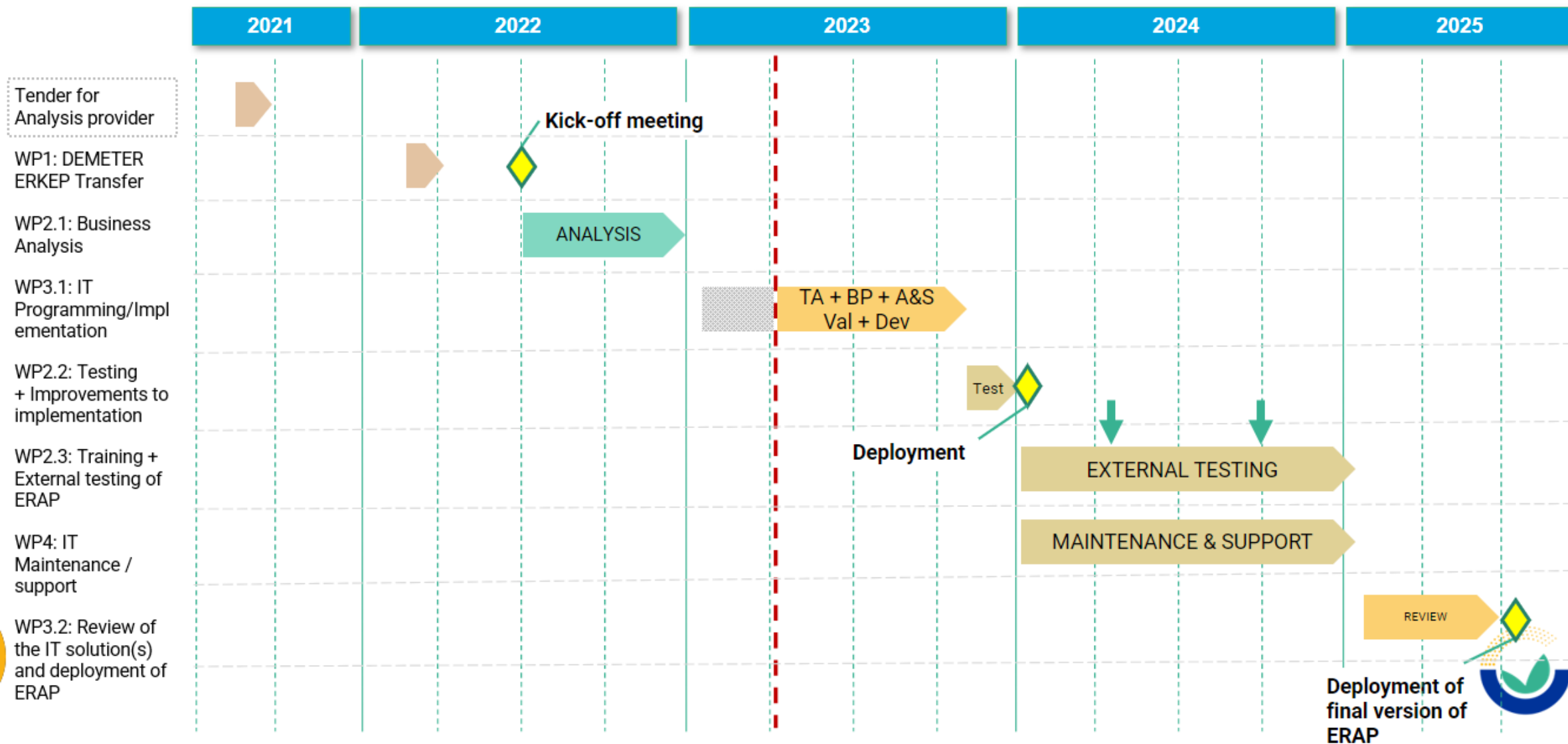
## Platform areas



# OVERVIEW OF BRIEFING NOTE DEVELOPMENT



# ERAP PLATFORM - TIMELINE



# STAY CONNECTED

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