



VALUEWASTE

Unlocking new value from urban biowaste

Amaia García-Bilbao

GAIKER:

Urban Circular Bioeconomy Webinar Series

5. SAFETY AND ACCEPTANCE OF BIOBASED PRODUCTS

Methods for assessing safety of bio-based products

June 16th 2021

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MEMBER OF
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& TECHNOLOGY ALLIANCE

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ALLIANCE



**Since 1998, we have carried out ADME-TOX studies
under the guarantee of Good Laboratory Practices**



CONTENTS:

1. New valuable nutrients from ValueWaste Project
2. Novel Food
3. Safety risk assessment



New valuable nutrients from ValueWaste Project

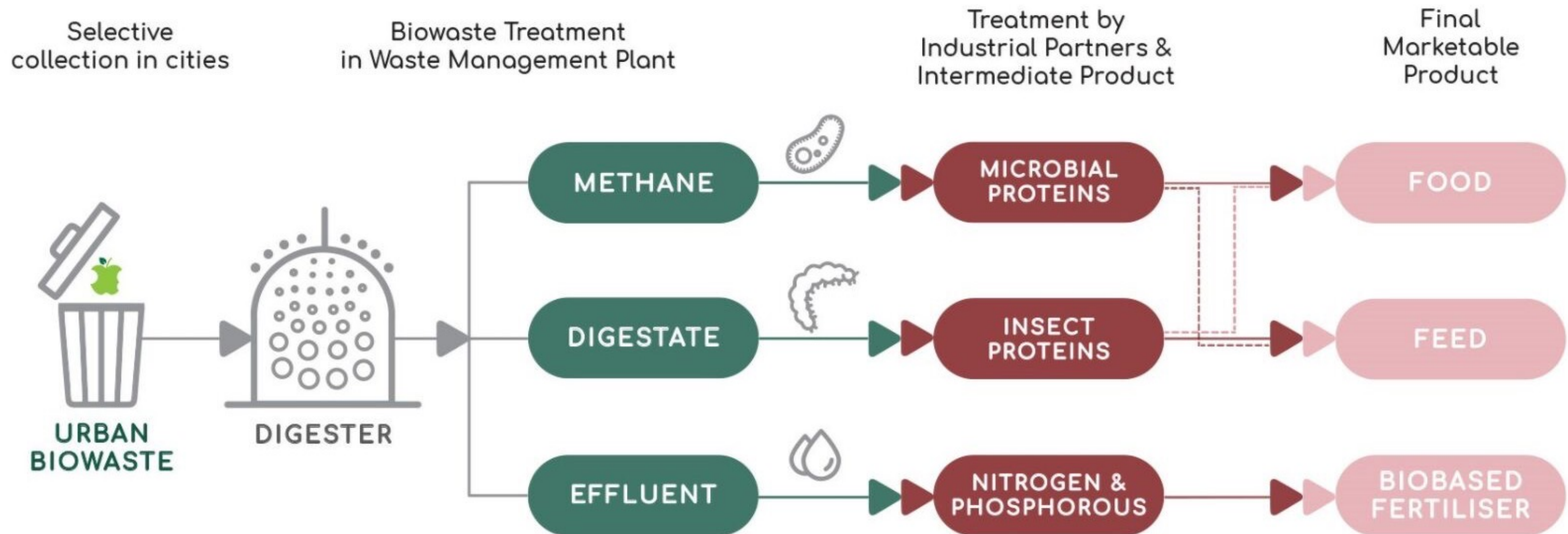
VALUEWASTE PROJECT:

VW proposes an integrated system for urban biowastes valorisation into key strategic products for the EU

- Municipal biowaste management challenge:
 - integrate a valorisation system in a city context
 - recover products with a market value
- 3 processing lines:

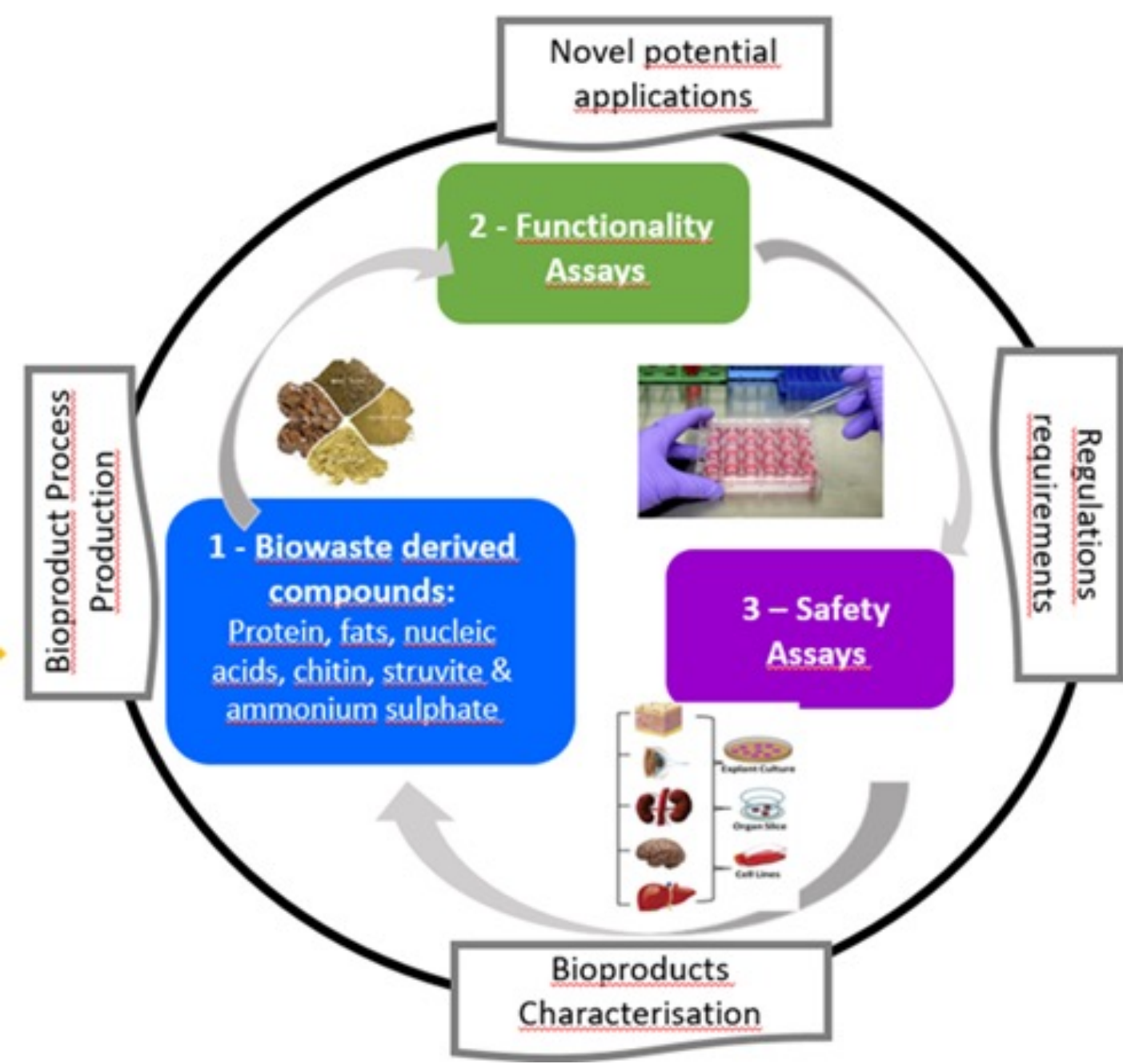
THREE VALORISING LINES

Of urban biowaste



GAIKER: Leader of WP5 (End-consumer products validation)

- assess **functionality** and potential **applications** of biowaste-derived products
- demonstrate that end products from the three valorising processes are fully **safety** and no longer poses any significant risk to human or animal



FUNCTIONALITY STUDIES

Intestinal barrier activity (mucin secretion)
Protein digestibility
Anti-tumour activity
Anti-diabetic activity
Anti-aging activity
Anti-angiogenic activity
Anti-oxidant activity
Anti-inflammatory activity
Anti-allergic activity
Anti-adipogenic activity
Metabolic activity

SAFETY STUDIES

Cytotoxicity Selection of sub-toxic doses (dosages)
In vitro gastrointestinal absorption and metabolism (ADME)
In vitro genotoxicity
Allergenicity
Toxicity (sub-synchronous)
Endocrine Disruption



Novel Food

Novel Food

- Under EU regulations, any food that was not consumed “significantly” prior to May 1997 is considered to be a **novel food** (10 categories)
- November 2015. The European Parliament and the Council adopted a new regulation: **Regulation (EU) 2015/2283 on novel foods**.
- Since January 2018, the European Commission has been responsible for authorising novel foods and, as part of the procedure, can ask **EFSA** to conduct a scientific risk assessment to establish their safety.

Novel Food: EFSA

- EFSA (European Food Safety Authority).
- Safety assessment based on dossiers provided by applicants

SCIENTIFIC OPINION



ADOPTED: 21 September 2016

doi: 10.2903/j.efsa.2016.4594

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

- January 2021 – EFSA published its first completed assessment of a proposed insect-derived food product.

SCIENTIFIC OPINION



ADOPTED: 24 November 2020

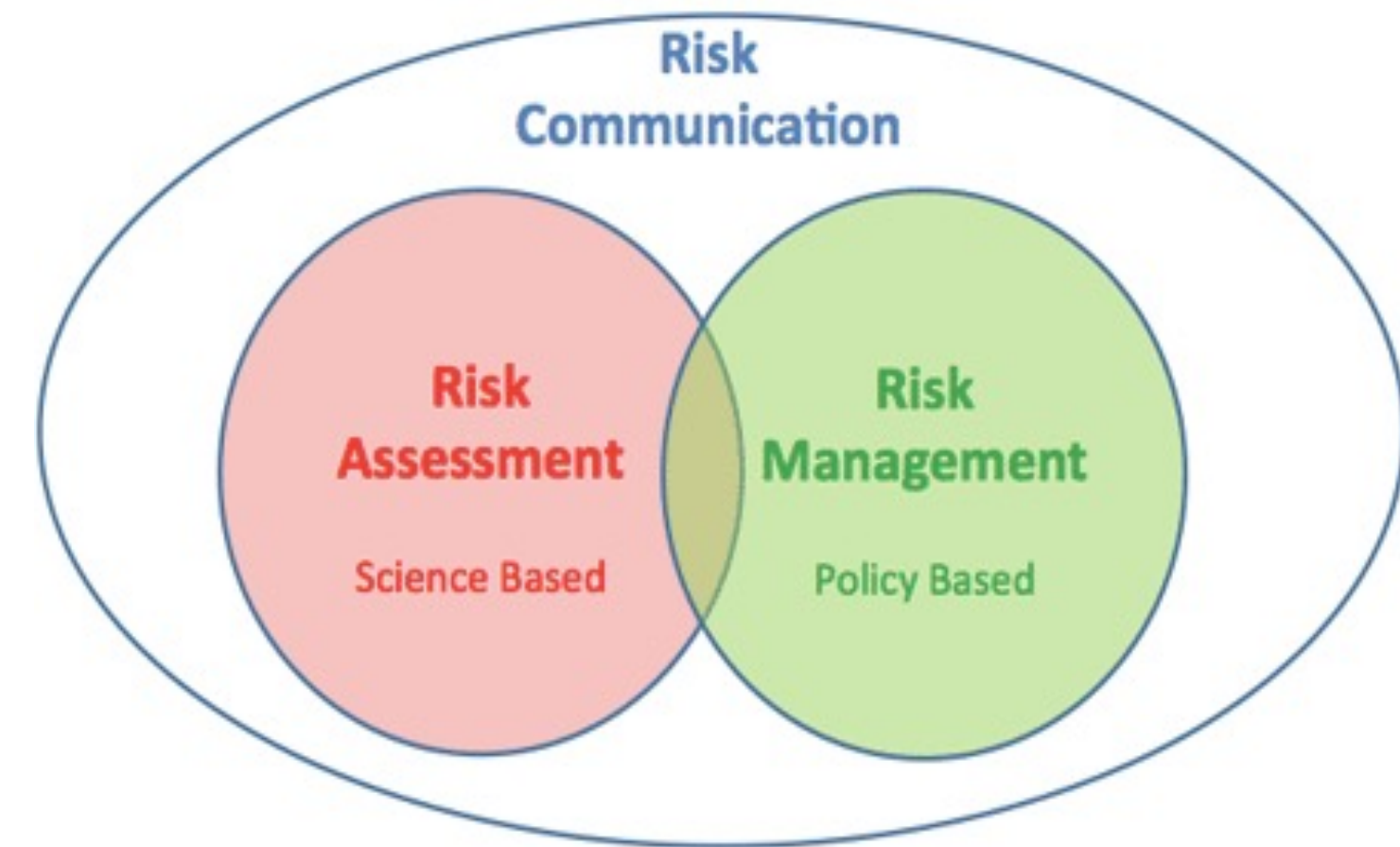
doi: 10.2903/j.efsa.2021.6343

Safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283



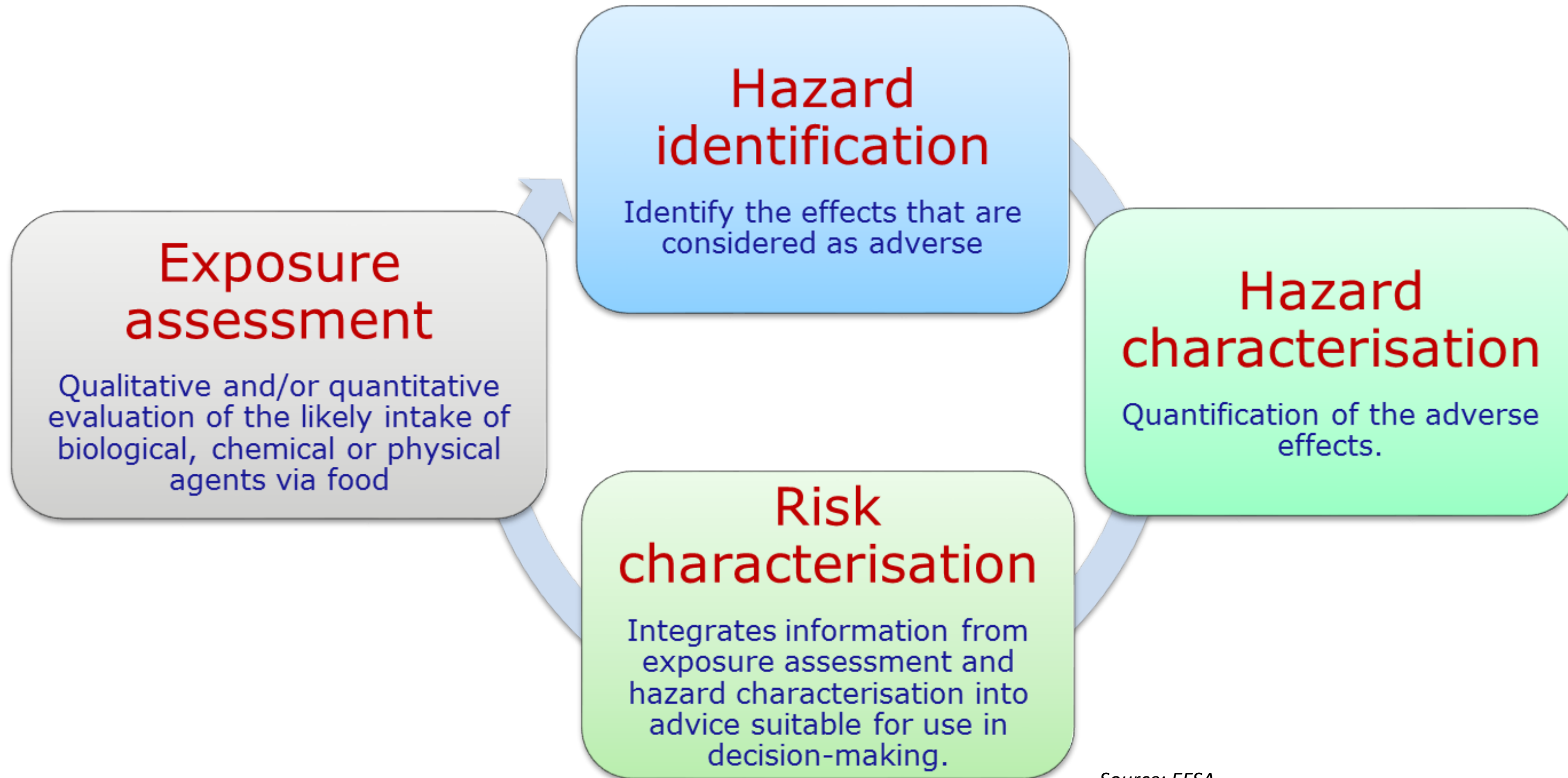
Safety Risk Assessment

- ❑ **RISK ASSESSMENT.** Quantitative evaluation of information on potential health hazards
- ❑ **RISK MANAGEMENT.** The process of weighing policy alternatives in the light of the results of the R.A and if required selecting and implementing appropriate control options.
- ❑ **RISK COMMUNICATION.** An interactive process of exchange of information and opinion.



Source: FAO

RISK ASSESSMENT



Source: EFSA

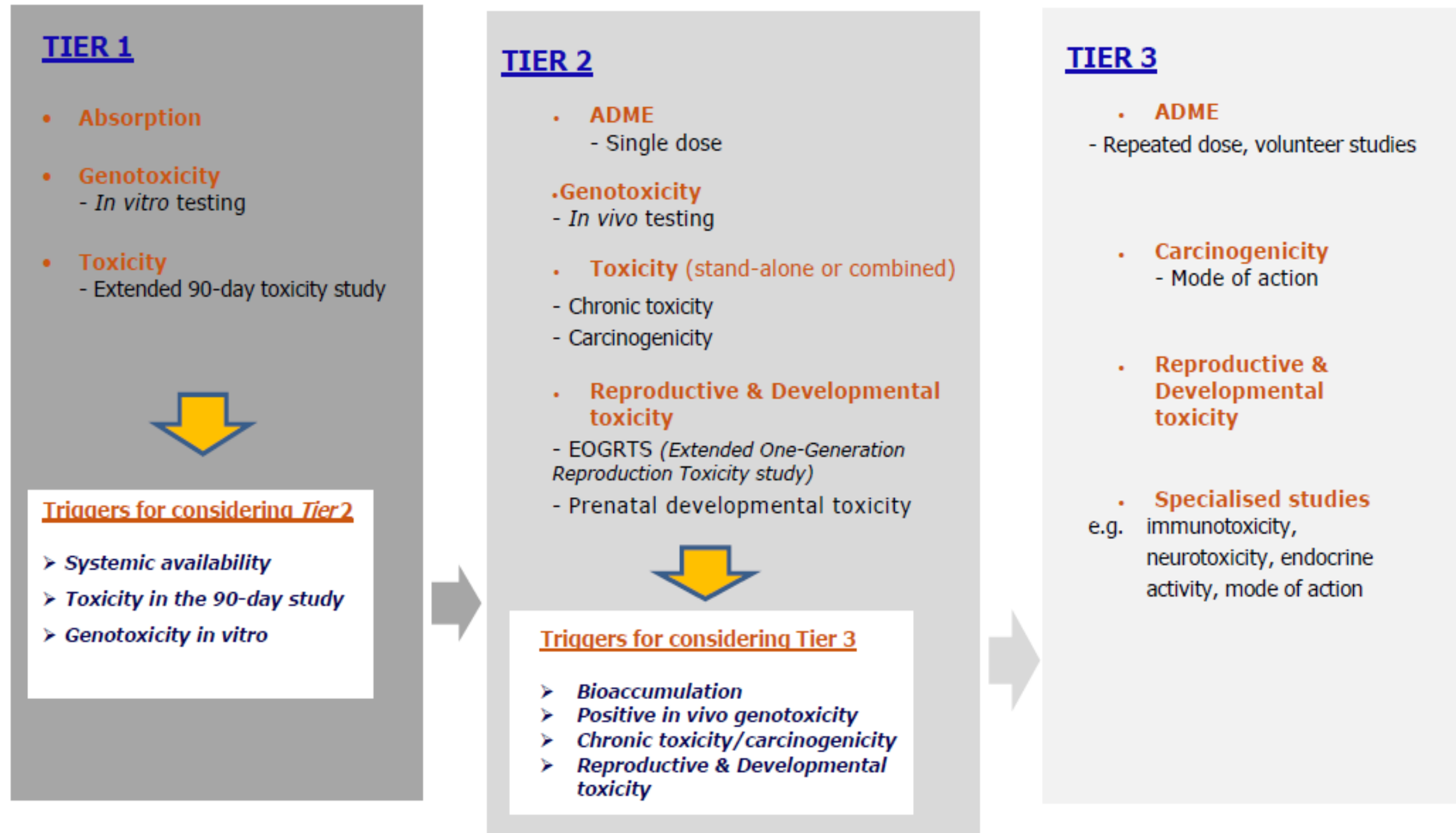
GUIDANCE ON THE PREPARATION AND PRESENTATION OF AN APPLICATION FOR AUTHORISATION OF A NOVEL FOOD IN THE CONTEXT OF REGULATION (EU) 2015/2286



- ☐ IDENTITY
- ☐ PRODUCTION PROCESS
- ☐ COMPOSITIONAL DATA
- ☐ SPECIFICATIONS
- ☐ HISTORY OF USE
- ☐ PROPOSED USES
- ☐ ADME
- ☐ NUTRITIONAL INFORMATION
- ☐ TOXICOLOGICAL DATA
- ☐ ALLERGENICITY



Tiered Toxicity Testing for Food Additives



EFSA Journal, 2012; 10(7): 2760

In conclusion....

- ★ In order to ensure the highest level of protection of human health, novel food must undergo a safety assessment before being placed on the EU market.
- ★ The food safety system in the EU has among the highest standards in the world.



THANK YOU!



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