

17<sup>TH</sup> OCTOBER 2023

10<sup>TH</sup> MEETING FOOD CONTACT MATERIAL NETWORK

# CHEMICALS STRATEGY FOR SUSTAINABILITY (CSS) ONE SUBSTANCE ONE ASSESSMENT (1S1A)

## AN UPDATE



**GLORIA LÓPEZ-GÁLVEZ**  
SCIENTIFIC OFFICER - FIP  
UNIT

# OUTLINE



1 INTRODUCTION

2 1S1A EFSA's  
ACTIVITIES

3 LEGISLATIVE  
PROPOSALS

4 SUMMARY

5 Q&A





# INTRODUCTION: CSS and 1S1A



# Chemical Strategy for Sustainability (CSS)

—

## EU Green Deal

## ‘Toxic-Free Environment’

## October 2020

Stronger EU legal framework to address pressing environmental and health concerns

**Simplifying and consolidating the legal framework.-**  
**One Substance One Assessment**

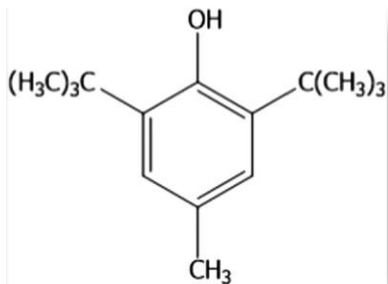
Innovating for safe and sustainable EU chemicals

Establishing a comprehensive knowledge base on chemicals

Providing a model to inspire chemicals management globally



# ONE SUBSTANCE ONE ASSESSMENT (I)



**Butylated hydroxy toluene (BHT)**

IUPAC name: 2,6-di-tert-butyl-p-cresol

CAS number: 128-37-0

**TODAY:**

**One Substance, SIX Assessments  
(one per use)**

Food  
Contact  
Material

Feed  
additive

Industrial  
chemical

Food  
Additive

Medicine-  
excipient

Cosmetic

**TOMORROW:**

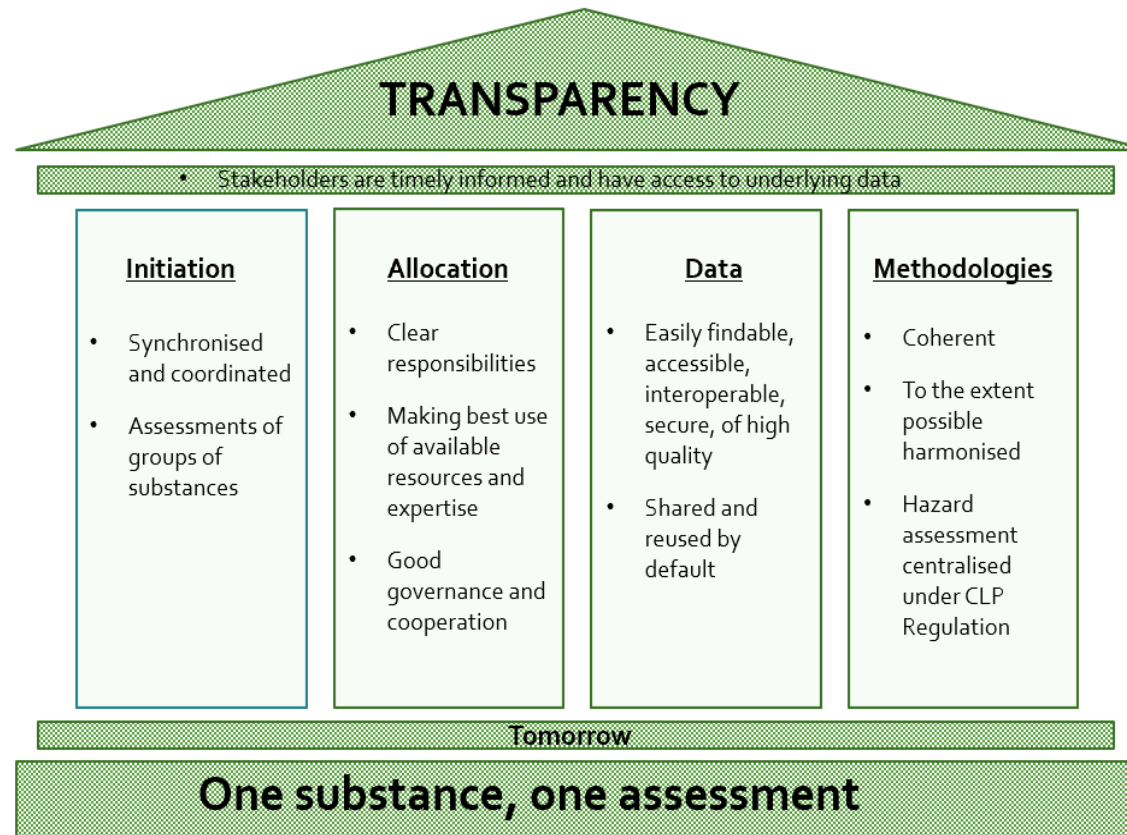
**One Substance, ONE Assessment  
with all uses**

- *Synchronised*
- *Same dataset*
- *Best use of resources*
- *No duplication, no risk of divergencies*
- *Facilitate the regulatory management*





# ONE SUBSTANCE ONE ASSESSMENT (II)





# ONE SUBSTANCE ONE ASSESSMENT (1S1A)

## EFSA's Activities





# Activities preparing 1S1A

**Early identification of cross-cutting substances**

- Piloting 1S1A; Analysis/Lessons learnt

**Procurement Study to map DR and RAM**

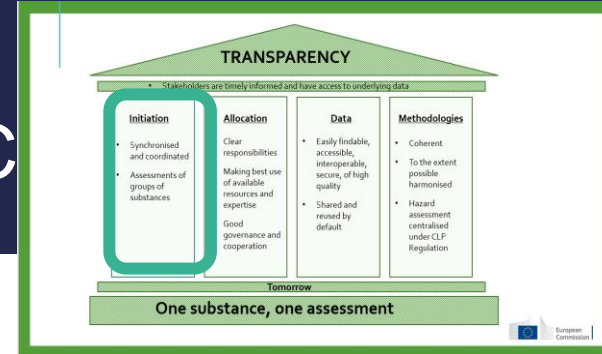
**Contribution to the EU-Common Data Platform on Chemicals (EU-CDPC)**

- OTHER: Focused 1S1A Inter-Agencies meetings
- Participation in various 1S1A preparatory activities let by EC: Repository of HBGV, Joint discussions with European Commission and Member States



# IDENTIFICATION OF CROSS-CUTTING SUBSTANCES

Available databases and tools  
Future: EU-CDPC



10 Self-mandates

70 Generic mandates

Procedure to involve relevant Agencies in place  
(Mandate Dialogue phase)

WORK on SUBSTANCE IDENTIFIERS

350

Applications for Regulated products mandates

# IDENTIFICATION OF CROSS-CUTTING SUBSTANCES

- The objective is to identify cross-cutting substances among all actors in EU performing risk assessment of chemicals. These are: EFSA, ECHA, EMA, the EC Sci Committees (SCCS and SCHEER) and the Member States.
- EFSA has very recently started a pilot to check cross-cutting substances (with the MSs and the sister Agencies and the two EC Sci Ctees) early in the Risk assessment process.
- Member States perform risk assessments of substances that might be found in food/feed: their on-going and past assessments are collected in a database which was developed by EFSA in 2016:

MS RA Plans: <https://r4eu.efsa.europa.eu/app/database>

- We invite you and your relevant colleagues to familiarize with the MS RA Plans database. And also with the OpenEFSA



| Date of Entry        | Date of Edit         | Country              | Organisation                     | Main Area                              | Title   | Description   |
|----------------------|----------------------|----------------------|----------------------------------|--|---|---|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text" value="All"/> | <input type="text" value="All"/>       | <input type="text" value="All"/>  | <input type="text" value="All"/>  |
| 2023-02-17           | 2023-02-17           | Lithuania            | KTU                              | Biological Hazards<br>Chemical Hazards | Research on innovative methods for the product production and safety assurance  | The aim of the work was to investigate the possibilities of wet extrusions and high-pressure technology applications on the parameters and shelf-life durability. |
| 2023-02-17           | 2023-02-17           | Lithuania            | KTU                              | Nutrition                              | Investigation of the influence of minerals and probiotic micro-organisms on the properties of a plant-derived butter-type product and development of an innovative technology for a butter analogue enriched with minerals and probiotics | Development of technology for a plant-derived butter-type product enriched with minerals and probiotic microorganisms. T food".                                   |

# IDENTIFICATION OF CROSS-CUTTING SUBSTANCES. FRAE



- EFSA has officially launched the **new journal** *Food Risk Assess Europe (FRAE)*, an open access repository of selected scientific articles from **national food safety agencies across the EU**.
- As an addition to our EFSA Journal on Wiley, FRAE aims to promote collaboration and provide a stronger evidence base for the **EU risk assessment community**.

- More info at:



<https://www.efsa.europa.eu/en/publications/food-risk-assess-europe>



[efsajournal@efsa.europa.eu](mailto:efsajournal@efsa.europa.eu)



# DATA SHARING / DATA USE AND RE-USE

- Feed additives
- Food Contact Materials
- Food additives, food enzymes and food flavourings
- Plant protection products



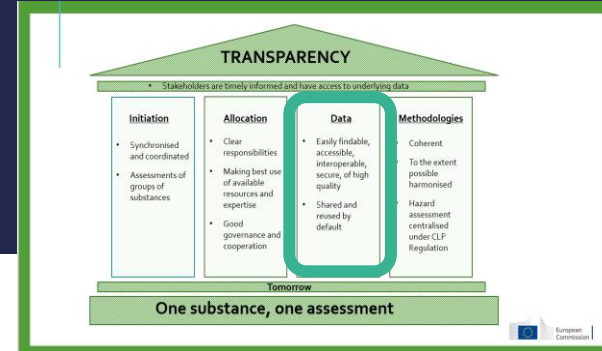
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Classification, labelling and packaging of substances and mixtures (CLP)
- Biocidal products



- Medicinal products for human use
- Medicinal products for veterinary use



- Safety of Toys
- Cosmetic products



## Legal

- Remove obstacles for reuse of data and better streamline flow of data

❖ **Common open data platform on chemicals**

❖ **Making data available in appropriate formats:**

- IUCLID for hazard and use data; IPCHEM for monitoring data

# PILOTING 1S1A CONCEPT IN CONCRETE ASSESSMENTS

## Collaboration with ECHA in the Implementation of Drinking Water Directive



Preliminary Work in the Drinking water Directive started in 2021 – EFSA contributed to the discussion of various topics: **Setting the tiers for toxicological data requirements, Information requirements on genotoxicity and reproductive toxicity, nanomaterials, Hazard and safety assessment and Substance identification and categorisation**



There are **3 pieces of legislation** already finalised:

- **Implementing Act.** Collect the information Requirements.
- **European Positive List.**
- **Application process**



During the implementation phase, FCM colleagues will be **part of the DW-RAC Working group**





# EXAMPLE OF DIVERGENCY ON DATA REQUIREMENTS

From the Pilot assessment being run: Drinking water Directive and Food Contact Matl's

**EFSA<sup>1</sup>**

**ECHA-REACH<sup>2</sup>**

**Two tests are requested:**

- Bacterial Reverse mutation assay (OECD TG 471)
- *In vitro* micronucleus test (OECD TG 487)<sup>3</sup>

*If both tests are negative*

**NO GENOTOXIC POTENTIAL**

**A third test is requested:**

- *In vitro* gene mutation in mammalian cells (OECD TG 476/OECD TG 490)

*If the test is negative*

**NO GENOTOXIC POTENTIAL**

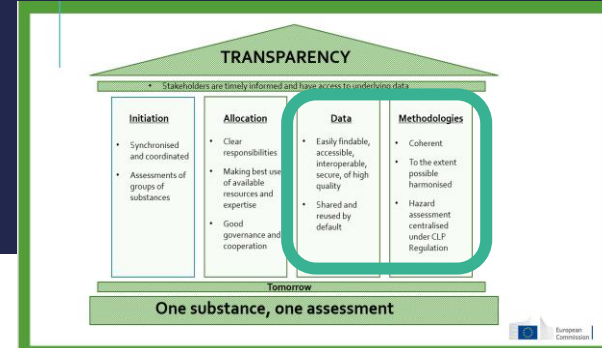
(1) Requirements from [Scientific Opinion of the EFSA's Scientific Committee of 2011](#) and [Clarifications of some aspects in 2017](#)

(2) Requirements from REACH Regulation, [Annex VII](#) (SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE) and [Annex VIII](#) (SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE)

(3) Until September 2022, the choice of '*In vitro* cytogenicity study in mammalian cells' or '*In vitro* micronucleus study' was possible for the second genotoxicity test. From September'22 only the '*In vitro* micronucleus study' is required as second test, and no choice is possible. Thus, the Decision of the ECHA's Member State Committee in its June 22's meeting approximates the approaches of the two Agencies.



# ALIGNMENT DR AND RAM



## PILOT findings

- Food Contact Material and Drinking Water (EFSA Sci. Ctee Guidance vs REACH)
- Data requirements for genotoxicity screening do not fully match

## PROBLEM

- There might be other areas with misalignments in DR and RAM
- Work via Outsourcing. **Procurement Subject:** "Mapping of DR and RAM linked to the regulatory frameworks and remits of the relevant EU Agencies (ECHA, EFSA and EMA) and EC Scientific Committees (SCCS and SCHEER)"

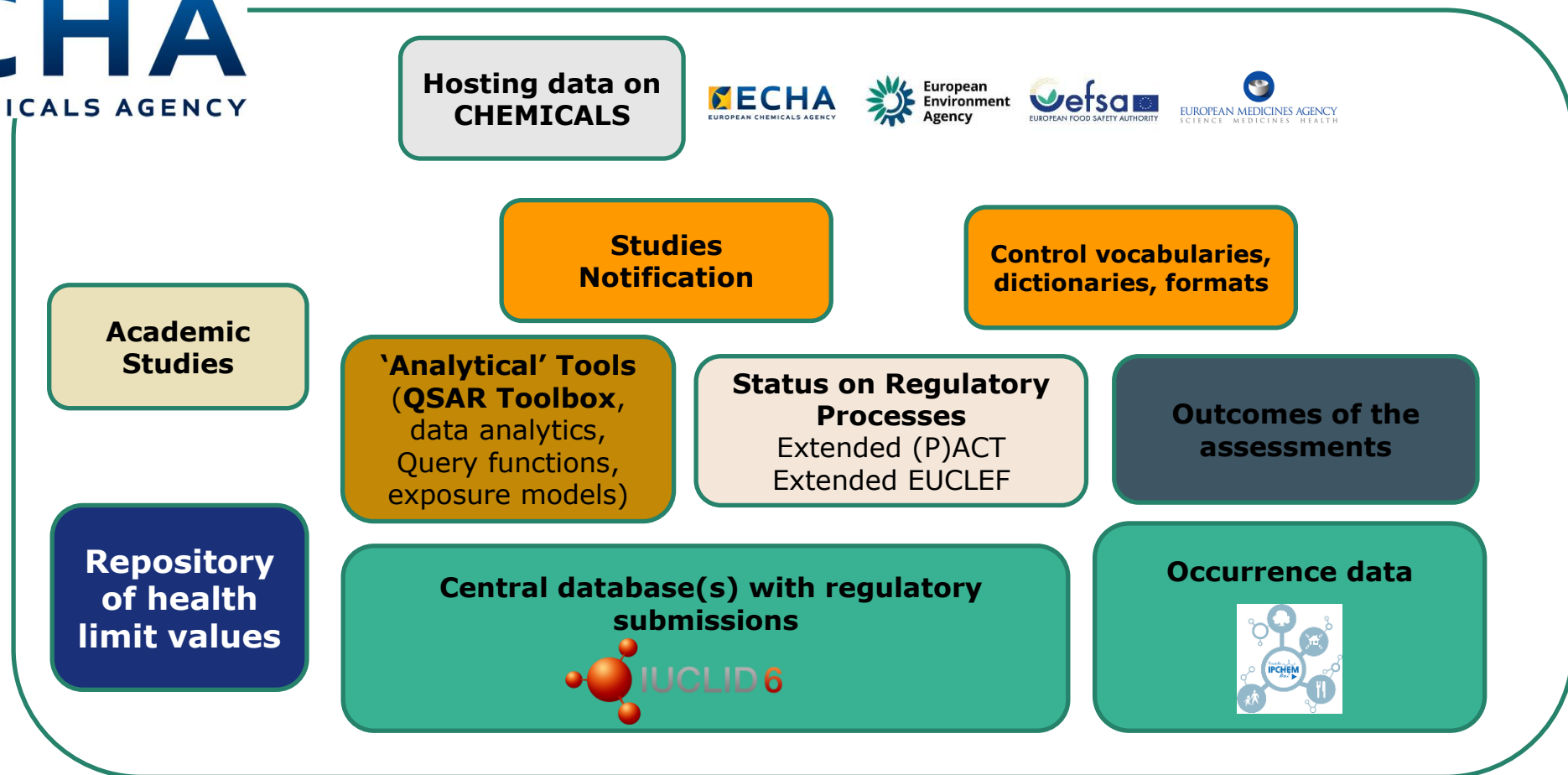
## RESULTS

- Expected by November 2023
- To be critically revised in the context of 1S1A

**Work on GUIDANCES  
Joint GUIDANCES**



# EU-COMMON DATA PLATFORM ON CHEMICALS





# ONE SUBSTANCE ONE ASSESSMENT (1S1A)

## Legal Proposals



# 'REVISION - CLASSIFICATION LABELLING AND PACKAGING REGULATION'

## Revision CLP Regulation. Adopted 19/12/2022.

- 1) Delegated Act - Change of Annex I. Introducing NEW hazard classes
- 2) Proposal for a revision of the CLP Regulation – Change of body text:
  - NEW: Right for the Commission to develop CLH proposals
  - NEW: **Empowerment for Agencies** *'The Commission may ask ECHA or EFSA to prepare a proposal for harmonised classification and labelling of substances and, '[...].'*

### METHODOLOGIES AND DATA

The Commission will:

- ensure that the CLP Regulation is the **central piece for hazard classification** and allows the Commission to initiate harmonised classifications<sup>76</sup>;





# 'RE-ATTRIBUTION OF TASKS'

Reallocation of tasks derived from the 1S1A implementation and from EC Scientific Committees

Tasks to EFSA, to contribute in:

- Operation and governance of the EU-CDPC
- Adopting formats and preparing controlled vocabularies
- Early Warning and Action System on Chemicals



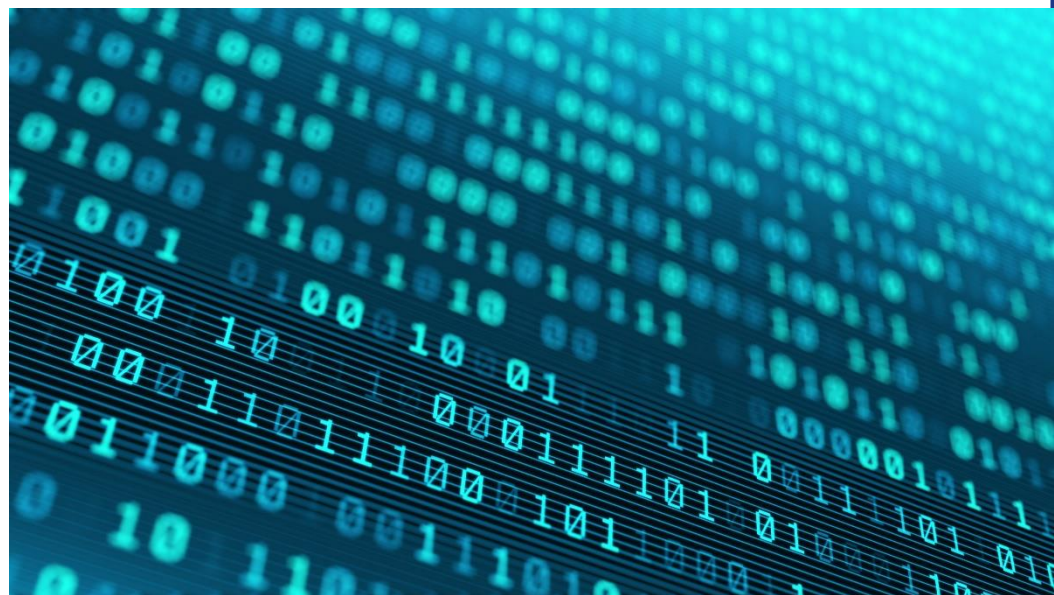
COOPERATION  
MS and Agencies



Preventing/Avoiding  
DIVERGING OPINIONS



# 'CHEMICAL DATA'



- **EU-Common Data Platform on Chemicals**
- **Data inter-operability, data use and re-use, removal of legislative barriers**  
*Crucial element in the success of 1S1A*
- **CSS Indicators**

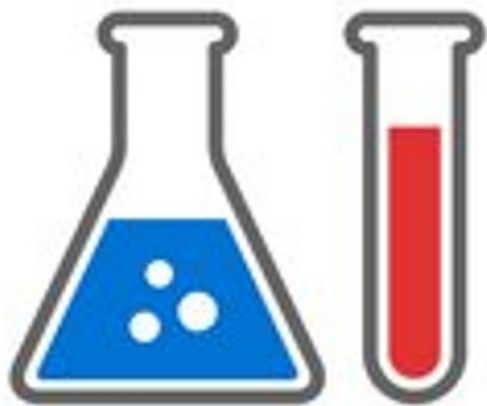




# SUMMARY/Take-home messages



# SUMMARY



**Legislative Proposals to be adopted**

**CHANGES in the way of working**

**Identification of Cross-cutting substances  
Substance Identifiers**

**Data Sharing/Data re-use  
STANDARD Data formats  
INCREASED interaction with sister Agencies/MS**

**Towards Alignment Data Requirements and RA Methodologies:  
Joint Working groups / Joint Guidance**



---

## Q&A





# STAY CONNECTED

## SUBSCRIBE TO

[efsa.europa.eu/en/news/newsletters](https://efsa.europa.eu/en/news/newsletters)  
[efsa.europa.eu/en/rss](https://efsa.europa.eu/en/rss)  
[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



## FOLLOW US ON TWITTER

[@efsa\\_eu](https://twitter.com/efsa_eu)                      [@methods\\_efsa](https://twitter.com/methods_efsa)  
[@plants\\_efsa](https://twitter.com/plants_efsa)                [@animals\\_efsa](https://twitter.com/animals_efsa)



## FOLLOW US ON INSTAGRAM

[@one\\_healthenv\\_eu](https://www.instagram.com/one_healthenv_eu)



## LISTEN TO OUR PODCAST

Science on the Menu – Spotify, Apple Podcast and YouTube



## FOLLOW US ON LINKEDIN

[Linkedin.com/company/efsa](https://linkedin.com/company/efsa)



## CONTACT US

[efsa.europe.eu/en/contact/askefsa](https://efsa.europe.eu/en/contact/askefsa)

