

EFET (Hellenic Food Authority) Conference,

7-8 November 2023

**CHEMICALS STRATEGY FOR SUSTAINABILITY (CSS)
ONE SUBSTANCE ONE ASSESSMENT (1S1A)
EFSA'S ACTIVITIES**



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OUTLINE



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(in the making)

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1. 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**

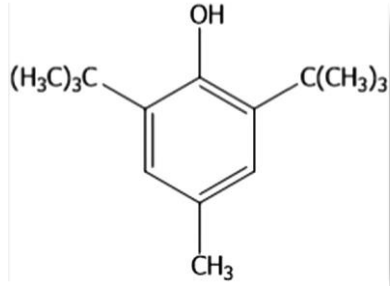
Innovating for safe and sustainable EU chemicals

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

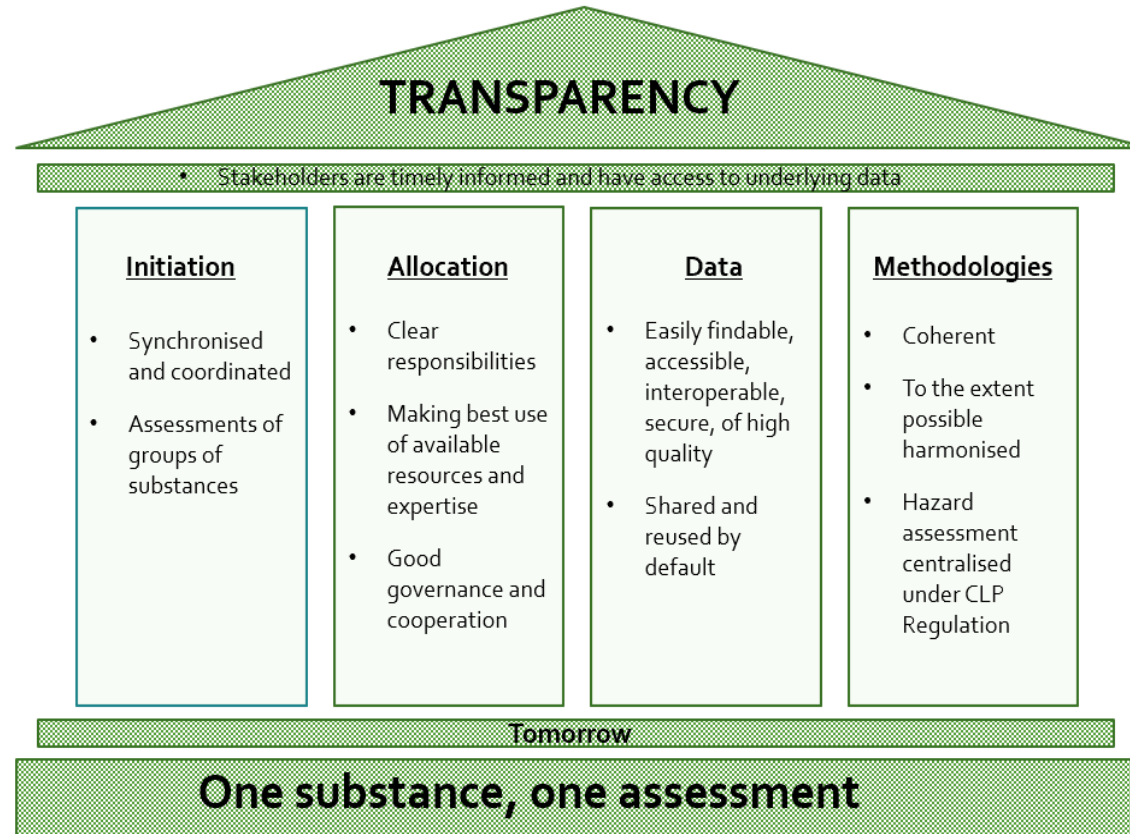
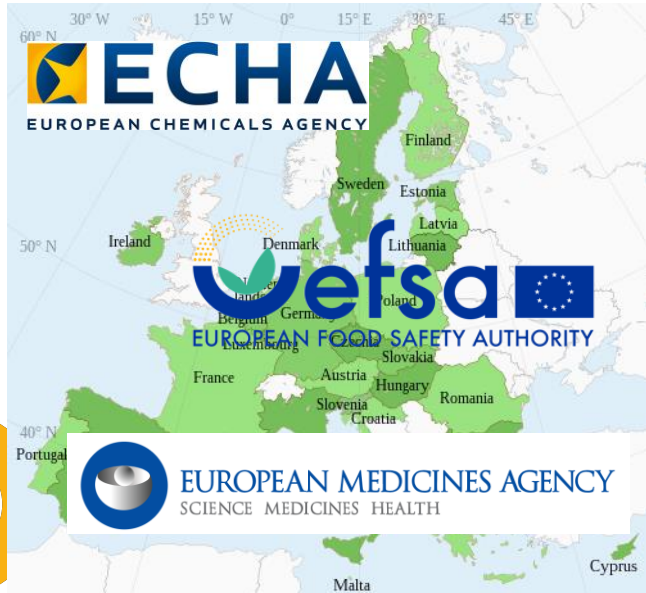
TOMORROW:

**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)



(Slide taken from EC Presentation to 80th Advisory Forum Meeting)





2. ONE SUBSTANCE ONE ASSESSMENT (1S1A) EFSA's Activities





Activities preparing 1S1A

Early identification of cross-cutting substances

Procurement Study to map Data Requirements and Risk Assessment Methodologies

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

Piloting 1S1A; Analysis/Lessons learnt

OTHER: Focused 1S1A Inter-Agencies meetings

Participation in various 1S1A preparatory activities led by EC: Repository of HBGV, Joint discussions with European Commission and Member States



EARLY 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 SCHEFF) and the Member States.
- EFSA has very recently started a pilot to check cross-cutting substances (with the MS Agencies and the two EC Sci Ctees) early in the Risk assessment process.
- Member States perform risk assessments of food/feed substances; the on-going assessments are collected in a database which was developed by EFSA in 2016:

Work on SUBSTANCE IDENTIFIERS

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

The screenshot shows the 'MS RA Plans' database interface. At the top right, there are logos for 'efsa European Food Safety Authority' and 'MS RA Plans'. Below the logos are buttons for 'View', 'Edit', and 'Visualization'. The main part of the interface is a table with the following columns: 'Date of Entry', 'Date of Edit', 'Country', 'Organisation', 'Main Area', 'Title', and 'Description'. Below the column headers are filter boxes, each containing the word 'All'. The table contains two rows of data:

Date of Entry	Date of Edit	Country	Organisation	Main Area	Title	Description
2023-02-17	2023-02-17	Lithuania	KTU	Biological Hazards 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".



EARLY IDENTIFICATION OF CROSS-CUTTING SUBSTANCES. FRAE

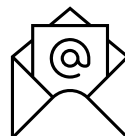


- EFSA has officially launched the **new journal *Food Risk Assess Europe (FRAE)***, an open access repository of selected scientific articles from **national food safety agencies across the EU**.
- As an addition to our EFSA Journal on Wiley, FRAE aims to promote collaboration and provide a stronger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

- More info at:



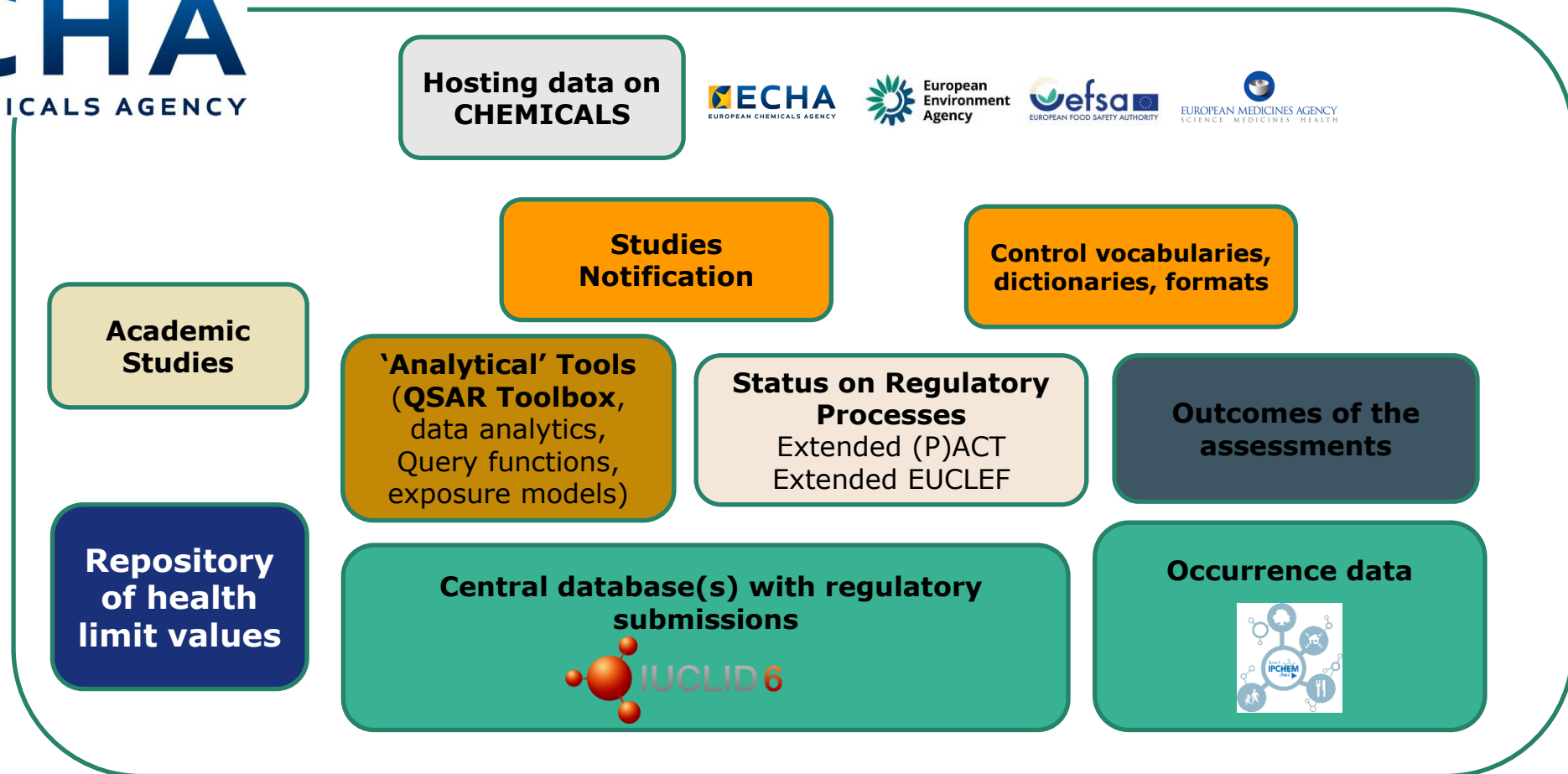
<https://www.efsa.europa.eu/en/publications/food-risk-assess-europe>



efsajournal@efsa.europa.eu



EU-COMMON DATA PLATFORM ON CHEMICALS



PROCUREMENT –

MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES

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





3. ONE SUBSTANCE ONE ASSESSMENT (1S1A) Legal Proposals (*in the making*)



'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 classifications⁷⁶;



'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



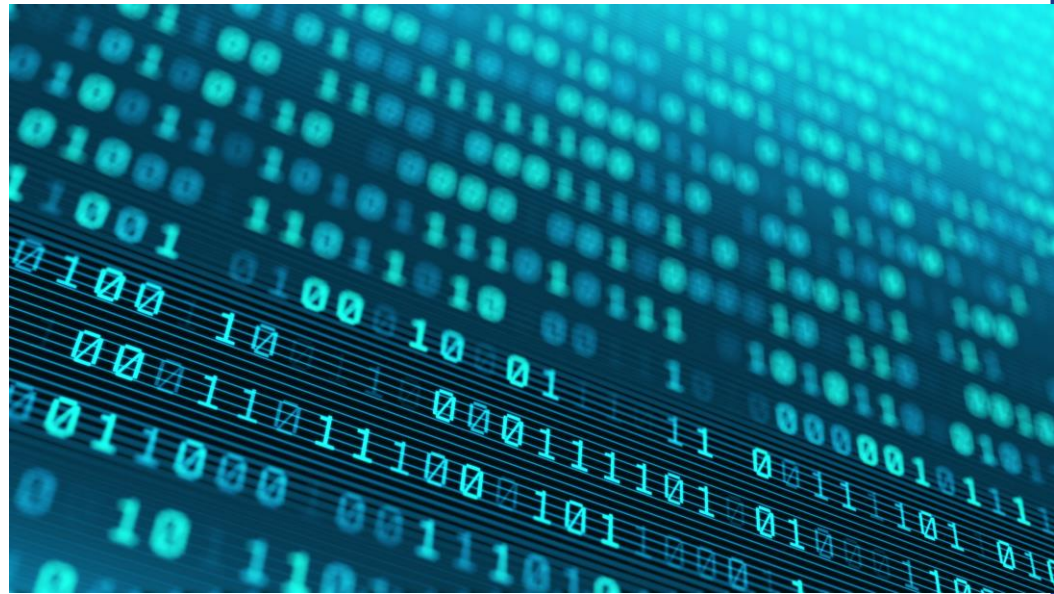
COOPERATION
MS and Agencies



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**

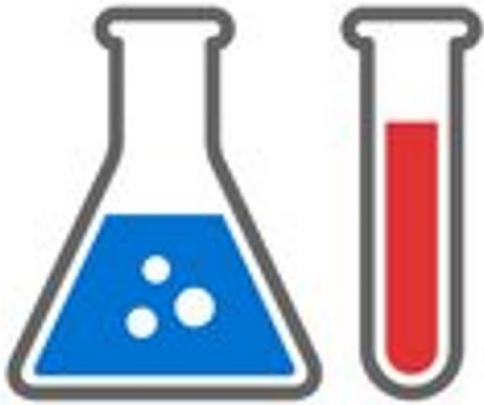




4. SUMMARY/Future work-Challenges



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/Member States**

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



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